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March 7, 2023
Public Hearing -Joint Committee for Review of Administrative Rules
Regarding DHS 144 as changed by CR 19-079
Testimony of Tara Czachor: Co-Founder of Wisconsin United for Freedom

Good morning. My name is Tara Czachor, and I am one of the co-founders of Wisconsin United for Freedom. I want to thank the chairs of this committee, Senator Nass and Representative Neylon, and the rest of the committee members for holding the public hearing today and providing the opportunity to give my public testimony on behalf of myself as a Wisconsin resident, and on behalf of Wisconsin United for Freedom.

Firstly, I am here speaking today as an educated mother of four children who are all in public schools and are affected by these rule changes. I am not going to list my college degree, because at the end of the day, none of that currently matters. We are here today to stand for freedom, and I do not believe one needs to have letters after our name in order to do so.

I am going to get right to the point for sake of time: the people of Wisconsin are tired. We are tired of governmental overreach over our lives. We are tired of the past 3 years of mandates. We are tired of being bombarded with constant "recommendations" by the top bureaucratic health agencies in our country and state, while they are knowingly looking the other way when citizens in our country have real, and valid concerns. We are tired of medical professionals acting as if the average person, the average Wisconsinite, is not smart enough, or fully capable, of making their own health care decisions. Let me tell you all – we are fully capable of making our own decisions and running our own lives – no college degree required.

With that said, I'd like to provide the committee members with some back story. Back in early 2019, news started to circulate of a bill being introduced that would remove Wisconsin's personal vaccine exemption for day care and K-12 students. That is right around the time that Wisconsin United for Freedom was born. We were moms and dads who decided to jump into politics because we realized that our children's futures were at stake. We held our first medical freedom rally at the state capitol. We started asking a lot of questions, requesting a lot of meetings, and we were successful in defending our vaccine exemption and the bill died in committee.

Right around this same time, we also became aware of the rule being proposed by Wisconsin DHS – this clearing house rule 19-079. Had we not become aware of it when we did, we would have completely missed the DHS public hearing, and the rule may have easily slipped through

the cracks and been passively passed without much opposition at all which is what we suspect DHS was hoping for.

Luckily, we did find out about it, and were able to rally a number of people to the DHS hearing in Madison. I wanted to mention that as soon as I found out there would be a public hearing hosted by DHS on these rule changes in July 2019, I was very concerned that many members our state would not be able to attend as the hearing was in Madison. I emailed and left phone messages with DHS to inquire about getting a phone number to attend the meeting by phone. After many days, I was emailed a Skype number to join the meeting by phone, however, the public notice that was posted was not amended or updated with this phone number despite my questioning. Why was it not updated to include the phone number for others in the state to attend? Either way, we did our best to get the word out about the hearing so that others from around the state could attend via Skype if they couldn't do so in person. DHS appeared surprised at the number of people in attendance, and Dr. Stephanie Schauer even said as much in her testimony to the Committee on Constitution and Ethics in March of 2020. They absolutely shouldn't have been surprised.

I attended the public hearing by phone. I won't get into the grave issues of that bureaucratic public hearing that was poorly run, however, the stakeholders of whom these rules would impact the most, such as Wisconsin parents, were not able to fully have their voices heard.

Moving on with the back story: the DHS public hearing came and went, and then March of 2020 came. Right before the COVID pandemic, we again rallied Wisconsinites to join us at a public hearing in the Committee on Constitution and Ethics. There were hundreds in attendance, and overflow rooms were needed. And what was it all about? It was about requirements. It was about mandates. It was about the fact that we want to preserve liberty and freedom in our country and stop any other additional vaccine from being added to our required schedule.

It was not about WI DHS proving that there was an emergency that required them to add this additional vaccine to the requirements. Let's be clear: there is no public health emergency related to meningococcal disease.

Representative Neylon asked Dr. Stephanie Schauer in the March 2020 Committee on Constitution and Ethics hearing, whether any of the public comments, either written or in person, were taken into consideration by the department after their public hearing, and whether or not any part of the clearing house rule was amended following the hearing. Her answer was aside from some minor tweaks, nothing significant was changed. What does that tell you? Doesn't that tell you that DHS does not care what we the people in Wisconsin actually think or what our concerns are? They took none of the concerns to heart, and made zero changes, and did what they were always planning to do anyway. The public hearing was merely held to just check a box in order to show that it was completed. It was nothing more than that.

We are very well aware that Wisconsin also has options in order to opt out of one or more of the required vaccinations WI DHS requires for school entry, however I want to make it very clear, that that specific information is absolutely not willingly provided to Wisconsinites via their health care providers, nurses, or school districts. It is not provided because 1), many of the

aforementioned individuals actually do not know that we have exemptions, and 2) our health care providers have a vested interest and are incentivized by pharmaceutical companies, and potentially health insurance companies as well, in insuring a high vaccination uptake with their patients.[1] [2]

The same process that Wisconsin DHS utilized to add this additional requirement of the meningococcal vaccine to the schedule, is the same process they would utilize in adding any other vaccine to the schedule. **How many is too many, and who gets to decide?** I was born in 1985, and around the time that I was born, there were 24 vaccine doses on the recommended schedule from birth to age 18.[3]

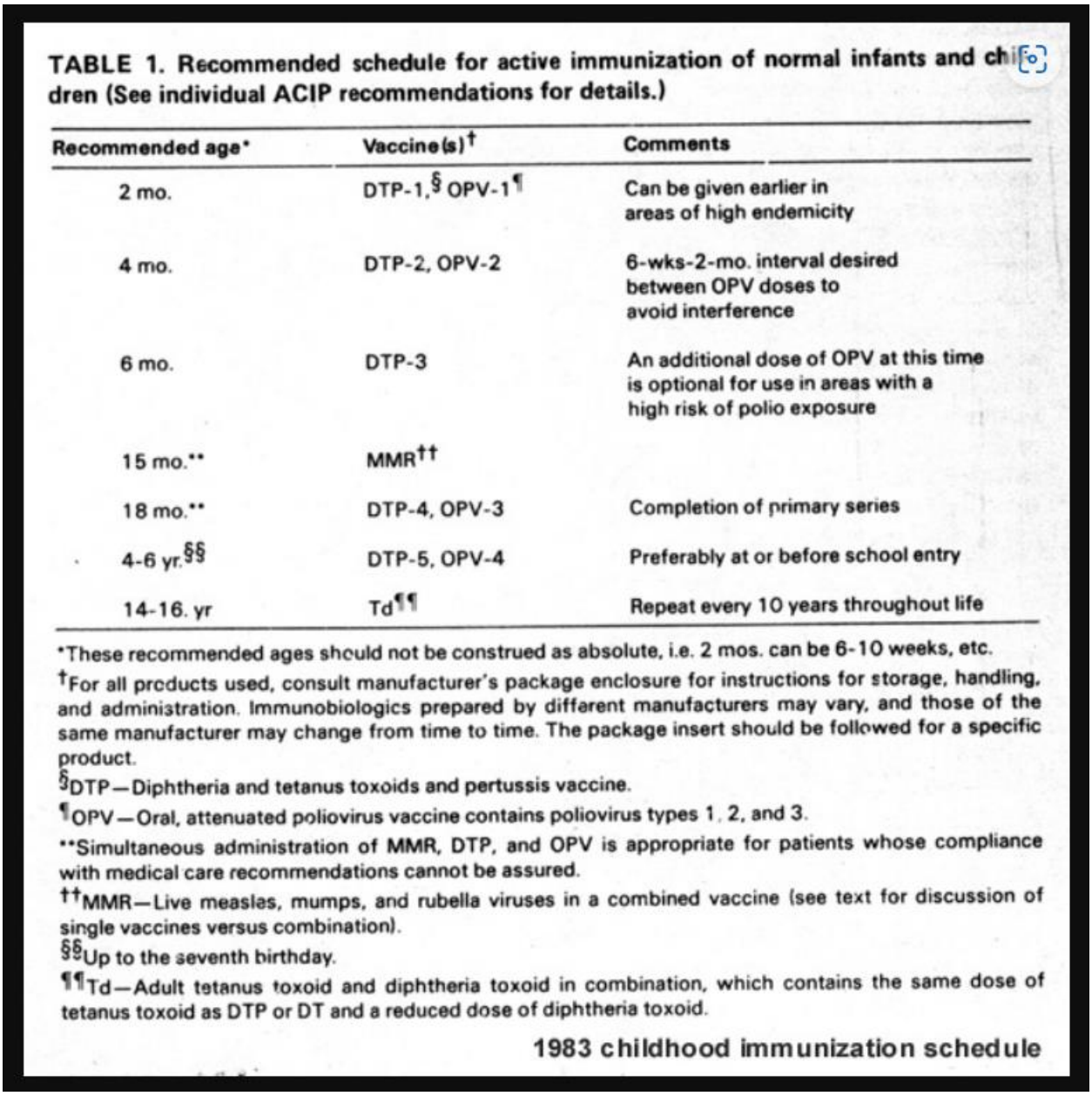

TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)

Recommended age*	Vaccine(s)†	Comments
2 mo.	DTP-1,§ OPV-1¶	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR††	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr.§§	DTP-5, OPV-4	Preferably at or before school entry
14-16. yr	Td¶¶	Repeat every 10 years throughout life

*These recommended ages should not be construed as absolute, i.e. 2 mos. can be 6-10 weeks, etc.

†For all products used, consult manufacturer's package enclosure for instructions for storage, handling, and administration. Immunobiologics prepared by different manufacturers may vary, and those of the same manufacturer may change from time to time. The package insert should be followed for a specific product.

§DTP—Diphtheria and tetanus toxoids and pertussis vaccine.

¶OPV—Oral, attenuated poliovirus vaccine contains poliovirus types 1, 2, and 3.

**Simultaneous administration of MMR, DTP, and OPV is appropriate for patients whose compliance with medical care recommendations cannot be assured.

††MMR—Live measles, mumps, and rubella viruses in a combined vaccine (see text for discussion of single vaccines versus combination).

§§Up to the seventh birthday.

¶¶Td—Adult tetanus toxoid and diphtheria toxoid in combination, which contains the same dose of tetanus toxoid as DTP or DT and a reduced dose of diphtheria toxoid.

1983 childhood immunization schedule

I would like to ask each of you to guess how many doses are on the schedule now- today- March 7th of 2023? The answer is 72. Yes, that's correct, 72 vaccine doses from birth to age 18.[4] If you'd like to add in doses women are expected to receive while pregnant, that number is 76.

2023: Average Pregnancy and Birth to age 18 ACIP Vaccine Recommendations

Pregnancy:

Tdap:	*1 dose of 3 vaccines per pregnancy = 3 doses*
Influenza:	*1 dose per pregnancy*

Birth:

Hepatitis B:	3 doses
Rotavirus:	3 doses
DTaP (Diphtheria, tetanus, acellular pertussis):	5 doses of 3 vaccines = 15 doses
Haemophilus influenzae type b (HIB):	4 doses
Pneumococcal conjugate:	4 doses
Inactivated poliovirus:	4 doses
COVID 19:	3 doses
Influenza: 6 months, age 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17,18 (19 doses)	
Measles, Mumps, Rubella:	2 doses of 3 vaccines = 6 doses
Varicella (Chicken Pox):	2 doses
Hep A:	2 doses
Tdap (Tetanus, diphtheria acellular pertussis):	3 doses
HPV:	2 doses
Meningococcal:	2 doses
Total:	**76 doses from pregnancy to 18**

I'm going to be very clear here, that we are not talking about the COVID vaccine – though we oppose that ever being added to the required schedule here in Wisconsin as well. However, again, the process that DHS currently used to add the meningococcal vaccine to the required schedule is the same process DHS will use in the future to add additional vaccine requirements. *It is completely unacceptable that an unelected bureaucratic administrative department is authorized with authority over adding vaccinations to our schedule, virtually keeping the legislature out of the process.* We do not elect those who work for Wisconsin DHS. We elect our elected officials and those who govern over our state. There needs to be more accountability on this issue, and the legislature needs to be part of it.

This administrative rule changing process was started in 2017-2020. It was in process within the same time frame various Wisconsin Medical associations were lobbying, supporting, and actively advocating for the removal of our personal vaccine exemption. In fact, at the public hearing in March, Dr. Stephanie Schauer stated that WI DHS created an advisory committee from representatives from several organizations. **Do you know that virtually every single organization that Wisconsin DHS collaborated with on this advisory committee are registered organizations that supported the removal of the personal vaccine exemption legislation, AB248, in 2019 that we effectively fought against?**[5] Please let this piece of information really sink in: virtually every single organization that was consulted to add an additional vaccine requirement to our WI schedule also lobbied, advocated and registered in support of the removal of vaccine choice here in Wisconsin. Virtually every single organization.

Do you know which group of people were not included in the advisory committee by WI DHS? Parents. Community members not a part of one of the medical associations. Moms and dads, grandmas and grandpas. Everyday Wisconsinites were not included or part of the process that would add to **requiring** another vaccination on our schedule. This is unacceptable.

The Advisory committee consisted of representatives from WI Dept Public Instruction, WI Chapter American Academy of Pediatrics, WI dept of health services Medicaid program, the Wisconsin Association of Local Health Departments and Boards, the WI Academy of Family Physicians, the Wisconsin Association of School Nurses, the Wisconsin Medical Society, and the Pharmacy Society of Wisconsin.

Not only did virtually all of the organizations DHS consulted with in creating these rules support the removal of vaccine choice here in WI, many of them **also** supported bills that would have allowed minors to be vaccinated without parental consent (2021-2022 AB583– Per Wisconsin Lobbying Website: Association of Local Health Departments and Boards and Wisconsin Public Health Association)[6]. Many of them publicly **opposed** legislation that would have prohibited businesses from discriminating against customers due to vaccination record as well (WI Association of Local Health Departments and Boards, Wisconsin Medical Society, Wisconsin Public Health Association).[7]

I would also like to add, that not a single physician that sits before you today from DHS has **any** liability whatsoever if a vaccine that they advocate for mandating on our Wisconsin schedule injures or kills someone- not one of them, and neither do the hospitals they work for, or the

pharmaceutical companies who make the products they utilize. Zero liability – zero personal risk to themselves, and zero lifelong implications. That risk is passed on to parents, of whom **they** are the ones who have to figure out how to get the care their child may need if they end up injured. **They** are financially responsible. **They** have to figure out oftentimes how to file a Vaccine Adverse Events Reporting System report. The parents. Not the doctors sitting in this room encouraging all of you to mandate a medical product in order for our children to attend school.

Let me ask those of you on this committee this – do you think there is a current vaccine available right now that WI DHS or the CDC **wouldn't** want to mandate? We firmly believe that those entities would remove all exemptions and mandate every single vaccine for every single man woman and child in this state if they were given free rein to do so. These agencies have lost our trust, and it is going to take a long time – if ever – for them to gain it back.

One of the comments we continued to hear about why this issue isn't that big of a deal, was that we have exemptions and we can just use an exemption. Are you aware that there is a movement by CDC and Public Health officials to remove exemptions? Take California, for example: they virtually have zero vaccine exemptions and now just recently, there was a piece of legislation introduced that would mandate the HPV vaccine for children to attend school there.[8]

How many is too many and who gets to decide?

Wisconsin is in an interesting space right now. I am not going to sugar coat things – I have 4 children and I don't have time to sugar coat things. I am first and foremost a mother – and the state has messed with my kids – all of our kids – enough. We understand the political dynamic. We understand that a lot of really good bills that many of us in this room support will either die in committee, or if it were to make it past both of our houses, Gov. Evers would veto it. We believe this is an incredible opportunity for our legislature to have the backs of Wisconsinites by voting to suspend this DHS rule 144.

We are not telling anyone in the state what decision to make. We are not telling any family to vaccinate their children for meningococcal disease, or not to do so. We simply believe that Wisconsinites are intelligent, hardworking, and fully capable citizens who are perfectly capable of making this decision with their own trusted health care provider. **We want more options, not less. We want less mandates, not more.**

With regards to the meningococcal vaccine mandate: meningococcal disease is a devastating disease, and we are incredibly fortunate that this disease is very rare. However, the rates of this disease had already dropped to historical lows prior to the CDC's recommendation for use of the vaccine in all 11 and 12-year old students. Rates have continued to drop and in 2019, there were approximately 375 cases in the entire United States. Of note, only 9 cases occurred from strains found in the meningococcal vaccine among persons 11 through 23 years of age. [9]

I am certain that when Wisconsin DHS authored rule number 4, they never once considered vaccine injury. Vaccine injury is real and many people are unaware of this fact. It is acknowledged by the federal government and there have been payouts made to families with

vaccine injuries. Vaccine injuries are extremely important, especially as it pertains to this meningococcal mandate. During the public hearing back in March of 2020, Dr. Stephanie Schauer made a comment along the lines of if it was your child who contracted meningococcal disease, it doesn't matter if it's rare. I would like to say that the same applies to parents who have children who have suffered with a vaccine injury. When it's your child, on either side of the aisle, it matters more than anything else. Why does WI DHS seem to think one kind of death matters more than another?

Even if it is acknowledged that the rare vaccine injury occurs, the number of injuries could cancel out the benefit of the vaccine. Within 9 months of the approval of the meningococcal vaccine, the CDC issued a health alert warning of an association between the vaccine and Guillain Barre Syndrome or GBS, a serious and devastating neurological disorder that causes paralysis and even deaths.[10] Additional reports of GBS occurring after vaccination continued to be reported, and this prompted the vaccine manufacturer to list GBS as a possible side effect of the vaccine.[11]

GBS is not the only serious reaction that has been linked to meningococcal vaccines. There are many reactions, some of the more serious reactions associated with this vaccine as listed in the vaccine package insert for the 3 available MenACWY vaccines include — anaphylaxis, convulsions, transverse myelitis and acute disseminated encephalomyelitis.[12] [13] [14]

In fact, for the 3 available MenACWY vaccines, Menactra, Menveo, and MenQuadfi, as of February 24, 2023, there have been 1,746 SERIOUS adverse events reported to the Vaccine Adverse Events Reporting System or VAERS, with most of these events resulting in hospitalization.[15] These are not the reports of a sore arm or swelling at the injection site. These are serious events that include GBS, transverse myelitis, and even death.

There have been 73 deaths reported to VAERS linked to the meningococcal vaccine, and while a report to VAERS does not mean that the vaccine was responsible for the death, it also doesn't rule out an association. Several of the death reports to VAERS were in individuals who died from meningococcal disease even though they were fully vaccinated. Several who did die, died from strain C, which is a strain that is targeted by the MenACYW vaccine. These reports indicate that the vaccine failed and did not protect against one of the few strains it was supposed to protect against.[16]

It is entirely possible that serious reactions occurring after the MenACWY vaccine are significantly higher because vaccine reactions are rarely reported. A 2011 report by Harvard Pilgrim Health Care, Inc. for the U.S. Department of Health and Human Services (HHS) stated that fewer than one percent of all vaccine adverse events are reported to the government. This report states the following -

> "Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low repotting rates preclude or slow the identification of "problem" drugs and vaccines

that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. "[17]

A logical next step would be to figure out how to implement new surveillance methods, but instead government officials stopped corresponding with Harvard Pilgrim Health Care and we have yet to see any improvements in reporting systems. Dr Stephanie Schauer commented at the last hearing that just because a report was filed to VAERS, doesn't mean causation is proven. What other system should parents and providers use? The CDC has had the ability to update this system and make it better, and they purposely choose not to! This is virtually the only way to submit a report, so when physician say that a report doesn't equal causation, it is extremely frustrating.

According to the VAERS reports, this means that instead of over 1,700 serious adverse events following MenACWY vaccines, the number could actually be 170,000. The more alarming number is that instead of 73 deaths, the death toll could be as high as 7,300.

In 1982, due to the unrelenting onslaught of civil suits over vaccine injuries and deaths, the four biggest vaccine makers at the time, Merck, Lederle, Connaugt, and Wyeth, went to Congress and threatened to stop selling vaccines in the United States unless they were granted liability from civil lawsuits. [18]

The National Childhood Vaccine Injury Act of 1986, which acknowledged that vaccines and deaths were real and that individuals and their families should be financially compensated, made it extremely difficult for individuals and families to sue in civil court for vaccine injuries and death. One of the provisions of the 1986 law was that a compensation program be set up to pay for injuries and deaths caused by vaccines and that U.S. taxpayers pay for it, through a 75-cent tax levied on all vaccines. In other words, even though the National Childhood Vaccine Injury Act of 1986 acknowledged that vaccine products caused harm and death, the makers of these products should not be held financially responsible for the harm their products cause.[19] [20]

The National Vaccine Injury Compensation Program (NVICP) was touted as a less expensive and quicker alternative to civil suits to compensate children and families who were ultimately harmed by vaccines. Individuals were still supposed to retain the right to sue a vaccine maker in civil court if they were denied compensation through the NVICP or if there was evidence that a vaccine maker could have made a vaccine safer — but chose not to.[21]

However, in February 2011, the U.S. Supreme Court, in Bruesewitz v. Wyeth, ruled that vaccines were "unavoidable unsafe" and granted pharmaceutical companies a complete liability shield.[22]

You can no longer sue a pharmaceutical company for damages caused by a vaccine - even if there is evidence that the drug maker knew that their product was defective and chose not to make it less harmful.

Instead, you must go through a highly adversarial claims process with the federal government for compensation and nearly 2 out of 3 claims are denied. Despite this, since 1988, over $4.5 billion dollars has been paid out to vaccine victims. [23]

Since 1988, there have been 124 claims filed in the federal Vaccine Injury Compensation Program (VICP) for the injuries and deaths following meningococcal vaccination, including 3 deaths and 121 serious injuries. 66 cases have been compensated, 28 dismissed, and the remaining are still pending. I do want to make this committee aware that persons injured or who die as a result of vaccination cannot sue in a court of law for damages. [24]

Given that meningococcal disease is rare, it is possible that the risks associated with this particular vaccine might outweigh the benefit. This vaccine must not be mandated. Health care providers and public health officials must ensure that parents are aware of the risks of this vaccine and allow them to make an educated decision based on the risks along with their child's personal health history.

If we have to fight these rules every 2 years for the rest of our lives, I can honestly tell you that we will. We will continue to show up, stand for freedom, and push back against heavy handed governmental overreach that we believe doesn't actually serve the people in our state.

Remember, Wisconsin DHS has lost the trust of the people – and DHS trying to assert their control with more mandates is certainly not going to help repair that broken trust.

As a mother – thank you to each committee member for attending today, and providing constituents, real moms and dads of Wisconsin, the ability to use their voice. I urge you to suspend rules 1, 2, 3, 4, and 5 of DHS 144 as changed by CR 19-079.

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[2] *COVID-19 Vaccine Provider Incentive program.* (2021, October). Retrieved March 6, 2023, from https://providers.anthem.com/docs/gpp/KY_CAID_PU_COVID19VaccineProviderIncentiveProgram.pdf?v=202201202223

[3] Centers for Disease Control. (1983). *CDC 1983 Immunization Schedule.* Retrieved February 22, 2023, from https://www.cdc.gov/vaccines/schedules/images/schedule1983s.jpg

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[7] Assembly Bill 303 - Lobbying in Wisconsin

[8] Bill Text - AB-659 Cancer Prevention Act.

[9] CDC Enhanced Meningococcal Disease Surveillance Report, 2019 2019.

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[18] Coulter HL, Fisher BL. DPT: A Shot in the Dark. Harcourt Brace Jovanovich 1985.

[19] U.s. code 42 USC CHAPTER 6A SUBCHAPTER XIX Part 2: From Title 42—THE PUBLIC HEALTH AND WELFARE - CHAPTER 6A—PUBLIC HEALTH SERVICE SUBCHAPTER XIX - VACCINES

[20] U.S. Code 42 USC CHAPTER 6A, SUBCHAPTER XIX, Part 2: National Vaccine Injury Compensation Program From Title 42—THE PUBLIC HEALTH AND WELFARE - CHAPTER 6A—PUBLIC HEALTH SERVICE SUBCHAPTER XIX—VACCINES

[21] U.s. code 42 USC CHAPTER 6A SUBCHAPTER XIX 2: From Title 42—THE PUBLIC HEALTH AND WELFARE - CHAPTER 6A—PUBLIC HEALTH SERVICE SUBCHAPTER XIX ... VACCINES

[22] U.S. Supreme Court. Bruesewitz v. Wyeth 09-152: Feb. 22, 2011.

[23] Health Resources & Services Administration (HRSA) Vaccine Injury Compensation Data through March 1, 2023. Mar. 1, 2023.

[24] Health Resources & Services Administration (HRSA) Vaccine Injury Compensation Data through March 1, 2023. Mar. 1, 2023.

COVID-19 Vaccine Provider Incentive program

Getting vaccinated against COVID-19 is one of the best and safest ways people can protect themselves and their families against the virus. As a participating practice in the COVID-19 Provider Vaccine Incentive program, we recognize your hard work by offering incentives for helping patients make the choice to become vaccinated.

Eligibility

The COVID-19 Vaccine Provider Incentive program is open to you if you are a participating Kentucky primary care provider with an Anthem Blue Cross and Blue Shield Medicaid (Anthem) panel size of 25 or more members. All Anthem members identified as receiving COVID-19 vaccination services are included in the methodology. Vaccine results will be determined by a COVID-19 vaccine claim or by confirmation from the Kentucky Vaccine Registry.

The results will be calculated for two time periods:

- September 1, 2021 – Initial incentive payment
- December 31, 2021 – Final incentive payment

How you can qualify for a bonus

If your practice meets the below thresholds for vaccination with at least one dose by September 1, 2021, you will receive the initial incentive payment based on the following rates:

- 30% Anthem members vaccinated – $20 bonus per vaccinated member
- 40% Anthem members vaccinated – $45 bonus per vaccinated member
- 50% Anthem members vaccinated – $70 bonus per vaccinated member
- 60% Anthem members vaccinated – $100 bonus per vaccinated member
- 75% Anthem members vaccinated – $125 bonus per vaccinated member

The final incentive payment is calculated based on members who are newly vaccinated between September 1, 2021 and December 31, 2021 (see the *Appendix* for calculation examples). If your practice meets the below thresholds for vaccination with at least one dose by December 1, 2021, you will receive the final incentive payment based on the following rates:

- 30%Anthem members vaccinated – $100 bonus per newly vaccinated member
- 40% Anthem members vaccinated – $150 bonus per newly vaccinated member
- 50% Anthem members vaccinated – $175 bonus per newly vaccinated member
- 60% Anthem members vaccinated – $200 bonus per newly vaccinated member
- 75% Anthem members vaccinated – $250 bonus per newly vaccinated member

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When you will receive your bonus

The first payment will be sent by electronic funds transfer or check based on the payment method used for claim reimbursement. Please allow 7 to 10 business days to receive payment. If you have not received it within that timeframe, reach out to a Provider Experience Consultant at 800-205-5870, option 3. The second payment will be generated on or before January 31, 2022.

Visit **https://providers.anthem.com/kentucky-provider/communications/covid-19-updates** for more information about the COVID-19 Vaccine Provider Incentive program. We greatly appreciate your partnership and look forward to working with you in the future.

Appendix

Below are examples to help illustrate Anthem Blue Cross and Blue Shield Medicaid (Anthem) COVID-19 Provider Incentive program payments.

Payment calculation examples

Payment thresholds		
Percent of Anthem Members Vaccinated	Initial Payment for Existing Vaccinated (Per Member)	Final Payment for Incremental Vaccinated (Per Member)
30%	$20	$100
40%	$45	$150
50%	$70	$175
60%	$100	$200
75%	$125	$250

Example 1 – Change in threshold			
	September 1, 2021	December 31, 2021	Newly Vaccinated Members
Vaccinated Members	78	105	+ 27
Total Provider Panel	250	251	
Vaccination Rate	31%	42%	
	Initial Payment	Final Payment	Total
Original Members	$1,560	–	$1,560
Incremental Members	–	$4,050	$4,050
Total	$1,560	$4,050	$5,610

In this example, Provider A:

- Grew their vaccinated panel from 31% to 42% by adding 27 new members vaccinated between September 1, 2021 and December 31, 2021
- Earned $1,560 initial payment for reaching the 30% threshold on September 1, 2021 ($20 x 78 vaccinated members)
- Earned $4,050 final payment for reaching the 40% threshold on December 31, 2021 ($150 x 27 newly vaccinated members)

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Example 2 – No change in threshold			
	September 1, 2021	December 31, 2021	Newly Vaccinated Members
Vaccinated Members	78	83	+5
Total Provider Panel	250	251	
Vaccination Rate	31%	33%	
	Initial Payment	Final Payment	Total
Original Members	$1,560	–	$1,560
Incremental Members	–	$500	$500
Total	$1,560	$500	$2,060

In this example, Provider B:

- Grew their vaccinated panel from 31% to 33% by adding 5 new members vaccinated between September 1, 2021 and December 31, 2021
- Earned $1,560 initial payment for reaching the 30% threshold on September 1, 2021 ($20 x 78 vaccinated members)
- Earned $500 final payment for staying in the 30% threshold on December 31, 2021 ($100 x 5 newly vaccinated members)

COVID-19 Vaccine Provider Incentive program

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Eligibility

The COVID-19 Vaccine Provider Incentive program is open to you if you are a participating Kentucky primary care provider with an Anthem Blue Cross and Blue Shield Medicaid (Anthem) panel size of 25 or more members. All Anthem members identified as receiving COVID-19 vaccination services are included in the methodology. Vaccine results will be determined by a COVID-19 vaccine claim or by confirmation from the Kentucky Vaccine Registry.

The results will be calculated for two time periods:

- September 1, 2021 – Initial incentive payment
- December 31, 2021 – Final incentive payment

How you can qualify for a bonus

If your practice meets the below thresholds for vaccination with at least one dose by September 1, 2021, you will receive the initial incentive payment based on the following rates:

- 30% Anthem members vaccinated – $20 bonus per vaccinated member
- 40% Anthem members vaccinated – $45 bonus per vaccinated member
- 50% Anthem members vaccinated – $70 bonus per vaccinated member
- 60% Anthem members vaccinated – $100 bonus per vaccinated member
- 75% Anthem members vaccinated – $125 bonus per vaccinated member

The final incentive payment is calculated based on members who are newly vaccinated between September 1, 2021 and December 31, 2021 (see the *Appendix* for calculation examples). If your practice meets the below thresholds for vaccination with at least one dose by December 1, 2021, you will receive the final incentive payment based on the following rates:

- 30%Anthem members vaccinated – $100 bonus per newly vaccinated member
- 40% Anthem members vaccinated – $150 bonus per newly vaccinated member
- 50% Anthem members vaccinated – $175 bonus per newly vaccinated member
- 60% Anthem members vaccinated – $200 bonus per newly vaccinated member
- 75% Anthem members vaccinated – $250 bonus per newly vaccinated member

AKYPEC-2982-21 October 2021

When you will receive your bonus

The first payment will be sent by electronic funds transfer or check based on the payment method used for claim reimbursement. Please allow 7 to 10 business days to receive payment. If you have not received it within that timeframe, reach out to a Provider Experience Consultant at 800-205-5870, option 3. The second payment will be generated on or before January 31, 2022.

Visit **https://providers.anthem.com/kentucky-provider/communications/covid-19-updates** for more information about the COVID-19 Vaccine Provider Incentive program. We greatly appreciate your partnership and look forward to working with you in the future.

Appendix

Below are examples to help illustrate Anthem Blue Cross and Blue Shield Medicaid (Anthem) COVID-19 Provider Incentive program payments.

Payment calculation examples

Payment thresholds		
Percent of Anthem Members Vaccinated	Initial Payment for Existing Vaccinated (Per Member)	Final Payment for Incremental Vaccinated (Per Member)
30%	$20	$100
40%	$45	$150
50%	$70	$175
60%	$100	$200
75%	$125	$250

Example 1 – Change in threshold			
	September 1, 2021	December 31, 2021	Newly Vaccinated Members
Vaccinated Members	78	105	+ 27
Total Provider Panel	250	251	
Vaccination Rate	31%	42%	
	Initial Payment	Final Payment	Total
Original Members	$1,560	–	$1,560
Incremental Members	–	$4,050	$4,050
Total	$1,560	$4,050	$5,610

In this example, Provider A:

- Grew their vaccinated panel from 31% to 42% by adding 27 new members vaccinated between September 1, 2021 and December 31, 2021
- Earned $1,560 initial payment for reaching the 30% threshold on September 1, 2021 ($20 x 78 vaccinated members)
- Earned $4,050 final payment for reaching the 40% threshold on December 31, 2021 ($150 x 27 newly vaccinated members)

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Example 2 – No change in threshold			
	September 1, 2021	December 31, 2021	Newly Vaccinated Members
Vaccinated Members	78	83	+5
Total Provider Panel	250	251	
Vaccination Rate	31%	33%	
	Initial Payment	Final Payment	Total
Original Members	$1,560	–	$1,560
Incremental Members	–	$500	$500
Total	$1,560	$500	$2,060

In this example, Provider B:

- Grew their vaccinated panel from 31% to 33% by adding 5 new members vaccinated between September 1, 2021 and December 31, 2021
- Earned $1,560 initial payment for reaching the 30% threshold on September 1, 2021 ($20 x 78 vaccinated members)
- Earned $500 final payment for staying in the 30% threshold on December 31, 2021 ($100 x 5 newly vaccinated members)

TABLE 1. Recommended schedule for active immunization of normal infants and children (See individual ACIP recommendations for details.)

Recommended age*	Vaccine(s)†	Comments
2 mo.	DTP-1,§ OPV-1¶	Can be given earlier in areas of high endemicity
4 mo.	DTP-2, OPV-2	6-wks-2-mo. interval desired between OPV doses to avoid interference
6 mo.	DTP-3	An additional dose of OPV at this time is optional for use in areas with a high risk of polio exposure
15 mo.**	MMR††	
18 mo.**	DTP-4, OPV-3	Completion of primary series
4-6 yr.§§	DTP-5, OPV-4	Preferably at or before school entry
14-16. yr	Td¶¶	Repeat every 10 years throughout life

*These recommended ages should not be construed as absolute, i.e. 2 mos. can be 6-10 weeks, etc.

†For all products used, consult manufacturer's package enclosure for instructions for storage, handling, and administration. Immunobiologics prepared by different manufacturers may vary, and those of the same manufacturer may change from time to time. The package insert should be followed for a specific product.

§DTP—Diphtheria and tetanus toxoids and pertussis vaccine.

¶OPV—Oral, attenuated poliovirus vaccine contains poliovirus types 1, 2, and 3.

**Simultaneous administration of MMR, DTP, and OPV is appropriate for patients whose compliance with medical care recommendations cannot be assured.

††MMR—Live measles, mumps, and rubella viruses in a combined vaccine (see text for discussion of single vaccines versus combination).

§§Up to the seventh birthday.

¶¶Td—Adult tetanus toxoid and diphtheria toxoid in combination, which contains the same dose of tetanus toxoid as DTP or DT and a reduced dose of diphtheria toxoid.

Recommended Child and Adolescent Immunization Schedule
for ages 18 years or younger

UNITED STATES
2023

Vaccines in the Child and Adolescent Immunization Schedule*

Vaccine	Abbreviation(s)	Trade name(s)
COVID-19	**1vCOV-mRNA**	Comirnaty®/Pfizer-BioNTech COVID-19 Vaccine
		SPIKEVAX®/Moderna COVID-19 Vaccine
	2vCOV-mRNA	Pfizer-BioNTech COVID-19 Vaccine, Bivalent
		Moderna COVID-19 Vaccine, Bivalent
	1vCOV-aPS	Novavax COVID-19 Vaccine
Dengue vaccine	**DEN4CYD**	Dengvaxia®
Diphtheria, tetanus, and acellular pertussis vaccine	**DTaP**	Daptacel® Infanrix®
Diphtheria, tetanus vaccine	**DT**	No trade name
Haemophilus influenzae type b vaccine	**Hib (PRP-T)**	ActHIB® Hiberix® PedvaxHIB®
	Hib (PRP-OMP)	
Hepatitis A vaccine	**HepA**	Havrix® Vaqta®
Hepatitis B vaccine	**HepB**	Engerix-B® Recombivax HB®
Human papillomavirus vaccine	**HPV**	Gardasil 9®
Influenza vaccine (inactivated)	**IIV4**	Multiple
Influenza vaccine (live, attenuated)	**LAIV4**	FluMist® Quadrivalent
Measles, mumps, and rubella vaccine	**MMR**	M-M-R II® Priorix®
Meningococcal serogroups A, C, W, Y vaccine	**MenACWY-D**	Menactra®
	MenACWY-CRM	Menveo®
	MenACWY-TT	MenQuadfi®
Meningococcal serogroup B vaccine	**MenB-4C**	Bexsero®
	MenB-FHbp	Trumenba®
Pneumococcal conjugate vaccine	**PCV13** **PCV15**	Prevnar 13® Vaxneuvance™
Pneumococcal polysaccharide vaccine	**PPSV23**	Pneumovax 23®
Poliovirus vaccine (inactivated)	**IPV**	IPOL®
Rotavirus vaccine	**RV1** **RV5**	Rotarix® RotaTeq®
Tetanus, diphtheria, and acellular pertussis vaccine	**Tdap**	Adacel® Boostrix®
Tetanus and diphtheria vaccine	**Td**	Tenivac® Tdvax™
Varicella vaccine	**VAR**	Varivax®
Combination vaccines *(use combination vaccines instead of separate injections when appropriate)*		
DTaP, hepatitis B, and inactivated poliovirus vaccine	**DTaP-HepB-IPV**	Pediarix®
DTaP, inactivated poliovirus, and *Haemophilus influenzae* type b vaccine	**DTaP-IPV/Hib**	Pentacel®
DTaP and inactivated poliovirus vaccine	**DTaP-IPV**	Kinrix® Quadracel®
DTaP, inactivated poliovirus, *Haemophilus influenzae* type b, and hepatitis B vaccine	**DTaP-IPV-Hib-HepB**	Vaxelis®
Measles, mumps, rubella, and varicella vaccine	**MMRV**	ProQuad®

*Administer recommended vaccines if immunization history is incomplete or unknown. Do not restart or add doses to vaccine series for extended intervals between doses. When a vaccine is not administered at the recommended age, administer at a subsequent visit. The use of trade names is for identification purposes only and does not imply endorsement by the ACIP or CDC.

How to use the child and adolescent immunization schedule

1 Determine recommended vaccine by age **(Table 1)**

2 Determine recommended interval for catch-up vaccination **(Table 2)**

3 Assess need for additional recommended vaccines by medical condition or other indication **(Table 3)**

4 Review vaccine types, frequencies, intervals, and considerations for special situations **(Notes)**

5 Review contraindications and precautions for vaccine types **(Appendix)**

Recommended by the Advisory Committee on Immunization Practices (www.cdc.gov/vaccines/acip) and approved by the Centers for Disease Control and Prevention (www.cdc.gov), American Academy of Pediatrics (www.aap.org), American Academy of Family Physicians (www.aafp.org), American College of Obstetricians and Gynecologists (www.acog.org), American College of Nurse-Midwives (www.midwife.org), American Academy of Physician Associates (www.aapa.org), and National Association of Pediatric Nurse Practitioners (www.napnap.org).

Report

- Suspected cases of reportable vaccine-preventable diseases or outbreaks to your state or local health department
- Clinically significant adverse events to the Vaccine Adverse Event Reporting System (VAERS) at www.vaers.hhs.gov or 800-822-7967

Questions or comments

Contact www.cdc.gov/cdc-info or 800-CDC-INFO (800-232-4636), in English or Spanish, 8 a.m.–8 p.m. ET, Monday through Friday, excluding holidays

Download the CDC Vaccine Schedules app for providers at www.cdc.gov/vaccines/schedules/hcp/schedule-app.html

Helpful information

- Complete Advisory Committee on Immunization Practices (ACIP) recommendations: www.cdc.gov/vaccines/hcp/acip-recs/index.html
- *General Best Practice Guidelines for Immunization* (including contraindications and precautions): www.cdc.gov/vaccines/hcp/acip-recs/general-recs/index.html
- Vaccine information statements: www.cdc.gov/vaccines/hcp/vis/index.html
- Manual for the Surveillance of Vaccine-Preventable Diseases (including case identification and outbreak response): www.cdc.gov/vaccines/pubs/surv-manual
- ACIP Shared Clinical Decision-Making Recommendations www.cdc.gov/vaccines/acip/acip-scdm-faqs.html

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Scan QR code for access to online schedule

CS310020-C

Table 1 Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

These recommendations must be read with the notes that follow. For those who fall behind or start late, provide catch-up vaccination at the earliest opportunity as indicated by the green bars.
To determine minimum intervals between doses, see the catch-up schedule (Table 2).

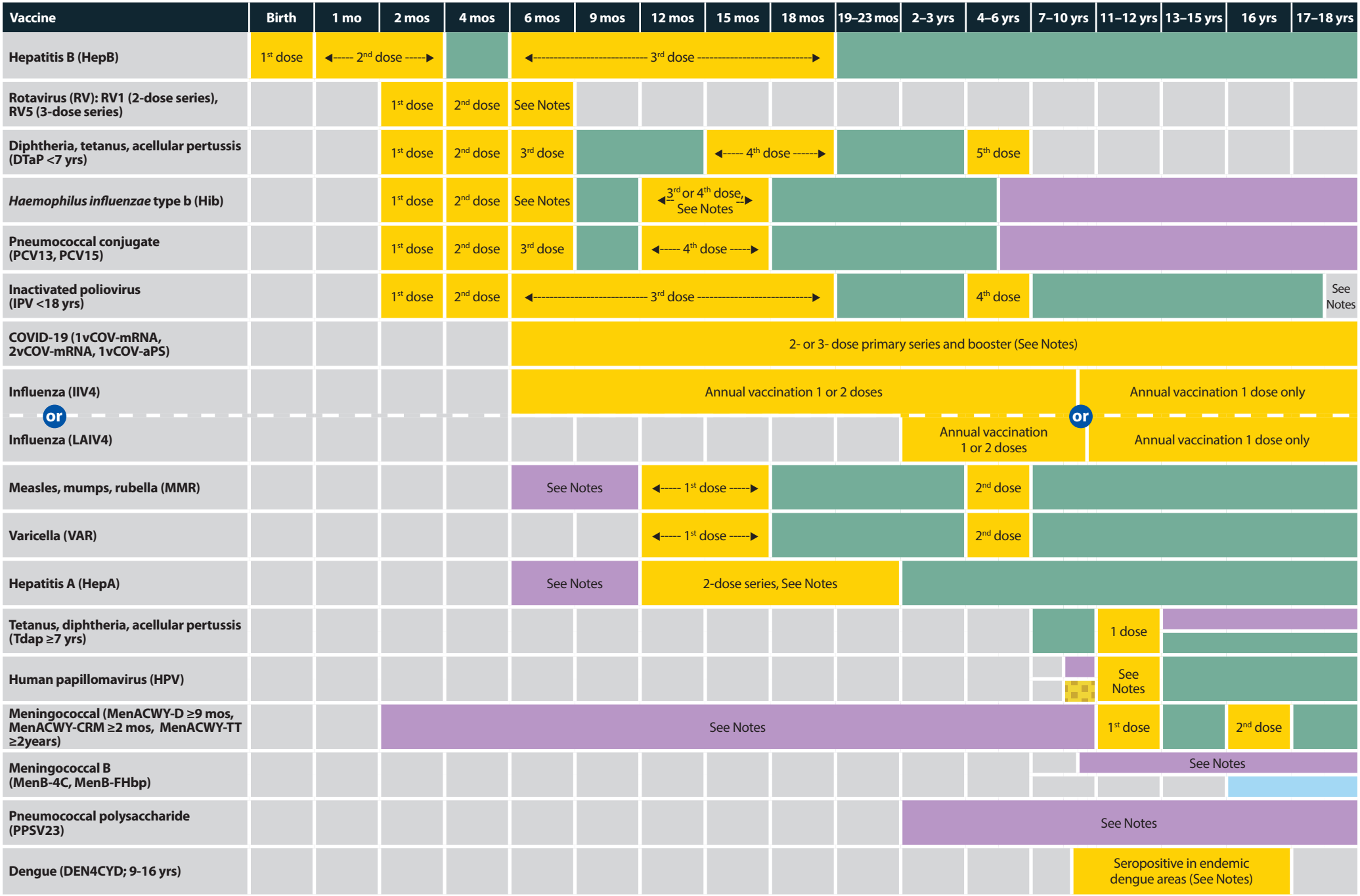

Table 2 Recommended Catch-up Immunization Schedule for Children and Adolescents Who Start Late or Who Are More than 1 Month Behind, United States, 2023

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age. **Always use this table in conjunction with Table 1 and the Notes that follow.**

Vaccine	Minimum Age for Dose 1	Minimum Interval Between Doses			
		Dose 1 to Dose 2	Dose 2 to Dose 3	Dose 3 to Dose 4	Dose 4 to Dose 5
Children age 4 months through 6 years					
Hepatitis B	Birth	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose** minimum age for the final dose is 24 weeks		
Rotavirus	6 weeks Maximum age for first dose is 14 weeks, 6 days.	**4 weeks**	**4 weeks** maximum age for final dose is 8 months, 0 days		
Diphtheria, tetanus, and acellular pertussis	6 weeks	**4 weeks**	**4 weeks**	**6 months**	**6 months**
Haemophilus influenzae type b	6 weeks	**No further doses needed** if first dose was administered at age 15 months or older. **4 weeks** if first dose was administered before the 1st birthday. **8 weeks (as final dose)** if first dose was administered at age 12 through 14 months.	**No further doses needed** if previous dose was administered at age 15 months or older **4 weeks** if current age is younger than 12 months ***and*** first dose was administered at younger than age 7 months ***and*** at least 1 previous dose was PRP-T (ActHib®, Pentacel®, Hiberix®), Vaxelis® or unknown **8 weeks *and* age 12 through 59 months (as final dose)** if current age is younger than 12 months ***and*** first dose was administered at age 7 through 11 months; OR if current age is 12 through 59 months ***and*** first dose was administered before the 1st birthday ***and*** second dose was administered at younger than 15 months; OR if both doses were PedvaxHIB® and were administered before the 1st birthday	**8 weeks (as final dose)** This dose only necessary for children age 12 through 59 months who received 3 doses before the 1st birthday.	
Pneumococcal conjugate	6 weeks	**No further doses needed** for healthy children if first dose was administered at age 24 months or older **4 weeks** if first dose was administered before the 1st birthday **8 weeks (as final dose for healthy children)** if first dose was administered at the 1st birthday or after	**No further doses needed** for healthy children if previous dose was administered at age 24 months or older **4 weeks** if current age is younger than 12 months and previous dose was administered at <7 months old **8 weeks (as final dose for healthy children)** if previous dose was administered between 7–11 months (wait until at least 12 months old); OR if current age is 12 months or older and at least 1 dose was administered before age 12 months	**8 weeks (as final dose)** this dose is only necessary for children aged 12 through 59 months regardless of risk, or age 60 through 71 months with any risk, who received 3 doses before age 12 months.	
Inactivated poliovirus	6 weeks	**4 weeks**	**4 weeks** if current age is <4 years **6 months (as final dose)** if current age is 4 years or older	**6 months (minimum age 4 years for final dose)**	
Measles, mumps, rubella	12 months	**4 weeks**			
Varicella	12 months	**3 months**			
Hepatitis A	12 months	**6 months**			
Meningococcal ACWY	2 months MenACWY-CRM 9 months MenACWY-D 2 years MenACWY-TT	**8 weeks**	See Notes	See Notes	
Children and adolescents age 7 through 18 years					
Meningococcal ACWY	Not applicable (N/A)	**8 weeks**			
Tetanus, diphtheria; tetanus, diphtheria, and acellular pertussis	7 years	**4 weeks**	**4 weeks** if first dose of DTaP/DT was administered before the 1st birthday **6 months (as final dose)** if first dose of DTaP/DT or Tdap/Td was administered at or after the 1st birthday	**6 months** if first dose of DTaP/DT was administered before the 1st birthday	
Human papillomavirus	9 years	**Routine dosing intervals are recommended.**			
Hepatitis A	N/A	**6 months**			
Hepatitis B	N/A	**4 weeks**	**8 weeks *and* at least 16 weeks after first dose**		
Inactivated poliovirus	N/A	**4 weeks**	**6 months** A fourth dose is not necessary if the third dose was administered at age 4 years or older and at least 6 months after the previous dose.	A fourth dose of IPV is indicated if all previous doses were administered at <4 years or if the third dose was administered <6 months after the second dose.	
Measles, mumps, rubella	N/A	**4 weeks**			
Varicella	N/A	**3 months** if younger than age 13 years. **4 weeks** if age 13 years or older			
Dengue	9 years	**6 months**	6 months		

Table 3

Recommended Child and Adolescent Immunization Schedule by Medical Indication, United States, 2023

Always use this table in conjunction with Table 1 and the Notes that follow.

VACCINE	INDICATION										
	Pregnancy	Immunocompromised status (excluding HIV infection)	HIV infection CD4+ count[a]		Kidney failure, end-stage renal disease, or on hemodialysis	Heart disease or chronic lung disease	CSF leak or cochlear implant	Asplenia or persistent complement component deficiencies	Chronic liver disease	Diabetes
			<15% or total CD4 cell count of <200/mm³	≥15% and total CD4 cell count of ≥200/mm³						
Hepatitis B										
Rotavirus		SCID[b]								
Diphtheria, tetanus, and acellular pertussis (DTaP)										
Haemophilus influenzae type b										
Pneumococcal conjugate										
Inactivated poliovirus										
COVID-19		See Notes	See Notes							
Influenza (IIV4)										
or										
Influenza (LAIV4)						Asthma, wheezing: 2–4yrs[c]				
Measles, mumps, rubella	*									
Varicella	*									
Hepatitis A										
Tetanus, diphtheria, and acellular pertussis (Tdap)										
Human papillomavirus	*									
Meningococcal ACWY										
Meningococcal B										
Pneumococcal polysaccharide										
Dengue										

- Vaccination according to the routine schedule recommended
- Recommended for persons with an additional risk factor for which the vaccine would be indicated
- Vaccination is recommended, and additional doses may be necessary based on medical condition or vaccine. See Notes.
- Precaution–vaccine might be indicated if benefit of protection outweighs risk of adverse reaction
- Contraindicated or not recommended–vaccine should not be administered
  *Vaccinate after pregnancy
- No recommendation/not applicable

a. For additional information regarding HIV laboratory parameters and use of live vaccines, see the *General Best Practice Guidelines for Immunization*, "Altered Immunocompetence," at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html and Table 4-1 (footnote J) at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.
b. Severe Combined Immunodeficiency
c. LAIV4 contraindicated for children 2–4 years of age with asthma or wheezing during the preceding 12 months

Notes

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

For vaccination recommendations for persons ages 19 years or older, see the Recommended Adult Immunization Schedule, 2023.

Additional information

- Consult relevant ACIP statements for detailed recommendations at www.cdc.gov/vaccines/hcp/acip-recs/index.html.
- For calculating intervals between doses, 4 weeks = 28 days. Intervals of ≥4 months are determined by calendar months.
- Within a number range (e.g., 12–18), a dash (–) should be read as "through."
- Vaccine doses administered ≤4 days before the minimum age or interval are considered valid. Doses of any vaccine administered ≥5 days earlier than the minimum age or minimum interval should not be counted as valid and should be repeated as age appropriate. **The repeat dose should be spaced after the invalid dose by the recommended minimum interval.** For further details, see Table 3-2, Recommended and minimum ages and intervals between vaccine doses, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/timing.html.
- Information on travel vaccination requirements and recommendations is available at www.cdc.gov/travel/.
- For vaccination of persons with immunodeficiencies, see Table 8-1, Vaccination of persons with primary and secondary immunodeficiencies, in *General Best Practice Guidelines for Immunization* at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/immunocompetence.html, and Immunization in Special Clinical Circumstances (In: Kimberlin DW, Barnett ED, Lynfield Ruth, Sawyer MH, eds. *Red Book: 2021–2024 Report of the Committee on Infectious Diseases*. 32nd ed. Itasca, IL: American Academy of Pediatrics; 2021:72–86).
- For information about vaccination in the setting of a vaccine-preventable disease outbreak, contact your state or local health department.
- The National Vaccine Injury Compensation Program (VICP) is a no-fault alternative to the traditional legal system for resolving vaccine injury claims. All vaccines included in the child and adolescent vaccine schedule are covered by VICP except dengue, PPSV23, and COVID-19 vaccines. COVID-19 vaccines that are authorized or approved by the FDA are covered by the Countermeasures Injury Compensation Program (CICP). For more information, see www.hrsa.gov/vaccinecompensation or www.hrsa.gov/cicp.

COVID-19 vaccination (minimum age: 6 months [Moderna and Pfizer-BioNTech COVID-19 vaccines], 12 years [Novavax COVID-19 Vaccine])

Routine vaccination

- **Primary series:**
  - **Age 6 months–4 years:** 2-dose series at 0, 4-8 weeks (Moderna) or 3-dose series at 0, 3-8, 11-16 weeks (Pfizer-BioNTech)
  - **Age 5–11 years:** 2-dose series at 0, 4-8 weeks (Moderna) or 2-dose series at 0, 3-8 weeks (Pfizer-BioNTech)
  - **Age 12–18 years:** 2-dose series at 0, 4-8 weeks (Moderna) or 2-dose series at 0, 3-8 weeks (Novavax, Pfizer-BioNTech)
- For **booster dose recommendations** see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

Special situations

Persons who are moderately or severely immunocompromised

- **Primary series**
  - **Age 6 months–4 years:** 3-dose series at 0, 4, 8 weeks (Moderna) or 3-dose series at 0, 3, 11 weeks (Pfizer-BioNTech)
  - **Age 5–11 years:** 3-dose series at 0, 4, 8 weeks (Moderna) or 3-dose series at 0, 3, 7 weeks (Pfizer-BioNTech)
  - **Age 12–18 years:** 3-dose series at 0, 4, 8 weeks (Moderna) or 2-dose series at 0, 3 weeks (Novavax) or 3-dose series at 0, 3, 7 weeks (Pfizer-BioNTech)
- **Booster dose:** see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html
- **Pre-exposure prophylaxis** (monoclonal antibodies) may be considered to complement COVID-19 vaccination. See www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised

For Janssen COVID-19 Vaccine recipients see COVID-19 schedule at www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html

Note: Administer an age-appropriate vaccine product for each dose. Current COVID-19 schedule and dosage formulation available at www.cdc.gov/vaccines/covid-19/downloads/COVID-19-immunization-schedule-ages-6months-older.pdf. For more information on Emergency Use Authorization (EUA) indications for COVID-19 vaccines, see www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines.

Dengue vaccination (minimum age: 9 years)

Routine vaccination

- Age 9–16 years living in areas with endemic dengue **AND** have laboratory confirmation of previous dengue infection
  - 3-dose series administered at 0, 6, and 12 months
- Endemic areas include Puerto Rico, American Samoa, US Virgin Islands, Federated States of Micronesia, Republic of Marshall Islands, and the Republic of Palau. For updated guidance on dengue endemic areas and pre-vaccination laboratory testing see www.cdc.gov/mmwr/volumes/70/rr/rr7006a1.htm?s_cid=rr7006a1_w and www.cdc.gov/dengue/vaccine/hcp/index.html
- Dengue vaccine should not be administered to children traveling to or visiting endemic dengue areas.

Diphtheria, tetanus, and pertussis (DTaP) vaccination (minimum age: 6 weeks [4 years for Kinrix® or Quadracel®])

Routine vaccination

- 5-dose series at age 2, 4, 6, 15–18 months, 4–6 years
  - **Prospectively:** Dose 4 may be administered as early as age 12 months if at least 6 months have elapsed since dose 3.
  - **Retrospectively:** A 4th dose that was inadvertently administered as early as age 12 months may be counted if at least 4 months have elapsed since dose 3.

Catch-up vaccination

- Dose 5 is not necessary if dose 4 was administered at age 4 years or older and at least 6 months after dose 3.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in children less than age 7 years with history of 3 or more doses of tetanus-toxoid-containing vaccine: For all wounds except clean and minor wounds, administer DTaP if more than 5 years since last dose of tetanus-toxoid-containing vaccine. For detailed information, see www.cdc.gov/mmwr/volumes/67/rr/rr6702a1.htm.

Notes

Haemophilus influenzae type b vaccination
(minimum age: 6 weeks)

Routine vaccination

- **ActHIB®, Hiberix®, Pentacel®, or Vaxelis®:** 4-dose series (3-dose primary series at age 2, 4, and 6 months, followed by a booster dose* at age 12–15 months)
  - *Vaxelis® is not recommended for use as a booster dose. A different Hib-containing vaccine should be used for the booster dose.
- **PedvaxHIB®:** 3-dose series (2-dose primary series at age 2 and 4 months, followed by a booster dose at age 12–15 months)

Catch-up vaccination

- **Dose 1 at age 7–11 months:** Administer dose 2 at least 4 weeks later and dose 3 (final dose) at age12–15 months or 8 weeks after dose 2 (whichever is later).
- **Dose 1 at age 12–14 months:** Administer dose 2 (final dose) at least 8 weeks after dose 1.
- **Dose 1 before age 12 months and dose 2 before age 15 months:** Administer dose 3 (final dose) at least 8 weeks after dose 2.
- **2 doses of PedvaxHIB® before age 12 months:** Administer dose 3 (final dose) at age12–59 months and at least 8 weeks after dose 2.
- **1 dose administered at age 15 months or older:** No further doses needed
- **Unvaccinated at age 15–59 months:** Administer 1 dose.
- **Previously unvaccinated children age 60 months or older who are not considered high risk:** Do not require catch-up vaccination

For other catch-up guidance, see Table 2. Vaxelis® can be used for catch-up vaccination in children less than age 5 years. Follow the catch-up schedule even if Vaxelis® is used for one or more doses. For detailed information on use of Vaxelis® see www.cdc.gov/mmwr/volumes/69/wr/mm6905a5.htm.

Special situations

- **Chemotherapy or radiation treatment:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Doses administered within 14 days of starting therapy or during therapy should be repeated at least 3 months after therapy completion.
- **Hematopoietic stem cell transplant (HSCT):**
  - 3-dose series 4 weeks apart starting 6 to 12 months after successful transplant, regardless of Hib vaccination history
- **Anatomic or functional asplenia (including sickle cell disease):**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated persons age 5 years or older*
  - 1 dose
- **Elective splenectomy:**
  Unvaccinated persons age 15 months or older*
  - 1 dose (preferably at least 14 days before procedure)
- **HIV infection:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

  Unvaccinated persons age 5–18 years*
  - 1 dose
- **Immunoglobulin deficiency, early component complement deficiency:**
  Age 12–59 months
  - Unvaccinated or only 1 dose before age 12 months: 2 doses, 8 weeks apart
  - 2 or more doses before age 12 months: 1 dose at least 8 weeks after previous dose

*_Unvaccinated_ = Less than routine series (through age 14 months) OR no doses (age 15 months or older)

Hepatitis A vaccination
(minimum age: 12 months for routine vaccination)

Routine vaccination

- 2-dose series (minimum interval: 6 months) at age 12–23 months

Catch-up vaccination

- Unvaccinated persons through age 18 years should complete a 2-dose series (minimum interval: 6 months).
- Persons who previously received 1 dose at age 12 months or older should receive dose 2 at least 6 months after dose 1.
- Adolescents age 18 years or older may receive the combined HepA and HepB vaccine, **Twinrix®**, as a 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

International travel

- Persons traveling to or working in countries with high or intermediate endemic hepatitis A (www.cdc.gov/travel/):
  - **Infants age 6–11 months**: 1 dose before departure; revaccinate with 2 doses (separated by at least 6 months) between age 12–23 months.
  - **Unvaccinated age 12 months or older**: Administer dose 1 as soon as travel is considered.

Hepatitis B vaccination
(minimum age: birth)

Routine vaccination

- 3-dose series at age 0, 1–2, 6–18 months **(use monovalent HepB vaccine for doses administered before age 6 weeks)**
  - Birth weight ≥2,000 grams: 1 dose within 24 hours of birth if medically stable
  - Birth weight <2,000 grams: 1 dose at chronological age 1 month or hospital discharge (whichever is earlier and even if weight is still <2,000 grams).
- Infants who did not receive a birth dose should begin the series as soon as possible (see Table 2 for minimum intervals).
- Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the birth dose.
- **Minimum intervals (see Table 2):** when 4 doses are administered, substitute "dose 4" for "dose 3" in these calculations
- **Final (3rd or 4th) dose:** age 6–18 months **(minimum age 24 weeks)**
- **Mother is HBsAg-positive**
  - **Birth dose (monovalent HepB vaccine only):** administer **HepB vaccine** and **hepatitis B immune globulin (HBIG)** (in separate limbs) within 12 hours of birth, regardless of birth weight.
  - **Birth weight <2000 grams:** administer 3 additional doses of HepB vaccine beginning at age 1 month (total of 4 doses)
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**
  - Test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

Notes

Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

- **Mother is HBsAg-unknown**

  If other evidence suggestive of maternal hepatitis B infection exists (e.g., presence of HBV DNA, HBeAg-positive, or mother known to have chronic hepatitis B infection), manage infant as if mother is HBsAg-positive

  - **Birth dose (monovalent HepB vaccine only):**
    - Birth weight ≥2,000 grams: administer **HepB vaccine** within 12 hours of birth. Determine mother's HBsAg status as soon as possible. If mother is determined to be HBsAg-positive, administer **HBIG** as soon as possible (in separate limb), but no later than 7 days of age.
    - Birth weight <2,000 grams: administer **HepB vaccine** and **HBIG** (in separate limbs) within 12 hours of birth. Administer 3 additional doses of **HepB vaccine** beginning at age 1 month (total of 4 doses)
  - **Final (3rd or 4th) dose:** administer at age 6 months **(minimum age 24 weeks)**
  - If mother is determined to be HBsAg-positive or if status remains unknown, test for HBsAg and anti-HBs at age 9–12 months. If HepB series is delayed, test 1–2 months after final dose. Do not test before age 9 months.

Catch-up vaccination

- Unvaccinated persons should complete a 3-dose series at 0, 1–2, 6 months. See Table 2 for minimum intervals
- Adolescents age 11–15 years may use an alternative 2-dose schedule with at least 4 months between doses (adult formulation **Recombivax HB®** only).
- Adolescents age 18 years or older may receive:
  - **Heplisav-B®:** 2-dose series at least 4 weeks apart
  - **PreHevbrio®:** 3-dose series at 0, 1, and 6 months
  - Combined HepA and HepB vaccine, **Twinrix®:** 3-dose series (0, 1, and 6 months) or 4-dose series (3 doses at 0, 7, and 21–30 days, followed by a booster dose at 12 months).

Special situations

- Revaccination is not generally recommended for persons with a normal immune status who were vaccinated as infants, children, adolescents, or adults.
- **Post-vaccination serology testing and revaccination** (if anti-HBs < 10mIU/mL) is recommended for certain populations, including:
  - Infants born to HBsAg-positive mothers
  - Persons who are predialysis or on maintenance dialysis
  - Other immunocompromised persons
  - For detailed revaccination recommendations, see www.cdc.gov/vaccines/hcp/acip-recs/vacc-specific/hepb.html.

Note: Heplisav-B and PreHevbrio are not recommended in pregnancy due to lack of safety data in pregnant persons

Human papillomavirus vaccination (minimum age: 9 years)

Routine and catch-up vaccination

- HPV vaccination routinely recommended at **age 11–12 years (can start at age 9 years)** and catch-up HPV vaccination recommended for all persons through age 18 years if not adequately vaccinated
- 2- or 3-dose series depending on age at initial vaccination:
  - **Age 9–14 years at initial vaccination**: 2-dose series at 0, 6–12 months (minimum interval: 5 months; repeat dose if administered too soon)
  - **Age 15 years or older at initial vaccination**: 3-dose series at 0, 1–2 months, 6 months (minimum intervals: dose 1 to dose 2: 4 weeks / dose 2 to dose 3: 12 weeks / dose 1 to dose 3: 5 months; repeat dose if administered too soon)
- **Interrupted schedules:** If vaccination schedule is interrupted, the series does not need to be restarted.
- No additional dose recommended when any HPV vaccine series has been completed using the recommended dosing intervals.

Special situations

- **Immunocompromising conditions, including HIV infection:** 3-dose series, even for those who initiate vaccination at age 9 through 14 years.
- **History of sexual abuse or assault:** Start at age 9 years
- **Pregnancy:** Pregnancy testing not needed before vaccination; HPV vaccination not recommended until after pregnancy; no intervention needed if vaccinated while pregnant

Influenza vaccination (minimum age: 6 months [IIV], 2 years [LAIV4], 18 years [recombinant influenza vaccine, RIV4])

Routine vaccination

- Use any influenza vaccine appropriate for age and health status annually:
  - 2 doses, separated by at least 4 weeks, for **children age 6 months–8 years** who have received fewer than 2 influenza vaccine doses before July 1, 2022, or whose influenza vaccination history is unknown (administer dose 2 even if the child turns 9 between receipt of dose 1 and dose 2)
  - 1 dose for **children age 6 months–8 years** who have received at least 2 influenza vaccine doses before July 1, 2022
  - 1 dose for **all persons age 9 years or older**
  - For the 2022-2023 season, see www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm.
  - For the 2023–24 season, see the 2023–24 ACIP influenza vaccine recommendations.

Special situations

- **Egg allergy, hives only**: Any influenza vaccine appropriate for age and health status annually
- **Egg allergy with symptoms other than hives** (e.g., angioedema, respiratory distress) or required epinephrine or another emergency medical intervention: Any influenza vaccine appropriate for age and health status may be administered. If using egg-based IIV4 or LAIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions.
- **Severe allergic reaction (e.g., anaphylaxis) to a vaccine component or a previous dose of any influenza vaccine:** see Appendix listing contraindications and precautions
- **Close contacts (e.g., caregivers, healthcare personnel) of severely immunosuppressed persons who require a protected environment:** these persons should not receive LAIV4. If LAIV4 is given, they should avoid contact with/caring for such immunosuppressed persons for 7 days after vaccination.

Measles, mumps, and rubella vaccination (minimum age: 12 months for routine vaccination)

Routine vaccination

- 2-dose series at age 12–15 months, age 4–6 years
- MMR or MMRV may be administered

Note: For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Catch-up vaccination

- Unvaccinated children and adolescents: 2-dose series at least 4 weeks apart
- The maximum age for use of MMRV is 12 years.
- Minimum interval between *MMRV* doses: 3 months

Notes

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Special situations

- **International travel**
  - **Infants age 6–11 months:** 1 dose before departure; revaccinate with 2-dose series at age 12–15 months (12 months for children in high-risk areas) and dose 2 as early as 4 weeks later.
  - **Unvaccinated children age 12 months or older:** 2-dose series at least 4 weeks apart before departure
- In mumps outbreak settings, for information about additional doses of MMR (including 3rd dose of MMR), see www.cdc.gov/mmwr/volumes/67/wr/mm6701a7.htm

Meningococcal serogroup A,C,W,Y vaccination (minimum age: 2 months [MenACWY-CRM, Menveo], 9 months [MenACWY-D, Menactra], 2 years [MenACWY-TT, MenQuadfi])

Routine vaccination

- 2-dose series at age 11–12 years; 16 years

Catch-up vaccination

- Age 13–15 years: 1 dose now and booster at age 16–18 years (minimum interval: 8 weeks)
- Age 16–18 years: 1 dose

Special situations

Anatomic or functional asplenia (including sickle cell disease), HIV infection, persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- **Menveo®***
  - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
  - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
  - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart
- **Menactra®**
  - **Persistent complement component deficiency or complement inhibitor use:**
    - Age 9–23 months: 2-dose series at least 12 weeks apart
    - Age 24 months or older: 2-dose series at least 8 weeks apart
  - **Anatomic or functional asplenia, sickle cell disease, or HIV infection:**
    - **Age 9–23 months**: Not recommended
    - **Age 24 months or older**: 2-dose series at least 8 weeks apart
    - **Menactra®** must be administered at least 4 weeks after completion of PCV series.
- **MenQuadfi®**
  - Dose 1 at age 24 months or older: 2-dose series at least 8 weeks apart

Travel to countries with hyperendemic or epidemic meningococcal disease, including countries in the African meningitis belt or during the Hajj (www.cdc.gov/travel/):

- Children less than age 24 months:
  - **Menveo®* (age 2–23 months)**
    - Dose 1 at age 2 months: 4-dose series (additional 3 doses at age 4, 6, and 12 months)
    - Dose 1 at age 3–6 months: 3- or 4-dose series (dose 2 [and dose 3 if applicable] at least 8 weeks after previous dose until a dose is received at age 7 months or older, followed by an additional dose at least 12 weeks later and after age 12 months)
    - Dose 1 at age 7–23 months: 2-dose series (dose 2 at least 12 weeks after dose 1 and after age 12 months)
  - **Menactra® (age 9–23 months)**
    - 2-dose series (dose 2 at least 12 weeks after dose 1; dose 2 may be administered as early as 8 weeks after dose 1 in travelers)
- Children age 2 years or older: 1 dose Menveo®*, Menactra®, or MenQuadfi®

First-year college students who live in residential housing (if not previously vaccinated at age 16 years or older) or military recruits:

- 1 dose **Menveo®*, Menactra®,** or **MenQuadfi®**

Adolescent vaccination of children who received MenACWY prior to age 10 years:

- **Children for whom boosters are recommended** because of an ongoing increased risk of meningococcal disease (e.g., those with complement component deficiency, HIV, or asplenia): Follow the booster schedule for persons at increased risk.
- **Children for whom boosters are not recommended** (e.g., a healthy child who received a single dose for travel to a country where meningococcal disease is endemic): Administer MenACWY according to the recommended adolescent schedule with dose 1 at age 11–12 years and dose 2 at age 16 years.

**Menveo has two formulations: lyophilized and liquid. The liquid formulation should not be used before age 10 years.*

Note: Menactra® should be administered either before or at the same time as DTaP. MenACWY may be administered simultaneously with MenB vaccines if indicated, but at a different anatomic site, if feasible.

For MenACWY **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Meningococcal serogroup B vaccination (minimum age: 10 years [MenB-4C, Bexsero®; MenB-FHbp, Trumenba®])

Shared clinical decision-making

- **Adolescents not at increased risk** age 16–23 years (preferred age 16–18 years) based on shared clinical decision-making:
  - **Bexsero®:** 2-dose series at least 1 month apart
  - **Trumenba®:** 2-dose series at least 6 months apart (if dose 2 is administered earlier than 6 months, administer a 3rd dose at least 4 months after dose 2)

Special situations

Anatomic or functional asplenia (including sickle cell disease), persistent complement component deficiency, complement inhibitor (e.g., eculizumab, ravulizumab) use:

- **Bexsero®:** 2-dose series at least 1 month apart
- **Trumenba®:** 3-dose series at 0, 1–2, 6 months (if dose 2 was administered at least 6 months after dose 1, dose 3 not needed; if dose 3 is administered earlier than 4 months after dose 2, a 4th dose should be administered at least 4 months after dose 3)

Note: Bexsero® and **Trumenba®** are not interchangeable; the same product should be used for all doses in a series.

For MenB **booster dose recommendations** for groups listed under "Special situations" and in an outbreak setting and additional meningococcal vaccination information, see www.cdc.gov/mmwr/volumes/69/rr/rr6909a1.htm.

Notes

Pneumococcal vaccination (minimum age: 6 weeks [PCV13], [PCV15], 2 years [PPSV23])

Routine vaccination with PCV

- 4-dose series at 2, 4, 6, 12–15 months

Catch-up vaccination with PCV

- Healthy children age 24–59 months with any incomplete* PCV series: 1 dose PCV
- For other catch-up guidance, see Table 2.

Note: PCV13 and PCV15 can be used interchangeably for children who are healthy or have underlying conditions. PCV15 is not indicated for children who have received 4 doses of PCV13 or another age appropriate complete PCV13 series.

Special situations

Underlying conditions below: When both PCV and PPSV23 are indicated, administer PCV first. PCV and PPSV23 should not be administered during the same visit.

Chronic heart disease (particularly cyanotic congenital heart disease and cardiac failure); chronic lung disease (including asthma treated with high-dose, oral corticosteroids); diabetes mellitus:

Age 2–5 years

- Any incomplete* series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after any prior PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)

Age 6–18 years

- Any incomplete* series with PCV: no further PCV doses needed
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)

Cerebrospinal fluid leak, cochlear implant:

Age 2–5 years

- Any incomplete* series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after any prior PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses)

Age 6–18 years

- No history of either PCV or PPSV23: 1 dose PCV, 1 dose PPSV23 at least 8 weeks later
- Any PCV but no PPSV23: 1 dose PPSV23 at least 8 weeks after the most recent dose of PCV
- PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent dose of PPSV23

Sickle cell disease and other hemoglobinopathies; anatomic or functional asplenia; congenital or acquired immunodeficiency; HIV infection; chronic renal failure; nephrotic syndrome; malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and other diseases associated with treatment with immunosuppressive drugs or radiation therapy; solid organ transplantation; multiple myeloma:

Age 2–5 years

- Any incomplete* series with:
  - 3 PCV doses: 1 dose PCV (at least 8 weeks after any prior PCV dose)
  - Less than 3 PCV doses: 2 doses PCV (8 weeks after the most recent dose and administered 8 weeks apart)
- No history of PPSV23: 1 dose PPSV23 (at least 8 weeks after completing all recommended PCV doses) and a dose 2 of PPSV23 5 years later

Age 6–18 years

- No history of either PCV or PPSV23: 1 dose PCV, 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- Any PCV but no PPSV23: 2 doses PPSV23 (dose 1 of PPSV23 administered 8 weeks after the most recent dose of PCV and dose 2 of PPSV23 administered at least 5 years after dose 1 of PPSV23)
- PPSV23 but no PCV: 1 dose PCV at least 8 weeks after the most recent PPSV23 dose and a dose 2 of PPSV23 administered 5 years after dose 1 of PPSV23 and at least 8 weeks after a dose of PCV

**Incomplete series* = Not having received all doses in either the recommended series or an age-appropriate catch-up series see Table 2 in ACIP pneumococcal recommendations at www.cdc.gov/mmwr/volumes/71/wr/mm7137a3.htm

For guidance on determining which pneumococcal vaccines a patient needs and when, please refer to the mobile app, which can be downloaded here: www.cdc.gov/vaccines/vpd/pneumo/hcp/pneumoapp.html

Poliovirus vaccination (minimum age: 6 weeks)

Routine vaccination

- 4-dose series at ages 2, 4, 6–18 months, 4–6 years; administer the final dose on or after age 4 years and at least 6 months after the previous dose.
- 4 or more doses of IPV can be administered before age 4 years when a combination vaccine containing IPV is used. However, a dose is still recommended on or after age 4 years and at least 6 months after the previous dose.

Catch-up vaccination

- In the first 6 months of life, use minimum ages and intervals only for travel to a polio-endemic region or during an outbreak.
- IPV is not routinely recommended for U.S. residents age 18 years or older.

Series containing oral polio vaccine (OPV), either mixed OPV-IPV or OPV-only series:

- Total number of doses needed to complete the series is the same as that recommended for the U.S. IPV schedule. See www.cdc.gov/mmwr/volumes/66/wr/mm6601a6.htm?s_%20cid=mm6601a6_w.
- Only trivalent OPV (tOPV) counts toward the U.S. vaccination requirements.
  - Doses of OPV administered before April 1, 2016, should be counted (unless specifically noted as administered during a campaign).
  - Doses of OPV administered on or after April 1, 2016, should not be counted.
  - For guidance to assess doses documented as "OPV," see www.cdc.gov/mmwr/volumes/66/wr/mm6606a7.htm?s_cid=mm6606a7_w.
- For other catch-up guidance, see Table 2.

Special situations

- **Adolescents aged 18 years at increased risk of exposure to poliovirus with:**
  - No evidence of a complete polio vaccination series (i.e., at least 3 doses): administer remaining doses (1, 2, or 3 doses) to complete a 3-dose series
  - Evidence of completed polio vaccination series (i.e., at least 3 doses): may administer one lifetime IPV booster

For detailed information, see: www.cdc.gov/vaccines/vpd/polio/hcp/recommendations.html

Notes

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Rotavirus vaccination
(minimum age: 6 weeks)

Routine vaccination

- **Rotarix®:** 2-dose series at age 2 and 4 months
- **RotaTeq®:** 3-dose series at age 2, 4, and 6 months
- If any dose in the series is either **RotaTeq®** or unknown, default to 3-dose series.

Catch-up vaccination

- Do not start the series on or after age 15 weeks, 0 days.
- The maximum age for the final dose is 8 months, 0 days.
- For other catch-up guidance, see Table 2.

Tetanus, diphtheria, and pertussis (Tdap) vaccination
(minimum age: 11 years for routine vaccination, 7 years for catch-up vaccination)

Routine vaccination

- **Adolescents age 11–12 years:** 1 dose Tdap
- **Pregnancy:** 1 dose Tdap during each pregnancy, preferably in early part of gestational weeks 27–36.
- Tdap may be administered regardless of the interval since the last tetanus- and diphtheria-toxoid-containing vaccine.

Catch-up vaccination

- **Adolescents age 13–18 years who have not received Tdap:** 1 dose Tdap, then Td or Tdap booster every 10 years
- **Persons age 7–18 years not fully vaccinated* with DTaP:** 1 dose Tdap as part of the catch-up series (preferably the first dose); if additional doses are needed, use Td or Tdap.
- **Tdap administered at age 7–10 years:**
  - **Children age 7–9 years** who receive Tdap should receive the routine Tdap dose at age 11–12 years.
  - **Children age 10 years** who receive Tdap do not need the routine Tdap dose at age 11–12 years.
- **DTaP inadvertently administered on or after age 7 years**:
  - **Children age 7–9 years**: DTaP may count as part of catch-up series. Administer routine Tdap dose at age 11–12 years.
  - **Children age 10–18 years**: Count dose of DTaP as the adolescent Tdap booster.
- For other catch-up guidance, see Table 2.

Special situations

- **Wound management** in persons age 7 years or older with history of 3 or more doses of tetanus-toxoid-containing vaccine: For clean and minor wounds, administer Tdap or Td if more than 10 years since last dose of tetanus-toxoid-containing vaccine; for all other wounds, administer Tdap or Td if more than 5 years since last dose of tetanus-toxoid-containing vaccine. Tdap is preferred for persons age 11 years or older who have not previously received Tdap or whose Tdap history is unknown. If a tetanus-toxoid-containing vaccine is indicated for a pregnant adolescent, use Tdap.
- For detailed information, see www.cdc.gov/mmwr/volumes/69/wr/mm6903a5.htm.

**Fully vaccinated* = 5 valid doses of DTaP OR 4 valid doses of DTaP if dose 4 was administered at age 4 years or older

Varicella vaccination
(minimum age: 12 months)

Routine vaccination

- 2-dose series at age 12–15 months, 4–6 years
- VAR or MMRV may be administered*
- Dose 2 may be administered as early as 3 months after dose 1 (a dose inadvertently administered after at least 4 weeks may be counted as valid)

**Note:* For dose 1 in children age 12–47 months, it is recommended to administer MMR and varicella vaccines separately. MMRV may be used if parents or caregivers express a preference.

Catch-up vaccination

- Ensure persons age 7–18 years without evidence of immunity (see *MMWR* at www.cdc.gov/mmwr/pdf/rr/rr5604.pdf) have a 2-dose series:
  - **Age 7–12 years**: Routine interval: 3 months (a dose inadvertently administered after at least 4 weeks may be counted as valid)
  - **Age 13 years and older**: Routine interval: 4–8 weeks (minimum interval: 4 weeks)
  - The maximum age for use of *MMRV* is 12 years.

Appendix Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2023

Guide to Contraindications and Precautions to Commonly Used Vaccines

Adapted from Table 4-1 in Advisory Committee on Immunization Practices (ACIP) General Best Practice Guidelines for Immunization: Contraindication and Precautions available at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html *and ACIP's Recommendations for the Prevention and Control of 2022-23 seasonal influenza with Vaccines available at* www.cdc.gov/mmwr/volumes/71/rr/rr7101a1.htm.

For COVID-19 vaccine contraindications and precautions see www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications

Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Influenza, egg-based, inactivated injectable (IIV4)	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg)	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Moderate or severe acute illness with or without fever
Influenza, cell culture-based inactivated injectable [(ccIIV4), Flucelvax® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any ccIIV of any valency, or to any component[3] of ccIIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, RIV, or LAIV of any valency. If using ccIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, recombinant injectable [(RIV4), Flublok® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) to any RIV of any valency, or to any component[3] of RIV4	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of any egg-based IIV, ccIIV, or LAIV of any valency. If using RIV4, administer in medical setting under supervision of health care provider who can recognize and manage severe allergic reactions. May consult an allergist. • Moderate or severe acute illness with or without fever
Influenza, live attenuated [LAIV4, Flumist® Quadrivalent]	• Severe allergic reaction (e.g., anaphylaxis) after previous dose of any influenza vaccine (i.e., any egg-based IIV, ccIIV, RIV, or LAIV of any valency) • Severe allergic reaction (e.g., anaphylaxis) to any vaccine component[3] (excluding egg) • Children age 2 –4 years with a history of asthma or wheezing • Anatomic or functional asplenia • Immunocompromised due to any cause including, but not limited to, medications and HIV infection • Close contacts or caregivers of severely immunosuppressed persons who require a protected environment • Pregnancy • Cochlear implant • Active communication between the cerebrospinal fluid (CSF) and the oropharynx, nasopharynx, nose, ear or any other cranial CSF leak • Children and adolescents receiving aspirin or salicylate-containing medications • Received influenza antiviral medications oseltamivir or zanamivir within the previous 48 hours, peramivir within the previous 5 days, or baloxavir within the previous 17 days	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of any type of influenza vaccine • Asthma in persons aged 5 years old or older • Persons with underlying medical conditions (other than those listed under contraindications) that might predispose to complications after wild-type influenza virus infection [e.g., chronic pulmonary, cardiovascular (except isolated hypertension), renal, hepatic, neurologic, hematologic, or metabolic disorders (including diabetes mellitus)] • Moderate or severe acute illness with or without fever

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states

Appendix

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Vaccine	Contraindicated or Not Recommended[1]	Precautions[2]
Dengue (DEN4CYD)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Lack of laboratory confirmation of a previous Dengue infection	• Pregnancy • HIV infection without evidence of severe immunosuppression • Moderate or severe acute illness with or without fever
Diphtheria, tetanus, pertussis (DTaP) Tetanus, diphtheria (DT)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For DTaP only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP or DTaP	• Guillain-Barré syndrome (GBS) within 6 weeks after previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid-containing vaccine • For DTaP only: Progressive neurologic disorder, including infantile spasms, uncontrolled epilepsy, progressive encephalopathy; defer DTaP until neurologic status clarified and stabilized • Moderate or severe acute illness with or without fever
Haemophilus influenzae type b (Hib)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Hiberix, ActHib, and PedvaxHIB only: History of severe allergic reaction to dry natural latex • Less than age 6 weeks	• Moderate or severe acute illness with or without fever
Hepatitis A (HepA)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin	• Moderate or severe acute illness with or without fever
Hepatitis B (HepB)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including yeast • *Pregnancy: Heplisav-B and PreHevbrio are not recommended due to lack of safety data in pregnant persons. Use other hepatitis B vaccines if HepB is indicated*[4].	• Moderate or severe acute illness with or without fever
Hepatitis A–Hepatitis B vaccine [HepA-HepB, (Twinrix®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] including neomycin and yeast	• Moderate or severe acute illness with or without fever
Human papillomavirus (HPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • *Pregnancy: HPV vaccination not recommended.*	• Moderate or severe acute illness with or without fever
Measles, mumps, rubella (MMR) Measles, mumps, rubella, and varicella (MMRV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • History of thrombocytopenia or thrombocytopenic purpura • Need for tuberculin skin testing or interferon-gamma release assay (IGRA) testing • Moderate or severe acute illness with or without fever • For MMRV only: Personal or family (i.e., sibling or parent) history of seizures of any etiology
Meningococcal ACWY (MenACWY) [MenACWY-CRM (Menveo®); MenACWY-D (Menactra®); MenACWY-TT (MenQuadfi®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For MenACWY-D and Men ACWY-CRM only: severe allergic reaction to any diphtheria toxoid– or CRM197–containing vaccine • For MenACWY-TT only: severe allergic reaction to a tetanus toxoid-containing vaccine	• For MenACWY-CRM only: Preterm birth if less than age 9 months • Moderate or severe acute illness with or without fever
Meningococcal B (MenB) [MenB-4C (Bexsero®); MenB-FHbp (Trumenba®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • For MenB-4C only: Latex sensitivity • Moderate or severe acute illness with or without fever
Pneumococcal conjugate (PCV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe allergic reaction (e.g., anaphylaxis) to any diphtheria-toxoid-containing vaccine or its component[3]	• Moderate or severe acute illness with or without fever
Pneumococcal polysaccharide (PPSV23)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Moderate or severe acute illness with or without fever
Poliovirus vaccine, inactivated (IPV)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3]	• Pregnancy • Moderate or severe acute illness with or without fever
Rotavirus (RV) [RV1 (Rotarix®), RV5 (RotaTeq®)]	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe combined immunodeficiency (SCID) • History of intussusception	• Altered immunocompetence other than SCID • Chronic gastrointestinal disease • RV1 only: Spina bifida or bladder exstrophy • Moderate or severe acute illness with or without fever
Tetanus, diphtheria, and acellular pertussis (Tdap) Tetanus, diphtheria (Td)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • For Tdap only: Encephalopathy (e.g., coma, decreased level of consciousness, prolonged seizures) not attributable to another identifiable cause within 7 days of administration of previous dose of DTP, DTaP, or Tdap	• Guillain-Barré syndrome (GBS) within 6 weeks after a previous dose of tetanus-toxoid–containing vaccine • History of Arthus-type hypersensitivity reactions after a previous dose of diphtheria-toxoid–containing or tetanus-toxoid–containing vaccine; defer vaccination until at least 10 years have elapsed since the last tetanus-toxoid–containing vaccine • For Tdap only: Progressive or unstable neurological disorder, uncontrolled seizures, or progressive encephalopathy until a treatment regimen has been established and the condition has stabilized • Moderate or severe acute illness with or without fever
Varicella (VAR)	• Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a vaccine component[3] • Severe immunodeficiency (e.g., hematologic and solid tumors, receipt of chemotherapy, congenital immunodeficiency, long-term immunosuppressive therapy or patients with HIV infection who are severely immunocompromised) • Pregnancy • Family history of altered immunocompetence, unless verified clinically or by laboratory testing as immunocompetent	• Recent (≤11 months) receipt of antibody-containing blood product (specific interval depends on product) • Receipt of specific antiviral drugs (acyclovir, famciclovir, or valacyclovir) 24 hours before vaccination (avoid use of these antiviral drugs for 14 days after vaccination) • Use of aspirin or aspirin-containing products • Moderate or severe acute illness with or without fever • If using MMRV, see MMR/MMRV for additional precautions

1. When a contraindication is present, a vaccine should NOT be administered. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
2. When a precaution is present, vaccination should generally be deferred but might be indicated if the benefit of protection from the vaccine outweighs the risk for an adverse reaction. Kroger A, Bahta L, Hunter P. ACIP General Best Practice Guidelines for Immunization. www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html
3. Vaccination providers should check FDA-approved prescribing information for the most complete and updated information, including contraindications, warnings, and precautions. Package inserts for U.S.-licensed vaccines are available at www.fda.gov/vaccines-blood-biologics/approved-products/vaccines-licensed-use-united-states.
4. For information on the pregnancy exposure registries for persons who were inadvertently vaccinated with Heplisav-B or PreHevbrio while pregnant, please visit heplisavbpregnancyregistry.com/ or www.prehevbrio.com/#safety.

Legislative Efforts

Bills And Resolutions

Principals do not report on the budget under the bill number, but by Budget Bill Subjects as published by the Legislative Fiscal Bureau. You can search for Budget Bill Subjects on the What Are They Lobbying About page.

Assembly Bill 583

Relating To: Relating to: vaccination of minors without parental consent.

Bill Text and History

Add to a FOCUS Subscription

Lobbying Principals

Principal Name	Notified Date	Communication Date	Comments	Supporting Documentation
Vaccine Choice Wisconsin	10/4/2021	N/A		
Wisconsin Association of Local Health Departments and Boards	10/20/2021	N/A		
Wisconsin Public Health Association	10/20/2021	N/A		

Assembly Bill 303

Relating To: Relating to: prohibiting businesses from discriminating against customers due to vaccination record.

Bill Text and History

Add to a FOCUS Subscription

Lobbying Principals

Principal Name	Notified Date	Communication Date	Comments	Supporting Documentation
NAIOP Wisconsin	6/14/2021	N/A		
Pro-Life Wisconsin	6/1/2021	N/A		
Vaccine Choice Wisconsin	5/5/2021	N/A		
Wisconsin Association of Local Health Departments and Boards	6/1/2021	N/A		
Wisconsin Family Action Inc	6/16/2021	N/A		
Wisconsin Medical Society	6/1/2021	N/A		
Wisconsin Public Health Association	6/1/2021	N/A		
Wisconsin Realtors Association	6/7/2021	N/A		

AB-659 Cancer Prevention Act. (2023-2024)

Date Published: 02/17/2023 09:00 PM

AMENDED IN ASSEMBLY FEBRUARY 17, 2023

CALIFORNIA LEGISLATURE— 2023–2024 REGULAR SESSION

ASSEMBLY BILL NO. 659

Introduced by Assembly Member Aguiar-Curry
(Coauthors: Assembly Members Wendy Carrillo, Friedman, Kalra, Ortega, Papan, and Blanca Rubio)
(Coauthor: Senator Wiener)

February 09, 2023

An act to amend Sections *1367.66,* 120325, 120335, and 120338 of the Health and Safety Code, *to amend Section 10123.18 of the Insurance Code, and to add Section 14132.04 to the Welfare and Institutions Code* relating to ~~immunizations.~~ *human papillomavirus.*

LEGISLATIVE COUNSEL'S DIGEST

AB 659, as amended, Aguiar-Curry. Cancer Prevention Act.

Existing law prohibits the governing authority of a school or other institution from unconditionally admitting any person as a pupil of any private or public elementary or secondary school, childcare center, day nursery, nursery school, family daycare home, or development center, unless prior to their admission to that institution they have been fully immunized. Existing law requires the documentation of immunizations for certain diseases, including, among others, measles, mumps, pertussis, and any other disease deemed appropriate by the State Department of Public Health, as specified. Existing law authorizes certain exemptions from these provisions subject to specified conditions.

Existing law requires the department to adopt and enforce regulations for these provisions and authorizes the department to specify the immunizing agents that may be utilized and the manner in which immunizations are administered.

This bill, the Cancer Prevention Act, would add human papillomavirus (HPV) to the above-described list of diseases for which immunization documentation is required. The bill would specifically prohibit the governing authority from unconditionally admitting or advancing any pupil to the 8th grade level of any private or public elementary or secondary school if the pupil has not been fully immunized against HPV. The bill would clarify the

department's authority to adopt HPV-related regulations for grades below the 8th grade level. By creating new duties for school districts, the bill would impose a state-mandated local program.
~~The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.~~

~~This bill would provide that, if the Commission on State Mandates determines that the bill contains costs mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.~~

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care, and makes a willful violation of the act a crime. Existing law provides for the regulation of health insurers by the Department of Insurance. Existing law requires a health care service plan contract or health insurance policy issued, amended, or renewed on or after January 1, 2002, to provide coverage for an annual cervical cancer screening test, including a human papillomavirus (HPV) screening test that is approved by the United States Food and Drug Administration (FDA).

Existing law provides for the Medi-Cal program, administered by the State Department of Health Care Services and under which health care services are provided to low-income individuals pursuant to a schedule of benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing law also establishes the Family Planning, Access, Care, and Treatment (Family PACT) Waiver Program, administered by the Office of Family Planning within the department, under which comprehensive clinical family planning services are provided to a person who has a family income at or below 200% of the federal poverty level, and who is eligible to receive these services.

This bill would expand the coverage requirement for an annual cervical cancer screening test to disability insurance policies that provide coverage for hospital, medical, or surgical benefits and would require a health care service plan contract or disability insurance policy that provides coverage for hospital, medical, or surgical benefits issued, amended, or renewed on or after January 1, 2024, to provide coverage without cost sharing for the HPV vaccine for persons for whom the vaccine is FDA approved. Because a willful violation of the bill's requirements relative to health care service plans would be a crime, the bill would impose a state-mandated local program. The bill would also expand comprehensive clinical family planning services under the Family PACT Waiver Program to include the HPV vaccine for persons for whom it is FDA approved.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that with regard to certain mandates no reimbursement is required by this act for a specified reason.

With regard to any other mandates, this bill would provide that, if the Commission on State Mandates determines that the bill contains costs so mandated by the state, reimbursement for those costs shall be made pursuant to the statutory provisions noted above.
Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. This act shall be known, and may be cited, as the Cancer Prevention Act.

SEC. 2. *Section 1367.66 of the Health and Safety Code is amended to read:*

1367.66. ~~Every individual or group~~ *(a) A* health care service plan contract, except for a specialized health care service plan,~~ that is~~ issued, amended, or renewed on or after January 1, 2002,~~ and that includes coverage for treatment or surgery of cervical cancer shall also be deemed to~~ *shall* provide coverage for an annual cervical cancer screening test upon the referral of the patient's physician and surgeon, a nurse practitioner, or a certified nurse midwife, providing care to the patient and operating within the scope of practice otherwise permitted for the licensee.

~~The~~

(1) The coverage for an annual cervical cancer screening test provided pursuant to this section shall include the conventional Pap test, a human papillomavirus screening test that is approved by the~~ federal~~ *United States* Food and Drug~~ Administration,~~ *Administration (FDA),* and the option of any cervical cancer screening test

approved by the ~~federal Food and Drug Administration,~~ *FDA,* upon the referral of the patient's health care provider.

~~Nothing in this section shall be construed to~~

(2) This subdivision does not establish a new mandated benefit or to prevent application of deductible or copayment provisions in an existing plan contract. The Legislature intends in this section to provide that cervical cancer screening services are deemed to be covered if the plan contract includes coverage for cervical cancer treatment or surgery.

(b) A health care service plan contract, except for a specialized health care service plan, issued, amended, or renewed on or after January 1, 2024, shall provide coverage for the human papillomavirus vaccine for enrollees for whom the vaccine is approved by the FDA. A health care service plan contract shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision.

~~**SEC. 2.**~~***SEC. 3.*** Section 120325 of the Health and Safety Code is amended to read:

120325. In enacting this chapter, but excluding Section 120380, and in enacting Sections 120400, 120405, 120410, and 120415, it is the intent of the Legislature to provide all of the following:

(a) A means for the eventual achievement of total immunization of appropriate age groups against the following childhood diseases:

(1) Diphtheria.

(2) Hepatitis B.

(3) Haemophilus influenzae type b.

(4) Measles.

(5) Mumps.

(6) Pertussis (whooping cough).

(7) Poliomyelitis.

(8) Rubella.

(9) Tetanus.

(10) Varicella (chickenpox).

(11) Human papillomavirus (HPV).

(12) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

(b) That the persons required to be immunized be allowed to obtain immunizations from whatever medical source they so desire, subject only to the condition that the immunization be performed in accordance with the regulations of the department and that a record of the immunization is made in accordance with the regulations.

(c) Exemptions from immunization for medical reasons.

(d) For the keeping of adequate records of immunization so that health departments, schools, and other institutions, parents or guardians, and the persons immunized will be able to ascertain that a child is fully or only partially immunized, and so that appropriate public agencies will be able to ascertain the immunization needs of groups of children in schools or other institutions.

(e) Incentives to public health authorities to design innovative and creative programs that will promote and achieve full and timely immunization of children.

~~**SEC. 3.**~~***SEC. 4.*** Section 120335 of the Health and Safety Code is amended to read:

120335. (a) As used in this chapter, "governing authority" means the governing board of each school district or the authority of each other private or public institution responsible for the operation and control of the institution or the principal or administrator of each school or institution.

(b) The governing authority shall not unconditionally admit any person as a pupil of any private or public elementary or secondary school, childcare center, day nursery, nursery school, family daycare home, or development center, unless, prior to their first admission to that institution, they have been fully immunized. The following are the diseases for which immunizations shall be documented:

(1) Diphtheria.

(2) Haemophilus influenzae type b.

(3) Measles.

(4) Mumps.

(5) Pertussis (whooping cough).

(6) Poliomyelitis.

(7) Rubella.

(8) Tetanus.

(9) Hepatitis B.

(10) Varicella (chickenpox).

(11) Human papillomavirus (HPV), as specified in subdivision (e).

(12) Any other disease deemed appropriate by the department, taking into consideration the recommendations of the Advisory Committee on Immunization Practices of the United States Department of Health and Human Services, the American Academy of Pediatrics, and the American Academy of Family Physicians.

(c) Notwithstanding subdivision (b), full immunization against hepatitis B shall not be a condition by which the governing authority shall admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school.

(d) The governing authority shall not unconditionally admit or advance any pupil to the 7th grade level of any private or public elementary or secondary school unless the pupil has been fully immunized against pertussis, including all pertussis boosters appropriate for the pupil's age.

(e) (1) The governing authority shall not unconditionally admit or advance any pupil to the 8th grade level of any private or public elementary or secondary school if the pupil has not been fully immunized against HPV.

(2) Paragraph (1) shall not be construed as prohibiting the department from adopting, and subdivision (b) shall not be construed as requiring the department to adopt, regulations imposing an immunization schedule against HPV for admission or advancement of pupils to grades below the 8th grade level for purposes of this section.

(f) The department may specify the immunizing agents that may be utilized and the manner in which immunizations are administered.

(g) This section does not apply to a pupil in a home-based private school or a pupil who is enrolled in an independent study program pursuant to Article 5.5 (commencing with Section 51744) of Chapter 5 of Part 28 of Division 4 of Title 2 of the Education Code and does not receive classroom-based instruction.

(h) (1) A pupil who, prior to January 1, 2016, submitted a letter or affidavit on file at a private or public elementary or secondary school, child daycare center, day nursery, nursery school, family daycare home, or development center stating beliefs opposed to immunization shall be allowed enrollment to any private or public elementary or secondary school, child daycare center, day nursery, nursery school, family daycare home, or development center within the state until the pupil enrolls in the next grade span.

(2) For purposes of this subdivision, "grade span" means each of the following:

(A) Birth to preschool.

(B) Kindergarten and grades 1 to 6, inclusive, including transitional kindergarten.

(C) Grades 7 to 12, inclusive.

(3) Except as provided in this subdivision, on and after July 1, 2016, the governing authority shall not unconditionally admit to any of those institutions specified in this subdivision for the first time, or admit or advance any pupil to 7th grade level, unless the pupil has been immunized for their age as required by this section.

(i) This section does not prohibit a pupil who qualifies for an individualized education program, pursuant to federal law and Section 56026 of the Education Code, from accessing any special education and related services required by their individualized education program.

~~**SEC. 4.**~~ ***SEC. 5.*** Section 120338 of the Health and Safety Code is amended to read:

120338. Notwithstanding Sections 120325 and 120335, any immunizations deemed appropriate by the department pursuant to paragraph (12) of subdivision (a) of Section 120325 or paragraph (12) of subdivision (b) of Section 120335, may be mandated before a pupil's first admission to any private or public elementary or secondary school, childcare center, day nursery, nursery school, family daycare home, or development center, only if exemptions are allowed for both medical reasons and personal beliefs.

~~SEC. 5.If the Commission on State Mandates determines that this act contains costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.~~

SEC. 6. *Section 10123.18 of the Insurance Code is amended to read:*

10123.18. (a) ~~Every individual or group policy of health insurance that provides coverage for hospital, medical, or surgical benefits, that is~~ *A disability insurance policy* issued, amended, or ~~renewed,~~ *renewed* on or after January 1, ~~2002,~~ *2024,* and that ~~includes~~ *provides* coverage for ~~treatment or surgery of cervical cancer shall also be deemed to~~ *hospital, medical, or surgical benefits shall* provide coverage, upon the referral of a patient's physician and surgeon, a nurse practitioner, or a certified nurse midwife, providing care to the patient and operating within the scope of practice otherwise permitted for the licensee, for an annual cervical cancer screening test.

~~The~~

(1) The coverage for an annual cervical cancer screening test provided pursuant to this section shall include the conventional Pap test, a human papillomavirus screening test that is approved by the ~~federal~~ *United States* Food and Drug ~~Administration,~~ *Administration (FDA)* and the option of any cervical cancer screening test approved by the ~~federal Food and Drug Administration,~~ *FDA,* upon the referral of the patient's health care provider.

~~Nothing in this section shall be construed to~~

(2) This subdivision does not require an individual or group policy to cover treatment or surgery for cervical cancer or to prevent application of deductible or copayment provisions contained in the policy or certificate, ~~nor shall this section be construed to~~ *and does not* require that coverage under an individual or group policy be extended to any other procedures.

(b) A disability insurance policy issued, amended, or renewed on or after January 1, 2024, that provides coverage for hospital, medical, or surgical benefits shall provide coverage for the human papillomavirus vaccine for insureds for whom the vaccine is approved by the FDA. The policy shall not impose a deductible, coinsurance, copayment, or any other cost-sharing requirement on the coverage provided pursuant to this subdivision.

~~(b)~~

(c) This section shall not apply to vision only, dental only, accident only, specified disease, hospital indemnity, Medicare supplement, CHAMPUS supplement, long-term care, or disability income insurance. For accident only, hospital indemnity, or specified disease insurance, coverage for benefits under this section shall apply only to the extent that the benefits are covered under the general terms and conditions that apply to all other benefits under the policy or certificate. ~~Nothing in this section shall be construed as imposing~~ *This section does not impose* a new benefit mandate on accident only, hospital indemnity, or specified disease insurance.

SEC. 7. *Section 14132.04 is added to the Welfare and Institutions Code, to read:*

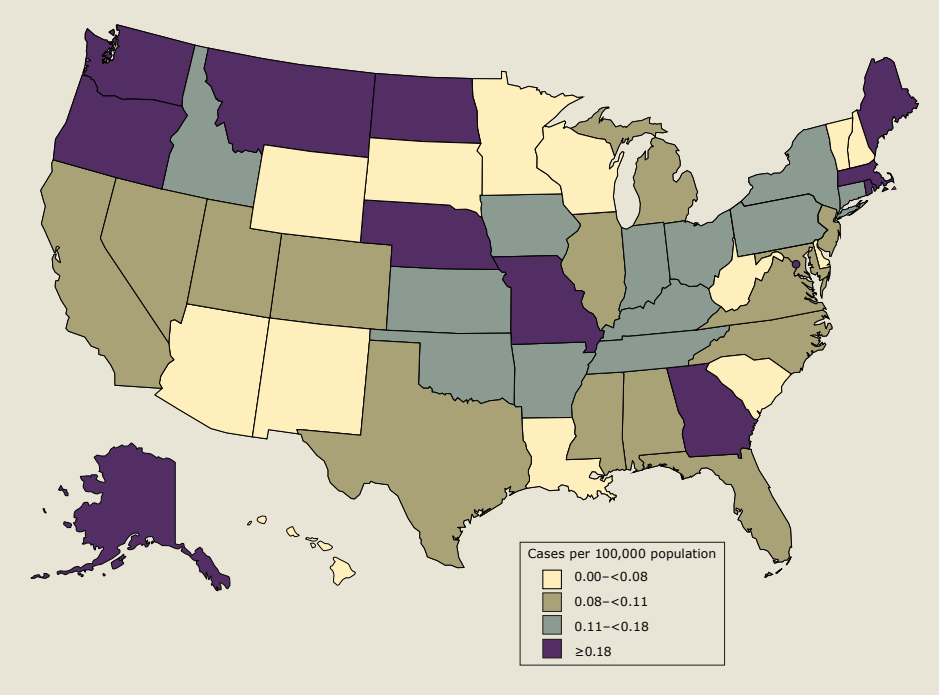
14132.04. *For purposes of subdivision (aa) of Section 14132, "comprehensive clinical family planning services" includes the human papillomavirus vaccine for persons for whom it is approved by the United States Food and Drug Administration.*

SEC. 8. *No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because, in that regard, this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.*

However, if the Commission on State Mandates determines that this act contains other costs mandated by the state, reimbursement to local agencies and school districts for those costs shall be made pursuant to Part 7 (commencing with Section 17500) of Division 4 of Title 2 of the Government Code.

Enhanced Meningococcal Disease Surveillance Report, 2019

Confirmed and Probable Cases Reported to the National Notifiable Diseases Surveillance System, 2019



As part of Enhanced Meningococcal Disease Surveillance (EMDS)*, additional data and isolates were collected from 50 state and 3 large jurisdiction health departments. In 2019, the population under surveillance was 328,239,523. EMDS focuses on: (1) collecting isolates from all cases; and (2) collecting complete case information, with an emphasis on college attendance for cases in people aged 15–24 years; history of sex with men for cases in males aged ≥16 years; and information on homelessness for all cases.

CSTE case definition: A confirmed case was defined as isolation of *Neisseria meningitidis* or detection of *N. meningitidis* by PCR from a normally sterile body site.

A probable case was defined as detection of *N. meningitidis* antigen by latex agglutination or immunohistochemistry.

*Funding for EMDS is provided by CDC through the Epidemiology and Laboratory Capacity for Infectious Diseases (ELC) Cooperative Agreement.

Meningococcal Disease Cases and Incidence by Serogroup and Age

Age (years)	B No. (Incidence†)	C No. (Incidence†)	W No. (Incidence†)	Y No. (Incidence†)	Nongroupable No. (Incidence†)	Other‡/Unknown No. (Incidence†)	Total No. (Incidence†)
<1	16 (0.42)	4 (0.11)	0 (0.00)	4 (0.11)	3 (0.08)	4 (0.11)	31 (0.82)
1–4	12 (0.08)	10 (0.06)	2 (0.01)	1 (0.01)	1 (0.01)	4 (0.03)	30 (0.19)
5–10	0 (0.00)	5 (0.02)	0 (0.00)	1 (0.00)	0 (0.00)	1 (0.00)	7 (0.03)
11–15	2 (0.01)	4 (0.02)	0 (0.00)	0 (0.00)	1 (0.00)	2 (0.01)	9 (0.04)
16–23	21 (0.06)	1 (0.00)	1 (0.00)	3 (0.01)	11 (0.03)	6 (0.02)	43 (0.13)
24–44	21 (0.02)	13 (0.01)	8 (0.01)	19 (0.02)	9 (0.01)	10 (0.01)	80 (0.09)
45–64	12 (0.01)	28 (0.03)	11 (0.01)	20 (0.02)	5 (0.01)	11 (0.01)	87 (0.10)
≥65	15 (0.03)	20 (0.04)	18 (0.03)	20 (0.04)	7 (0.01)	8 (0.01)	88 (0.16)
Total	**99 (0.03)**	**85 (0.03)**	**40 (0.01)**	**68 (0.02)**	**37 (0.01)**	**46 (0.01)**	**375 (0.11)**

Includes all confirmed and probable cases reported from all jurisdictions. †Cases per 100,000 population. ‡Includes 3 serogroup E cases.

National Center for Immunization and Respiratory Diseases
Office of Infectious Diseases

Case Fatality

Serogroup	No. deaths	CFR†
B	6	6.1
C	8	9.6
W	3	7.7
Y	8	11.8
NG	5	13.5
Unknown	5	13.9
Overall	**35**	**9.6**

Age (years)	No. deaths	CFR†
<1	4	12.9
1–4	1	3.3
5–10	1	16.7
11–15	0	0.0
16–23	4	9.5
24–44	4	5.2
45–64	12	14.1
≥65	9	10.5
Overall	**35**	**9.6**

Includes all confirmed and probable cases reported from all jurisdictions; †Case fatality ratio (CFR): deaths per 100 cases with known outcome; 9 (2%) cases with unknown outcome.

Laboratory Confirmation Method

83.9% (313/373) of confirmed cases were confirmed by culture; of those 266 (85.0%) had isolates submitted to CDC.
10.7% (40/373) of confirmed cases were confirmed by PCR.
4.3% (16/373) of confirmed cases had unknown laboratory confirmation method.

Outbreaks

94.4% (354/375) of cases had information on association with an outbreak; of those, 15 (4.2%) were part of an outbreak.

Complement inhibitor use

75.2% (282/375) of cases had information on use of a complement component inhibitor; of those, 5 (1.8%) were taking a complement inhibitor.

Homelessness

94.1% (353/375) of cases had information on homelessness; of those, 9 (2.6%) were experiencing homelessness.

History of sex with men among cases in men

Among cases in men aged ≥16 years, 66.9% (101/151) had information on history of sex with men; of those, 10 (9.9%) were identified as men who had sex with men (MSM).

College attendance among cases in people aged 18-24 years

Among cases in people aged 18-24 years, 95.4% (41/43) had information on college attendance; 21 (51.2%) were attending college.

Symptoms

77.6% (291/375) of cases had symptom information available; of those 4 (1.4%) had gastrointestinal symptoms (nausea, vomiting, or diarrhea) in the absence of typical meningococcal symptoms (headache, fever, neck stiffness, rash).

Antibiotic-resistant serogroup Y

68 NmY cases were reported. 57 (83.8%) had isolates available for characterization at CDC; of those, 8 (14.0%) were found to be ciprofloxacin- and penicillin-resistant, and 5 (8.8%) were found to be penicillin-resistant only.

Meningococcal Disease Cases and Incidence by Serogroup and College Attendance*

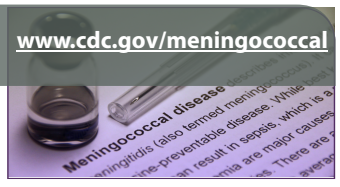
	B No. (Incidence†)	C No. (Incidence†)	W No. (Incidence†)	Y No. (Incidence†)	Nongroupable No. (Incidence†)	Total** No. (Incidence†)
Attending college‡	12 (0.10)	0 (0.00)	0 (0.00)	0 (0.00)	7 (0.06)	**21 (0.18)**
Not attending college‡	6 (0.03)	1 (0.01)	2 (0.01)	3 (0.02)	5 (0.03)	**20 (0.11)**

*Among cases in people aged 18-24 years. **Includes 4 cases with unknown serogroup and 1 serogroup E case. †Cases per 100,000 population. ‡Assumes 38.3% of 18–24 year olds attending college[1]

Vaccination Status among cases 18-24 years

MenACWY (meningococcal conjugate vaccine) receipt:
College students: 100% (21/21) had information on MenACWY receipt; of those 95.2% received ≥1 dose of MenACWY .
Persons not attending college: 80.0% (16/20) had information on MenACWY receipt; of those 75.0% received ≥1 dose of MenACWY.

MenB (serogroup B meningococcal vaccine) receipt:
College students: 76.2% (16/21) had information on MenB receipt; of those 56.3% received ≥ 1 dose of MenB.
Persons not attending college: 55.0% (11/20) had information on MenB receipt; of those 0 received MenB.



HIV Infection among Meningococcal Disease Cases

Data collected on HIV status will allow CDC to assess the impact of the recent Advisory Committee on Immunization Practices recommendation for use of MenACWY vaccination in HIV-infected persons.[2]

54.7% (205/375) of cases had information on HIV status; of those, 6 (2.9%) were identified as HIV-infected.

[1]U.S. Department of Education. Institute of Education Sciences NCES. Integrated Postsecondary Education Data System Fall Enrollment Survey. https://nces.ed.gov/ipeds/Home/UseTheData, 2015.

[2]MacNeil JR, Rubin LG, Patton M, Ortega-Sanchez IR, Martin SW. Recommendations for Use of Meningococcal Conjugate Vaccines in HIV-infected Persons — Advisory Committee on Immunization Practices, 2016. *MMWR Morb Mortal Wkly Rep* 2016;65:1189–1194. DOI: http://dx.doi.org/10.15585/mmwr.mm6543a3.

This is an official
CDC HEALTH ADVISORY

Distributed via Health Alert Network
Friday, September 30, 2005, 19:00 EDT (7:00 PM EDT)
CDCHAN-00237-2005-09-30-ADV-N

FDA and CDC Issue Alert on Menactra Meningococcal Vaccine and Guillain Barre Syndrome

The Food and Drug Administration (FDA) and Centers for Disease Control and Prevention (CDC) are alerting consumers and health care providers to five reports of Guillain Barre Syndrome (GBS) following administration of Meningococcal Conjugate Vaccine A, C, Y, and W135 (trade name Menactra), manufactured by Sanofi Pasteur. It is not known yet whether these cases were caused by the vaccine or are coincidental. FDA and CDC are sharing this information with the public now and actively investigating the situation because of its potentially serious nature.

Guillain Barre Syndrome (GBS) is a serious neurological disorder that can occur, often in healthy individuals, either spontaneously or after certain infections. GBS typically causes increasing weakness in the legs and arms that can be severe and require hospitalization.

Meningococcal infection, which Menactra prevents, is a major cause of bacterial meningitis, affecting approximately 1 in 100,000 people annually. The infection can be life threatening:

10-14 percent of cases are fatal and 11-19 percent of survivors may have permanent disability.

According to Jesse Goodman, MD, Director of FDA's Center for Biologics Evaluation and Research, at the present time there are no changes in recommendations for vaccination; individuals should continue to follow their doctors' recommendations. FDA and CDC are not able to determine if any or all of the cases were due to vaccination. The current information is very preliminary and the two agencies are continuing to evaluate the situation.

Because of the potentially serious nature of this matter, FDA and CDC are asking any persons with knowledge of any possible cases of GBS occurring after Menactra to report them to the Vaccine Adverse Event Reporting System (VAERS) to help the agencies further evaluate the matter. Individuals can report to VAERS on the web at www.vaers.hhs.gov or by phone at 1-800-822-7967.
The five cases of GBS reported following administration of Menactra occurred in individuals living in NY, OH, PA, and NJ. All five patients were 17 or 18 years of age and developed weakness or abnormal sensations in the arms or legs, two-four weeks after vaccination. All individuals are reported to be recovering or to have recovered. More than 2.5 million doses of Menactra vaccine have been distributed to date. The rate of GBS based on the number of cases reported following administration of Menactra is similar to what might have been expected to occur by coincidence, that is, even without vaccination. However, the timing of the events is of concern. Also, vaccine adverse events are not always reported to FDA so there may be additional cases of which we are unaware at this time.

Prelicensure studies conducted by Sanofi Pasteur of more than 7000 recipients of Menactra showed no GBS cases. CDC conducted a rapid study using available health care organization databases and found that no cases of GBS have been reported to date among 110,000 Menactra recipients.

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national and international organizations.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please call 800-835-4709 or 240-402-8010, extension 1. CBER Consumer Affairs Branch or send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MENVEO safely and effectively. See full prescribing information for MENVEO.

MENVEO [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine] solution for injection, for intramuscular use

Initial U.S. Approval: 2010

----------RECENT MAJOR CHANGES----------

Dosage and Administration (2.1, 2.2, 2.3) 10/2022

---------- INDICATIONS AND USAGE----------

MENVEO is a vaccine indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 in individuals 2 months through 55 years of age.

MENVEO does not prevent *N. meningitidis* serogroup B infections. (1)

----------DOSAGE AND ADMINISTRATION----------

- For intramuscular injection only (0.5 mL). (2)

MENVEO is supplied as either:

- Two vials: A vial containing the MenCYW-135 liquid conjugate component (gray cap) and a vial containing the MenA lyophilized conjugate component (orange cap). The contents of the vials must be combined to form MENVEO prior to administration. This presentation is for use in individuals 2 months through 55 years of age. (2.1, 2.2),

OR

- One vial containing MENVEO (pink cap). This presentation does not require reconstitution before use. This presentation is for use in individuals 10 through 55 years of age. (2.1, 2.2)

Primary Vaccination

- In children initiating vaccination at 2 months of age, administer as a 4-dose series at 2, 4, 6, and 12 months of age. (2.4)
- In children initiating vaccination at 7 months through 23 months of age, administer as a 2-dose series with the second dose administered in the second year of life and at least 3 months after the first dose. (2.4)
- In individuals aged 2 through 55 years, administer as a single dose. (2.4)

Booster Vaccination

- A single booster dose of MENVEO may be administered to individuals aged 15 through 55 years who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine. (2.4)

---------- DOSAGE FORMS AND STRENGTHS----------

Solution for injection. A single dose is 0.5 mL. (3)

---------- CONTRAINDICATIONS ----------

Severe allergic reaction (e.g., anaphylaxis) to a previous dose of MENVEO, to any component of this vaccine, or to any other diphtheria toxoid-containing vaccine. (4)

---------- WARNINGS AND PRECAUTIONS ----------

- Syncope (fainting) has occurred in association with administration of MENVEO. Procedures should be in place to avoid injury from fainting. (5.2)
- Apnea following intramuscular vaccination has been observed in some infants born prematurely. A decision about when to administer MENVEO to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination. (5.5)

---------- ADVERSE REACTIONS ----------

- Common solicited adverse reactions (≥10%) among children initiating vaccination at 2 months of age and receiving the 4-dose series were tenderness (24% to 41%) and erythema at injection site (11% to 15%), irritability (42% to 57%), sleepiness (29% to 50%), persistent crying (21% to 41%), change in eating habits (17% to 23%), vomiting (5% to 11%), and diarrhea (8% to 16%). (6.1)
- Common solicited adverse reactions (≥10%) among children initiating vaccination at 7 months through 23 months of age and receiving the 2-dose series were tenderness (10% to 16%) and erythema at injection site (12% to 15%), irritability (27% to 40%), sleepiness (17% to 29%), persistent crying (12-21%), change in eating habits (12% to 20%), and diarrhea (10% to 16%). (6.1)
- Common solicited adverse reactions (≥10%) among children aged 2 through 10 years who received MENVEO were injection site pain (31%), erythema (23%), irritability (18%), induration (16%), sleepiness (14%), malaise (12%), and headache (11%). (6.1)
- Common solicited adverse reactions (≥10%) among adolescents and adults who received a single dose of MENVEO were pain at the injection site (41%), headache (30%), myalgia (18%), malaise (16%), and nausea (10%). Similar rates of solicited adverse reactions were observed following a single booster dose. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact GlaxoSmithKline at 1-888-825-5249 or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 10/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

MENVEO is a vaccine indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 in individuals 2 months through 55 years of age.

MENVEO does not prevent *N. meningitidis* serogroup B infections.

2 DOSAGE AND ADMINISTRATION

For intramuscular injection only.

2.1 MENVEO Presentations

MENVEO is supplied in two presentations, a two-vial presentation and a one-vial presentation.

Two-Vial Presentation

The two-vial presentation includes a vial with a gray cap containing the MenCYW-135 liquid conjugate component and a vial with an orange cap containing the MenA lyophilized conjugate component. The contents of the vials must be combined to form MENVEO prior to administration. This presentation is for use in individuals 2 months through 55 years of age.

One-Vial Presentation

The one-vial presentation contains MENVEO in a single vial with a pink cap and does not require reconstitution before use. This presentation is for use in individuals 10 through 55 years of age.

2.2 Preparation

Reconstitution Instructions for MENVEO Two-Vial Presentation

Use the MenCYW-135 liquid conjugate component (Vial 1, gray cap) to reconstitute the MenA lyophilized conjugate component (Vial 2, orange cap) to form MENVEO. Invert Vial 2 and shake well until the lyophilized conjugate component is dissolved. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine. See Figures 1 through 4.

Administer MENVEO immediately **or** store between 36°F and 77°F (2°C and 25°C) for up to 8 hours. Shake well before using. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.

Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile graduated syringe, withdraw the entire contents of Vial 1 containing the MenCYW-135 liquid conjugate component while slightly tilting the vial.

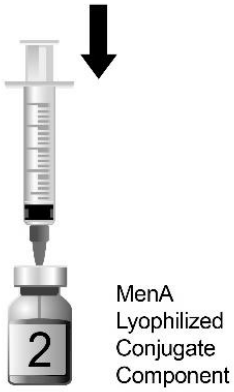


Figure 2. Slowly transfer entire contents of the syringe into Vial 2 containing the MenA lyophilized conjugate component.

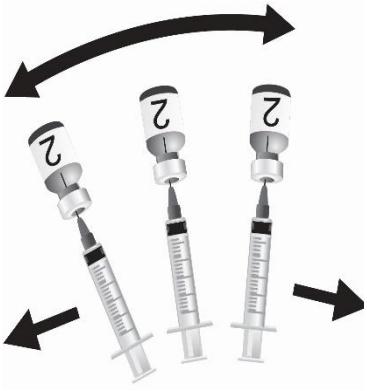


Figure 3. Invert the vial and shake well until lyophilized conjugate component is completely dissolved.

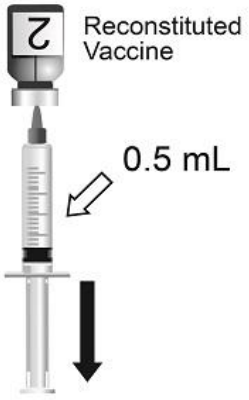


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine.

Instructions for MENVEO One-Vial Presentation

The MENVEO presentation that is supplied in a single vial with a pink cap does NOT require reconstitution. Withdraw 0.5 mL from the vial.

2.3 Administration

MENVEO is a clear, colorless solution, free from visible foreign particles. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, MENVEO should not be administered.

Administer a single 0.5-mL dose by intramuscular injection.

2.4 Dosing Schedule

The dosing schedule is as follows:

Primary Vaccination

Table 1. Dosing Schedule for MENVEO Primary Vaccination

MENVEO Two-Vial Presentation	
Infants Aged 2 Months	4-dose series at 2, 4, 6, and 12 months of age
Children Aged 7 through 23 Months	2-dose series with the second dose administered in the second year of life and at least 3 months after the first dose
Children Aged 2 through 10 Years	A single dose For children aged 2 through 5 years at continued high risk of meningococcal disease, a second dose may be administered 2 months after the first dose.
Adolescents and Adults Aged 11 through 55 Years	A single dose
MENVEO One-Vial Presentation	
Adolescents and Adults Aged 10 through 55 Years	A single dose

Booster Vaccination

Adolescents and Adults Aged 15 through 55 Years: A single booster dose of MENVEO using either the two-vial presentation or the one-vial presentation may be administered to individuals who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of a meningococcal (serogroups A, C, Y, W-135) conjugate vaccine.

3 DOSAGE FORMS AND STRENGTHS

MENVEO is a solution for intramuscular injection. A single dose is 0.5 mL.

4 CONTRAINDICATIONS

Do not administer MENVEO to individuals with a severe allergic reaction (e.g., anaphylaxis) to a previous dose of MENVEO, to any component of this vaccine, or to any other diphtheria toxoid-containing vaccine. *[See Description (11).]*

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate medical treatment must be available should an acute allergic reaction, including an anaphylactic reaction, occur following administration of MENVEO.

5.2 Syncope

Syncope (fainting) has occurred in association with administration of MENVEO. Procedures should be in place to avoid injury from fainting.

5.3 Altered Immunocompetence

Reduced Immune Response

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MENVEO.

Complement Deficiency

Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *N. meningitidis*, including invasive disease caused by serogroups A, C, Y, and W, even if they develop antibodies following vaccination with MENVEO. *[See Clinical Pharmacology (12.1).]*

5.4 Guillain-Barré Syndrome

Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another U.S.-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision by the healthcare professional to administer MENVEO to persons with a history of GBS should take into account the expected benefits and potential risks.

5.5 Apnea in Premature Infants

Apnea following intramuscular vaccination has been observed in some infants born prematurely. A decision about when to administer MENVEO to an infant born prematurely should be based on consideration of the individual infant's medical status and the potential benefits and possible risks of vaccination.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in clinical trials of a vaccine cannot be directly compared with rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Overall, in clinical studies, 36,146 individuals 2 months through 55 years of age were administered at least one dose of MENVEO supplied in the two-vial presentation and 1,337 individuals 10 through 44 years of age were administered one dose of MENVEO supplied in the one-vial presentation. The safety data for the two-vial presentation are relevant to the safety of the one-vial presentation because each presentation contains the same meningococcal conjugated oligosaccharides. *[See Description (11).]*

Primary Vaccination Studies

Children Aged 2 through 23 Months: The safety of MENVEO in infants vaccinated at 2, 4, 6, and 12 months of age was evaluated in 3 randomized multicenter clinical studies (NCT00474526, NCT00806195, NCT01000311) conducted in the U.S., Australia, Canada, Taiwan, and several countries of Latin America in which 8,735 infants received at least 1 dose of MENVEO and routine infant vaccines (diphtheria toxoid; acellular pertussis; tetanus toxoid [DTaP]; inactivated polio types 1, 2, and 3 [IPV]; hepatitis B; *Haemophilus influenzae* type b (Hib) antigens; pentavalent rotavirus; and 7-valent pneumococcal conjugate [PCV7]). With Dose 4 of MENVEO, toddlers received concomitantly the following vaccines: 7-valent pneumococcal conjugate; measles, mumps, rubella, and varicella; and inactivated hepatitis A. A total of 2,864 infants in these studies received the routine infant/toddler vaccines only. The infants who received MENVEO were Caucasian (33%), Hispanic (44%), African American (8%), Asian (8%), and other racial/ethnic groups (7%); 51% were male, with a mean age of 65.1 days (Standard Deviation [SD]: 7.5 days) at the time of first vaccination.

Safety data for administration of 2 doses of MENVEO in children aged 6 through 23 months are available from 3 randomized studies (NCT00474526, NCT00310856, NCT00626327) conducted in the U.S., Latin America, and Canada, of which one U.S. study specifically addressed the safety of MENVEO administered concomitantly with measles, mumps, rubella, and varicella vaccine (MMRV). The 1,985 older infants and toddlers who received 2 doses of MENVEO were Caucasian (49%), Hispanic (32%), African American (11%), and other racial/ethnic groups (8%), 51% male, with a mean age of 10.1 months (SD: 2.0 months).

Children Aged 2 through 10 Years: The safety of MENVEO in children aged 2 through 10 years was evaluated in 4 clinical trials (NCT00310817, NCT00262028, NCT00329849, NCT00616421) conducted in North America (66%), Latin America (28%), and Europe (6%) in which 3,181 subjects received MENVEO and 2,116 subjects received comparator vaccines (either Meningococcal Polysaccharide Vaccine, Groups A, C, Y, and W-135 Combined - MENOMUNE, Sanofi Pasteur [n = 861], or Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine - MENACTRA, Sanofi Pasteur [n = 1,255]). The subjects aged 2 through 10 years who received MENVEO were Caucasian (69%), Hispanic (13%), African American (7%), and other racial/ethnic groups (6%), 51% male, with a mean age of 5.2 years. The safety of a second dose of MENVEO administered 2 months following a first dose was studied in 351 children aged 2 through 5 years.

Adolescents and Adults: The safety of MENVEO in individuals aged 11 through 55 years was evaluated in 5 randomized controlled clinical trials (NCT01018732, NCT00329901, NCT00450437, NCT00474487, NCT00518180) in which 6,185 participants received MENVEO alone (5,286 participants), MENVEO concomitant with other vaccine(s) (899 participants), or a U.S.-licensed comparator vaccine (1,966 participants). In the concomitant trials (NCT00329901, NCT00518180) MENVEO was given with vaccines containing: tetanus toxoid, diphtheria toxoid, and pertussis (Tdap), or Tdap with human papillomavirus (HPV). The comparator vaccine was either MENOMUNE (209 participants) or MENACTRA (1,757 participants). The trials were conducted in North America (46%), Latin America (41%), and Europe (13%). In 2 of the studies, subjects received concomitant vaccination with Tdap or with Tdap plus HPV. Overall, in these studies, subjects were Caucasian (50%), followed by Hispanic (40%), African American (7%), and other racial/ethnic groups (3%). Among recipients of MENVEO, 61%, 17%, and 22% were in the 11- through 18-year, 19- through 34-year, and 35- through 55-year age groups, respectively, with a mean age of 23.5 years (SD: 12.9 years). Among recipients of MENACTRA, 31%, 32%, and 37% were in the 11- through 18-year, 19- through 34-year, and 35- through 55-year age groups, respectively, with a mean age of 29.2 years (SD: 13.4 years). Among MENOMUNE recipients, 100% were in the 11- through 18-year age group, and the mean age was 14.2 years (SD: 1.8 years).

The safety of MENVEO one-vial presentation was evaluated in 2 randomized clinical trials (NCT03652610, NCT03433482). In these studies, 1,337 subjects aged 10 through 44 years were administered a single dose of MENVEO supplied in the one-vial presentation and contributed to study analyses and 1,332 subjects 10 through 40 years of age were administered MENVEO supplied in the two-vial presentation. The studies were conducted in Australia, Belgium, Canada, Germany, and Italy (NCT03652610), and in Brazil, Estonia, Finland, France, Mexico, Russian Federation, South Africa, Spain, and Turkey (NCT03433482). Overall, in these studies, subjects were White (80.8%), followed by Hispanic or Latino ethnicity (12.8 %), other racial groups (11.4%), African American (4.3 %), Asian (3.0 %), American Indian or Alaskan Native (0.3%), and Native Hawaiian or other Pacific Islander (0.1%). Overall, 25.6% of individuals were aged 10 through 17 years, and 74.4% were aged 18 through 44 years.

Booster Vaccination Study

In a multicenter, open-label trial (NCT02986854) conducted in the U.S., 601 subjects aged 15 to 51 years received a single booster dose of MENVEO 4 to 6 years after prior vaccination with MENVEO (n = 301; median age: 16 years) or MENACTRA (n = 300; median age: 16 years). Across booster groups of MENVEO, 81% of subjects were White and 50% were female.

In most trials, solicited local and systemic adverse reactions were monitored daily for 7 days following each (one or more) vaccination and recorded on a diary card. Participants were monitored for unsolicited adverse events which included adverse events requiring a physician visit or Emergency Department visit (i.e., medically-attended) or which led to a subject's withdrawal from the study. Among children, adolescents, and adults aged 2 to 55 years,

medically significant adverse events and serious adverse events (SAEs) were monitored for 6 months after vaccination. Across the studies of infants and toddlers aged 2 through 23 months, either all medically-attended or all medically-significant adverse events were collected in the period between the infant dose(s) and the toddler doses and during the 6-month period after the toddler dose.

Solicited Adverse Reactions in the Primary Vaccination Studies

The reported frequencies of solicited local and systemic adverse reactions from U.S. infants in the largest multinational safety study of MENVEO (NCT00806195) are presented in Table 2. Among the U.S. participants in the group receiving MENVEO with routine vaccines, 51% were female; 64% were Caucasian, 12% were African American, 15% were Hispanic, 2% were Asian, and 7% were of other racial/ethnic groups.

In infants initiating vaccination at 2 months of age and receiving the 4-dose series, common solicited adverse reactions (≥10%) were tenderness (24% to 41%) and erythema at injection site (11% to 15%), irritability (42% to 57%), sleepiness (29% to 50%), persistent crying (21% to 41%), change in eating habits (17% to 23%), vomiting (5% to 11%), and diarrhea (8% to 16%). The rates of solicited adverse reactions reported for subjects aged 2 months and older receiving MENVEO with routine vaccines at 2, 4, 6, and 12 months of age were comparable to rates among subjects who only received routine vaccines.

Table 2. Rates of Solicited Adverse Reactions Reported in U.S. Infants, Aged 2 Months and Older, during the 7 Days following Each Vaccination of MENVEO Administered with Routine Infant/Toddler Vaccines, or Routine Infant/Toddler Vaccines Alone at 2, 4, 6, and 12 Months of Age[a]

	Dose 1		Dose 2		Dose 3		Dose 4	
Adverse Reactions	**MENVEO with Routine[b]** %	**Routine Vaccines[b]** %	**MENVEO with Routine[b]** %	**Routine Vaccines[b]** %	**MENVEO with Routine[b]** %	**Routine Vaccines[b]** %	**MENVEO with Routine[b]** %	**Routine Vaccines[b]** %
Local Adverse Reactions[c]	**n = 1,250-1,252**	**n = 428**	**n = 1,205-1,207**	**n = 399**	**n = 1,056-1,058**	**n = 351-352**	**n = 1,054-1,055**	**n = 334-337**
Tenderness, any	41	45	31	36	24	32	29	39
Tenderness, severe[d]	3	5	2	2	1	3	1	1
Erythema, any	11	14	12	21	14	23	15	25
Erythema, >50 mm	<1	<1	0	0	0	0	0	0
Induration, any	8	16	9	17	8	19	8	21
Induration, >50 mm	0	<1	0	0	0	0	0	0

Systemic Adverse Reactions	**n = 1,246-1,251**	**n = 427-428**	**n = 1,119-1,202**	**n = 396-398**	**n = 1,050-1,057**	**n = 349-350**	**n = 1,054-1,056**	**n = 333-337**
Irritability, any	57	59	48	46	42	38	43	42
Irritability, severe[e]	2	2	1	3	1	1	2	1
Sleepiness, any	50	50	37	36	30	30	29	27
Sleepiness, severe[f]	2	1	1	1	<1	<1	1	0
Persistent crying, any	41	38	28	24	22	17	21	18
Persistent crying, ≥3 hours	2	2	2	2	1	1	1	1
Change in eating habits, any	23	24	18	17	17	13	19	16
Change in eating habits, severe[g]	1	1	1	1	1	<1	1	0
Vomiting, any	11	9	7	6	6	4	5	4
Vomiting, severe[h]	<1	0	<1	0	<1	0	<1	0
Diarrhea, any	16	11	11	8	8	6	13	9
Diarrhea, severe[i]	<1	<1	<1	<1	1	<1	1	1
Rash[j]	3	3	3	4	3	3	4	3
Fever ≥38.0°C[k]	3	2	4	6	7	6	9	7
Fever 38.0-38.9°C	3	2	4	5	7	6	6	5
Fever 39.0-39.9°C	0	0	1	1	<1	0	2	2
Fever ≥40.0°C	0	<1	0	<1	0	0	<1	0

Clinicaltrials.gov Identifier NCT00806195.

n = Number of subjects who completed the diary card for a given symptom at the specified vaccination.

[a] As-Treated Safety Subpopulation = U.S. children who received at least 1 dose of study vaccine and whose diary cards were completed per protocol and returned to the site.

[b] Routine infant/toddler vaccines include DTaP-IPV-Hib and PCV7 at Doses 1, 2, 3, and PCV7, MMRV, and Hepatitis A vaccines at Dose 4. HBV and rotavirus vaccines were allowed according to Advisory Committee on Immunization Practices (ACIP) recommendations.

[c] Local reactogenicity of MENVEO and PCV7 was assessed.

[d] Tenderness, severe = Cried when injected limb moved.

[e] Irritability, severe = Unable to console.

[f] Sleepiness, severe = Sleeps most of the time, hard to arouse.

[g] Change in eating habits, severe = Missed >2 feeds.

[h] Vomiting, severe = Little/no intake for more prolonged time.

[i] Diarrhea, severe = ≥6 liquid stools, no solid consistency.

[j] Rash was assessed only as present or not present, without a grading for severity.

[k] Axillary temperature.

The safety of a second dose of MENVEO administered at 12 months of age concomitantly with MMRV was investigated in a randomized, controlled, multicenter study (NCT00626327) conducted in the U.S. The rates of solicited adverse reactions reported were comparable between the concomitantly administered group (MENVEO with MMRV) and the group which received MMRV alone or MENVEO alone. The frequency and severity of solicited local and systemic reactions occurring within 7 days following vaccination at 12 months of age are shown in Table 3. In subjects who received both MENVEO and MMRV at 12 months of age local reactions at both injection sites were evaluated separately. Body temperature measurements were collected for 28 days following the 12-months-of-age visit, when MMRV was administered to the vaccinees. Common solicited adverse reactions (≥10%) among children initiating vaccination at 7 months through 23 months of age and receiving the 2-dose series were tenderness (10% to 16%) and erythema at injection site (12% to 15%), irritability (27% to 40%), sleepiness (17% to 29%), persistent crying (12% to 21%), change in eating habits (12% to 20%), and diarrhea (10% to 16%). An examination of the fever profile during this period showed that MENVEO administered with MMRV did not increase the frequency or intensity of fever above that observed for the MMRV-only group.

Table 3. Rates of Solicited Adverse Reactions Reported in U.S. Toddlers during the 7 Days following Vaccination with MENVEO Administered at 7-9 Months and 12 Months of Age, MENVEO Administered Alone at 7-9 Months and with MMRV at 12 Months of Age, and MMRV Administered Alone at 12 Months of Age[a]

	MENVEO		MENVEO + MMRV		MMRV
Adverse Reactions	**MENVEO 7-9 Months %**	**MENVEO 12 Months %**	**MENVEO 7-9 Months %**	**MENVEO with MMRV 12 Months %**	**MMRV 12 Months %**
Local Adverse Reactions– MENVEO	**n = 460-462**	**n = 381-384**	**n = 430-434**	**n = 386-387**	
Tenderness, any	11	10	11	16	N/A
Tenderness, severe[b]	<1	<1	<1	0	N/A
Erythema, any	15	13	13	12	N/A
Erythema, >50 mm	<1	<1	0	1	N/A
Induration, any	8	8	7	8	N/A
Induration, >50 mm	<1	<1	0	1	N/A
Local Adverse Reactions– MMRV				**n = 382-383**	**n = 518-520**
Tenderness, any	N/A	N/A	N/A	16	19
Tenderness, severe[b]	N/A	N/A	N/A	0	<1
Erythema, any	N/A	N/A	N/A	15	14
Erythema, >50 mm	N/A	N/A	N/A	1	<1
Induration, any	N/A	N/A	N/A	13	8
Induration, >50 mm	N/A	N/A	N/A	<1	0

Systemic Adverse Reactions	**n = 461-463**	**n = 385-386**	**n = 430-434**	**n = 387-389**	**n = 522-524**
Irritability, any	40	27	37	37	44
Irritability, severe[c]	2	2	2	1	3
Sleepiness, any	26	17	29	26	32
Sleepiness, severe[d]	2	1	1	1	2
Persistent crying, any	21	12	20	19	20
Persistent crying, ≥3 hours	2	1	1	1	2
Change in eating habits, any	17	12	17	20	20
Change in eating habits, severe[e]	<1	1	1	2	1
Vomiting, any	9	6	9	6	6
Vomiting, severe[f]	<1	<1	<1	<1	<1
Diarrhea, any	16	10	15	15	20
Diarrhea, severe[g]	2	1	<1	1	2
Rash[h]	3	5	6	6	8
Fever ≥38.0°C[i]	5	5	6	9	7
Fever 38.0-38.9°C	3	3	5	7	7
Fever 39.0-39.9°C	2	2	1	1	1
Fever ≥40.0°C	<1	1	<1	<1	0

Clinicaltrials.gov Identifier NCT00626327.

n = Number of subjects who completed the diary card for a given symptom at the specified vaccination.

[a] As-Treated Safety Subpopulation = U.S. children who received at least 1 dose of study vaccine and whose diary cards were completed per protocol and returned to the site.

[b] Tenderness, severe = Cried when injected limb moved.

[c] Irritability, severe = Unable to console.

[d] Sleepiness, severe = Sleeps most of the time, hard to arouse.

[e] Change in eating habits, severe = Missed >2 feeds.

[f] Vomiting, severe = Little/no intake for more prolonged time.

[g] Diarrhea, severe = ≥6 liquid stools, no solid consistency.

[h] Rash was assessed only as present or not present, without a grading for severity.

[i] Axillary temperature.

In clinical trials of children aged 2 through 10 years (NCT00310817, NCT00262028, NCT00329849, NCT00616421), the most frequently occurring adverse reactions (≥10%) among all subjects who received MENVEO were injection site pain (31%), erythema (23%), irritability (18%), induration (16%), sleepiness (14%), malaise (12%), and headache (11%). Among

subjects aged 11 through 55 years, the most frequently occurring adverse reactions (≥10%) among all subjects who received MENVEO were pain at the injection site (41%), headache (30%), myalgia (18%), malaise (16%), and nausea (10%).

The rates of solicited adverse reactions reported for subjects aged 2 through 5 years and 6 through 10 years who received a single dose of MENVEO or MENACTRA in a randomized, controlled, multicenter study (NCT00616421) conducted in the U.S. and Canada are shown in Table 4. Following a second dose of MENVEO administered to children aged 2 through 5 years, the most common solicited adverse reactions (≥10%) were pain at injection site (28%), erythema (22%), irritability (16%), induration (13%), and sleepiness (12%). The solicited adverse reactions from a separate randomized, controlled, multicenter study conducted in the U.S. in adolescents and adults (NCT00450437) are provided in Tables 5 and 6, respectively. In neither study were concomitant vaccines administered with the study vaccines.

Table 4. Rates of Solicited Adverse Reactions within 7 Days following a Single Vaccination in Children Aged 2 through 5 Years and 6 through 10 Years

	Participants Aged 2 through 5 Years					
	MENVEO n = 693 %			**MENACTRA n = 684 %**		
Adverse Reactions	**Any**	**Moderate**	**Severe**	**Any**	**Moderate**	**Severe**
Local Adverse Reactions						
Injection site pain[a]	33	6	1	35	8	0.4
Erythema[b]	27	5	1	25	3	0.3
Induration[b]	18	2	0.4	18	2	0.3
Systemic Adverse Reactions[e]						
Irritability[a]	21	6	1	22	7	1
Sleepiness[a]	16	3	1	18	5	1
Change in eating[a]	9	2	1	10	2	0.3
Diarrhea[a]	7	1	0.1	8	1	0
Headache[a]	5	1	0	6	1	0.3
Rash[c]	4	-	-	5	-	-
Arthralgia[a]	3	1	0.1	4	1	0
Vomiting[a]	3	1	0.1	3	1	0
Fever[d]	2	0.4	0	2	0.3	0

	Participants Aged 6 through 10 Years					
	MENVEO n = 582 %			MENACTRA n = 571 %		
Adverse Reactions	**Any**	**Moderate**	**Severe**	**Any**	**Moderate**	**Severe**
Local Adverse Reactions						
Injection site pain[a]	39	8	1	45	10	2
Erythema[b]	28	5	1	22	2	0.2
Induration[b]	17	2	0.3	13	2	0
Systemic Adverse Reactions[e]						
Headache[a]	18	3	1	13	2	1
Malaise[a]	14	3	1	11	3	1
Myalgia[a]	10	2	1	10	2	1
Nausea[a]	8	2	1	6	2	0.4
Arthralgia[a]	6	1	0	4	1	0.4
Chills[a]	5	1	0	5	1	0.4
Rash[c]	5	-	-	3	-	-
Fever[d]	2	1	0	2	0	0.4

Clinicaltrials.gov Identifier NCT00616421.

[a] Moderate: Some limitation in normal daily activity, Severe: Unable to perform normal daily activity.

[b] Moderate: ≥50-100 mm, Severe: >100 mm.

[c] Rash was assessed only as present or not present, without a grading for severity.

[d] Fever grading: Any: ≥38°C, Moderate: 39-39.9°C, Severe: ≥40°C. Parents reported the use of antipyretic medication to treat or prevent symptoms in 11% and 13% of subjects aged 2 through 5 years, 9% and 10% of subjects aged 6 through 10 years for MENVEO and MENACTRA, respectively.

[e] Different systemic reactions were solicited in different age groups.

Table 5. Rates of Solicited Adverse Reactions within 7 Days following Vaccination in Individuals Aged 11 through 18 Years

Adverse Reactions	MENVEO n = 1,631 %			MENACTRA n = 539 %		
	Any	**Moderate**	**Severe**	**Any**	**Moderate**	**Severe**
Local Adverse Reactions						
Injection site pain[a]	44	9	1	53	11	1
Erythema[b]	15	2	0.4	16	1	0
Induration[b]	12	2	0.2	11	1	0
Systemic Adverse Reactions						
Headache[a]	29	8	2	28	7	1
Myalgia[a]	19	4	1	18	5	0.4
Nausea[a]	12	3	1	9	2	1
Malaise[a]	11	3	1	12	5	1
Chills[a]	8	2	1	7	1	0.2
Arthralgia[a]	8	2	0.4	6	1	0
Rash[c]	3	-	-	3	-	-
Fever[d]	1	0.4	0	1	0	0

Clinicaltrials.gov Identifier NCT00450437.

[a] Moderate: Some limitation in normal daily activity, Severe: Unable to perform normal daily activity.

[b] Moderate: ≥50-100 mm, Severe: >100 mm.

[c] Rash was assessed only as present or not present, without a grading for severity.

[d] Fever grading: Any: ≥38°C, Moderate: 39-39.9°C, Severe: ≥40°C.

Table 6. Rates of Solicited Adverse Reactions within 7 Days following Vaccination in Individuals Aged 19 through 55 Years

Adverse Reactions	MENVEO n = 1,018 %			MENACTRA n = 336 %		
	Any	Moderate	Severe	Any	Moderate	Severe
Local Adverse Reactions						
Injection site pain[a]	38	7	0.3	41	6	0
Erythema[b]	16	2	1	12	1	0
Induration[b]	13	1	0.4	9	0.3	0
Systemic Adverse Reactions						
Headache[a]	25	7	2	25	7	1
Myalgia[a]	14	4	0.5	15	3	1
Malaise[a]	10	3	1	10	2	1
Nausea[a]	7	2	0.4	5	1	0.3
Arthralgia[a]	6	2	0.4	6	1	1
Chills[a]	4	1	0.1	4	1	0
Rash[c]	2	-	-	1	-	-
Fever[d]	1	0.3	0	1	0.3	0

Clinicaltrials.gov Identifier NCT00450437.

[a] Moderate: Some limitation in normal daily activity, Severe: Unable to perform normal daily activity.

[b] Moderate: ≥50-100 mm, Severe: >100 mm.

[c] Rash was assessed only as present or not present, without a grading for severity.

[d] Fever grading: Any: ≥38°C, Moderate: 39-39.9°C, Severe: ≥40°C.

In studies NCT03652610 and NCT03433482, there were no notable differences in frequency and severity of solicited adverse reactions within 7 days following vaccination in individuals who received the one-vial presentation compared to individuals who received the two-vial presentation.

Solicited Adverse Reactions in the Booster Vaccination Study (Adolescents and Adults)

A multicenter, open-label clinical trial (NCT02986854) was conducted in the U.S. in subjects aged 15 through 55 years *[see Clinical Studies (14.1)]*. The methodology for evaluating solicited adverse reactions, unsolicited adverse events, and SAEs after a booster dose of MENVEO was similar to the primary vaccination studies. The most common solicited local and systemic adverse reactions within 7 days of vaccination were pain at injection site (36%) and fatigue (38%), respectively.

Solicited Adverse Reactions following Concomitant Vaccine Administration

The safety of 4-dose series of MENVEO administered concomitantly with U.S.-licensed routine infant and toddler vaccines was evaluated in one pivotal trial (NCT00806195). The safety of a 2-dose series of MENVEO initiated at 7-9 months of age, with the second dose administered concomitantly with U.S.-licensed MMRV vaccine at 12 months of age, was evaluated in one pivotal trial (NCT00626327). Rates of solicited adverse reactions which occurred 7 days following vaccination are shown in Tables 2 and 3, respectively. There was no significant increase in the rates of solicited systemic or local reactions observed in recipients of routine childhood vaccines when concomitantly vaccinated with MENVEO. *[See Drug Interactions (7.1).]*

The safety of MENVEO administered concomitantly with Tdap and HPV was evaluated in a single-center study (NCT00518180) conducted in Costa Rica. Solicited local and systemic adverse reactions were reported as noted above. In this study, subjects aged 11 through 18 years received MENVEO concomitantly with Tdap and HPV (n = 540), or MENVEO followed 1 month later by Tdap and then 1 month later by HPV (n = 541), or Tdap followed 1 month later by MENVEO and then 1 month later by HPV (n = 539). Some solicited systemic adverse reactions were more frequently reported in the group that received MENVEO, Tdap, and HPV concomitantly, (headache 40%, malaise 25%, myalgia 27%, and arthralgia 17%) compared with the group that first received MENVEO alone (headache 36%, malaise 20%, myalgia 19%, and arthralgia 11%). Among subjects administered MENVEO alone (1 month prior to Tdap), 36% reported headache, 20% malaise, and 16% myalgia. Among subjects administered MENVEO 1 month after Tdap, 27% reported headache, 18% malaise, and 16% myalgia.

Serious Adverse Events in All Safety Studies

SAEs in subjects receiving a 4-dose series of MENVEO at 2, 4, 6, and 12 months were evaluated in 3 randomized, multicenter clinical studies (NCT00474526, NCT00806195, NCT01000311). In the 2 controlled studies (NCT00806195, NCT01000311), the proportions of infants randomized to receive the 4-dose series of MENVEO concomitantly with routine vaccinations and infants who received routine vaccinations alone that reported SAEs during different study periods were, respectively: a) 2.7% and 2.2% during the infant series, b) 2.5% and 2.5% between the infant series and the toddler dose, c) 0.3% and 0.3% in the 1 month following the toddler dose, and d) 1.6% and 2.2% during the 6-month follow-up period after the last dose. In the third study (NCT00474526), which was controlled up to the toddler dose, the proportions of infants randomized to dosing regimens that included receiving 4 doses of MENVEO concomitantly with routine vaccinations at 2, 4, 6, and 12 months and infants who received routine vaccinations alone that reported SAEs during different study periods were, respectively: a) 3.5% and 3.6% during the infant series, and b) 2.8% and 3.3% between the infant series and the toddler dose, and c) 0.5% and 0.7% in the 1 month following the toddler dose. In the same study, 1.9% of infants randomized to receive the 4-dose series of MENVEO concomitantly with routine vaccinations reported SAEs during the 6-month follow-up period after the toddler dose. The

most common SAEs reported in these 3 studies were wheezing, pneumonia, gastroenteritis, and convulsions, and most occurred at highest frequency after the infant series.

In a study of older infants (NCT00626327) randomized to receive the 2-dose series of MENVEO concomitantly with MMRV at 12 months of age, the rates of SAEs during the study, including the 6-month follow-up period after the last dose, were 3.6% and 3.8% for the groups receiving MENVEO with MMRV and MENVEO only, respectively. Infants receiving MMRV alone, who had a shorter period of study participation as they were enrolled at 12 months of age, had a lower rate of SAEs (1.5%). Among 1,597 study subjects included in the safety population, the most commonly reported SAEs in all study arms combined were dehydration (0.4%) and gastroenteritis (0.3%). Across the submitted studies of individuals aged 2 through 23 months within 28 days of vaccination, 2 deaths were reported in the groups receiving MENVEO (one case of sudden death and one case of sepsis), while no deaths were reported in the control group. None of the deaths was assessed as related to vaccination. Among subjects with symptom onset within 42 days of vaccination (Days 12, 25, 29), 3/12,049 (0.02%, 95% CI: [0.01%, 0.07%]) recipients of MENVEO and 0/2,877 (0%, 95% CI: [0%, 0.13%]) control recipients were diagnosed with Kawasaki Disease. One case of acute disseminated encephalomyelitis with symptom onset 29 days post Dose 4 was observed in a participant given MENVEO coadministered with routine U.S. childhood vaccines at 12 months of age (including measles, mumps, and rubella vaccine [MMR] and varicella vaccine).

The information regarding SAEs in subjects aged 2 through 10 years was derived from 3 randomized, controlled clinical trials (NCT00262028, NCT00329849, NCT00616421). Safety follow-up ranged from 6 through 12 months and included 2,883 subjects administered MENVEO. SAEs reported during the safety follow-up periods occurred in 21/2,883 (0.7%) subjects receiving MENVEO, in 7/1,255 (0.6%) MENACTRA subjects, and 2/861 (0.2%) MENOMUNE subjects. In the subjects receiving either 1 or 2 doses of MENVEO, there were 6 subjects with pneumonia, 3 subjects with appendicitis, and 2 subjects with dehydration; all other events were reported to occur in one subject. Among 1,255 subjects administered a single dose of MENACTRA and 861 subjects administered MENOMUNE, there were no events reported to occur in more than 1 subject. The SAEs occurring within the first 30 days after receipt of each vaccine were as follows: MENVEO (6/2,883 [0.2%]) — appendicitis, pneumonia, staphylococcal infection, dehydration, febrile convulsion, and tonic convulsion; MENACTRA (1/1255 [0.1%]) — inguinal hernia; MENOMUNE (2/861 [0.2%]) — abdominal pain, lobar pneumonia. In a supportive study (NCT00310817), 298 subjects received 1 or 2 doses of MENVEO and 22 (7%) had SAEs over a 13-month follow-up period including 13 subjects with varicella and 2 subjects with laryngitis. All other events were reported to occur in 1 subject. During the 30 days post vaccination in this study, 1 limb injury and 1 case of varicella were reported.

The information regarding SAEs in subjects aged 11 through 55 years was derived from 5 randomized, controlled clinical trials (NCT01018732, NCT00329901, NCT00450437,

NCT00474487, NCT00518180). SAEs reported within 6 months of vaccination occurred in 40/6,185 (0.6%) subjects receiving MENVEO, 13/1,757 (0.7%) MENACTRA subjects, and 5/209 (2.4%) MENOMUNE subjects. During the 6 months following immunization, SAEs reported by more than 1 subject were as follows: MENVEO - appendicitis (3 subjects), road traffic accident (3 subjects), and suicide attempt (5 subjects); MENACTRA - intervertebral disc protrusion (2 subjects); MENOMUNE - none. SAEs that occurred within 30 days of vaccination were reported by 7 of 6,185 (0.1%) subjects in the group receiving MENVEO, 4 of 1,757 (0.2%) subjects in the MENACTRA group, and by none of 209 subjects in the MENOMUNE group. The events that occurred during the first 30 days post immunization with MENVEO were: vitello-intestinal duct remnant, Cushing's syndrome, viral hepatitis, pelvic inflammatory disease, intentional multiple-drug overdose, simple partial seizure, and suicidal depression. The events that occurred during the first 30 days post immunization with MENACTRA were: herpes zoster, fall, intervertebral disc protrusion, and angioedema.

In the 2 clinical studies (NCT03652610, NCT03433482) which evaluated the safety of the one-vial presentation of MENVEO, SAEs were reported by 14 subjects (1.0%) who received the one-vial presentation of MENVEO and 14 subjects (1.1%) who received the two-vial presentation of MENVEO within the 6-month follow-up period after vaccination. No deaths were reported. None of the SAEs were related to the study vaccines.

6.2 Postmarketing Experience

In addition to reports in clinical trials, the following adverse reactions have been identified during postapproval use of MENVEO. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to the vaccine.

Blood and Lymphatic System Disorders

Local lymphadenopathy.

Ear and Labyrinth Disorders

Hearing impaired, ear pain, vertigo, vestibular disorder.

Eye Disorders

Eyelid ptosis.

General Disorders and Administration Site Conditions

Injection site pruritus; pain; erythema; inflammation; and swelling, including extensive swelling of the vaccinated limb; fatigue; malaise; pyrexia.

Immune System Disorders

Hypersensitivity reactions, including anaphylaxis.

Infections and Infestations

Vaccination site cellulitis.

Injury, Poisoning, and Procedural Complications

Fall, head injury.

Investigation

Alanine aminotransferase increased, body temperature increased.

Musculoskeletal and Connective Tissue Disorders

Arthralgia, bone pain.

Nervous System Disorders

Dizziness, syncope, tonic convulsion, headache, facial paresis, balance disorder.

Respiratory, Thoracic, and Mediastinal Disorders

Oropharyngeal pain.

Skin and Subcutaneous Tissue Disorders

Skin exfoliation.

Postmarketing Observational Safety Study

In a postmarketing observational safety study conducted in a U.S. health maintenance organization, data from electronic health records of 48,899 persons aged 11 through 21 years were used to evaluate pre-specified events of interest following vaccination with MENVEO. Using a self-controlled case series method, Bell's palsy showed a statistically significant increased risk in the period 1 to 84 days post vaccination compared with the control period, with an overall adjusted relative incidence of 2.9 (95% CI: 1.1-7.5). Among the 8 reported cases of Bell's palsy, 6 cases occurred in persons who received MENVEO concomitantly with one or more of the following vaccines: Tdap, HPV, and Influenza vaccine. All reported Bell's palsy cases resolved.

7 DRUG INTERACTIONS

7.1 Concomitant Administration with Other Vaccines

Do not mix MENVEO or any of its components with any other vaccine or diluent in the same syringe or vial.

In 2 clinical trials of infants initiating vaccination at 2 months of age (NCT00474526, NCT01000311), MENVEO was given concomitantly at 2, 4, and 6 months with routine infant vaccines: diphtheria toxoid; acellular pertussis; tetanus toxoid; inactivated polio types 1, 2, and 3; hepatitis B; *Haemophilus influenzae* type b antigens; pentavalent rotavirus; and 7-valent pneumococcal conjugate vaccine. For Dose 4 given at 12 months of age, MENVEO was given

concomitantly with the following vaccines: 7-valent pneumococcal conjugate, MMRV, or measles, mumps, and rubella vaccine and varicella vaccine (MMR+V), and inactivated hepatitis A. In a clinical trial of older infants (aged 7 months and older) and toddlers (NCT00626327), MENVEO was administered concomitantly with MMRV or MMR+V vaccine(s) at 12 months of age. No immune interference was observed for the concomitantly administered vaccines, including most pneumococcal vaccine serotypes (post Dose 3); no immune interference was observed post Dose 4 for any pneumococcal vaccine serotypes (NCT00474526, NCT01000311). *[See Clinical Studies (14.1).]*

For children aged 2 through 10 years, no data are available to evaluate safety and immunogenicity of other childhood vaccines when administered concomitantly with MENVEO.

In a clinical trial in adolescents (NCT00518180), MENVEO was given concomitantly with the following: Tdap and HPV; no interference was observed in meningococcal immune responses when compared with MENVEO given alone. Lower geometric mean antibody concentrations (GMCs) for antibodies to the pertussis antigens filamentous hemagglutinin (FHA) and pertactin were observed when MENVEO was administered concomitantly with Tdap and HPV as compared with Tdap alone. *[See Clinical Studies (14.1).]*

7.2 Immunosuppressive Treatments

Immunosuppressive therapies, such as irradiation, antimetabolite medications, alkylating agents, cytotoxic drugs, and corticosteroids (when used in greater than physiologic doses) may reduce the immune response to MENVEO. *[See Warnings and Precautions (5.3).]* The immunogenicity of MENVEO has not been evaluated in persons receiving such therapies.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

There are no adequate and well-controlled studies of MENVEO in pregnant women in the U.S. There was a pregnancy exposure registry conducted from 2014-2017 that included 82 subjects. Available data do not suggest an increased risk of major birth defects and miscarriage in women who received MENVEO within 28 days prior to conception or during pregnancy *(see Data)*.

A developmental toxicity study was performed in female rabbits administered 0.5 mL (at each occasion) of MENVEO prior to mating and during gestation. A single human dose is 0.5 mL. This study revealed no adverse effects on fetal or pre-weaning development *(see Data)*.

Data

Human Data: A pregnancy exposure registry (2014 to 2017) included 82 pregnancies with known outcomes with exposure within 28 days prior to conception or during pregnancy. Miscarriage was reported for 12.2% of pregnancies with exposure to MENVEO within 28 days prior to conception or during pregnancy (10/82). Major birth defects were reported for 3.6% of live born infants whose mothers were exposed within 28 days prior to conception or during pregnancy (2/55). The rates of miscarriage and major birth defects were consistent with estimated background rates.

Animal Data: In a developmental toxicity study, female rabbits were administered MENVEO by intramuscular injection on Days 29, 15, and 1 prior to mating and on Gestation Days 7 and 20. The total dose was 0.5 mL at each occasion (a single human dose is 0.5 mL). No adverse effects on pre-weaning development up to Postnatal Day 29 were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation

Risk Summary

It is not known whether the vaccine components of MENVEO are excreted in human milk. Data are not available to assess the effects of MENVEO in the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for MENVEO and any potential adverse effects on the breastfed child from MENVEO or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of MENVEO in children aged younger than 2 months have not been established.

Safety and effectiveness of the one-vial presentation of MENVEO in children aged younger than 10 years have not been established. *[See Dosage and Administration (2).]*

For children 2 months through 9 years of age, only the two-vial presentation is approved for use. *[See Dosage and Administration (2).]*

8.5 Geriatric Use

Safety and effectiveness of MENVEO in adults aged 65 years and older have not been established.

11 DESCRIPTION

MENVEO [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine] is a sterile liquid vaccine administered by intramuscular injection that contains *N. meningitidis* serogroup A, C, Y, and W-135 oligosaccharides conjugated individually to *Corynebacterium diphtheriae* CRM_{197} protein. The polysaccharides are produced by bacterial fermentation of *N. meningitidis* (serogroups A, C, Y, or W-135). *N. meningitidis* strains A, C, Y, and W-135 are each cultured and grown on Franz Complete medium and treated with formaldehyde. MenA, MenW-135, and MenY polysaccharides are purified by several extraction and precipitation steps. MenC polysaccharide is purified by a combination of chromatography and precipitation steps.

The protein carrier (CRM_{197}) is produced by bacterial fermentation and is purified by a series of chromatography and ultrafiltration steps. *C. diphtheriae* is cultured and grown on CY medium containing yeast extracts and amino acids.

The oligosaccharides are prepared for conjugation from purified polysaccharides by hydrolysis, sizing, and reductive amination. After activation, each oligosaccharide is covalently linked to the CRM_{197} protein. The resulting glycoconjugates are purified to yield the 4 drug substances, which compose the final vaccine. The vaccine contains no preservative or adjuvant. Each dose of vaccine contains 10 mcg MenA oligosaccharide; 5 mcg of each of MenC, MenY, and MenW-135 oligosaccharides; and 25.4 to 65.5 mcg CRM_{197} protein. Residual formaldehyde per dose is estimated to be not more than 0.30 mcg.

The vials in which the vaccine components are contained are composed of Type I glass, USP.

The container closures (synthetic rubber stoppers) are not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Neisseria meningitidis is a gram-negative diplococcus that causes life-threatening invasive disease such as meningitis and sepsis. Globally, 5 serogroups, A, B, C, Y, and W-135 cause almost all invasive meningococcal infections. The presence of serum bactericidal antibodies protects against invasive meningococcal disease.[1] Vaccination with MENVEO leads to the production of bactericidal antibodies directed against the capsular polysaccharides of serogroups A, C, Y, and W-135.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

MENVEO has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility in animals. Vaccination of female rabbits with MENVEO had no effect on fertility. *[See Use in Specific Populations (8.1).]*

14 CLINICAL STUDIES

For all age groups, effectiveness has been inferred from the measurement of serogroup-specific anticapsular antibodies with bactericidal activity using pooled human serum that lacked bactericidal activity as the source of exogenous complement (hSBA).

14.1 Primary Vaccination Studies

In the absence of a licensed comparator vaccine for use in infants, the pre-specified endpoint for effectiveness of MENVEO in U.S. infants receiving a 4-dose series at 2, 4, 6, and 12 months of age was the proportion of subjects achieving an hSBA ≥1:8, with the lower limit of the 2-sided 95% CI for the point estimate being ≥80% of vaccinees for serogroup A, and ≥85% of vaccinees for serogroups C, W-135, and Y 1 month following the final dose.

The effectiveness of MENVEO in subjects aged 2 through 55 years was assessed by comparing the hSBA responses to immunization with MENVEO to those following immunization with the licensed meningococcal quadrivalent conjugate vaccine MENACTRA.

The primary effectiveness endpoint was hSBA seroresponse to each serogroup 28 days after vaccination. Seroresponse was defined as: a) post-vaccination hSBA ≥1:8 for subjects with a baseline hSBA <1:4; or, b) at least 4-fold higher than baseline titers for subjects with a pre-vaccination hSBA ≥1:4. Secondary endpoints included the proportion of subjects with post-vaccination hSBA ≥1:8 and the hSBA Geometric Mean Titer (GMT) for each serogroup. In a separate group of children aged 2 through 5 years randomized to receive 2 doses of MENVEO administered 2 months apart, seroresponse rate, proportion with post-vaccination hSBA ≥1:8, and GMT were determined for each serogroup.

Immunogenicity in Infants/Toddlers Aged 2 Months through 12 Months

The effectiveness of MENVEO in infants was assessed in a randomized, controlled, multicenter study (NCT01000311). Among the subjects receiving MENVEO who were included in the per-protocol analysis, the mean age at enrollment was 65 days, 51% were male, 67% were Caucasian, 6% were African American, 15% were Hispanic, 2% were Asian, and 9% were noted as other racial/ethnic groups. The pre-defined criteria for immunogenicity were met for all 4 serogroups A, C, W-135, and Y at 1 month following completion of a 4-dose series at 2, 4, 6, and 12 months of age (Table 7).

The percentage of subjects with hSBA ≥1:8 at 7 months was 94% to 98% for serogroups C, W-135, and Y and 76% for serogroup A.

Table 7. Bactericidal Antibody Responses following Administration of MENVEO with Routine Infant/Toddler Vaccines at 2, 4, 6, and 12 Months of Age

Serogroup		Post 3rd Dose	Post 4th Dose
A		**n = 202**	**n = 168**
	% ≥1:8 95% CI	76 (69, 81)	89 (83[a], 93)
	GMT 95% CI	21 (17, 26)	54 (44, 67)
C		**n = 199**	**n = 156**
	% ≥1:8 95% CI	94 (90, 97)	95 (90[a], 98)
	GMT 95% CI	74 (62, 87)	135 (107, 171)
W-135		**n = 194**	**n = 153**
	% ≥1:8 95% CI	98 (95, 99)	97 (93[a], 99)
	GMT 95% CI	79 (67, 92)	215 (167, 227)
Y		**n = 188**	**n = 153**
	% ≥1:8 95% CI	94 (89, 97)	96 (92[a], 99)
	GMT 95% CI	51 (43, 61)	185 (148, 233)

Clinicaltrials.gov Identifier NCT01000311.

% ≥1:8 = Proportions of subjects with hSBA ≥1:8 against a given serogroup; CI = Confidence interval; GMT = Geometric mean antibody titer; n = Number of infants eligible for inclusion in the Per-Protocol Immunogenicity population for whom serological results were available for the post-Dose 3 and post-Dose 4 evaluations.

Serum Bactericidal Assay with exogenous human complement source (hSBA).

[a] Pre-specified criteria for adequacy of immune response were met (lower limit of the 95% CI >80% for serogroup A and >85% for serogroups C, W, and Y).

The effectiveness of 2 doses of MENVEO given at 7-9 months and 12 months of age was assessed in a randomized, multicenter, controlled clinical trial (NCT00626327) conducted in the U.S. This study also investigated the concomitant administration of MENVEO and MMRV. The per-protocol population for assessing the response to 2 doses of MENVEO consisted of 386 subjects. Among subjects who completed the per-protocol analysis, their mean age at enrollment was 8.5 months (SD: 0.8 months), 50% were male; 61% were Caucasian, 15% were Hispanic, 10% were African American, 4% were Asian, and 10% were noted as other racial/ethnic groups.

Among the per-protocol population, after MENVEO administered at 7-9 and at 12 months, the proportions of subjects with hSBA ≥1:8 for serogroups A, C, W-135, and Y were respectively: 88% (84-91), 100% (98-100), 98% (96-100), 96% (93-99).

Immunogenicity in Children Aged 2 Years through 10 Years

Effectiveness in subjects aged 2 through 10 years was evaluated in a randomized, multicenter, active-controlled clinical study (NCT00616421) comparing hSBA responses following 1 dose of MENVEO or MENACTRA. The study was conducted in the U.S. and Canada and was stratified by age (2 through 5 years and 6 through 10 years). The per-protocol population evaluated after a single dose of vaccine consisted of 1,170 subjects who received MENVEO and 1,161 who received MENACTRA (Table 8) and included serological results for 89% to 95% of subjects, depending on serogroup and age group. Demographics for the 616 and 619 subjects aged 2 through 5 years for MENVEO and MENACTRA were as follows: mean age 3.6 years (SD: 1.1) vs. 3.6 years (SD: 1.1), 51% vs. 52% male, 62% vs. 62% Caucasian, 14% vs. 13% Hispanic, 12% vs. 13% African American, 6% vs. 4% Asian, and 7% vs. 8% other racial/ethnic groups, respectively. Demographics were for 554 and 542 per-protocol subjects aged 6 through 10 years for MENVEO and MENACTRA were as follows: mean age 7.9 years (SD: 1.4) vs. 8.1 years (SD: 1.4), 52% vs. 56% male, 66% vs. 66% Caucasian, 14% vs. 14% African American, 7% vs. 7% Hispanic, 5% vs. 6% Asian, and 8% vs. 8% other racial/ethnic groups, respectively. In a separate group of children aged 2 through 5 years randomized to receive 2 doses of MENVEO administered 2 months apart, the per-protocol population evaluated after 2 doses of MENVEO consisted of 297 subjects and included serologic results for 96% to 99% of subjects, depending on serogroup.

In study participants aged 2 through 5 years and 6 through 10 years, non-inferiority of MENVEO to MENACTRA for the proportion of subjects with a seroresponse was demonstrated for serogroups C, W-135, and Y, but not for serogroup A (Table 8).

Table 8. Comparison of Bactericidal Antibody Responses[a] to MENVEO and MENACTRA 28 Days after Vaccination of Subjects Aged 2 through 5 Years and 6 through 10 Years

	2-5 Years			6-10 Years		
Endpoint by Serogroup	**MENVEO (95% CI)**	**MENACTRA (95% CI)**	**Percent Difference (MENVEO – MENACTRA) or GMT Ratio (MENVEO/ MENACTRA) (95% CI)**	**MENVEO (95% CI)**	**MENACTRA (95% CI)**	**Percent Difference (MENVEO – MENACTRA) or GMT Ratio (MENVEO/ MENACTRA) (95% CI)**
A	**n = 606**	**n = 611**		**n = 551**	**n = 541**	
% Seroresponse[b]	72 (68, 75)	77 (73, 80)	-5 (-10, -0)[c]	77 (73, 80)	83 (79, 86)	-6 (-11, -1)[c]
% ≥1:8	72 (68, 75)	78 (74, 81)	-6 (-11, -1)	77 (74, 81)	83 (80, 86)	-6 (-11, -1)
GMT	26 (22, 30)	25 (21, 29)	1.04 (0.86, 1.27)	35 (29, 42)	35 (29, 41)	1.01 (0.83, 1.24)
C	**n = 607**	**n = 615**		**n = 554**	**n = 539**	
% Seroresponse[b]	60 (56, 64)	56 (52, 60)	4 (-2, 9)[d]	63 (59, 67)	57 (53, 62)	6 (0, 11)[d]
% ≥1:8	68 (64, 72)	64 (60, 68)	4 (-1, 10)	77 (73, 80)	74 (70, 77)	3 (-2, 8)
GMT	18 (15, 20)	13 (11, 15)	1.33 (1.11, 1.6)	36 (29, 45)	27 (21, 33)	1.36 (1.06, 1.73)
W-135	**n = 594**	**n = 605**		**n = 542**	**n = 533**	
% Seroresponse[b]	72 (68, 75)	58 (54, 62)	14 (9, 19)[d]	57 (53, 61)	44 (40, 49)	13 (7, 18)[d]
% ≥1:8	90 (87, 92)	75 (71, 78)	15 (11, 19)	91 (88, 93)	84 (81, 87)	7 (3, 11)
GMT	43 (38, 50)	21 (19, 25)	2.02 (1.71, 2.39)	61 (52, 72)	35 (30, 42)	1.72 (1.44, 2.06)
Y	**n = 593**	**n = 600**		**n = 545**	**n = 539**	
% Seroresponse[b]	66 (62, 70)	45 (41, 49)	21 (16, 27)[d]	58 (54, 62)	39 (35, 44)	19 (13, 24)[d]
% ≥1:8	76 (72, 79)	57 (53, 61)	19 (14, 24)	79 (76, 83)	63 (59, 67)	16 (11, 21)
GMT	24 (20, 28)	10 (8.68, 12)	2.36 (1.95, 2.85)	34 (28, 41)	14 (12, 17)	2.41 (1.95, 2.97)

Clinicaltrials.gov Identifier NCT00616421.
CI = Confidence interval; GMT = Geometric mean antibody titer.
[a] Serum Bactericidal Assay with exogenous human complement source (hSBA).
[b] Seroresponse was defined as: Subjects with a pre-vaccination hSBA <1:4, a post-vaccination titer of >1:8 and among subjects with a pre-vaccination hSBA ≥1:4, a post-vaccination titer at least 4-fold higher than baseline.
[c] Non-inferiority criterion not met (the lower limit of the 2-sided 95% CI ≤-10% for vaccine group differences).
[d] Non-inferiority criterion met (the lower limit of the 2-sided 95% CI >-10% for vaccine group differences [MENVEO minus MENACTRA]).

In the 297 per-protocol subjects aged 2 through 5 years observed at 1 month after the second dose of MENVEO, the proportions of subjects with seroresponse (95% CI) were: 91% (87-94), 98% (95-99), 89% (85-92), and 95% (91-97) for serogroups A, C, W-135, and Y, respectively. The proportion of subjects with hSBA ≥1:8 (95% CI) were 91% (88-94), 99% (97-100), 99% (98-100), and 98% (95-99) for serogroups A, C, W-135, and Y, respectively. The hSBA GMTs (95% CI) for this group were 64 (51-81), 144 (118-177), 132 (111-157), and 102 (82-126) for serogroups A, C, W-135, and Y, respectively.

Immunogenicity in Adolescents Aged 11 Years through 18 Years

Effectiveness in subjects aged 11 through 55 years was evaluated in a randomized, multicenter, active-controlled clinical study (NCT00450437) comparing the hSBA responses following 1 dose of MENVEO or MENACTRA. The study was conducted in the U.S. and stratified by age (11 through 18 years and 19 through 55 years). This study enrolled 3,539 participants, who were randomized to receive a dose of MENVEO (n = 2,663) or MENACTRA (n = 876). Among subjects who completed the per-protocol evaluation for immunogenicity (n = 3,393, MENVEO = 2,549, MENACTRA = 844), demographics for subjects receiving MENVEO and MENACTRA, respectively, were as follows: mean age 23.9 (SD: 13.6) vs. 23.7 (SD: 13.7), 42% vs. 42% male, 79% vs. 78% Caucasian, 8% vs. 9% African American, 7% vs. 7% Hispanic, 3% vs. 3% Asian, 2% vs. 3% other racial/ethnic groups. Immunogenicity for each serogroup was assessed in a subset of study participants (Tables 9 and 10).

In study participants aged 11 through 18 years, non-inferiority of MENVEO to MENACTRA was demonstrated for all 4 serogroups for the proportion of subjects with a seroresponse (Table 9).

Table 9. Comparison of Bactericidal Antibody Responses[a] to MENVEO and MENACTRA 28 Days after Vaccination of Subjects Aged 11 through 18 Years

Endpoint by Serogroup	Bactericidal Antibody Response[a]		Comparison of MENVEO and MENACTRA	
	MENVEO (95% CI)	MENACTRA (95% CI)	MENVEO/ MENACTRA (95% CI)	MENVEO minus MENACTRA (95% CI)
A	**n = 1,075**	**n = 359**		
% Seroresponse[b]	75 (72, 77)	66 (61, 71)		8 (3, 14)[c]
% ≥1:8	75 (73, 78)	67 (62, 72)	-	8 (3, 14)
GMT	29 (24, 35)	18 (14, 23)	1.63 (1.31, 2.02)	-
C	**n = 1,396**	**n = 460**		
% Seroresponse[b]	76 (73, 78)	73 (69, 77)		2 (-2, 7)[c]
% ≥1:8	85 (83, 87)	85 (81, 88)	-	0 (-4, 4)
GMT	50 (39, 65)	41 (30, 55)	1.22 (0.97, 1.55)	-
W-135	**n = 1,024**	**n = 288**		
% Seroresponse[b]	75 (72, 77)	63 (57, 68)		12 (6, 18)[c]
% ≥1:8	96 (95, 97)	88 (84, 92)	-	8 (4, 12)
GMT	87 (74, 102)	44 (35, 54)	2.00 (1.66, 2.42)	-
Y	**n = 1,036**	**n = 294**		
% Seroresponse[b]	68 (65, 71)	41 (35, 47)		27 (20, 33)[c]
% ≥1:8	88 (85, 90)	69 (63, 74)	-	19 (14, 25)
GMT	51 (42, 61)	18 (14, 23)	2.82 (2.26, 3.52)	-

Clinicaltrials.gov Identifier NCT00450437.

CI = Confidence interval; GMT = Geometric mean antibody titer.

[a] Serum Bactericidal Assay with exogenous human complement source (hSBA).

[b] Seroresponse was defined as: a) post-vaccination hSBA ≥1:8 for subjects with a pre-vaccination hSBA <1:4; or, b) at least 4-fold higher than baseline titers for subjects with a pre-vaccination hSBA ≥1:4.

[c] Non-inferiority criterion for the primary endpoint met (the lower limit of the 2-sided 95% CI >-10% for vaccine group differences [MENVEO minus MENACTRA]).

Immunogenicity in Adults Aged 19 Years through 55 Years

The study in subjects aged 11 through 55 years was a randomized, multicenter, active-controlled clinical trial (NCT00450437) conducted in the U.S. and stratified by age (11 through 18 years and 19 through 55 years) as described above.

In study participants aged 19 through 55 years, non-inferiority of MENVEO to MENACTRA was demonstrated for all 4 serogroups for the proportion of subjects with a seroresponse (Table 10).

Table 10. Comparison of Bactericidal Antibody Responses to MENVEO and MENACTRA 28 Days after Vaccination of Subjects Aged 19 through 55 Years

	Bactericidal Antibody Response[a]		**Comparison of MENVEO and MENACTRA**	
Endpoint by Serogroup	**MENVEO (95% CI)**	**MENACTRA (95% CI)**	**MENVEO/ MENACTRA (95% CI)**	**MENVEO minus MENACTRA (95% CI)**
A	**n = 963**	**n = 321**		
% Seroresponse[b]	67 (64, 70)	68 (63, 73)		-1 (-7, 5)[c]
% ≥1:8	69 (66, 72)	71 (65, 76)	-	-2 (-7, 4)
GMT	31 (27, 36)	30 (24, 37)	1.06 (0.82, 1.37)	-
C	**n = 902**	**n = 300**		
% Seroresponse[b]	68 (64, 71)	60 (54, 65)		8 (2, 14)[c]
% ≥1:8	80 (77, 83)	74 (69, 79)	-	6 (1, 12)
GMT	50 (43, 59)	34 (26, 43)	1.50 (1.14, 1.97)	-

W-135	**n = 484**	**n = 292**		
% Seroresponse[b]	50 (46, 55)	41 (35, 47)		9 (2, 17)[c]
% ≥1:8	94 (91, 96)	90 (86, 93)	-	4 (0, 9)
GMT	111 (93, 132)	69 (55, 85)	1.61 (1.24, 2.1)	-
Y	**n = 503**	**n = 306**		
% Seroresponse[b]	56 (51, 60)	40 (34, 46)		16 (9, 23)[c]
% ≥1:8	79 (76, 83)	70 (65, 75)	-	9 (3, 15)
GMT	44 (37, 52)	21 (17, 26)	2.10 (1.60, 2.75)	-

Clinicaltrials.gov Identifier NCT00450437.

CI = Confidence interval; GMT = Geometric mean antibody titer.

[a] Serum Bactericidal Assay with exogenous human complement source (hSBA).

[b] Seroresponse was defined as: a) post-vaccination hSBA >1:8 for subjects with a pre-vaccination hSBA <1:4; or, b) at least 4-fold higher than baseline titers for subjects with a pre-vaccination hSBA ≥1:4.

[c] Non-inferiority criterion for the primary endpoint met (the lower limit of the 2-sided 95% CI >-10% for vaccine group differences [MENVEO minus MENACTRA]).

Immunogenicity of MENVEO One-Vial Presentation in Individuals Aged 10 Years through 40 Years

Immunogenicity of MENVEO one-vial presentation was evaluated in an observer-blind randomized, multicenter, controlled clinical trial in individuals aged 10 to 40 years (NCT03433482). The study compared the immune response of the MENVEO one-vial presentation to the MENVEO two-vial presentation.

The primary analysis demonstrated non-inferiority of MenA serogroup hSBA GMTs at 28 days post-vaccination for the MENVEO one-vial presentation group compared to the MENVEO two-vial presentation group (lower limit of the two-sided 95% CI for the ratio of hSBA GMTs against serogroup A between the MENVEO one-vial presentation group and the MENVEO two-vial presentation group was greater than 0.5). Secondary analyses showed comparable immune responses against *N. meningitidis* serogroups C, W-135 and Y as measured by hSBA GMTs. Additional secondary analyses demonstrated comparable percentages of subjects with hSBA titers ≥8, and percentages of subjects with a ≥4-fold rise in titers compared to baseline for serogroups A, C, W-135 and Y.

14.2 Booster Vaccination Study

Immunogenicity in Adolescents and Adults Aged 15 Years through 55 Years

For a description of study design and number of participants, see section 6.1 Booster Vaccination Study. The co-primary immunogenicity endpoints were hSBA seroresponse to each serogroup 29 days a) following a booster vaccination with MENVEO given to subjects who received a prior dose of MENVEO, and b) following a booster vaccination with MENVEO given to subjects who received a prior dose of MENACTRA. Seroresponse was defined as: a) post-vaccination hSBA ≥1:16 for subjects with a baseline hSBA <1:4 or b) at least 4-fold higher than baseline titers for subjects with a pre-vaccination hSBA ≥1:4. Secondary endpoints included the proportions of subjects with post-vaccination hSBA ≥1:8, the hSBA GMTs for each serogroup, and antibody titers against each serogroup 4 to 6 years after a prior dose (as measured by percentages of subjects with hSBA titers ≥1:8 and hSBA GMTs prior to booster vaccination).

Seroresponse rates at Day 29 following a booster vaccination with MENVEO were 97% for serogroup A, 95% for serogroup C, 96% for serogroup W-135, and 97% for serogroup Y, in subjects who had received a prior dose of MENVEO (n = 290). At Day 6, following a booster vaccination, seroresponse rates were 39%, 51%, 50%, and 49% for serogroups A, C, W-135, and Y, respectively, in subjects who had received a prior dose of MENVEO.

The hSBA GMTs were 13, 92, 112, and 63 for serogroups A, C, W-135, and Y at Day 6, and 210, 1160, 1395, and 1067, respectively, for the 4 serogroups at Day 29 following a booster dose of MENVEO.

Overall, similar seroresponse rates and GMTs were observed for those subjects who received a booster vaccination with MENVEO following a prior dose of MENACTRA (n = 282).

Prior to booster vaccination, the percentage of subjects with hSBA titers >1:8 for serogroups A, C, W-135, and Y were 12%, 62%, 76%, and 54% for those who received a prior dose of MENVEO 4 to 6 years earlier, and 15%, 54%, 77%, and 47% for those who received a prior dose of MENACTRA 4 to 6 years earlier. The hSBA GMTs for serogroups A, C, W-135, and Y prior to booster vaccination were 3, 16, 23, and 9 following a prior vaccination with MENVEO and 3, 11, 23, and 8 following a prior vaccination with MENACTRA.

14.3 Immunogenicity of Concomitantly Administered Vaccines

In U.S. infants (NCT00474526, NCT01000311) who received MENVEO concomitantly with DTaP-IPV-Hib and PCV7 at 2, 4, and 6 months of age and HBV administered according to ACIP recommendations, there was no evidence for reduced antibody response to pertussis antigens (GMC to pertussis toxin, filamentous hemagglutinin, fimbriae, and pertactin), diphtheria toxoid (antibody levels ≥0.1 IU/mL), tetanus toxoid (antibody levels ≥0.1 IU/mL), poliovirus types 1, 2, and 3 (neutralizing antibody levels ≥1:8 to each virus), *Haemophilus influenzae* type b (anti-PRP antibody ≥0.15 mcg/mL), hepatitis B (anti-hepatitis B surface antigen ≥10 mIU/mL), or most serotypes of PCV7 (antibody levels ≥0.35 mcg/mL) relative to the response in infants

administered DTaP-IPV-Hib, PCV7, and HBV. The immune responses to DTaP-IPV-Hib, PCV7, and HBV were evaluated 1 month following Dose 3. No interference was observed for pertussis based on GMC ratios, or for the other concomitantly administered vaccines, with the exception of pneumococcal serotype 6B and 23F, for which interference was suggested post Dose 3. No interference was observed post Dose 4 for these serotypes.

There was no evidence for interference in the immune response to MMR and varicella vaccines (among initially seronegative children) in terms of percentages of children with anti-measles antibodies ≥255 mIU/mL, anti-mumps ≥10 ELISA antibody units, anti-rubella ≥10 IU/mL, and anti-varicella ≥5 gp ELISA units/mL, administered at 12 months of age (NCT00626327) concomitantly with MENVEO relative to these vaccines administered alone. The immune responses to MMR and varicella vaccines were evaluated 6 weeks post vaccination.

For children aged 2 through 10 years, no data are available for evaluating safety and immunogenicity of other childhood vaccines when administered concomitantly with MENVEO.

For individuals aged 11 through 18 years, the effect of concomitant administration of MENVEO with Tdap and HPV was evaluated in a study (NCT00518180) conducted in Costa Rica (see also section 6.1 for the safety results from this trial). Subjects were randomized to receive one of the following regimens at the start of the trial: MENVEO plus Tdap plus HPV (n = 540); MENVEO alone (n = 541); Tdap alone (n = 539). Subjects were healthy adolescents aged 11 through 18 years (mean age between groups was 13.8 to 13.9 years). For antigens of MENVEO, the proportion (95% CI) of subjects achieving an hSBA seroresponse among those who received MENVEO plus Tdap plus HPV vs. MENVEO alone, respectively, were: serogroup A 80% (76, 84) vs. 82% (78, 85); serogroup C 83% (80, 87) vs. 84% (80, 87); serogroup W-135 77% (73, 80) vs. 81% (77, 84); serogroup Y 83% (79, 86) vs. 82% (79, 86). Among subjects who received Tdap plus MENVEO plus HPV, compared with Tdap alone, the proportions (95% CI) of subjects who achieved an anti-tetanus or anti-diphtheria toxoids levels ≥1.0 IU/mL in the 2 groups, respectively, were 100% (99, 100) vs. 98% (96, 99) and 100% (99, 100) vs. 100% (99, 100). For pertussis antigens, among subjects who received Tdap plus MENVEO plus HPV, compared with Tdap alone, the responses respectively for anti-pertussis toxin GMCs (95% CI) were 51 (47, 55) vs. 63 (58, 69) ELISA Units (EU)/mL, for anti-filamentous hemagglutinin were 342 (310, 376) vs. 511 (464, 563) EU/mL, and for anti-pertactin were 819 (727, 923) vs. 1,197 (1,061, 1,350) EU/mL. Because there are no established serological correlates of protection for pertussis, the clinical implications of the lower pertussis antigen responses are unknown.

15 REFERENCES

1. Goldschneider I, Gotschlich EC, Artenstein MS. Human immunity to the meningococcus. I. The role of humoral antibodies. *J Exp Med*. (1969);129:1307-1326.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 MENVEO Two-Vial Presentation

MENVEO two-vial presentation is supplied in cartons containing:

- 5 Vials containing MenCYW-135 Liquid Conjugate Component (Vial 1; gray cap)
- 5 Vials containing MenA Lyophilized Conjugate Component (Vial 2; orange cap)

One vial of MenCYW-135 liquid conjugate component (Vial 1) and one vial of MenA lyophilized conjugate component (Vial 2) must be combined before use to form a single dose (0.5 mL) of MENVEO (packaged without syringes or needles). Each carton contains 5 doses of MENVEO.

The container closures (synthetic rubber stoppers) are not made with natural rubber latex.

Table 11. MENVEO: Two-Vial Presentation

Presentation	Carton NDC Number	MenCYW-135 Liquid Conjugate Component (Vial 1; gray cap) NDC Number	MenA Lyophilized Conjugate Component (Vial 2; orange cap) NDC Number
Carton of 10 vials (5 doses)	NDC 58160-955-09	5 Vials NDC 58160-959-01	5 Vials NDC 58160-958-01

Storage before Reconstitution

Do not freeze. Frozen/previously frozen product should be discarded.

Store refrigerated, away from the freezer compartment, at 36°F to 46°F (2°C to 8°C).

Protect from light. Vaccine must be maintained at 36°F to 46°F (2°C to 8°C) during transport.

Do not use after the expiration date.

Storage after Reconstitution

The reconstituted vaccine should be used immediately but may be held at 36°F to 77°F (2°C to 25°C) for up to 8 hours. Do not freeze. Discard reconstituted vaccine if it has been frozen or not used within 8 hours.

16.2 MENVEO One-Vial Presentation

MENVEO one-vial presentation is supplied in cartons containing:

- 10 Vials containing MENVEO (pink cap)

Each carton contains 10 single dose vials of MENVEO. Each dose is 0.5 mL.

The container closures (synthetic rubber stoppers) are not made with natural rubber latex.

Table 12. MENVEO: One-Vial Presentation

Presentation	Carton NDC Number	MENVEO (pink cap) NDC Number
Carton of 10 vials (10 doses)	NDC 58160-827-30	10 Vials NDC 58160-827-03

Do not freeze. Frozen/previously frozen product should be discarded.

Store refrigerated, away from the freezer compartment, at 36°F to 46°F (2°C to 8°C).

Protect from light. Vaccine must be maintained at 36°F to 46°F (2°C to 8°C) during transport.

Do not use after the expiration date.

17 PATIENT COUNSELING INFORMATION

Give the recipient, parent, or guardian the Vaccine Information Statements, which are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Provide the following information to the vaccine recipient, parent, or guardian:

- Potential benefits and risks of immunization with MENVEO.
- The importance of completing the immunization series.
- Potential for adverse reactions that have been temporally associated with administration of MENVEO or other vaccines containing similar components.
- Reporting any adverse reactions to their healthcare provider.

Manufactured by:
GSK Vaccines, Srl

Bellaria-Rosia 53018, Sovicille (SI), Italy
US License No. 1617

Distributed by:
GlaxoSmithKline
Durham, NC 27701

MNV:7PI

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Menactra® safely and effectively. See full prescribing information for Menactra vaccine.

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine
Solution for Intramuscular Injection

Initial U.S. Approval: 2005

----------RECENT MAJOR CHANGES ----------

Warnings and Precautions, Altered Immunocompetence (5.3) 4/2018

----------INDICATIONS AND USAGE----------

Menactra is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in individuals 9 months through 55 years of age. Menactra does not prevent *N meningitidis* serogroup B disease. (1)

----------DOSAGE AND ADMINISTRATION----------

A 0.5 mL dose for intramuscular injection. (2)

Primary Vaccination:

- Children 9 through 23 months of age: Two doses, three months apart.
- Individuals 2 through 55 years of age: A single dose.

Booster Vaccination:

- A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose.

----------DOSAGE FORMS AND STRENGTHS----------

Solution supplied in 0.5 mL single-dose vials (3)

----------CONTRAINDICATIONS----------

- Severe allergic reaction (eg, anaphylaxis) after a previous dose of a meningococcal capsular polysaccharide-, diphtheria toxoid- or CRM_{197}-containing vaccine, or to any component of Menactra. (4)

----------WARNINGS AND PRECAUTIONS----------

- Persons previously diagnosed with Guillain-Barré syndrome (GBS) may be at increased risk of GBS following receipt of Menactra. The decision to give Menactra should take into account the potential benefits and risks. (5.1)

----------ADVERSE REACTIONS----------

- Common (≥10%) solicited adverse events in infants and toddlers 9 and 12 months of age were injection site tenderness, erythema, and swelling; irritability, abnormal crying, drowsiness, appetite loss, vomiting, and fever. (6)
- Common (≥10%) solicited adverse events in individuals 2 through 55 years of age who received a single dose were injection site pain, redness, induration, and swelling; anorexia and diarrhea. Other common solicited adverse events were irritability and drowsiness (2-10 years of age), headache, fatigue, malaise, and arthralgia (11-55 years of age). (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc. at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or http://vaers.hhs.gov.

----------DRUG INTERACTIONS----------

- When Menactra and DAPTACEL® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed) are to be administered to children 4 through 6 years of age, preference should be given to simultaneous administration of the 2 vaccines or administration of Menactra prior to DAPTACEL. Administraton of Menactra one month after DAPTACEL has been shown to reduce meningococcal antibody responses to Menactra. (7.1)
- Pneumococcal antibody responses to some serotypes in Prevnar (PCV7) were decreased following co-administration of Menactra and PCV7. (7.1)

----------USE IN SPECIFIC POPULATIONS----------

- Safety and effectiveness of Menactra have not been established in children younger than 9 months of age, pregnant women, nursing mothers, and adults older than 55 years of age. (8.1, 8.2, 8.4, 8.5)
- A pregnancy registry is available. Contact Sanofi Pasteur Inc. at 1-800-822-2463. (8.1)

See **17 PATIENT_COUNSELING_INFORMATION**.

Revised: April 2018

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION:

1 INDICATIONS AND USAGE

Menactra®, Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine, is indicated for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y and W-135. Menactra is approved for use in individuals 9 months through 55 years of age. Menactra does not prevent *N meningitidis* serogroup B disease.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

Menactra is a clear to slightly turbid solution. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, the vaccine should not be administered.

Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe.

2.2 Dose and Schedule

Menactra is administered as a 0.5 mL dose by intramuscular injection. Do not administer this product intravenously or subcutaneously.

Primary Vaccination:

- In children 9 through 23 months of age, Menactra is given as a 2-dose series three months apart.

- Individuals 2 through 55 years of age, Menactra is given as a single dose.

Booster Vaccination:

- A single booster dose may be given to individuals 15 through 55 years of age at continued risk for meningococcal disease, if at least 4 years have elapsed since the prior dose.

3 DOSAGE FORMS AND STRENGTHS

Menactra is a solution supplied in 0.5 mL single-dose vials. [See *Description (11)* for a complete listing of ingredients.]

4 CONTRAINDICATIONS

Severe allergic reaction (eg, anaphylaxis) after a previous dose of a meningococcal capsular polysaccharide-, diphtheria toxoid- or CRM_{197}-containing vaccine, or to any component of Menactra [see *Description (11)*].

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome

Persons previously diagnosed with Guillain-Barré syndrome (GBS) may be at increased risk of GBS following receipt of Menactra. The decision to give Menactra should take into account the potential benefits and risks.

GBS has been reported in temporal relationship following administration of Menactra (1) (2). The risk of GBS following Menactra vaccination was evaluated in a post-marketing retrospective cohort study [see *Post-Marketing Experience (6.2)*].

5.2 Preventing and Managing Allergic Vaccine Reactions

Prior to administration, the healthcare provider should review the immunization history for possible vaccine sensitivity and previous vaccination-related adverse reactions to allow an assessment of benefits and risks. Epinephrine and other appropriate agents used for the control of immediate allergic reactions must be immediately available should an acute anaphylactic reaction occur.

5.3 Altered Immunocompetence

- *Reduced Immune Response*

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to Menactra.

- *Complement Deficiency*

Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *N meningitidis*, including invasive disease caused by serogroups A, C, Y and W-135, even if they develop antibodies following vaccination with Menactra. [See *Clinical Pharmacology (12).*]

5.4 Limitations of Vaccine Effectiveness

Menactra may not protect all recipients.

5.5 Syncope

Syncope (fainting) has been reported following vaccination with Menactra. Procedures should be in place to prevent falling injury and manage syncopal reactions.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a vaccine cannot be directly compared to rates in the clinical trials of another vaccine and may not reflect the rates observed in practice.

Children 9 Through 12 Months of Age

The safety of Menactra was evaluated in four clinical studies that enrolled 3721 participants who received Menactra at 9 and 12 months of age. At 12 months of age these children also received one or more other recommended vaccines [Measles, Mumps, Rubella and Varicella Virus Vaccine Live (MMRV) or Measles, Mumps, and Rubella Virus Vaccine (MMR) and Varicella Virus Vaccine Live (V) each manufactured by Merck & Co., Inc., Pneumococcal 7-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein) manufactured by Wyeth Pharmaceuticals Inc. (PCV7), Hepatitis A Vaccine manufactured by Merck & Co., Inc. (HepA). A control group of 997 children

was enrolled at 12 months of age and received two or more childhood vaccines [MMRV (or MMR+V), PCV7, HepA] at 12 months of age [see *Concomitant Vaccine Administration (14.3)*]. Three percent of individuals received MMR and V, instead of MMRV, at 12 months of age.

The primary safety study was a controlled trial that enrolled 1256 children who received Menactra at 9 and 12 months of age. At 12 months of age these children received MMRV (or MMR+V), PCV7 and HepA. A control group of 522 children received MMRV, PCV7 and HepA. Of the 1778 children, 78% of participants (Menactra, N=1056; control group, N=322) were enrolled at United States (US) sites and 22% at a Chilean site. (Menactra, N=200; control group, N=200).

Individuals 2 Through 55 Years of Age

The safety of Menactra was evaluated in eight clinical studies that enrolled 10,057 participants aged 2-55 years who received Menactra and 5,266 participants who received Menomune® – A/C/Y/W-135, Meningococcal Polysaccharide Vaccine, Groups A, C, Y and W-135 Combined. There were no substantive differences in demographic characteristics between the vaccine groups. Among Menactra recipients 2-55 years of age 24.0%, 16.2%, 40.4% and 19.4% were in the 2-10, 11-14, 15-25 and 26-55-year age groups, respectively. Among Menomune – A/C/Y/W-135 recipients 2-55 years of age 42.3%, 9.3%, 30.0% and 18.5% were in the 2-10, 11-14, 15-25 and 26-55-year age groups, respectively. The three primary safety studies were randomized, active-controlled trials that enrolled participants 2-10 years of age (Menactra, N=1713; Menomune – A/C/Y/W-135, N=1519), 11-18 years of age (Menactra, N=2270; Menomune – A/C/Y/W-135, N=972) and 18-55 years of age (Menactra, N=1384; Menomune – A/C/Y/W-135, N=1170), respectively. Of the 3232 children 2-10 years of age, 68% of participants (Menactra, N=1164;

Menomune – A/C/Y/W-135, N=1031) were enrolled at US sites and 32% (Menactra, N=549; Menomune – A/C/Y/W-135, N=488) of participants at a Chilean site. The median ages in the Chilean and US subpopulations were 5 and 6 years, respectively. All adolescents and adults were enrolled at US sites. As the route of administration differed for the two vaccines (Menactra given intramuscularly, Menomune – A/C/Y/W-135 given subcutaneously), study personnel collecting the safety data differed from personnel administering the vaccine.

Booster Vaccination Study

In an open-label trial conducted in the US, 834 individuals were enrolled to receive a single dose of Menactra 4-6 years after a prior dose. The median age of participants was 17.1 years at the time of the booster dose.

Safety Evaluation

Participants were monitored after each vaccination for 20 or 30 minutes for immediate reactions, depending on the study. Solicited injection site and systemic reactions were recorded in a diary card for 7 consecutive days after each vaccination. Participants were monitored for 28 days (30 days for infants and toddlers) for unsolicited adverse events and for 6 months post-vaccination for visits to an emergency room, unexpected visits to an office physician, and serious adverse events. Unsolicited adverse event information was obtained either by telephone interview or at an interim clinic visit. Information regarding adverse events that occurred in the 6-month post-vaccination time period was obtained via a scripted telephone interview.

Serious Adverse Events in All Safety Studies

Serious adverse events (SAEs) were reported during a 6-month time period following vaccinations in individuals 9 months through 55 years of age. In children who received Menactra at 9 months and at 12 months of age, SAEs occurred at a rate of 2.0% - 2.5%. In participants who received one or more childhood vaccine(s) (without co-administration of Menactra) at 12 months of age, SAEs occurred at a rate of 1.6% - 3.6%, depending on the number and type of vaccines received. In children 2-10 years of age, SAEs occurred at a rate of 0.6% following Menactra and at a rate of 0.7% following Menomune – A/C/Y/W-135. In adolescents 11 through 18 years of age and adults 18 years through 55 years of age, SAEs occurred at a rate of 1.0% following Menactra and at a rate of 1.3% following Menomune – A/C/Y/W-135. In adolescents and adults, SAEs occurred at a rate of 1.3% following booster vaccination with Menactra.

Solicited Adverse Events in the Primary Safety Studies

The most frequently reported solicited injection site and systemic adverse reactions within 7 days following vaccination in children 9 months and 12 months of age (Table 1) were injection site tenderness and irritability.

The most frequently reported solicited injection site and systemic adverse reactions in US children aged 2-10 years of age (Table 2) were injection site pain and irritability. Diarrhea, drowsiness, and anorexia were also common.

The most commonly reported solicited injection site and systemic adverse reactions in adolescents, ages 11-18 years (Table 3), and adults, ages 18-55 years (Table 4), after a single dose

were injection site pain, headache and fatigue. Except for redness in adults, injection site reactions were more frequently reported after Menactra vaccination than after Menomune – A/C/Y/W-135 vaccination.

Table 1: Percentage of US Participants Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration at 9 Months and 12 Months of Age

	Menactra at 9 months of age N[d]=998 - 1002			Menactra + PCV7[a]+ MMRV[b] + HepA[c] at 12 months of age N[d]=898 - 908			PCV7[a] + MMRV[b] + HepA[c] at 12 months of age N[d]=302 - 307		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site									
Tenderness[e]									
Menactra Site	37.4	4.3	0.6	48.5	7.5	1.3	-	-	-
PCV7 Site	-	-	-	45.6	9.4	1.6	45.7	8.3	0.3
MMRV Site	-	-	-	38.9	7.1	1.0	43.0	5.2	0.0
HepA Site	-	-	-	43.4	8.7	1.4	40.9	4.6	0.3
Erythema[f]									
Menactra Site	30.2	2.5	0.3	30.1	1.3	0.1	-	-	-
PCV7 Site	-	-	-	29.4	2.6	0.2	32.6	3.0	0.7
MMRV Site	-	-	-	22.5	0.9	0.3	33.2	5.9	0.0
HepA Site	-	-	-	25.1	1.1	0.0	26.6	0.7	0.0
Swelling[f]									
Menactra Site	16.8	0.9	0.2	16.2	0.9	0.1	-	-	-
PCV7 Site	-	-	-	19.5	1.3	0.4	16.6	1.3	0.7
MMRV Site	-	-	-	12.1	0.4	0.1	14.1	0.3	0.0
HepA Site	-	-	-	16.4	0.7	0.2	13.5	0.0	0.3
Systemic									
Irritability[g]	56.8	23.1	2.9	62.1	25.7	3.7	64.8	28.7	4.2
Abnormal crying[h]	33.3	8.3	2.0	40.0	11.5	2.4	39.4	10.1	0.7
Drowsiness[i]	30.2	3.5	0.7	39.8	5.3	1.1	39.1	5.2	0.7
Appetite loss[j]	30.2	7.1	1.2	35.7	7.6	2.6	31.9	6.5	0.7
Vomiting[k]	14.1	4.6	0.3	11.0	4.4	0.2	9.8	2.0	0.0
Fever[l]	12.2	4.5	1.1	24.5	11.9	2.2	21.8	7.3	2.6

[a] PCV7 (Prevnar®) = Pneumococcal 7-valent Conjugate Vaccine

[b] MMRV (ProQuad®) = Measles, Mumps, Rubella and Varicella Virus Vaccine Live

[c] HepA (VAQTA®) = Hepatitis A Vaccine, Inactivated

[d] N = The number of participants with available data.

[e] Grade 2: cries and protests when injection site is touched, Grade 3: cries when injected limb is moved, or the movement of the injected limb is reduced.

[f] Grade 2: ≥1.0 inches to <2.0 inches, Grade 3: ≥2.0 inches.

[g] Grade 2: requires increased attention, Grade 3: inconsolable.

[h] Grade 2: 1 to 3 hours, Grade 3: >3 hours.

[i] Grade 2: not interested in surroundings or did not wake up for a feed/meal, Grade 3: sleeping most of the time or difficult to wake up.

[j] Grade 2: missed 1 or 2 feeds/meals completely, Grade 3: refuses ≥3 feeds/meals or refuses most feeds/meals.

[k] Grade 2: 2 to 5 episodes per 24 hours, Grade 3: ≥6 episodes per 24 hours or requiring parenteral hydration.

[l] Grade 2: >38.5°C to ≤39.5°C, Grade 3: >39.5°C.

Table 2: Percentage of US Participants 2 Years Through 10 Years of Age Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration

	Menactra N[a]=1156 - 1157			Menomune – A/C/Y/W-135 N[a]=1027		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site						
Pain[b]	45.0	4.9	0.3	26.1	2.5	0.0
Redness[c]	21.8	4.6	3.9	7.9	0.5	0.0
Induration[c]	18.9	3.4	1.4	4.2	0.6	0.0
Swelling[c]	17.4	3.9	1.9	2.8	0.3	0.0
Systemic						
Irritability[d]	12.4	3.0	0.3	12.2	2.6	0.6
Diarrhea[e]	11.1	2.1	0.2	11.8	2.5	0.3
Drowsiness[f]	10.8	2.7	0.3	11.2	2.5	0.5
Anorexia[g]	8.2	1.7	0.4	8.7	1.3	0.8
Arthralgia[h]	6.8	0.5	0.2	5.3	0.7	0.0
Fever[i]	5.2	1.7	0.3	5.2	1.7	0.2
Rash[j]	3.4	-	-	3.0	-	-
Vomiting[k]	3.0	0.7	0.3	2.7	0.7	0.6
Seizure[j]	0.0	-	-	0.0	-	-

[a] N = The total number of participants reporting at least one solicited reaction. The median age of participants was 6 years in both vaccine groups.

[b] Grade 2: interferes with normal activities, Grade 3: disabling, unwilling to move arm.

[c] Grade 2: 1.0-2.0 inches, Grade 3: >2.0 inches.

[d] Grade 2: 1-3 hours duration, Grade 3: >3 hours duration.

[e] Grade 2: 3-4 episodes, Grade 3: ≥5 episodes.

[f] Grade 2: interferes with normal activities, Grade 3: disabling, unwilling to engage in play or interact with others.

[g] Grade 2: skipped 2 meals, Grade 3: skipped ≥3 meals.

[h] Grade 2: decreased range of motion due to pain or discomfort, Grade 3: unable to move major joints due to pain.

[i] Oral equivalent temperature; Grade 2: 38.4°C to 39.4ºC, Grade 3: ≥39.5ºC.

[j] These solicited adverse events were reported as present or absent only.

[k] Grade 2: 2 episodes, Grade 3: ≥3 episodes.

Note: During the study Grade 1, Grade 2, and Grade 3 were collected as Mild, Moderate, and Severe respectively.

Table 3: Percentage of Participants 11 Years Through 18 Years of Age Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration With a Single Dose

	Menactra Na=2264 - 2265			Menomune – A/C/Y/W-135 Na=970		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site						
Pain[b]	59.2[c]	12.8[c]	0.3	28.7	2.6	0.0
Induration[d]	15.7[c]	2.5[c]	0.3	5.2	0.5	0.0
Redness[d]	10.9[c]	1.6[c]	0.6[c]	5.7	0.4	0.0
Swelling[d]	10.8[c]	1.9[c]	0.5[c]	3.6	0.3	0.0
Systemic						
Headache[e]	35.6[c]	9.6[c]	1.1	29.3	6.5	0.4
Fatigue[e]	30.0[c]	7.5	1.1[c]	25.1	6.2	0.2
Malaise[e]	21.9[c]	5.8[c]	1.1	16.8	3.4	0.4
Arthralgia[e]	17.4[c]	3.6[c]	0.4	10.2	2.1	0.1
Diarrhea[f]	12.0	1.6	0.3	10.2	1.3	0.0
Anorexia[g]	10.7[c]	2.0	0.3	7.7	1.1	0.2
Chills[e]	7.0[c]	1.7[c]	0.2	3.5	0.4	0.1
Fever[h]	5.1[c]	0.6	0.0	3.0	0.3	0.1
Vomiting[i]	1.9	0.4	0.3	1.4	0.5	0.3
Rash[j]	1.6	-	-	1.4	-	-
Seizure[j]	0.0	-	-	0.0	-	-

[a] N = The number of participants with available data.

[b] Grade 2: interferes with or limits usual arm movement, Grade 3: disabling, unable to move arm.

[c] Denotes $p < 0.05$ level of significance. The *p*-values were calculated for each category and severity using Chi Square test.

[d] Grade 2: 1.0-2.0 inches, Grade 3: >2.0 inches.

[e] Grade 2: interferes with normal activities, Grade 3: requiring bed rest.

[f] Grade 2: 3-4 episodes, Grade 3: ≥5 episodes.

[g] Grade 2: skipped 2 meals, Grade 3: skipped ≥3 meals.

[h] Oral equivalent temperature; Grade 2: 38.5°C to 39.4ºC, Grade 3: ≥39.5ºC.

[i] Grade 2: 2 episodes, Grade 3: ≥3 episodes.

[j] These solicited adverse events were reported as present or absent only.

Note: During the study Grade 1, Grade 2, and Grade 3 were collected as Mild, Moderate, and Severe respectively.

Table 4: Percentage of Participants 18 Years Through 55 Years of Age Reporting Solicited Adverse Reactions Within 7 Days Following Vaccine Administration With a Single Dose

	Menactra Na=1371			Menomune – A/C/Y/W-135 Na=1159		
Reaction	**Any**	**Grade 2**	**Grade 3**	**Any**	**Grade 2**	**Grade 3**
Local/Injection Site						
Pain[b]	53.9[c]	11.3[c]	0.2	48.1	3.3	0.1
Induration[d]	17.1[c]	3.4[c]	0.7[c]	11.0	1.0	0.0
Redness[d]	14.4	2.9	1.1[c]	16.0	1.9	0.1
Swelling[d]	12.6[c]	2.3[c]	0.9[c]	7.6	0.7	0.0
Systemic						
Headache[e]	41.4	10.1	1.2	41.8	8.9	0.9
Fatigue[e]	34.7	8.3	0.9	32.3	6.6	0.4
Malaise[e]	23.6	6.6[c]	1.1	22.3	4.7	0.9
Arthralgia[e]	19.8[c]	4.7[c]	0.3	16.0	2.6	0.1
Diarrhea[f]	16.0	2.6	0.4	14.0	2.9	0.3
Anorexia[g]	11.8	2.3	0.4	9.9	1.6	0.4
Chills[e]	9.7[c]	2.1[c]	0.6[c]	5.6	1.0	0.0
Vomiting[h]	2.3	0.4	0.2	1.5	0.2	0.4
Fever[i]	1.5[c]	0.3	0.0	0.5	0.1	0.0
Rash[j]	1.4	-	-	0.8	-	-
Seizure[j]	0.0	-	-	0.0	-	-

[a] N = The number of participants with available data.

[b] Grade 2: interferes with or limits usual arm movement, Grade 3: disabling, unable to move arm.

[c] Denotes $p < 0.05$ level of significance. The *p*-values were calculated for each category and severity using Chi Square test.

[d] Grade 2: 1.0-2.0 inches, Grade 3: >2.0 inches.

[e] Grade 2: interferes with normal activities, Grade 3: requiring bed rest.

[f] Grade 2: 3-4 episodes, Grade 3: ≥5 episodes.

[g] Grade 2: skipped 2 meals, Grade 3: skipped ≥3 meals.

[h] Grade 2: 2 episodes, Grade 3: ≥3 episodes.

[i] Oral equivalent temperature; Grade 2: 39.0°C to 39.9ºC, Grade 3: ≥40.0ºC.

[j] These solicited adverse events were reported as present or absent only.

Note: During the study Grade 1, Grade 2, and Grade 3 were collected as Mild, Moderate, and Severe respectively.

Solicited Adverse Events in a Booster Vaccination Study

For a description of the study design and number of participants, [see *Clinical Trials Experience, Booster Vaccination Study (6.1)*]. The most common solicited injection site and systemic reactions within 7 days of vaccination were pain (60.2%) and myalgia (42.8%), respectively. Overall rates of solicited injection site reactions and solicited systemic reactions were similar to those observed in adolescents and adults after a single Menactra dose. The majority of solicited reactions were Grade 1 or 2 and resolved within 3 days.

Adverse Events in Concomitant Vaccine Studies

Solicited Injection Site and Systemic Reactions when Given with Routine Pediatric Vaccines

For a description of the study design and number of participants, [see *Clinical Trials Experience (6.1), Concomitant Vaccine Administration (14.3)*]. In the primary safety study, 1378 US children were enrolled to receive Menactra alone at 9 months of age and Menactra plus one or more other routinely administered vaccines (MMRV, PCV7 and HepA) at 12 months of age (N=961). Another group of children received two or more routinely administered vaccines (MMRV, PCV7 and HepA) (control group, n=321) at 12 months of age. The frequency of occurrence of solicited adverse events is presented in Table 1. Participants who received Menactra and the concomitant

vaccines at 12 months of age described above reported similar frequencies of tenderness, redness and swelling at the Menactra injection site and at the concomitant vaccine injection sites. Tenderness was the most frequent injection site reaction (48%, 39%, 46% and 43% at the Menactra, MMRV, PCV7 and HepA sites, respectively). Irritability was the most frequent systemic reaction, reported in 62% of recipients of Menactra plus concomitant vaccines, and 65% of the control group. [See *Concomitant Vaccine Administration (14.3).*]

In a randomized, parallel group, US multi-center clinical trial conducted in children 4 through 6 years of age, Menactra was administered as follows: 30 days after concomitant DAPTACEL®, Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed, (DTaP), manufactured by Sanofi Pasteur Limited + IPOL®, Poliovirus Vaccine Inactivated, (IPV), manufactured by Sanofi Pasteur SA [Group A]; concomitantly with DAPTACEL followed 30 days later by IPV [Group B]; concomitantly with IPV followed 30 days later by DAPTACEL [Group C]. Solicited injection site and systemic reactions were recorded in a diary card for 7 consecutive days after each vaccination. For all study groups, the most frequently reported solicited local reaction at the Menactra site was pain: 52.2%, 60.9% and 56.0% of participants in Groups A, B and C, respectively. For all study groups, the most frequently reported systemic reaction following the administration of Menactra alone or with the respective concomitant vaccines was myalgia: 24.2%, 37.3% and 26.7% of participants in Groups A, B and C, respectively. Fever >39.5ºC occurred at <1.0% in all groups. [See *Concomitant Vaccine Administration (14.3).*]

Solicited Injection Site and Systemic Reactions when Given with Tetanus and Diphtheria Toxoid Adsorbed Vaccine

In a clinical study, rates of local and systemic reactions after Menactra and Tetanus and Diphtheria Toxoid Adsorbed (Td) vaccine manufactured by Sanofi Pasteur Inc. were compared [see *Drug Interactions (7)*, and *Concomitant Vaccine Administration (14.3)* for study description]. Injection site pain was reported more frequently after Td vaccination than after Menactra vaccination (71% versus 53%). The overall rate of systemic adverse events was higher when Menactra and Td vaccines were given concomitantly than when Menactra was administered 28 days after Td vaccine (59% versus 36%). In both groups, the most common reactions were headache (Menactra + Td vaccine, 36%; Td vaccine + Placebo, 34%; Menactra alone, 22%) and fatigue (Menactra + Td vaccine, 32%; Td vaccine + Placebo, 29%; Menactra alone, 17%). Fever ≥40.0ºC occurred at ≤0.5% in all groups.

Solicited Injection Site and Systemic Reactions when Given with Typhoid Vi Polysaccharide Vaccine

In a clinical study, rates of local and systemic reactions after Menactra and Typhim Vi® [Typhoid Vi Polysaccharide Vaccine] (Typhoid), produced by Sanofi Pasteur SA were compared [see *Drug Interactions (7)* and *Concomitant Vaccine Administration (14.3)*] for a description of the concomitantly administered vaccine, study design and number of participants. More participants experienced pain after Typhoid vaccination than after Menactra vaccination (Typhoid + Placebo, 76% versus Menactra + Typhoid, 47%). The majority (70%-77%) of injection site solicited reactions for both groups at either injection site were reported as Grade 1 and resolved within 3 days post-vaccination. In both groups, the most common systemic reaction was headache (Menactra +

Typhoid, 41%; Typhoid + Placebo, 42%; Menactra alone, 33%) and fatigue (Menactra + Typhoid, 38%; Typhoid + Placebo, 35%; Menactra alone, 27%). Fever ≥40.0ºC and seizures were not reported in either group.

6.2 Post-Marketing Experience

In addition to reports in clinical trials, worldwide voluntary adverse events reports received since market introduction of Menactra are listed below. This list includes serious events and/or events which were included based on severity, frequency of reporting or a plausible causal connection to Menactra. Because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to vaccination.

- *Blood and Lymphatic System Disorders*

  Lymphadenopathy

- *Immune System Disorders*

  Hypersensitivity reactions such as anaphylaxis/anaphylactic reaction, wheezing, difficulty breathing, upper airway swelling, urticaria, erythema, pruritus, hypotension

- *Nervous System Disorders*

  Guillain-Barré syndrome, paraesthesia, vasovagal syncope, dizziness, convulsion, facial palsy, acute disseminated encephalomyelitis, transverse myelitis

- *Musculoskeletal and Connective Tissue Disorders*

Myalgia

- *General Disorders and Administrative Site Conditions*

  Large injection site reactions, extensive swelling of the injected limb (may be associated with erythema, warmth, tenderness or pain at the injection site).

Post-marketing Safety Study

The risk of GBS following receipt of Menactra was evaluated in a US retrospective cohort study using healthcare claims data from 9,578,688 individuals 11 through 18 years of age, of whom 1,431,906 (15%) received Menactra. Of 72 medical chart-confirmed GBS cases, none had received Menactra within 42 days prior to symptom onset. An additional 129 potential cases of GBS could not be confirmed or excluded due to absent or insufficient medical chart information. In an analysis that took into account the missing data, estimates of the attributable risk of GBS ranged from 0 to 5 additional cases of GBS per 1,000,000 vaccinees within the 6-week period following vaccination.

7 DRUG INTERACTIONS

7.1 Concomitant Administration with Other Vaccines

Menactra vaccine was concomitantly administered with Typhim Vi® [Typhoid Vi Polysaccharide Vaccine] (Typhoid) and Tetanus and Diphtheria Toxoids Adsorbed, For Adult Use (Td) vaccine, in individuals 18 through 55 and 11 through 17 years of age, respectively. In children 4 through 6 years of age, Menactra was co-administered with DAPTACEL, and in children younger than 2

years of age, Menactra was co-administered with one or more of the following vaccines: PCV7, MMR, V, MMRV, or HepA [see *Clinical Studies (14)* and *Adverse Reactions (6)*].

When Menactra and DAPTACEL are to be administered to children 4 through 6 years of age, preference should be given to simultaneous administration of the 2 vaccines or administration of Menactra prior to DAPTACEL. Administration of Menactra one month after DAPTACEL has been shown to reduce meningococcal antibody responses to Menactra. Data are not available to evaluate the immune response to Menactra administered to younger children following DAPTACEL or to Menactra administered to persons <11 years of age following other diphtheria toxoid-containing vaccines [see *Clinical Studies (14.3)*].

Pneumococcal antibody responses to some serotypes in PCV7 were decreased following co-administration of Menactra and PCV7 [see *Concomitant Vaccine Administration (14.3)*].

Do not mix Menactra with other vaccines in the same syringe. When Menactra is administered concomitantly with other injectable vaccines, the vaccines should be administered with different syringes and given at separate injection sites.

7.2 Immunosuppressive Therapies

Immunosuppressive therapies, including irradiation, antimetabolites, alkylating agents, cytotoxic drugs, and corticosteroids (used in greater than physiologic doses) may reduce the immune response to vaccines.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Menactra during pregnancy. To enroll in or obtain information about the registry, call Sanofi Pasteur at 1-800-822-2463.

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. There are no adequate and well-controlled studies of Menactra administration in pregnant women in the US. Available data suggest that rates of major birth defects and miscarriage in women who received Menactra 30 days prior to pregnancy or during pregnancy are consistent with estimated background rates.

A developmental toxicity study was performed in female mice given 0.1 mL (in divided doses) of Menactra prior to mating and during gestation (a single human dose is 0.5 mL). The study revealed no evidence of harm to the fetus due to Menactra [see *Animal Data (8.1)*].

Data

Human Data

A pregnancy registry spanning 11 years (2005-2016) included 222 reports of exposure to Menactra from 30 days before or at any time during pregnancy. Of these reports, 87 had known

pregnancy outcomes available and were enrolled in the pregnancy registry prior to the outcomes being known. Outcomes among these prospectively followed pregnancies included 2 major birth defects and 6 miscarriages.

Animal Data

A developmental toxicity study was performed in female mice. The animals were administered 0.1 mL of Menactra (in divided doses) at each of the following time points: 14 days prior to mating, and on Days 6 and 18 of gestation (a single human dose is 0.5 mL). There were no vaccine-related fetal malformations or variations, and no adverse effects on pre-weaning development observed in the study.

8.2 Lactation

Risk Summary

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Menactra and any potential adverse effects on the breastfed child from Menactra. Data are not available to assess the effects of Menactra on the breastfed infant or on milk production/excretion.

8.4 Pediatric Use

Menactra is not approved for use in infants under 9 months of age. Available data show that infants administered three doses of Menactra (at 2, 4, and 6 months of age) had diminished responses to each meningococcal vaccine serogroup compared to older children given two doses at 9 and 12 months of age.

8.5 Geriatric Use

Safety and effectiveness of Menactra in adults older than 55 years of age have not been established.

11 DESCRIPTION

Menactra is a sterile, intramuscularly administered vaccine that contains *N meningitidis* serogroup A, C, Y and W-135 capsular polysaccharide antigens individually conjugated to diphtheria toxoid protein. *N meningitidis* A, C, Y and W-135 strains are cultured on Mueller Hinton agar (3) and grown in Watson Scherp (4) media containing casamino acid. The polysaccharides are extracted from the *N meningitidis* cells and purified by centrifugation, detergent precipitation, alcohol precipitation, solvent extraction and diafiltration. To prepare the polysaccharides for conjugation, they are depolymerized, derivatized, and purified by diafiltration. Diphtheria toxin is derived from *Corynebacterium diphtheriae* grown in modified culture medium containing hydrolyzed casein (5) and is detoxified using formaldehyde. The diphtheria toxoid protein is purified by ammonium sulfate fractionation and diafiltration. The derivatized polysaccharides are covalently linked to diphtheria toxoid and purified by serial diafiltration. The four meningococcal components, present as individual serogroup-specific glycoconjugates, compose the final formulated vaccine. No preservative or adjuvant is added during manufacture. Each 0.5 mL dose may contain residual amounts of formaldehyde of less than 2.66 mcg (0.000532%), by calculation. Potency of Menactra is determined by quantifying the amount of each polysaccharide antigen that is conjugated to diphtheria toxoid protein and the amount of unconjugated polysaccharide present.

Menactra is manufactured as a sterile, clear to slightly turbid liquid. Each 0.5 mL dose of vaccine is formulated in sodium phosphate buffered isotonic sodium chloride solution to contain 4 mcg each of meningococcal A, C, Y and W-135 polysaccharides conjugated to approximately 48 mcg of diphtheria toxoid protein carrier.

The vial stopper is not made with natural rubber latex.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The presence of bactericidal anti-capsular meningococcal antibodies has been associated with protection from invasive meningococcal disease (6) (7). Menactra induces the production of bactericidal antibodies specific to the capsular polysaccharides of serogroups A, C, Y and W-135.

13 NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Menactra has not been evaluated for carcinogenic or mutagenic potential, or for impairment of male fertility. A developmental animal toxicity study showed that Menactra had no effects on female fertility in mice [see *Pregnancy* (*8.1*)].

14 CLINICAL STUDIES

14.1 Efficacy

The serum bactericidal assay (SBA) used to test sera contained an exogenous complement source that was either human (SBA-H) or baby rabbit (SBA-BR). (8)

The response to vaccination following two doses of vaccine administered to children 9 and 12 months of age and following one dose of vaccine administered to children 2 through 10 years of age was evaluated by the proportion of participants having an SBA-H antibody titer of 1:8 or greater, for each serogroup. In individuals 11 through 55 years of age, the response to vaccination with a single dose of vaccine was evaluated by the proportion of participants with a 4-fold or greater increase in bactericidal antibody to each serogroup as measured by SBA-BR. For individuals 2 through 55 years of age, vaccine efficacy after a single dose was inferred from the demonstration of immunologic equivalence to a US-licensed meningococcal polysaccharide vaccine, Menomune – A/C/Y/W-135 vaccine as assessed by SBA.

14.2 Immunogenicity

Children 9 through 12 Months of Age

In a randomized, US, multi-center trial, children received Menactra at 9 months and 12 months of age. The first Menactra dose was administered alone, followed by a second Menactra dose given alone (N=404), or with MMRV (N=302), or with PCV7 (N=422). For all participants, sera were obtained approximately 30 days after last vaccination. There were no substantive differences in demographic characteristics between the vaccine groups. The median age range for administration of the first dose of Menactra was 278-279 days of age.

Table 5: Bactericidal Antibody Responses[a] 30 Days Following a Second Dose of Menactra Administered Alone or Concomitantly Administered with MMRV or PCV7 at 12 Months of Age

		Vaccinations administered at 12 months of age following a dose of Menactra at 9 months of age					
		Menactra		Menactra + MMRV		Menactra + PCV7	
		(N=272-277)[b]		(N=177-180)[b]		(N=264-267)[b]	
Serogroup			(95% CI)[c]		(95% CI)[c]		(95% CI)[c]
A	% ≥1:8[d]	95.6	(92.4; 97.7)	92.7	(87.8; 96.0)	90.5	(86.3; 93.8)
	GMT	54.9	(46.8; 64.5)	52.0	(41.8; 64.7)	41.0	(34.6; 48.5)
C	% ≥1:8[d]	100.0	(98.7; 100.0)	98.9	(96.0; 99.9)	97.8	(95.2; 99.2)
	GMT	141.8	(123.5; 162.9)	161.9	(136.3; 192.3)	109.5	(94.1; 127.5)
Y	%≥1:8[d]	96.4	(93.4; 98.2)	96.6	(92.8; 98.8)	95.1	(91.8; 97.4)
	GMT	52.4	(45.4; 60.6)	60.2	(50.4; 71.7)	39.9	(34.4; 46.2)
W-135	%≥1:8[d]	86.4	(81.8; 90.3)	88.2	(82.5; 92.5)	81.2	(76.0; 85.7)
	GMT	24.3	(20.8; 28.3)	27.9	(22.7; 34.3)	17.9	(15.2; 21.0)

[a] Serum bactericidal assay with an exogenous human complement (SBA-H) source.

[b] N=Number of participants with at least one valid serology result from a blood sample obtained between Days 30 to 44 post vaccination.

[c] 95% CIs for the proportions are calculated based on the Clopper-Pearson Exact method and normal approximation for that of the GMTs.

[d] The proportion of participants achieving an SBA-H titer of at least 1:8 thirty days after the second dose of Menactra.

Administration of Menactra to children at 12 months and 15 months of age was evaluated in a US study. Prior to the first dose, 33.3% [n=16/48] of participants had an SBA-H titer ≥1:8 to Serogroup A, and 0-2% [n=0-1 of 50-51] to Serogroups C, Y and W-135. After the second dose, percentages of participants with an SBA-H titer ≥1:8 were: 85.2%, Serogroup A [n=46/54]; 100.0%, Serogroup C [n=54/54]; 96.3%, Serogroup Y [n=52/54]; 96.2%, Serogroup W-135 [n=50/52].

Individuals 2 through 55 Years of Age

Immunogenicity was evaluated in three comparative, randomized, US, multi-center, active controlled clinical trials that enrolled children (2 through 10 years of age), adolescents (11 through 18 years of age), and adults (18 through 55 years of age). Participants received a single dose of Menactra (N=2526) or Menomune – A/C/Y/W-135 (N=2317). For all age groups studied, sera were obtained before and approximately 28 days after vaccination. [Blinding procedures for safety assessments are described in *Adverse Reactions (6)*.]

In each of the trials, there were no substantive differences in demographic characteristics between the vaccine groups, between immunogenicity subsets or the overall study population. In the study of children 2 through 10 years of age, the median age of participants was 3 years; 95% completed the study. In the adolescent trial, the median age for both groups was 14 years; 99% completed the study. In the adult trial, the median age for both groups was 24 years; 94% completed the study.

Immunogenicity in Children 2 through 10 Years of Age

Of 1408 enrolled children 2 through 10 years of age, immune responses evaluated in a subset of Menactra participants (2 through 3 years of age, n=52; 4-10 years of age, n=84) and Menomune – A/C/Y/W-135 participants (2 through 3 years of age, n=53; 4-10 years of age, n=84) were comparable for all four serogroups (Table 6).

Table 6: Comparison of Bactericidal Antibody Responses[a] to Menactra and Menomune – A/C/Y/W-135 28 Days after Vaccination for a Subset of Participants 2 through 3 Years of Age and 4 through 10 Years of Age

		Ages 2 through 3 Years				Ages 4 through 10 Years			
		Menactra		Menomune – A/C/Y/W-135		Menactra		Menomune – A/C/Y/W-135	
		N[b]=48-52		N[b]=50-53		N[b]=84		N[b]=84	
Serogroup			(95% CI)[c]		(95% CI)[c]		(95% CI)[c]		(95% CI)[c]
A	% ≥1:8[d]	73	(59,84)	64	(50,77)	81	(71,89)	55	(44,66)
	GMT	10	(8,13)	10	(7,12)	19	(14,26)	7	(6,9)
C	% ≥1:8[d]	63	(48,76)	38	(25,53)	79	(68,87)	48	(37,59)
	GMT	27	(14,52)	11	(5,21)	28	(19,41)	12	(7,18)
Y	% ≥1:8[d]	88	(75,95)	73	(59,84)	99	(94,100)	92	(84,97)
	GMT	51	(31,84)	18	(11,27)	99	(75,132)	46	(33,66)
W-135	% ≥1:8[d]	63	(47,76)	33	(20,47)	85	(75,92)	79	(68,87)
	GMT	15	(9,25)	5	(3,6)	24	(18,33)	20	(14,27)

[a] Serum bactericidal assay with an exogenous human complement (SBA-H) source.

[b] N=Number of subset participants with at least one valid serology result at Day 0 and Day 28.

[c] The 95% CI for the Geometric Mean Titer (GMT) was calculated based on an approximation to the normal distribution.

[d] The proportion of participants achieving an SBA-H titer of at least 1:8 was assessed using a 10% non-inferiority margin and a one-sided Type 1 error rate of 0.025.

In the subset of participants 2 through 3 years of age with undetectable pre-vaccination titers (ie, SBA-H titers <1:4 at Day 0), seroconversion rates (defined as the proportions of participants with

SBA-H titers ≥1:8 by Day 28) were similar between the Menactra and Menomune – A/C/Y/W-135 recipients. Menactra participants achieved seroconversion rates of: 57%, Serogroup A (n=12/21); 62%, Serogroup C (n=29/47); 84%, Serogroup Y (n=26/31); 53%, Serogroup W-135 (n=20/38). The seroconversion rates for Menomune – A/C/Y/W-135 recipients were: 55%, Serogroup A (n=16/29); 30%, Serogroup C (n=13/43); 57%, Serogroup Y (n=17/30); 26%, Serogroup W-135 (n=11/43).

In the subset of participants 4 through 10 years of age with undetectable pre-vaccination titers (ie, SBA-H titers <1:4 at Day 0), seroconversion rates (defined as the proportions of participants with SBA-H titers ≥1:8 by Day 28) were similar between the Menactra and Menomune – A/C/Y/W-135 recipients. Menactra participants achieved seroconversion rates of: 69%, Serogroup A (n=11/16); 81%, Serogroup C (n=50/62); 98%, Serogroup Y (n=45/46); 69%, Serogroup W-135 (n=27/39). The seroconversion rates for Menomune – A/C/Y/W-135 recipients were: 48%, Serogroup A (n=10/21); 38%, Serogroup C (n=19/50); 84%, Serogroup Y (n=38/45); 68%, Serogroup W-135 (n=26/38).

Immunogenicity in Adolescents 11 through 18 Years of Age

Results from the comparative clinical trial conducted in 881 adolescents aged 11 through 18 years showed that the immune responses to Menactra and Menomune – A/C/Y/W-135 were similar for all four serogroups (Table 7).

In participants with undetectable pre-vaccination titers (ie, SBA-BR titers <1:8 at Day 0), seroconversion rates (defined as the proportions of participants achieving a ≥4-fold rise in SBA-

BR titers by Day 28) were similar between the Menactra and Menomune – A/C/Y/W-135 recipients. Menactra participants achieved seroconversion rates of: 100%, Serogroup A (n=81/81); 99%, Serogroup C (n=153/155); 98%, Serogroup Y (n=60/61); 98%, Serogroup W-135 (n=161/164). The seroconversion rates for Menomune – A/C/Y/W-135 recipients were: 100%, Serogroup A (n=93/93); 99%, Serogroup C (n=151/152); 100%, Serogroup Y (n=47/47); 99%, Serogroup W-135 (n=138/139).

Immunogenicity in Adults 18 through 55 Years of Age

Results from the comparative clinical trial conducted in 2554 adults aged 18 through 55 years showed that the immune responses to Menactra and Menomune – A/C/Y/W-135 were similar for all four serogroups (Table 7).

Table 7: Comparison of Bactericidal Antibody Responses[a] to Menactra and Menomune – A/C/Y/W-135 28 Days after Vaccination for Participants 11 through 18 Years of Age and 18 through 55 Years of Age

		Ages 11 through 18 Years				Ages 18 through 55 Years			
		Menactra		Menomune – A/C/Y/W-135		Menactra		Menomune – A/C/Y/W-135	
		N[b]=423		N[b]=423		N[b]=1280		N[b]=1098	
Serogroup			(95% CI)[c]		(95% CI)[c]		(95% CI)[c]		(95% CI)[c]
A	% ≥4-fold rise[d]	92.7	(89.8, 95.0)	92.4	(89.5, 94.8)	80.5	(78.2, 82.6)	84.6	(82.3, 86.7)
	GMT	5483	(4920, 6111)	3246	(2910, 3620)	3897	(3647, 4164)	4114	(3832, 4417)
C	% ≥4-fold rise[d]	91.7	(88.7, 94.2)	88.7	(85.2, 91.5)	88.5	(86.6, 90.2)	89.7	(87.8, 91.4)
	GMT	1924	(1662, 2228)	1639	(1406, 1911)	3231	(2955, 3533)	3469	(3148, 3823)
Y	% ≥4-fold rise[d]	81.8	(77.8, 85.4)	80.1	(76.0, 83.8)	73.5	(71.0, 75.9)	79.4	(76.9, 81.8)
	GMT	1322	(1162, 1505)	1228	(1088, 1386)	1750	(1597, 1918)	2449	(2237, 2680)
W-135	% ≥4-fold rise[d]	96.7	(94.5, 98.2)	95.3	(92.8, 97.1)	89.4	(87.6, 91.0)	94.4	(92.8, 95.6)
	GMT	1407	(1232, 1607)	1545	(1384, 1725)	1271	(1172, 1378)	1871	(1723, 2032)

[a] Serum bactericidal assay with baby rabbit complement (SBA-BR).

[b] N=Number of subset participants with at least one valid serology result at Day 0 and Day 28.

[c] The 95% CI for the Geometric Mean Titer (GMT) was calculated based on an approximation to the normal distribution.

[d] Menactra was non-inferior to Menomune – A/C/Y/W-135. Non-inferiority was assessed by the proportion of participants with a 4-fold or greater rise in SBA-BR titer for *N meningitidis* serogroups A, C, Y and W-135 using a 10% non-inferiority margin and a one-sided Type I error rate of 0.05.

In participants with undetectable pre-vaccination titers (ie, SBA-BR titers <1:8 at Day 0), seroconversion rates (defined as the proportions of participants achieving a ≥4-fold rise in SBA-BR titers by Day 28) were similar between the Menactra and Menomune – A/C/Y/W-135 recipients. Menactra participants achieved seroconversion rates of: 100%, Serogroup A (n=156/156); 99%, Serogroup C (n=343/345); 91%, Serogroup Y (n=253/279); 97%, Serogroup W-135 (n=360/373). The seroconversion rates for Menomune – A/C/Y/W-135 recipients were: 99%, Serogroup A (n=143/144); 98%, Serogroup C (n=297/304); 97%, Serogroup Y (n=221/228); 99%, Serogroup W-135 (n=325/328).

Immunogenicity in Adolescents and Adults Following Booster Vaccination

For a description of the study design and number of participants, [see *Clinical Trials Experience, Booster Vaccination Study* (*6.1*).] Prior to revaccination, the percentage of participants (n=781) with an SBA-H titer ≥1:8 were 64.5%, 44.2%, 38.7%, and 68.5% for Serogroups A, C, Y and W-135, respectively. Among the subset of trial participants (n=112) for whom SBA-H responses at Day 6 were assessed, 86.6%, 91.1%, 94.6%, and 92.0% achieved a ≥4-fold rise in SBA-H titer for Serogroups A, C, Y and W-135, respectively. The proportions of participants (n=781) who achieved a ≥4-fold rise in SBA-H titer by Day 28 were 95.0%, 95.3%, 97.1%, and 96% for Serogroups A, C, Y and W-135, respectively. The proportions of participants who achieved an SBA-H titer ≥1:8 by Day 28 were >99% for each serogroup.

14.3 Concomitant Vaccine Administration

MMRV (or MMR + V) or PCV7

In a US, active-controlled trial, 1179 children received Menactra at 9 months and 12 months of age. At 12 months of age these children received Menactra concomitantly with MMRV (N=616), or MMR + V (N=48), or PCV7 (N=250). Another group of 12-month old children received MMRV + PCV7 (N=485). Sera were obtained approximately 30 days after the last vaccinations. Measles, mumps, rubella and varicella antibody responses among children who received Menactra and MMRV (or MMR and V) were comparable to corresponding antibody responses among children who received MMRV and PCV7.

When Menactra was given concomitantly with PCV7, the non-inferiority criteria for comparisons of pneumococcal IgG GMCs (upper limit of the two-sided 95% CI of the GMC ratio ≤2) were not met for 3 of 7 serotypes (4, 6B, 18C). In a subset of participants with available sera, pneumococcal opsonophagocytic assay GMT data were consistent with IgG GMC data.

Td Vaccine

In a double-blind, randomized, controlled trial, 1021 participants aged 11 through 17 years received Td vaccine and Menactra concomitantly (N=509), or Td vaccine followed one month later by Menactra (N=512). Sera were obtained approximately 28 days after each respective vaccination. The proportions of participants with a 4-fold or greater increase in SBA-BR titer to meningococcal Serogroups C, Y and W-135 were higher when Menactra was given concomitantly with Td vaccine (86%-96%) than when Menactra was given one month following Td vaccine (65%-91%). Anti-tetanus and anti-diphtheria antibody responses were similar in both study groups.

Typhim Vi

In a double-blind, randomized, controlled trial, 945 participants aged 18 through 55 years received Typhim Vi and Menactra concomitantly (N=469), or Typhim Vi followed one month later by Menactra (N=476). Sera were obtained approximately 28 days after each respective vaccination. The antibody responses to Menactra and to Typhim Vi components were similar in both study groups.

DAPTACEL and IPV

In a randomized, parallel group, US multi-center clinical trial conducted in children 4 through 6 years of age, Menactra was administered as follows: 30 days after concomitant DTaP (DAPTACEL®, Sanofi Pasteur Limited) + IPV (IPOL®, Sanofi Pasteur SA) [Group A]; concomitantly with DAPTACEL followed 30 days later by IPV [Group B]; concomitantly with IPV followed 30 days later by DAPTACEL [Group C]. Sera were obtained approximately 30 days after each respective vaccination. [See *Clinical Trials Experience (6.1)*.]

When Menactra was administered 30 days after DAPTACEL (and IPV) [Group A], significantly lower SBA-H GMTs to all 4 meningococcal serogroups were observed compared to Menactra (and IPV) administered 30 days prior to DAPTACEL [Group C]. When Menactra was administered concomitantly with DAPTACEL [Group B], SBA-H GMTs to meningococcal serogroups A, C, and W-135 were non-inferior to those observed after Menactra (and IPV) [Group C]. The non-inferiority criterion was marginally missed for meningococcal serogroup Y. Non-inferiority of SBA-H GMTs following concomitant administration of Menactra and

DAPTACEL compared to those after concomitant Menactra and IPV was concluded if the upper limit of the 2-sided 95% CI of ($GMT_{Group\ C}$ divided by $GMT_{Group\ B}$) computed separately for each of the serogroups was <2.

The respective SBA-H GMTs and proportion (%) of Group A, B, and C study participants achieving an SBA-H titer of ≥1:8 are displayed in Table 8.

Table 8: Bactericidal Antibody Responses[a] 30 Days Following Menactra Administered Alone or Concomitantly with DAPTACEL or IPV

		Vaccines administered at Visit 1 and 30 days later at Visit 2					
	Visit 1 Visit 2	Group A DAPTACEL + IPV Menactra		Group B Menactra + DAPTACEL IPV		Group C Menactra + IPV DAPTACEL	
		(N=250)[b]		(N=238)[b]		(N=121)[b]	
Serogroup			**(95% CI)[c]**		**(95% CI)[c]**		**(95% CI)[c]**
A	% ≥1:8[d]	49.6	(41.0; 58.3)	67.2	(58.4; 75.1)	64.4	(54.4; 73.6)
	GMT	6.7	(5.7; 8.0)	10.8	(8.7; 13.3)	10.4	(8.1; 13.3)
C	% ≥1:8[d]	20.3	(13.9; 28.0)	50.4	(41.5; 59.2)	50.5	(40.5; 60.5)
	GMT	3.3	(2.7; 3.9)	8.1	(6.3; 10.5)	7.8	(5.8; 10.7)
Y	%≥1:8[d]	44.2	(35.8; 52.9)	80.2	(72.3; 86.6)	88.5	(80.7; 93.9)
	GMT	6.5	(5.1; 8.2)	18.1	(14.2; 22.9)	26.2	(20.0; 34.4)
W-135	%≥1:8[d]	55.1	(46.4; 63.5)	87.8	(80.9; 92.9)	82.7	(74.0; 89.4)
	GMT	8.4	(6.7; 10.6)	22.8	(18.5; 28.1)	21.7	(16.6; 28.4)

[a] Serum bactericidal assay with an exogenous human complement (SBA-H) source.

[b] N=Total number of the subjects in the study population per group.

[c] 95% CIs for the proportions are calculated based on the Clopper-Pearson Exact method and normal approximation for that of the GMTs.

[d] The proportion of participants achieving an SBA-H titer of at least 1:8, 30 days after Menactra.

When Menactra was administered concomitantly with DAPTACEL, antibody responses to three of the pertussis antigens (pertussis toxin, filamentous hemagglutinin, and pertactin) (GMCs), tetanus toxin (% participants with antibody concentrations ≥1.0 IU/mL), and diphtheria toxin (% participants with antibody concentrations ≥1.0 IU/mL) were non-inferior to those observed after DAPTACEL and IPV. The pertussis anti-fimbriae GMCs were marginally lower when Menactra and DAPTACEL were administered concomitantly.

15 REFERENCES

1 CDC. Guillain-Barré syndrome among recipients of Menactra® meningococcal conjugate vaccine-United States, June 2005-September 2006. MMWR Morb Mortal Wkly Rep 2006;55:1120-1124. Erratum in: MMWR Morb Mortal Wkly Rep 2006;55(43):1177.

2 Harvard Medical School/Harvard Pilgrim Health Care Institute. Risk of Guillain-Barré Syndrome Following Meningococcal Conjugate (MCV4) Vaccination. Final Study Report, Revised March 11, 2010.

3 Mueller JH, et al. A protein-free medium for primary isolation of the gonococcus and meningococcus. Proc Soc Exp Biol Med 1941;48:330-333.

4 Watson RG, et al. The specific hapten of group C (group IIa) meningococcus. I. Preparation and immunological behavior. J Immunol 1958;81:331-336.

5 Mueller JH, et al. Production of diphtheria toxin of high potency (100 Lf) on a reproducible medium. J Immunol 1941;40:21-32.

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7 Goldschneider I, et al. Human immunity to the meningococcus. I. The role of humoral antibodies. J Exp Med 1969;129:1307-1326.

8 Maslanka SE, et al. Standardization and a multilaboratory comparison of Neisseria meningitidis serogroup A and C serum bactericidal assays. Clin and Diag Lab Immunol 1997;4:156-167.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

- Single-dose vial, 0.5 mL (NDC 49281-589-58). Supplied as a package of 5 vials (NDC 49281-589-05).

16.2 Storage and Handling

Store at 2° to 8°C (35° to 46°F). DO NOT FREEZE. Frozen/previously frozen product should not be used. Do not use after the expiration date.

17 PATIENT COUNSELING INFORMATION

Vaccine Information Statements are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization to the patient, parent, or guardian. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines).

Inform the patients, parents or guardians about:

- Potential benefits and risks of immunization with Menactra.
- Potential for adverse reactions that have been temporally associated with administration of Menactra or other vaccines containing similar components.
- Reporting any adverse reactions to their healthcare provider.
- The Sanofi Pasteur Inc. Pregnancy Registry, as appropriate [see *Pregnancy* (*8.1*)].

Menactra® is a registered trademark of Sanofi, its affiliates and subsidiaries.

Manufactured by:

Sanofi Pasteur Inc.

Swiftwater PA 18370 USA

7186

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HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use MENQUADFI® safely and effectively. See full prescribing information for MENQUADFI.

MenQuadfi, Meningococcal (Groups A, C, Y, W) Conjugate Vaccine

Solution for Intramuscular Injection

Initial U.S. Approval: 2020

----------INDICATIONS AND USAGE----------

MenQuadfi is a vaccine indicated for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. MenQuadfi is approved for use in individuals 2 years of age and older. (1)

MenQuadfi does not prevent *N. meningitidis* serogroup B disease.

----------DOSAGE AND ADMINISTRATION----------

0.5 mL dose for intramuscular injection. (2)

Primary Vaccination

- Individuals 2 years of age and older: a single dose.

Booster Vaccination

- A single dose of MenQuadfi may be administered to individuals 15 years of age and older who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (groups A, C, W, Y) conjugate vaccine.

----------DOSAGE FORMS AND STRENGTHS----------

Solution for injection in 0.5 mL single-dose vial. (3)

----------CONTRAINDICATIONS----------

Severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi or any other tetanus toxoid-containing vaccine. (4)

----------ADVERSE REACTIONS----------

Most commonly reported adverse reactions (≥10%) following a primary dose were as follows:

- Children 2 through 9 years of age, pain (38.6%), erythema (22.6%), and swelling (13.8%) at the injection site; malaise (21.1%), myalgia (20.1%), and headache (12.5%). (6)
- Adolescents aged 10 through 17 years of age, injection site pain (34.8%–45.2%), myalgia (27.4%–35.3%), headache (26.5%–30.2%), and malaise (19.4%–26.0%). (6)
- Adults aged 18 through 55 years, injection site pain (41.9%), myalgia (35.6%), headache (29.0%), and malaise (22.9%). (6)
- Adults 56 years of age and older, pain at the injection site (25.5%), myalgia (21.9%), headache (19.0%), and malaise (14.5%). (6)

In adolescents and adults, rates of solicited adverse reactions following a booster dose were comparable to those observed following primary vaccination. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Sanofi Pasteur Inc., Discovery Drive, Swiftwater, PA 18370 at 1-800-822-2463 (1-800-VACCINE) or VAERS at 1-800-822-7967 or www.vaers.hhs.gov.

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 06/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

MenQuadfi® is a vaccine indicated for active immunization for the prevention of invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, W, and Y. MenQuadfi is indicated for use in individuals 2 years of age and older.

MenQuadfi does not prevent *N. meningitidis* serogroup B disease.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation for Administration

MenQuadfi is a clear, colorless solution.

Parenteral drug products should be inspected visually for particulate matter and/or discoloration prior to administration, whenever solution and container permit. If any of these conditions exist, the vaccine should not be administered. Discard the vial with any unused portion.

2.2 Dose and Schedule

Administer MenQuadfi as a single 0.5 mL injection intramuscularly.

Primary Vaccination

- Individuals 2 years of age and older receive a single dose.

Booster Vaccination

- A single dose of MenQuadfi may be administered to individuals 15 years of age and older who are at continued risk for meningococcal disease if at least 4 years have elapsed since a prior dose of meningococcal (groups A, C, W, Y) conjugate vaccine.

3 DOSAGE FORMS AND STRENGTHS

MenQuadfi is a sterile solution for intramuscular injection supplied in 0.5 mL single-dose vials.

4 CONTRAINDICATIONS

Severe allergic reaction to any component of the vaccine, or after a previous dose of MenQuadfi or any other tetanus toxoid-containing vaccine [*see Description (11)*].

5 WARNINGS AND PRECAUTIONS

5.1 Management of Acute Allergic Reactions

Appropriate observation and medical treatment should always be readily available in case of an anaphylactic event following the administration of the vaccine.

5.2 Altered Immunocompetence

Reduced Immune Response

Some individuals with altered immunocompetence, including some individuals receiving immunosuppressant therapy, may have reduced immune responses to MenQuadfi.

Complement Deficiency

Persons with certain complement deficiencies and persons receiving treatment that inhibits terminal complement activation (for example, eculizumab) are at increased risk for invasive disease caused by *N. meningitidis*, including invasive disease caused by serogroups A, C, W, and Y, even if they develop antibodies following vaccination with MenQuadfi [*see Clinical Pharmacology (12.1)*].

5.3 Syncope

Syncope (fainting) can occur following, or even before, vaccination with MenQuadfi.

Procedures should be in place to prevent falling and injury and to manage syncope.

5.4 Guillain-Barré Syndrome

Guillain-Barré syndrome (GBS) has been reported in temporal relationship following administration of another U.S.-licensed meningococcal quadrivalent polysaccharide conjugate vaccine. The decision by the healthcare professional to administer MenQuadfi to persons with a history of GBS should take into account the expected benefits and potential risks.

5.5 Tetanus Immunization

Immunization with MenQuadfi does not substitute for routine tetanus immunization.

5.6 Limitations of Vaccine Effectiveness

Vaccination with MenQuadfi may not protect all vaccine recipients.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trial(s) of a vaccine cannot be directly compared to rates in the clinical trial(s) of another vaccine and may not reflect the rates observed in practice.

The safety of a single dose of MenQuadfi in individuals 2 years of age and older was evaluated in five randomized, active-controlled, multi-center clinical studies conducted in the US and Puerto Rico. In these studies, a total of 4,919 participants received either a primary dose (N = 4517) or a booster dose (N = 402) of MenQuadfi and were included in the safety analyses.

Safety Monitoring

Participants were monitored for immediate reactions for 30 minutes following vaccination while at the study site. Solicited injection site and systemic reactions were recorded by participants or by parents/guardians in a diary card at home daily for 7 days following vaccination. All unsolicited adverse events that occurred within 30 days following vaccination were recorded by participants or by parents/guardians and collected by the study site at the next visit. Unsolicited adverse events that were medically attended (i.e., visits to an emergency room, or an unexpected visit to a health care provider), and all serious adverse events (SAEs) were collected for at least 6 months after vaccination.

Primary Vaccination Studies

Children 2 through 9 years of age

The safety of MenQuadfi in children 2 years through 9 years of age was evaluated in Study 1 (NCT03077438). The safety analysis set included 498 participants who received MenQuadfi and 494 participants who received Menveo [Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine]. Of the participants 2 through 9 years of age who received MenQuadfi (N = 498), 50.2% were 2 through 5 years of age, 49.8% were 6 through 9 years of age, 49.0% were female, 80.5% were White, 13.3% were Black or African American, 0.4% were Asian, 5.2% were of other racial groups, and 22.9% were of Hispanic or Latino ethnicity. There were no substantive differences in demographic characteristics between the vaccine groups.

The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menveo (Study 1) are presented in Table 1.

SAEs occurred at a rate of 1.4% following MenQuadfi and at a rate of 0.6% following Menveo during the entire study period. Most SAEs occurred more than 30 days following vaccination and were commonly occurring events in the general population in this age group. No SAEs were determined to be vaccine related.

Table 1: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menveo in Children 2 through 9 Years of Age (Study 1)*

	MenQuadfi (N†=484-487) %		Menveo (N†=479-486) %	
Adverse Reactions	Any	Grade 3	Any	Grade 3
Local Reactions				
Injection Site Pain‡	38.6	0.6	42.4	1.0
Injection Site Erythema§	22.6	3.1	31.5	9.9
Injection Site Swelling§	13.8	1.4	21.5	5.6
Systemic Reactions				
Myalgia¶	20.1	0.4	23.0	0.8
Malaise¶	21.1	1.8	20.4	1.0
Headache¶	12.5	0.0	11.5	0.4
Fever#	1.9	0.0	2.7	0.4

* Clinical trial identifier NCT03077438
† N is the number of vaccinated participants with available data for the events listed
‡ Grade 3: Unable to perform usual activities
§ Any: > 0 mm; Grade 3: ≥ 50 mm
¶ Grade 3: Prevents daily activity
# Any: ≥ 100.4°F (38.0°C); Grade 3: ≥ 102.1°F (39.0°C)

Adolescents 10 through 17 years of age

The safety of MenQuadfi in adolescents 10 through 17 years of age was evaluated in two clinical trial studies Study 2 (NCT02199691) and Study 3 (NCT02842853). The safety analysis set in these two studies included 3,196 participants who received MenQuadfi alone (1,684 participants), MenQuadfi concomitantly with Adacel® [Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed] (Tdap) and Gardasil® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] (HPV) (392 participants), the concomitant vaccines without MenQuadfi (296 participants), or a U.S.-licensed comparator meningococcal vaccine (824 participants). The comparator meningococcal vaccine was either Menveo (501 participants) or Menactra® [Meningococcal (Groups A, C, Y, and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine] (323 participants).

Of the participants 10 through 17 years of age who received MenQuadfi (N = 1,684), 49.6% were female. Among those with reported race and ethnicity, 79.3% were White, 14.2% were Black or African American, 1.1% were Asian, 5.4% were of other racial groups, and 21.5% were of Hispanic or Latino ethnicity. Mean age was 11.9 years at time of administration. There were no substantive differences in demographic characteristics between the vaccine groups.

The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menveo and Menactra are presented in Table 2. The most common injection site and systemic reactions occurring after MenQuadfi administration (in Study 2 and Study 3) were injection site pain (45.2% and 34.8%) and myalgia (35.3% and 27.4%), respectively.

In Study 2, SAEs occurred at a rate of 0.8% following MenQuadfi and 0.8% following Menveo. In Study 3, SAEs occurred at a rate of 0.3% following MenQuadfi and 0.9% following Menactra. No SAEs were determined to be vaccine related.

Table 2: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menveo in Individuals 10 through 17 Years of Age Study 2* and MenQuadfi or Menactra in Individuals 10 through 17 Years of Age Study 3†

	Study 2				Study 3			
	MenQuadfi (N‡=494-496) %		Menveo (N‡=488-491) %		MenQuadfi (N‡=1129-1159) %		Menactra (N‡=310-314) %	
Adverse Reactions	Any	Grade 3	Any	Grade 3	Any	Grade 3	Any	Grade 3
Local Reactions								
Injection Site Pain§	45.2	1.4	42.5	1.0	34.8	1.8	41.4	2.2
Injection Site Erythema¶	5.0	0.4	7.5	1.2	4.5	0.3	4.5	0.3
Injection Site Swelling¶	5.4	0.2	6.5	0.4	4.1	<0.1	4.8	0.0
Systemic Reactions								
Myalgia§	35.3	1.6	35.2	1.8	27.4	1.9	31.2	1.9
Headache§	30.2	1.8	30.9	1.8	26.5	2.3	28.0	1.9
Malaise§	26.0	2.2	26.4	2.8	19.4	1.2	23.9	1.3
Fever#	1.4	0.4	1.2	0.6	0.7	0.2	0.6	0.0

* Clinical trial identifier NCT02199691
† Clinical trial identifier NCT02842853
‡ N is the number of vaccinated participants with available data for the events listed
§ Grade 3: Prevents daily activity
¶ Any: > 25 mm; Grade 3: > 100 mm
#Any: ≥ 100.4°F (38.0°C); Grade 3: ≥ 102.1°F (39.0°C)

Among 296 participants who received Tdap and HPV concomitantly (without MenQuadfi) and 392 participants who received MenQuadfi concomitantly with Tdap and HPV, there were no notable differences in the rates of systemic solicited adverse reactions within 7 days following vaccination.

Dizziness within 30 minutes following vaccination was experienced by 1 (0.2%) participant who received MenQuadfi in Study 2 (NCT02199691) and 2 (0.2%) participants who received MenQuadfi in Study 3 (NCT02842853). Three participants in Study 2 experienced syncope

within 30 minutes following vaccination: 1 (0.2%) participant who received Menveo, 1 (0.3%) participant who received MenQuadfi concomitantly with Tdap and HPV, and 1 (0.3%) participant who received Tdap and HPV concomitantly (without MenQuadfi). These events were non-serious and spontaneously resolved on the same day.

Adults 18 through 55 years of age

The safety of MenQuadfi in adults 18 through 55 years of age was evaluated in Study 3 (NCT02842853). The safety analysis set included 1,495 participants who received MenQuadfi and 312 participants who received Menactra. Of the participants 18 years through 55 years of age who received MenQuadfi (N = 1,495), 65.2% were female. Among those with reported race and ethnicity, 73.3% were White, 21.0% were Black or African American, 2.2% were Asian, 3.5% were of other racial groups, and 20.0% were of Hispanic or Latino ethnicity. Mean age was 39.4 years at time of administration.

The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menactra are presented in Table 3.

Dizziness within 30 minutes following vaccination was experienced by 5 (0.3%) participants who received MenQuadfi and 1 (0.3%) participant who received Menactra. These events were non-serious and spontaneously resolved on the same day.

SAEs occurred at a rate of 1.6% following MenQuadfi and at a rate of 0.6% following Menactra during the entire study period. No SAEs were determined to be vaccine related.

Table 3: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menactra in Individuals 18 through 55 Years of Age (Study 3)*

	MenQuadfi (N[†]=1,441-1,460) %		Menactra (N[†]=297-301) %	
Adverse Reactions	Any	Grade 3	Any	Grade 3
Local Reactions				
Injection Site Pain[‡]	41.9	1.9	35.0	1.3
Injection Site Erythema[§]	5.1	0.3	3.7	0.3
Injection Site Swelling[§]	4.3	0.2	3.4	0.3
Systemic Reactions				
Myalgia[‡]	35.6	3.6	31.2	2.3
Headache[‡]	29.0	2.9	27.6	2.7

	MenQuadfi (N†=1,441-1,460) %		Menactra (N†=297-301) %	
Adverse Reactions	Any	Grade 3	Any	Grade 3
Malaise‡	22.9	2.9	18.9	3.3
Fever¶	1.4	0.1	1.7	0.7

* Clinical trial identifier NCT02842853
† N is the number of vaccinated participants with available data for the events listed
‡ Grade 3: Prevents daily activity
§ Any: > 25 mm; Grade 3: > 100 mm
¶ Any: ≥ 100.4°F (38.0°C); Grade 3: ≥ 102.1°F (39.0°C)

Adults 56 years of age and older

The safety of MenQuadfi in adults 56 years of age and older was evaluated in Study 4 (NCT02842866). The safety analysis set included 448 participants who received MenQuadfi intramuscularly and 453 participants who received a non-conjugate comparator meningococcal vaccine, Menomune® – A/C/Y/W-135 [Meningococcal Polysaccharide Vaccine, Groups A, C, Y, and W-135 Combined], subcutaneously. Of the participants 56 years of age and older who received MenQuadfi (N = 448), 44.4% were 56 through 64 years of age, 55.6% were 65 years of age and older, 57.6% were female, 86.6% were White, 11.6% were Black or African American, 1.1% were Asian, 0.4% were of other racial groups and 7.8% were of Hispanic or Latino ethnicity. Mean age was 67.0 years at time of administration.

The rates and severity of the solicited adverse reactions that occurred within 7 days following MenQuadfi compared with Menomune in Study 4 (NCT02842866) are presented in Table 4.

SAEs occurred at a rate of 3.3% following MenQuadfi and at a rate of 3.3% following Menomune during the entire study period. No SAEs were determined to be vaccine related.

Table 4: Percentages of Solicited Injection-Site Reactions and Systemic Adverse Reactions within 7 Days after Vaccination with MenQuadfi or Menomune in Individuals 56 Years of Age and Older Study 4*

	MenQuadfi (N†=436-443) %		Menomune‡ (N†=449-451) %	
Adverse Reactions	Any	Grade 3	Any	Grade 3
Local Reactions				
Injection Site Pain§	25.5	0.7	9.6	0.7
Injection Site Erythema¶	5.2	0.2	0.0	0.0

	MenQuadfi (N†=436-443) %		Menomune‡ (N†=449-451) %	
Adverse Reactions	Any	Grade 3	Any	Grade 3
Injection Site Swelling¶	4.5	0.0	0.0	0.0
Systemic Reactions				
Myalgia§	21.9	1.6	15.3	1.3
Headache§	19.0	0.7	14.6	0.7
Malaise§	14.5	1.4	11.3	1.8
Fever#	2.1	0.2	0.4	0.0

* Clinical trial identifier NCT02842866
† N is the number of vaccinated participants with available data for the events listed
‡ Menomune was given subcutaneously
§ Grade 3: Prevents daily activity
¶ Any: > 25 mm; Grade 3: > 100 mm
# Any: ≥ 100.4°F (38.0°C); Grade 3: ≥ 102.1°F (39.0°C)

Booster Vaccination Study

The safety of MenQuadfi in previously vaccinated adolescents and adults 15 years of age and older was evaluated in Study 5 (NCT02752906). All randomized participants had received a primary dose of either (Menveo or Menactra) 4 to 10 years previously. The safety analysis set included 402 participants who received a single booster dose of MenQuadfi (median age: 17.8 years) and 407 participants who received a single booster dose of Menactra (median age: 17.9 years). Of the participants who received MenQuadfi, 51.5% were female, 85.1% were White, 9.7% were Black, 2.7 % were Asian and 2.2 % were of other racial groups, and 15.7% were of Hispanic or Latino ethnicity.

The most commonly reported solicited adverse reactions (≥10%) within 7 days of MenQuadfi booster vaccination were injection site pain (44.7%) and headache (37.9%), myalgia (36.7%), and malaise (27.6%). The majority of solicited adverse reactions were Grade 1 or 2 and resolved within 3 days. Compared with recipients of a Menactra booster dose, recipients of a MenQuadfi booster dose had higher rates of injection site erythema (MenQuadfi 5.0%, Menactra 1.5%) and swelling (MenQuadfi 4.0%, Menactra 0.7%). Overall rates of solicited adverse reactions were comparable to those observed in unvaccinated adolescents and adults after a single MenQuadfi dose.

SAEs occurred at a rate of 1.2% following MenQuadfi and at a rate of 1.0% following Menactra during the entire study period. No SAEs were determined to be vaccine related.

7 DRUG INTERACTIONS

7.1 Concomitant Administration with Other Vaccines

In a clinical trial in adolescents 10 through 17 years of age, MenQuadfi was administered concomitantly with Tdap and HPV [*see Adverse Reactions (6)* and *Clinical Studies (14.3)*].

Lower geometric mean antibody concentrations (GMCs) for antibodies to the pertussis antigens filamentous hemagglutinin (FHA), pertactin (PRN) and fimbriae (FIM) were observed when MenQuadfi was co-administered with Tdap and HPV, compared to concomitant administration of Tdap and HPV (without MenQuadfi) [*see Clinical Studies (14.3)*].

7.2 Immunosuppressive Treatments

Immunosuppressive therapies may reduce the immune response to MenQuadfi [*see Warnings and Precautions (5)*].

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to MenQuadfi during pregnancy. To enroll in or obtain information about the registry, call Sanofi Pasteur at 1-800-822-2463.

Risk Summary

All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

There are no clinical studies of MenQuadfi in pregnant women. Available human data on MenQuadfi administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

A developmental toxicity study in female rabbits administered a full human dose (0.5 mL) prior to mating and during gestation period revealed no evidence of harm to the fetus due to MenQuadfi (see *Animal Data*).

Data

Animal Data

In a developmental toxicity study, female rabbits received a human dose of MenQuadfi by intramuscular injection on five occasions: 30 days and 10 days prior to mating, gestation days 6, 12 and 27. No adverse effects on pre-weaning development up to post-natal day 35 were observed. There were no vaccine-related fetal malformations or variations observed.

8.2 Lactation

Risk Summary

It is not known whether MenQuadfi is excreted in human milk. Data are not available to assess the effects of MenQuadfi on the breastfed infant or on milk production/excretion.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for MenQuadfi and any potential adverse effects on the breastfed child from MenQuadfi or from the underlying maternal condition. For preventive vaccines, the underlying maternal condition is susceptibility to disease prevented by the vaccine.

8.4 Pediatric Use

Safety and effectiveness of MenQuadfi have not been established in individuals younger than 2 years of age in the US.

8.5 Geriatric Use

A total of 249 participants 65 years of age and older, including 71 participants 75 years of age or older, in Study 4 received one dose of MenQuadfi [*see Adverse Reactions (6.1)* and *Clinical Studies (14.1)*].

MenQuadfi recipients ≥ 65 years of age had lower GMTs and seroresponse rates for all serogroups compared to MenQuadfi recipients 56 through 64 years of age [*see Clinical Studies (14.1)*].

11 DESCRIPTION

MenQuadfi is a sterile liquid vaccine administered by intramuscular injection that contains *Neisseria meningitidis* serogroup A, C, W, and Y capsular polysaccharide antigens that are individually conjugated to tetanus toxoid protein. *N. meningitidis* A, C, W, and Y strains are cultured on Mueller Hinton agar medium and grown in Watson Scherp medium. The polysaccharides are extracted from the *N. meningitidis* cells and purified by centrifugation, detergent precipitation, alcohol precipitation, solvent extraction, and diafiltration. To prepare the polysaccharides for conjugation, Serogroup A is activated with carbonyldiimidazole (CDI), derivatized with adipic acid dihydrazide (ADH), and purified by diafiltration. Serogroups C, W, and Y are depolymerized, activated with periodate, and purified by diafiltration.

Clostridium tetani is fermented in media to generate tetanus toxin, which is purified by ammonium sulfate precipitation to yield purified tetanus toxin (PTT) and detoxified with formaldehyde to yield purified tetanus protein (PTP). The PTP is then concentrated and filtered to yield concentrated tetanus protein (CTP). The activated/derivatized polysaccharides are covalently linked to tetanus toxoid and purified by chromatography and serial diafiltration. The four meningococcal components, present as individual serogroup-specific glycoconjugates, compose the final formulated vaccine.

MenQuadfi is manufactured as a sterile, clear, colorless solution. Each 0.5 mL dose of vaccine contains 10 microgram each of meningococcal A, C, W, and Y polysaccharide antigens conjugated to approximately 55 micrograms tetanus toxoid protein carrier; 3.35 mg sodium chloride (0.67%), and 1.23 mg sodium acetate (30 mM). Potency of MenQuadfi is determined by quantifying the amount of each polysaccharide antigen that is conjugated to tetanus toxoid protein and the amount of unconjugated polysaccharide present.

No preservative or adjuvant is added during manufacture. Each 0.5 mL dose may contain residual amounts of formaldehyde of less than 3 mcg/mL, by calculation.

The vial in which the vaccine components are contained is composed of USP Type I borosilicate glass. The vial stopper is a chlorobutyl synthetic polyisoprene blend stopper (not made with natural rubber latex).

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Invasive meningococcal disease (IMD) is caused by the bacterium *N. meningitidis*, a gram-negative diplococcus found exclusively in humans. The presence of bactericidal anti-capsular meningococcal antibodies in serum has been associated with protection from IMD. MenQuadfi induces the production of bactericidal antibodies specific to the capsular polysaccharides of *N. meningitidis* serogroups A, C, W, and Y.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

MenQuadfi has not been evaluated for carcinogenic or mutagenic potential or for impairment of male fertility. MenQuadfi administered to female rabbits had no effects on fertility [*see Use in Specific Population (8.1)*].

14 CLINICAL STUDIES

To infer effectiveness of MenQuadfi, the immunogenicity in persons 2 years of age and older was evaluated using a serogroup-specific serum bactericidal assay with exogenous human complement (hSBA). The hSBA responses following a single dose of MenQuadfi for primary vaccination were assessed in four studies, and the hSBA responses following a single dose of MenQuadfi for booster vaccination were assessed in one study. Serum was collected at baseline and 30 days post-vaccination to measure antibodies with hSBA. The hSBA geometric mean titers (GMTs) and proportion of participants who achieved hSBA seroresponse (defined below) were evaluated.

- Seroresponse rate for each serogroup: the proportion of participants with an hSBA
    - pre-vaccination titer < 1:8 who achieved a post-vaccination titer ≥ 1:16, or
    - pre-vaccination titer ≥ 1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

Non-inferiority of MenQuadfi seroresponse rates versus those for comparator vaccines was demonstrated for all 4 serogroups in individuals 2 years of age and older who received a primary vaccination and in individuals 15 years of age and older who received a booster vaccination at least 4 years following a previous dose of a meningococcal (groups A, C, W, Y) conjugate vaccine.

14.1 Primary Vaccination

Immunogenicity in Children 2 through 9 Years of Age

Immunogenicity of MenQuadfi compared to Menveo in participants 2 through 9 years of age was evaluated in Study 1 (NCT03077438). The hSBA seroresponse rate and GMTs are presented in Table 5.

Immune non-inferiority, based on seroresponse rates, was demonstrated for MenQuadfi as compared to Menveo for all four serogroups.

Table 5: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menveo 30 Days after Vaccination of Participants 2 through 9 Years of Age (Study 1)*

Endpoint†	MenQuadfi (95% CI)	Menveo (95% CI)	Percent difference MenQuadfi minus Menveo‡ (95% CI)
A	N=455-456	N=458	
% Participants achieving Seroresponse	55.4 (50.7; 60.0)	47.8 (43.2; 52.5)	7.6 (1.1, 14.0)
GMT	25 (22; 28)	23 (20; 26)	
C	N=458	N=458-459	
% Participants achieving Seroresponse	95.2 (92.8; 97.0)	47.8 (43.2; 52.5)	47.4 (42.2, 52.2)
GMT	238 (209; 270)	17.0 (14; 20)	
W	N=458	N=459	
% Participants achieving Seroresponse	78.8 (74.8; 82.5)	64.1 (59.5; 68.4)	14.8 (8.9, 20.5)
GMT	38 (34; 42)	26 (23; 30)	

Y	N=458	N=459	
% Participants achieving Seroresponse	91.5 (88.5; 93.9)	79.3 (75.3; 82.9)	12.2 (7.7, 16.7)
GMT	69 (61; 77)	44 (38; 50)	

* Clinical trial identifier NCT03077438

† Seroresponse rate (primary endpoint) for each serogroup: the proportion of participants with an hSBA pre-vaccination titer < 1:8 who achieved a post-vaccination titer ≥ 1:16, or pre-vaccination titer ≥ 1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

‡ Overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is > -10% for all four serogroups.

N: number of participants in per-protocol analysis set with valid serology results.

95% CI of the single proportion calculated from the exact binomial method.

95% CI of the difference calculated from the Wilson Score method without continuity correction.

Immunogenicity in Adolescents 10 through 17 Years of Age

Immunogenicity of MenQuadfi compared to Menveo in participants 10 through 17 years of age was evaluated in Study 2 (NCT02199691). Study 2 was conducted in healthy meningococcal vaccine naïve participants and evaluated seroresponse rates following administration with either MenQuadfi alone, Menveo alone, MenQuadfi co-administered with Tdap, and HPV, or Tdap and HPV alone. The hSBA seroresponse rate and GMTs for Study 2 are presented in Table 6.

Immune non-inferiority, based on seroresponse, was demonstrated for MenQuadfi as compared to Menveo for all four serogroups.

Study 2 (NCT02199691) was conducted in healthy meningococcal vaccine naïve male and female participants and evaluated seroresponses following administration with either MenQuadfi alone; Menveo alone; MenQuadfi co-administered with Tdap, and HPV; or Tdap and HPV alone. The hSBA seroresponse rate and GMTs for the MenQuadfi alone and Menveo alone groups are presented in Table 6.

Table 6: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menveo 30 Days after Vaccination of Participants 10 through 17 Years of Age Study 2*

Endpoint†	MenQuadfi (95% CI)	Menveo (95% CI)	Percent difference MenQuadfi minus Menveo‡ (95% CI)
A	N=463	N=464	
% Participants achieving Seroresponse	70.2 (65.8; 74.3)	60.3 (55.7; 64.8)	9.8 (3.7;15.9)

Endpoint†	MenQuadfi (95% CI)	Menveo (95% CI)	Percent difference MenQuadfi minus Menveo‡ (95% CI)
GMT	44 (39; 50)	35 (30; 41)	
C	N=462	N=463	
% Participants achieving Seroresponse	96.1 (93.9, 97.7)	61.6 (57.0, 66.0)	34.5 (29.7; 39.3)
GMT	387 (329; 456)	51 (41; 64)	
W	N=463	N=464	
% Participants achieving Seroresponse	84.2 (80.6; 87.4)	56.0 (51.4; 60.6)	28.2 (22.5; 33.7)
GMT	87 (78; 97)	36 (32; 41)	
Y	N=462-463	N=464	
% Participants achieving Seroresponse	91.1 (88.2; 93.6)	66.8 (62.3;71.1)	24.3 (19.2; 29.3)
GMT	76 (66; 87)	28 (24; 32)	

* Clinical trial identifier NCT02199691

† Seroresponse rate (primary endpoint) for each serogroup: the proportion of participants with an hSBA pre-vaccination titer < 1:8 who achieved a post-vaccination titer ≥ 1:16, or pre-vaccination titer ≥ 1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

‡ Overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is > -10% for all four serogroups.

N: number of participants in per-protocol analysis set with valid serology results.

95% CI of the single proportion calculated from the exact binomial method.

95% CI of the difference calculated from the Wilson Score method without continuity correction.

Study 3 evaluated the immunogenicity of MenQuadfi (N=1097-1098) compared to Menactra (N=300) in healthy meningococcal-naïve participants 10 through 17 years of age. Seroresponse rates for MenQuadfi were noninferior to those of Menactra for all serogroups based on the same noninferiority criteria defined for Study 2.

Immunogenicity in Adults 18 through 55 Years of Age

Immunogenicity of MenQuadfi compared to Menactra in participants 18 through 55 years of age was evaluated in Study 3 (NCT02842853). The hSBA seroresponse rate and GMTs are presented in Table 7.

Immune non-inferiority, based on seroresponse rates, was demonstrated for MenQuadfi as compared to Menactra for all four serogroups.

Table 7: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menactra 30 Days after Vaccination of Participants 18 through 55 Years of Age Study 3*

Endpoint†	MenQuadfi (95% CI)	Menactra (95% CI)	Percent difference MenQuadfi minus Menactra‡ (95% CI)
A	N=1,406-1,408	N=293	
% Participants achieving Seroresponse	73.5 (71.2; 75.8)	53.9 (48.0; 59.7)	19.6 (13.5; 25.8)
GMT	106 (97; 117)	52 (43; 64)	
C	N=1,406-1,408	N=293	
% Participants achieving Seroresponse	83.4 (81.4; 85.3)	42.3 (36.6; 48.2)	41.1 (35.0; 46.9)
GMT	234 (210; 261)	37 (29; 49)	
W	N=1,408-1,410	N=293	
% Participants achieving Seroresponse	77.0 (74.7; 79.2)	50.2 (44.3; 56.0)	26.8 (20.7; 32.9)
GMT	76 (69; 83)	33 (26; 42)	

Endpoint†	MenQuadfi (95% CI)	Menactra (95% CI)	Percent difference MenQuadfi minus Menactra‡ (95% CI)
Y	N=1,408-1,410	N=293	
% Participants achieving Seroresponse	88.1 (86.3; 89.8)	60.8 (54.9; 66.4)	27.4 (21.7; 33.3)
GMT	219 (200; 239)	55 (42; 70)	

* Clinical trial identifier NCT02842853

† Seroresponse rate (primary endpoint) for each serogroup: the proportion of participants with an hSBA pre-vaccination titer < 1:8 who achieved a post-vaccination titer ≥ 1:16, or pre-vaccination titer ≥ 1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

‡ The overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is > -10% for all four serogroups.

N: number of participants in per-protocol analysis set with valid serology results.

95% CI of the single proportion calculated from the exact binomial method.

95% CI of the difference calculated from the Wilson Score method without continuity correction.

Immunogenicity in Adults 56 Years of Age and Older

Immunogenicity of MenQuadfi compared to Menomune in participants 56 years and older was evaluated in Study 4 (NCT02842866).

Enrollment was stratified by age category: 56 through 64 years of age (44.3%), 65 through 74 years of age (39.7%), and 75 years of age and older (15.9%). The overall mean age of participants who received MenQuadfi was 66.9 years; range: 56 through 89.8 years of age. The mean age for participants in the 56 through 64 years age stratum who received MenQuadfi was 60.4 years, the mean age for participants ≥ 65 years age stratum who received MenQuadfi was 72.2 years.

The hSBA seroresponse rate and GMTs are presented in Table 8.

Immune non-inferiority, based on seroresponse rates, was demonstrated for MenQuadfi as compared to Menomune for all four serogroups.

Table 8: Comparison of Bactericidal Antibody Responses to MenQuadfi and Menomune in Naïve Older Adults and Elderly 30 Days after Vaccination Study 4*

Endpoint†	MenQuadfi (95% CI)	Menomune (95% CI)	Percent difference MenQuadfi minus Menomune‡ (95% CI)
A	N=433	N=431	
% Participants achieving Seroresponse	58.2 (53.4; 62.9)	42.5 (37.7; 47.3)	15.7 (9.08; 22.2)
GMT	55 (47; 65)	31 (27; 37)	
C	N=433	N=431	
% Participants achieving Seroresponse	77.1 (72.9; 81.0)	49.7 (44.8; 54.5)	27.5 (21.2; 33.5)
GMT	101 (84; 123)	25 (21; 30)	
W	N=433	N=431	
% Participants achieving Seroresponse	62.6 (57.8; 67.2)	44.8 (40.0; 49.6)	17.8 (11.2; 24.2)
GMT	28 (24; 33)	15 (13; 18)	
Y	N=433	N=431	
% Participants achieving Seroresponse	74.4 (70.0; 78.4)	43.4 (38.7; 48.2)	31.0 (24.6; 37.0)
GMT	69 (59; 81)	21 (17; 25)	

*Clinical trial identifier NCT02842866

† Seroresponse rate (primary endpoint) for each serogroup: the proportion of participants with an hSBA pre-vaccination titer < 1:8 who achieved a post-vaccination titer ≥ 1:16, or pre-vaccination titer ≥ 1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer.

‡ The overall non-inferiority would be demonstrated if the lower limit of the 2-sided 95% CI is > -10% for all four serogroups.
N: number of participants in per-protocol analysis set with valid serology results.
95% CI of the single proportion calculated from the exact binomial method.
95% CI of the difference calculated from the Wilson Score method without continuity correction.

14.2 Booster

Immunogenicity of a booster dose of MenQuadfi compared to a booster dose of Menactra was evaluated in Study 5 (NCT02752906). The study-enrolled participants 15 years of age and older who had received a primary dose of Menveo or Menactra 4 to 10 years previously.

Immune non-inferiority, based on seroresponse rates, was demonstrated for MenQuadfi as compared to Menactra for all four serogroups.

For a description of study design and number of participants, see section 6.1 Booster Vaccination Study. The primary immunogenicity endpoint was hSBA seroresponse to each serogroup 30 days following booster vaccination with MenQuadfi or Menactra given to participants who received a prior dose of Menveo or Menactra 4 to 10 years ago. Seroresponse was defined as the proportion of participants with an hSBA pre-vaccination titer < 1:8 who achieved a post-vaccination titer ≥ 1:16, or pre-vaccination titer ≥ 1:8 who achieved a post-vaccination titer at least 4-fold greater than the pre-vaccination titer. The other endpoints included the proportions of participants with post-vaccination hSBA ≥1:8 and the hSBA GMTs for each serogroup. These endpoints were also evaluated at 6 days post vaccination in a subset.

Seroresponse rates at Day 30 following booster vaccination with MenQuadfi were 92.2% for serogroup A, 97.1% for serogroup C, 98.2% for serogroup W, and 97.4% for serogroup Y, as compared to 87.1% for serogroup A, 91.8% for serogroup C, 90.7% for serogroup W, and 95.6% for serogroup Y, following booster vaccination with Menactra. At Day 6, following booster vaccination with MenQuadfi, seroresponse rates were 72.7%, 83.6%, 94.5%, and 90.9% for serogroups A, C, W, and Y, respectively.

The hSBA GMTs were 173, 334, 499, and 302 for serogroups A, C, W, and Y at Day 6, and 497, 2618, 1747, and 2070, respectively, for the 4 serogroups at Day 30 following booster dose of MenQuadfi.

Overall, similar seroresponse rates were observed for those participants who received booster vaccination with Menactra.

14.3 Immunogenicity of Concomitantly Administered Vaccines

Concomitant administration of MenQuadfi with Tdap and HPV in adolescents 10 through 17 years was evaluated in Study 2 (NCT02199691). In this randomized study, 503 participants received MenQuadfi alone, 392 received MenQuadfi coadministered with Tdap and HPV, 296 received Tdap and HPV alone. A fourth group received Menveo alone (N=501).

No evidence of interference in hSBA seroresponse rates was observed when MenQuadfi was coadministered with Tdap and HPV. Antibody responses to HPV, and to the tetanus and diphtheria antigens were similar when Tdap and HPV were administered with and without MenQuadfi. Anti-pertussis GMC responses were non-inferior for the pertussis toxoid antigen, but did not meet non-inferiority for the FHA, PRN, and FIM antigens. The clinical relevance of the diminished responses to the pertussis antigens is unknown.

16 HOW SUPPLIED/STORAGE AND HANDLING

MenQuadfi is supplied in a single-dose vial (NDC 49281-590-58):

in packages of 1 vial (NDC 49281-590-01);

in packages of 5 vials (NDC 49281-590-05);

in packages of 10 vials (NDC 49281-590-10).

Not all pack sizes may be marketed.

The vial stopper is not made with natural rubber latex.

Store at 2°C to 8°C (35°F to 46°F). Do not freeze. Do not use vaccine that has been frozen. Do not use after expiration date.

17 PATIENT COUNSELING INFORMATION

Vaccine Information Statements are required by the National Childhood Vaccine Injury Act of 1986 to be given prior to immunization to the patient, parent, or guardian. These materials are available free of charge at the Centers for Disease Control and Prevention (CDC) website (www.cdc.gov/vaccines). Inform the patients, parents or guardians about:

- Potential benefits and risks of immunization with MenQuadfi.
- Potential for adverse reactions that have been temporally associated with administration of MenQuadfi or other vaccines containing similar components.
- Reporting any adverse reactions to their healthcare provider.
- The Sanofi Pasteur Inc. Pregnancy Registry, as appropriate [*see Pregnancy (8.1)*].

Manufactured by:
Sanofi Pasteur Inc.
Swiftwater PA 18370 USA

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Grant Final Report

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Electronic Support for Public Health–Vaccine Adverse Event Reporting System (ESP:VAERS)

Inclusive dates: 12/01/07 - 09/30/10

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Abstract

Purpose: To develop and disseminate HIT evidence and evidence-based tools to improve healthcare decision making through the use of integrated data and knowledge management.

Scope: To create a generalizable system to facilitate detection and clinician reporting of vaccine adverse events, in order to improve the safety of national vaccination programs.

Methods: Electronic medical records available from all ambulatory care encounters in a large multi-specialty practice were used. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions were evaluated for values suggestive of an adverse event.

Results: Restructuring at CDC and consequent delays in terms of decision making have made it challenging despite best efforts to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial and comparison of ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. However, Preliminary data were collected and analyzed and this initiative has been presented at a number of national symposia.

Key Words: electronic health records, vaccinations, adverse event reporting

Final Report

Purpose

This research project was funded to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS), via the following aims:

Aim 1. Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration.

Aim 2. Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS).

Aim 3. Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.

Aim 4. Distribute documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems.

Scope

Public and professional confidence in vaccination depends on reliable postmarketing surveillance systems to ensure that rare and unexpected adverse effects are rapidly identified. The goal of this project is to improve the quality of vaccination programs by improving the quality of physician adverse vaccine event detection and reporting to the national Vaccine Adverse Event Reporting System (VAERS). This project is serving as an extension of the Electronic Support for Public Health (ESP) project, an automated system using electronic health record (EHR) data to detect and securely report cases of certain diseases to a local public health authority. ESP provides a ready-made platform for automatically converting clinical, laboratory, prescription, and demographic data from almost any EHR system into database tables on a completely independent server, physically located and secured by the same logical and physical security as the EHR data itself. The ESP:VAERS project developed criteria and algorithms to identify important adverse events related to vaccinations in ambulatory care EHR data, and made attempts at formatting and securely sending electronic VAERS reports directly to the Centers for Disease Control and Prevention (CDC).

Patient data were available from Epic System's Certification Commission for Health Information Technology-certified EpicCare system at all ambulatory care encounters within Atrius Health, a large multispecialty group practice with over 35 facilities. Every patient receiving a vaccine was automatically identified, and for the next 30 days, their health care diagnostic codes, laboratory tests, and medication prescriptions are evaluated for values

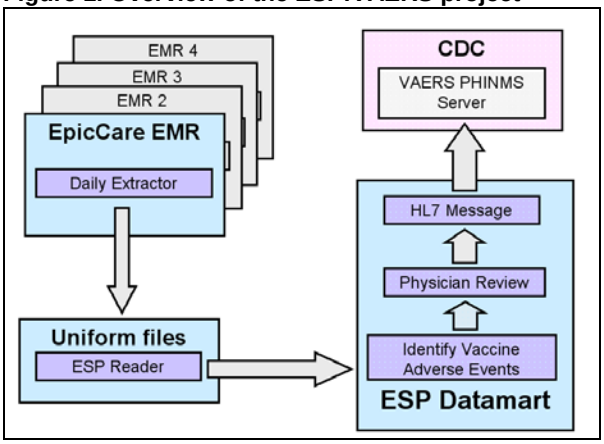
suggestive of an adverse vaccine event. When a possible adverse event was detected, it was recorded, and the appropriate clinician was to be notified electronically.

Clinicians in-basket messaging was designed to provide a preview a pre-populated report with information from the EHR about the patient, including vaccine type, lot number, and possible adverse effect, to inform their clinical judgment regarding whether they wish to send a report to VAERS. Clinicians would then have the option of adding free-text comments to pre-populated VAERS reports or to document their decision not to send a report. The CDC's Public Health Information Network Messaging System (PHIN-MS) software was installed within the facilities so that the approved reports could be securely transferred to VAERS as electronic messages in an interoperable health data exchange format using Health Level 7 (HL7).

Methods

The goal of Aim 1: *Identify required data elements, and develop systems to monitor ambulatory care electronic medical records for adverse events following vaccine administration,* and Aim 2: *Prepare, and securely submit clinician approved, electronic reports to the national Vaccine Adverse Event Reporting System (VAERS),* was to construct the below flow of data in order to support the first two Aims:

Figure 1. Overview of the ESP:VAERS project



Existing and functioning ESP components are shown on the left, and Aims 1 and 2 on the right. ESP:VAERS flags every vaccinated patient, and prospectively accumulate that patient's diagnostic codes, laboratory tests, allergy lists, vital signs, and medication prescriptions. A main component of Aim 1 was to *Develop AE criteria to assess these parameters for new or abnormal values that might be suggestive of an adverse effect.* A reporting protocol & corresponding algorithms were developed to detect potential adverse event cases using diagnostic codes, and methods were tested to identify prescriptions or abnormal laboratory values that might be suggestive of an adverse effect. These algorithms were designed to seek both expected and unexpected adverse effects.

This reporting protocol was approved by both internal & external partners. We initially prepared a draft document describing the elements, algorithms, interval of interest after vaccination, and actions for broad classes of post-vaccination events, including those to be reported immediately without delay (such as acute anaphylactic reaction following vaccination), those never to be reported (such as routine check-ups following vaccination) and those to be reported at the discretion and with additional information from the attending physician through a feedback mechanism. The draft was then widely circulated as an initial / working draft for comment by relevant staff in the CDC and among our clinical colleagues at Atrius. In addition to review by the internal CDC Brighton Collaboration liaison, this protocol has also received review & comment via the CDC's Clinical Immunization Safety Assessment (CISA) Network.

The goal of Aim 2 was the *Development of HL7 messages code for ESP:VAERS to ensure secure transmission to CDC via PHIN-MS*. The HL7 specification describing the elements for an electronic message to be submitted to Constella, the consultants engaged by CDC for this project was implemented. Synthetic and real test data was been generated and transmitted between Harvard and Constella. However, real data transmissions of non-physician approved reports to the CDC was unable to commence, as by the end of this project, the CDC had yet to respond to multiple requests to partner for this activity.

The goal of Aim 3 was to *Comprehensively evaluate ESP:VAERS performance in a randomized trial, and in comparison to existing VAERS and Vaccine Safety Datalink data.*

We had initially planned to evaluate the system by comparing adverse event findings to those in the Vaccine Safety Datalink project—a collaborative effort between CDC's Immunization Safety Office and eight large managed care organizations. Through a randomized trial, we would also test the hypothesis that the combination of secure, computer-assisted, clinician-approved, adverse event detection, and automated electronic reporting will substantially increase the number, completeness, validity, and timeliness of physician-approved case reports to VAERS compared to the existing spontaneous reporting system; however, due to restructuring at CDC and consequent delays in terms of decision making, it became impossible to move forward with discussions regarding the evaluation of ESP:VAERS performance in a randomized trial, and compare ESP:VAERS performance to existing VAERS and Vaccine Safety Datalink data. Therefore, the components under this particular Aim were not achieved.

Aim 4 *Distribution of documentation and application software developed and refined in Aims 1 and 2 that are portable to other ambulatory care settings and to other EMR systems* has been successfully completed. Functioning source code is available to share under an approved open source license. ESP:VAERS source code is available as part of the ESP source code distribution. It is licensed under the LGPL, an open source license compatible with commercial use. We have added the ESP:VAERS code, HL7 and other specifications and documentation to the existing ESP web documentation and distribution resource center http://esphealth.org, specifically, the Subversion repository available at:
http://esphealth.org/trac/ESP/wiki/ESPVAERS.

Results

Preliminary data were collected from June 2006 through October 2009 on 715,000 patients, and 1.4 million doses (of 45 different vaccines) were given to 376,452 individuals. Of these doses, 35,570 possible reactions (2.6 percent of vaccinations) were identified. This is an average of 890 possible events, an average of 1.3 events per clinician, per month. These data were presented at the 2009 AMIA conference.

In addition, ESP:VAERS investigators participated on a panel to explore the perspective of clinicians, electronic health record (EHR) vendors, the pharmaceutical industry, and the FDA towards systems that use proactive, automated adverse event reporting.

Adverse events from drugs and vaccines are common, but underreported. Although 25% of ambulatory patients experience an adverse drug event, less than 0.3% of all adverse drug events and 1-13% of serious events are reported to the Food and Drug Administration (FDA). Likewise, fewer than 1% of vaccine adverse events are reported. Low reporting rates preclude or slow the identification of "problem" drugs and vaccines that endanger public health. New surveillance methods for drug and vaccine adverse effects are needed. Barriers to reporting include a lack of clinician awareness, uncertainty about when and what to report, as well as the burdens of reporting: reporting is not part of clinicians' usual workflow, takes time, and is duplicative. Proactive, spontaneous, automated adverse event reporting imbedded within EHRs and other information systems has the potential to speed the identification of problems with new drugs and more careful quantification of the risks of older drugs.

Unfortunately, there was never an opportunity to perform system performance assessments because the necessary CDC contacts were no longer available and the CDC consultants responsible for receiving data were no longer responsive to our multiple requests to proceed with testing and evaluation.

Inclusion of AHRQ Priority Populations

The focus of our project was the Atrius Health (formerly HealthOne) provider & patient community. This community serves several AHRQ inclusion populations, specifically low-income and minority populations in primarily urban settings.

Atruis currently employs approximately 700 physicians to serve 500,000 patients at more than 18 office sites spread throughout the greater Metropolitan Boston area. The majority of Atruis physicians are primary care internal medicine physicians or pediatricians but the network also includes physicians from every major specialty.

The entire adult and pediatric population served by Atruis was included in our adverse event surveillance system (ESP:VAERS). Atruis serves a full spectrum of patients that reflects the broad diversity of Eastern Massachusetts. A recent analysis suggests that the population served by Atruis is 56% female, 16.6% African American, 4% Hispanic. The prevalence of type 2 diabetes in the adult population is 5.7%. About a quarter of the Atruis population is under age 18.

List of Publications and Products

ESP:VAERS [source code available as part of the ESP source code distribution]. Licensed under the GNU Lesser General Public License (LGPL), an open source license compatible with commercial use. Freely available under an approved open source license at: http://esphealth.org.

Lazarus, R, Klompas M, Hou X, Campion FX, Dunn J, Platt R. Automated Electronic Detection & Reporting of Adverse Events Following Vaccination: ESP:VAERS. The CDC Vaccine Safety Datalink (VSD) Annual Meeting. Atlanta, GA; April, 2008.

Lazarus R, Klompas M Automated vaccine adverse event detection and reporting from electronic medical records. CDC Public Health Informatics Network (PHIN) Conference August 27, 2008.

Klompas M, Lazarus R ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 17th.

Lazarus R, Klompas M, Kruskal B, Platt R Temporal patterns of fever following immunization in ambulatory care data identified by ESP:VAERS Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

Linder J, Klompas M, Cass B, et al. Spontaneous Electronic Adverse Event Reporting: Perspectives from Clinicians, EHR Vendors, Biopharma, and the FDA. Presented at the American Medical Informatics Association Annual Symposium; 2009 November 14–18: San Francisco, CA.

42 USC CHAPTER 6A, SUBCHAPTER XIX, Part 2: National Vaccine Injury Compensation Program

From Title 42—THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A—PUBLIC HEALTH SERVICE
SUBCHAPTER XIX—VACCINES

PART 2—NATIONAL VACCINE INJURY COMPENSATION PROGRAM

SUBPART A—PROGRAM REQUIREMENTS

§300aa–10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program [1] for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(July 1, 1944, ch. 373, title XXI, §2110, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–239, title VI, §6601(b), Dec. 19, 1989, 103 Stat. 2285.)

EDITORIAL NOTES

PRIOR PROVISIONS

A prior section 300aa–10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

A prior section 2110 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

AMENDMENTS

1989—Subsec. (c). Pub. L. 101–239 added subsec. (c).

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 1989 AMENDMENT

Section 6601(s) of Pub. L. 101–239, as amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–11 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] shall apply as follows:

"(A) Petitions filed after the date of enactment of this section [Dec. 19, 1989] shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] as amended by this section.

"(B) Petitions currently pending in which the evidentiary record is closed shall continue to proceed under the Program in accordance with the law in effect before the date of the enactment of this section, except that if the United States Court of Federal Claims is to review the findings of fact and conclusions of law of a special master on such a petition, the court may receive further evidence in conducting such review.

"(C) Petitions currently pending in which the evidentiary record is not closed shall proceed under the Program in accordance with the law as amended by this section.

All pending cases which will proceed under the Program as amended by this section shall be immediately suspended for 30 days to enable the special masters and parties to prepare for proceeding under the Program as amended by this section. In determining the 240-day period prescribed by section 2112(d) of the Public Health Service Act [42 U.S.C. 300aa–12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 U.S.C. 300aa–21(b)], as so amended, any period of suspension under the preceding sentence shall be excluded.

"(2) The amendments to section 2115 of the Public Health Service Act [42 U.S.C. 300aa–15] shall apply to all pending and subsequently filed petitions."

Effective Date

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, as amended, set out as a note under section 300aa–1 of this title.

[1] *So in original. Probably should be capitalized.*

§300aa–11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and

(II) such person elects under section 300aa–21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa–21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa–16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court [1] is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine. A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(f) Maternal immunization

(1) In general

Notwithstanding any other provision of law, for purposes of this subpart, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

(2) Definition

As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1 except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term "mean".

(July 1, 1944, ch. 373, title XXI, §2111, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 100–203, title IV, §§4302(b), 4304(a), (b), 4306, 4307(1), (2), Dec. 22, 1987, 101 Stat. 1330–221, 1330-223, 1330-224; Pub. L. 101–239, title VI, §6601(c)(1)–(7), Dec. 19, 1989, 103 Stat. 2285, 2286; Pub. L. 101–502, §5(a), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 102–168, title II, §201(h)(1), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–43, title XX, §2012, June 10, 1993, 107 Stat. 214; Pub. L. 105–277, div. C, title XV, §1502, Oct. 21, 1998, 112 Stat. 2681–741; Pub. L. 106–310, div. A, title XVII, §1701(a), Oct. 17, 2000, 114 Stat. 1151; Pub. L. 114–255, div. A, title III, §3093(c)(2), (3), Dec. 13, 2016, 130 Stat. 1152.)

Editorial Notes

Codification

In subsecs. (a)(2)(A), (3), (4), (5)(A), (8), and (b)(1)(B), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 300aa–11, act July 1, 1944, §2112, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

A prior section 2111 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

Amendments

2016—Subsec. (b)(2). Pub. L. 114–255, §3093(c)(3), inserted at end "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine."

Subsec. (f). Pub. L. 114–255, §3093(c)(2), added subsec. (f).

2000—Subsec. (c)(1)(D)(iii). Pub. L. 106–310 added cl. (iii).

1998—Subsec. (c)(1)(D)(i). Pub. L. 105–277 struck out "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000" before ", or (ii) died".

1993—Subsec. (a)(10). Pub. L. 103–43 added par. (10).

1992—Subsec. (a)(1), (2)(A)(i)(I). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (a)(2)(A)(i), (ii). Pub. L. 102–168 realigned margins of cls. (i) and (ii).

1990—Subsec. (a)(2)(A). Pub. L. 101–502, §5(a)(1), substituted "unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—" and cls. (i) and (ii) for "unless—

"(i) a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death,

"(ii) the United States Claims Court has issued a judgment under section 300aa–12 of this title on such petition, and

"(iii) such person elects under section 300aa–21(a) of this title to file such an action."

Subsec. (a)(5)(A). Pub. L. 101–502, §5(a)(2), struck out "without prejudice" after "without prejudice or costs".

Subsec. (a)(5)(B). Pub. L. 101–502, §5(a)(3), substituted "plaintiff" for "plaintiff who".

Subsec. (d). Pub. L. 101–502, §5(a)(4), struck out "(d) except as provided in paragraph (3)," before "(d) Additional information".

Subsec. (e). Pub. L. 101–502, §5(a)(5), substituted "(e) Schedule" for "(e)(e) Schedule".

1989—Subsec. (a)(1). Pub. L. 101–239, §6601(c)(1), substituted "filing of a petition containing the matter prescribed in subsection (c)" for "filing of a petition" and inserted at end "The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title."

Subsec. (a)(2)(A)(i). Pub. L. 101–239, §6601(c)(2), struck out "under subsection (b) of this section" after "section 300aa–16 of this title,".

Subsec. (a)(5)(A). Pub. L. 101–239, §6601(c)(3)(A), substituted "petition to have such action dismissed without prejudice or costs" for "elect to withdraw such action".

Subsec. (a)(5)(B). Pub. L. 101–239, §6601(c)(3)(B), substituted "has pending" for "on October 1, 1988, had pending" and struck out "does not withdraw the action under subparagraph (A)" after "vaccine-related injury or death".

Subsec. (a)(6). Pub. L. 101–239, §6601(c)(4), substituted "November 15, 1988" for "the effective date of this subpart" in two places.

Subsec. (a)(8). Pub. L. 101–239, §6601(c)(5), added par. (8). Former par. (8) redesignated (9).

Subsec. (a)(9). Pub. L. 101–239, §6601(c)(5), (7), redesignated par. (8) as (9) and realigned margin.

Subsec. (c)(1). Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(1)" in introductory provisions.

Subsec. (c)(2). Pub. L. 101–239, §6601(c)(6)(B), (C), added par. (2) and redesignated former par. (2) as subsec. (d).

Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(2)".

Subsec. (c)(3). Pub. L. 101–239, §6601(c)(6)(C), (D), added par. (3). Former par. (3) redesignated subsec. (e).

Subsec. (d). Pub. L. 101–239, §6601(c)(6)(B), redesignated former subsec. (c)(2) as subsec. (d), expanded margin to full measure, inserted subsec. designation and heading, substituted "A petition may also include other available" for "all available", struck out "(including autopsy reports, if any)" after "relevant medical records", and substituted "administration of the vaccine." for "administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and".

Subsec. (e). Pub. L. 101–239, §6601(c)(6)(D), redesignated former subsec. (c)(3) as subsec. (e), expanded margin to full measure, inserted subsec. designation and heading, and substituted "The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition" for "appropriate".

1987—Subsec. (a)(1). Pub. L. 100–203, §4307(1), which directed that par. (1) be amended by substituting "with the United States Claims Court" for "with the United States district court for the district in which the petitioner resides or the injury or death occurred", was executed making the substitution for "with the United States district court for the district in which the petitioner resides or in which the injury or death occurred", as the probable intent of Congress.

Subsec. (a)(2)(A). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(2)(A)(ii). Pub. L. 100–203, §4307(2), substituted "the United States Claims Court" for "a district court of the United States".

Subsec. (a)(3). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(4). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(5)(A). Pub. L. 100–203, §4302(b)(2), substituted "after the effective date of this subpart" for "after the effective date of this subchapter".

Pub. L. 100–203, §4302(b)(1), substituted "who on the effective date of this subpart" for "who on the effective date of this part".

Subsec. (a)(5)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(6). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part" in two places.

Subsec. (a)(7). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Subsec. (a)(8). Pub. L. 100–203, §4304(a), added par. (8).

Subsec. (b)(1)(A). Pub. L. 100–203, §4304(b)(1), substituted "may, if the person meets the requirements of subsection (c)(1), file" for "may file".

Subsec. (b)(1)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (c)(1)(D). Pub. L. 100–203, §4304(b)(2), substituted "for more than 6 months" for "for more than 1 year", "and incurred" for ", (ii) incurred", and "(ii)" for "(iii)".

Statutory Notes and Related Subsidiaries

Change of Name

References to United States Claims Court deemed to refer to United States Court of Federal Claims, see section 902(b) of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 2000 Amendment

Pub. L. 106–310, div. A, title XVII, §1701(b), Oct. 17, 2000, 114 Stat. 1151, provided that: "The amendment made by subsection (a) [amending this section] takes effect upon the date of the enactment of this Act [Oct. 17, 2000], including with respect to petitions under section 2111 of the Public Health Service Act [42 U.S.C. 300aa–11] that are pending on such date."

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Pub. L. 102–168, title II, §201(i), Nov. 26, 1991, 105 Stat. 1104, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–12, 300aa–15, 300aa–16, 300aa–19, and 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title] shall take effect on the date of the enactment of this Act [Nov. 26, 1991].

"(2) The amendments made by subsections (d) and (f) [amending sections 300aa–12, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as if the amendments had been in effect on and after October 1, 1988."

Effective Date of 1990 Amendment

Pub. L. 101–502, §5(h), Nov. 3, 1990, 104 Stat. 1289, provided that: "The amendments made by subsections (f)(1) and (g) [amending section 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title and enacting provisions set out as a note under section 300aa–12 of this title] shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) [amending this section and sections 300aa–12, 300aa–13, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as of September 30, 1990."

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] *See Change of Name note below.*

§300aa–12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa–11 of

this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa–11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa–11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa–11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's [1] judgment with such court of appeals.

(g) Notice

If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa–21(b) of this title or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be.

(July 1, 1944, ch. 373, title XXI, §2112, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3761; amended Pub. L. 100–203, title IV, §§4303(d)(2)(A), 4307(3), 4308(a), (b), Dec. 22, 1987, 101 Stat. 1330–222, 1330-224; Pub. L. 100–360, title IV, §411(o)(2), (3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(d)–(i), Dec. 19, 1989, 103 Stat. 2286–2290; Pub. L. 101–502, §5(b), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117; Pub. L. 102–168, title II, §201(c), (d)(1), (h)(2), (3), Nov. 26, 1991, 105 Stat. 1103, 1104; Pub. L. 102–572, title IX, §902(b), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(c), Aug. 10, 1993, 107 Stat. 646.)

Editorial Notes

Codification

In subsec. (c)(4), "on December 19, 1989," substituted for "upon the date of the enactment of this subsection" and "on the date of the enactment of this subsection".

In subsec. (d)(3)(D), "October 1, 1988," substituted for "the effective date of this part".

Prior Provisions

A prior section 300aa–12, act July 1, 1944, §2113, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

A prior section 2112 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

Amendments

1993—Subsec. (d)(3)(D). Pub. L. 103–66 substituted "30 months (but for not more than 6 months at a time)" for "540 days".

1992—Subsecs. (a), (c) to (g). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" and "Court of Federal Claims" for "Claims Court", wherever appearing.

1991—Subsec. (d)(3)(D). Pub. L. 102–168, §201(c), (h)(2), realigned margin and substituted "540 days" for "180 days".

Subsec. (g). Pub. L. 102–168, §201(h)(3), made technical amendment to underlying provisions of original Act.

Pub. L. 102–168, §201(d)(1), substituted "or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be" for "and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take certain actions" before period at end.

1990—Subsec. (d)(3)(D). Pub. L. 101–502, §5(b)(1), added subpar. (D).

Subsec. (g). Pub. L. 101–502, §5(b)(2), added subsec. (g).

1989—Subsec. (a). Pub. L. 101–239, §6601(d), substituted "and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction" for "shall have jurisdiction (1)", ". The United States Claims Court may issue" for ", and (2) to issue", and "deems" for "deem".

Subsec. (b)(1). Pub. L. 101–239, §6601(f), substituted "In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28." for "The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 300aa–11(b) of this title. Except as provided in paragraph (2), no other person may intervene in any such proceeding."

Subsec. (c). Pub. L. 101–239, §6601(e)(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 101–239, §6601(e)(1), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (d)(1). Pub. L. 101–239, §6601(g)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Following receipt of a petition under subsection (a) of this section, the United States Claims Court shall designate a special master to carry out the functions authorized by paragraph (2)."

Subsec. (d)(2) to (4). Pub. L. 101–239, §6601(g)(2), added pars. (2) to (4) and struck out former par. (2) which prescribed functions of special masters.

Subsec. (e). Pub. L. 101–239, §6601(h), substituted "Action by United States Claims Court" for "Action by court" as heading and amended text generally. Prior to amendment, text read as follows:

"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed."

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 101–239, §6601(i), inserted "within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals" after "with such court of appeals".

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (e) as (f).

1988—Subsec. (c)(2). Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(a), see 1987 Amendment note below.

Subsec. (e). Pub. L. 100–360, §411(o)(2), made technical amendment to directory language of Pub. L. 100–203, §4307(3)(C), see 1987 Amendment note below.

Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(b), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4307(3)(A), substituted "United States Claims Court" for "district courts of the United States" and "the court" for "the courts".

Subsec. (c)(1). Pub. L. 100–203, §4307(3)(B), substituted "the United States Claims Court" for "the district court of the United States in which the petition is filed".

Subsec. (c)(2). Pub. L. 100–203, §4308(a), as added by Pub. L. 100–360, §411(o)(3)(A), inserted ", shall prepare and submit to the court proposed findings of fact and conclusions of law," in introductory provisions and struck out subpar. (E) which read as follows: "prepare and submit to the court proposed findings of fact and conclusions of law."

Subsec. (e). Pub. L. 100–203, §4308(b), as added by Pub. L. 100–360, §411(o)(3)(A), inserted "within 60 days of the date of the judgment" after "petition filed".

Pub. L. 100–203, §4307(3)(C), as amended by Pub. L. 100–360, §411(o)(2), substituted "the United States Claims Court" for "a district court of the United States" and "for the Federal Circuit" for "for the circuit in which the court is located".

Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e) and struck out former subsec. (e) relating to administration of an award.

Subsec. (f). Pub. L. 100–203, §4303(d)(2)(A), struck out subsec. (f) which related to revision of an award.

Subsec. (g). Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e).

Statutory Notes and Related Subsidiaries

Change of Name

"United States magistrate judges" substituted for "United States magistrates" in subsec. (c)(6)(C) pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and

Judicial Procedure.

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by section 201(d)(1) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 240-day period prescribed in subsec. (d) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Termination of Reporting Requirements

For termination, effective May 15, 2000, of provisions in subsec. (c)(6)(E) of this section relating to reporting annually to the Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 13 of House Document No. 103–7.

Review by 3-Judge Panel

Section 322(c) of Pub. L. 99–660, as added by Pub. L. 101–502, §5(g)(2), Nov. 3, 1990, 104 Stat. 1288, and amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that: "If the review authorized by section 2112(f) [42 U.S.C. 300aa–12(f)] is held invalid because the judgment of the United States Court of Federal Claims being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Court of Federal Claims. Such panel shall not include the judge who participated in such judgment."

[Enactment of section 322(c) of Pub. L. 99–660 by section 5(g)(2) of Pub. L. 101–502, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

[1] *So in original. Probably should be a reference to the United States Court of Federal Claims.*

§300aa–13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa–11 of this title.

(July 1, 1944, ch. 373, title XXI, §2113, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3763; amended Pub. L. 100–203, title IV, §4307(4), Dec. 22, 1987, 101 Stat. 1330–224; Pub. L. 101–239, title VI, §6601(j), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 101–502, §5(c), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Editorial Notes

Prior Provisions

A prior section 300aa–13, act July 1, 1944, §2114, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

A prior section 2113 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

Amendments

1992—Subsec. (c). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

1990—Subsec. (c). Pub. L. 101–502 inserted "the" after "special masters of".

1989—Subsecs. (a)(1), (b). Pub. L. 101–239, §6601(j)(1), substituted "special master or court" for "court" wherever appearing.

Subsec. (c). Pub. L. 101–239, §6601(j)(2), inserted "special masters of" after "established by the".

1987—Subsec. (c). Pub. L. 100–203 substituted "the United States Claims Court" for "a district court of the United States".

Statutory Notes and Related Subsidiaries

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above	Not applicable

which illness, disability, injury, or condition arose within the time period prescribed	

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) Vaccines recommended for use in pregnant women

The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.

(July 1, 1944, ch. 373, title XXI, §2114, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3764; amended Pub. L. 101–239, title VI, §6601(k), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 103–66, title XIII, §13632(a)(2), Aug. 10, 1993, 107 Stat. 645; Pub. L. 114–255, div. A, title III, §3093(c)(1), Dec. 13, 2016, 130 Stat. 1152.)

Editorial Notes

Prior Provisions

A prior section 300aa–14, act July 1, 1944, §2115, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

A prior section 2114 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

Amendments

2016—Subsec. (e)(3). Pub. L. 114–255 added par. (3).

1993—Subsec. (e). Pub. L. 103–66 amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: "The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table."

1989—Subsec. (a). Pub. L. 101–239, §6601(k)(1), substituted "(b)(2)" for "(c)(2)" in items I.D. and II.C. in table.

Subsec. (b)(3)(B). Pub. L. 101–239, §6601(k)(2), substituted "300aa–11 of this title" for "300aa–11(b) of this title".

Statutory Notes and Related Subsidiaries

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Revisions of Vaccine Injury Table

The Vaccine Injury Table as modified by regulations promulgated by the Secretary of Health and Human Services is set out at 42 CFR 100.3.

Pub. L. 103–66, title XIII, §13632(a)(3), Aug. 10, 1993, 107 Stat. 646, provided that: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for

compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a))."

§300aa–15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa–16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e).[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before October 1, 1988, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before October 1, 1988, in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa–11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa–21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa–12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa–21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa–21(a) of this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1988, shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title XXI, §2115, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3767; amended Pub. L. 100–203, title IV, §§4302(b), 4303(a)–(d)(1), (e), (g), 4307(5), (6), Dec. 22, 1987, 101 Stat. 1330–221 to 1330-223, 1330-225; Pub. L. 100–360, title IV, §411(o)(1), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(c)(8), (l), Dec. 19, 1989, 103 Stat. 2286, 2290; Pub. L. 101–502, §5(d), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(e), (f), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–531, title III, §314, Oct. 27, 1992, 106 Stat. 3508; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(b), Aug. 10, 1993, 107 Stat. 646.)

Editorial Notes

References in Text

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in subsec. (f)(3), is title II of Pub. L. 99–177, Dec. 12, 1985, 99 Stat. 1038. Part C of the Act is classified generally to subchapter I (§900 et seq.) of chapter 20 of Title 2, The Congress. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Codification

In subsecs. (a), (b), (e)(2), (f)(4)(B), (i), and (j), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 300aa–15, act July 1, 1944, §2116, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

A prior section 2115 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

Amendments

1993—Subsec. (j). Pub. L. 103–66 substituted "$110,000,000 for each succeeding fiscal year" for "$80,000,000 for each succeeding fiscal year".

1992—Subsecs. (e)(1), (f)(2). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

Subsec. (j). Pub. L. 102–531 increased authorization for fiscal year 1993 from $80,000,000 to $110,000,000.

1991—Subsec. (f)(4)(A). Pub. L. 102–168, §201(e)(1)(A), (2), struck out "of the proceeds" after "portion" and substituted "Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "trust fund".

Subsec. (f)(4)(B). Pub. L. 102–168, §201(e)(1)(B), which directed substitution of "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion" for "paid in 4 equal installments of which all or portion of the proceeds" was executed by making the substitution for

"paid in 4 equal annual installments of which all or a portion of the proceeds" to reflect the probable intent of Congress.

Subsec. (f)(4)(C). Pub. L. 102–168, §201(f), added subpar. (C).

1990—Subsec. (e)(2). Pub. L. 101–502, §5(d)(1), inserted "of compensation" before "limited to the costs".

Subsec. (f)(2). Pub. L. 101–502, §5(d)(2)(A), substituted "section 300aa–21(a)" for "section 300aa–21(b)".

Subsec. (f)(4)(B). Pub. L. 101–502, §5(d)(2)(B), substituted "subsection (j)" for "subsection (i)" and "the limitation on civil actions prescribed by section 300aa–21(a) of this title" for "section 300aa–11(a) of this title".

Subsec. (j). Pub. L. 101–502, §5(d)(3), inserted before period at end of first sentence ", and $80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B)".

1989—Subsec. (b). Pub. L. 101–239, §6601(l)(1), substituted "may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—" and cls. (1) to (3) for "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000."

Subsec. (e)(1). Pub. L. 101–239, §6601(l)(2)(A), substituted "In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover" for "The judgment of the United States Claims Court on a petition filed under section 300aa–11 of this title awarding compensation shall include an amount to cover".

Pub. L. 101–239, §6601(l)(2)(B), (C), substituted "the special master or court may award an amount of compensation to cover" for "the court may include in the judgment an amount to cover" and "the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition" for "the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action".

Subsec. (e)(2). Pub. L. 101–239, §6601(l)(2)(D), which directed amendment of par. (2) by substituting "the special master or court may also award an amount of compensation" for "the judgment of the court on such petition may include an amount", could not be executed because of the prior amendment by Pub. L. 101–239, §6601(c)(8)(B), see Amendment note below.

Pub. L. 101–239, §6601(c)(8), substituted "and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed" for "and elected under section 300aa–11(a)(4) of this title to withdraw such action" and "in awarding compensation on such petition the special master or court may include" for "the judgment of the court on such petition may include".

Subsec. (e)(3). Pub. L. 101–239, §6601(l)(2)(E), substituted "awarded as compensation by the special master or court under paragraph (1)" for "included under paragraph (1) in a judgment on such petition".

Subsec. (f)(3). Pub. L. 101–239, §6601(l)(3)(A), inserted "under the Program and the costs of carrying out the Program" after "Payments of compensation".

Subsec. (f)(4)(A). Pub. L. 101–239, §6601(l)(3)(B), struck out "made in a lump sum" after "the Program shall be" and inserted "and shall be paid from the trust fund in a lump sum of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner" after "elements of the compensation".

Subsec. (f)(4)(B). Pub. L. 101–239, §6601(l)(3)(C), substituted "determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum" for "paid in 4 equal annual installments".

Subsec. (g). Pub. L. 101–239, §6601(l)(4)(A), inserted "(other than under title XIX of the Social Security Act)" after "State health benefits program".

Subsec. (h). Pub. L. 101–239, §6601(l)(4)(B), inserted before period at end ", except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act".

Subsec. (i)(1). Pub. L. 101–239, §6601(l)(5), which directed amendment of par. (1) by substituting "(j)" for "(i)", could not be executed because "(i)" did not appear.

Subsec. (j). Pub. L. 101–239, §6601(l)(6), struck out "and" after "fiscal year 1991," and inserted ", $80,000,000 for fiscal year 1993" after "fiscal year 1992".

1988—Subsec. (i)(1). Pub. L. 100–360, §411(o)(1)(A), substituted "by the Secretary from appropriations under subsection (j)" for "from appropriations under subsection (i)".

Subsec. (j). Pub. L. 100–360, §411(o)(1)(B), inserted "to the Department of Health and Human Services".

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Pub. L. 100–203, §4303(d)(1)(A), struck out last two sentences which read as follows: "Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum."

Subsec. (a)(1). Pub. L. 100–203, §4303(c), struck out last sentence of subpars. (A) and (B) each of which read as follows: "The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa–11(c)(1)(D)(ii) of this title."

Subsec. (b). Pub. L. 100–203, §4303(e), substituted "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000" for "shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e)(1). Pub. L. 100–203, §4307(5), substituted "of the United States Claims Court" for "of a court" in two places.

Subsec. (e)(2). Pub. L. 100–203, §4302(b), substituted "effective date of this subpart, filed a" for "effective date of this subchapter, filed a" and "effective date of this subpart in preparing" for "effective date of this part in preparing".

Subsec. (f). Pub. L. 100–203, §4303(d)(1)(B), (g), added par. (4) and redesignated a second subsec. (f), relating to the Program not being primarily liable, as subsec. (g).

Subsec. (f)(2). Pub. L. 100–203, §4307(6), substituted "United States Claims Court" for "district court of the United States".

Subsecs. (g), (h). Pub. L. 100–203, §4303(g), redesignated a second subsec. (f), relating to the Program not being liable, as (g) and redesignated former subsec. (g) as (h).

Subsecs. (i), (j). Pub. L. 100–203, §4303(a), (b), added subsecs. (i) and (j).

Statutory Notes and Related Subsidiaries

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by section 201(f) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

Amendment by Pub. L. 101–239 applicable to all pending and subsequently filed petitions, see section 6601(s)(2) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

[1] *So in original. Probably should be preceded by another closing parenthesis.*

§300aa–16. Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before October 1, 1988, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if —

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa–11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action or (2) an election is made under section 300aa–21(b) of this title to withdraw the petition.

(July 1, 1944, ch. 373, title XXI, §2116, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3769; amended Pub. L. 100–203, title IV, §4302(b)(2), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(m)(1), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(e), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(2), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 103–66, title XIII, §13632(a)(1), Aug. 10, 1993, 107 Stat. 645.)

Editorial Notes

Codification

In subsec. (a)(1) to (3), "October 1, 1988" and "October 1, 1988," substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 2116 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

Amendments

1993—Subsec. (b). Pub. L. 103–66 substituted "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file" for "such person may file".

1991—Subsec. (c). Pub. L. 102–168 substituted "or (2)" for ", (2)" and struck out ", or (3) the petition is considered withdrawn under section 300aa–21(b) of this title."

1990—Subsec. (a)(1). Pub. L. 101–502, §5(e)(1), substituted "28 months" for "24 months" and inserted before comma at end "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine".

Subsec. (c). Pub. L. 101–502, §5(e)(2), substituted "and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action, (2) an election is made under section 300aa–21(b)

of this title to withdraw the petition, or (3) the petition is considered withdrawn under section 300aa–21(b) of this title" for "and ending on the date a final judgment is entered on the petition".

1989—Subsec. (c). Pub. L. 101–239 substituted "300aa–11 of this title" for "300aa–11(b) of this title".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this subchapter" in pars. (1) to (3).

Statutory Notes and Related Subsidiaries

Effective Date of 1991 Amendment

Amendment by Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–17. Subrogation

(a) General rule

Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrograted [1] to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) Disposition of amounts recovered

Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(July 1, 1944, ch. 373, title XXI, §2117, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3770; amended Pub. L. 100–203, title IV, §4307(7), Dec. 22, 1987, 101 Stat. 1330–225; Pub. L. 101–239, title VI, §6601(m)(2), Dec. 19, 1989, 103 Stat. 2291.)

Editorial Notes

Amendments

1989—Subsec. (b). Pub. L. 101–239 substituted "the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "the trust fund which has been established to provide compensation under the Program".

1987—Subsec. (a). Pub. L. 100–203 struck out par. (1) designation before "Upon" and struck out par. (2) which read as follows: "In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 300aa–15 of this title for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1)."

Statutory Notes and Related Subsidiaries

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] *So in original. Probably should be "subrogated".*

§300aa–18. Repealed. Pub. L. 100–203, title IV, §4303(d)(2)(B), Dec. 22, 1987, 101 Stat. 1330–222

Section, act July 1, 1944, ch. 373, title XXI, §2118, as added Nov. 14, 1986, Pub. L. 99–660, title III, §311(a), 100 Stat. 3771, provided for annual increases for inflation of compensation under subsections (a)(2) and (a)(4) of section 300aa–15 of this title and civil penalty under section 300aa–27(b) of this title.

§300aa–19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of October 1, 1988. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5 for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa–27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of

section 300aa–25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

(July 1, 1944, ch. 373, title XXI, §2119, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3771; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(g), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–531, title III, §312(d)(14), Oct. 27, 1992, 106 Stat. 3505.)

Editorial Notes

Codification

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1992—Subsec. (a)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1991—Subsec. (c). Pub. L. 102–168 inserted "present at the meeting" before period at end.

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part" in last sentence.

Statutory Notes and Related Subsidiaries

Termination of Advisory Commissions

Advisory commissions established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a commission established by the President or an officer of the Federal Government, such commission is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a commission established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

References in Other Laws to GS–16, 17, or 18 Pay Rates

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

SUBPART B—ADDITIONAL REMEDIES

§300aa–21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa–12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa–11 of this title shall file with the clerk of the United States Court of Federal Claims—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection

does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa–11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa–11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa–12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa–12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa–12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa–11 of this title shall, except as provided in section 300aa–16(c) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, ch. 373, title XXI, §2121, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3772; amended Pub. L. 100–203, title IV, §§4304(c), 4307(8), 4308(c), Dec. 22, 1987, 101 Stat. 1330–224, 1330-225; Pub. L. 100–360, title IV, §411(o)(3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(n), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(f), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(3), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Editorial Notes

Codification

In subsec. (a), "October 1, 1988," and "October 1, 1988" substituted for "the effective date of this part".

Amendments

1992—Subsecs. (a), (b). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (b). Pub. L. 102–168 substituted "Continuance or withdrawal of petition" for "Withdrawal of petition" in heading, redesignated introductory provisions of par. (1) as introductory provisions of subsec. (b) and substituted "a notice in writing choosing to continue or to withdraw the petition" for "a notice in writing withdrawing the petition", redesignated subpars. (A) and (B) of former par. (1) as pars. (1) and (2), respectively, and realigned margins, struck out at end of former par. (1) "If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph.", and struck out par. (2) which read as follows: "If a special master or the court does not enter a decision or make a judgment on a petition filed under section 300aa–11 of this title within 30 days of the provision of the notice in accordance with section 300aa–12(g) of this title, the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under paragraph (1)."

1990—Subsec. (a). Pub. L. 101–502, §5(f)(1), in closing provisions, inserted after second sentence "If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered." and inserted "for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988" after "actions" in last sentence.

Subsec. (b). Pub. L. 101–502, §5(f)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "If the United States Claims Court fails to enter a judgment under section 300aa–12 of this title on a petition filed under section 300aa–11 of this title within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special

master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed, the petitioner may submit to the court a notice in writing withdrawing the petition. An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made. A person who has submitted a notice under this subsection may, notwithstanding section 300aa–11(a)(2) of this title, thereafter maintain a civil action for damages in a State or Federal court without regard to this subpart and consistent with otherwise applicable law."

1989—Subsec. (a). Pub. L. 101–239, §6601(n)(1)(A), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: "After the judgment of the United States Claims Court under section 300aa–11 of this title on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court —".

Pub. L. 101–239, §6601(n)(1)(B), amended last sentence generally. Prior to amendment, last sentence read as follows: "If a person elects to receive compensation under a judgment of the court or is deemed to have accepted the judgment of the court, such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered."

Subsec. (b). Pub. L. 101–239, §6601(n)(2), substituted "within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title)" for "within 365 days" in first sentence and amended second sentence generally. Prior to amendment, second sentence read as follows: "Such a notice shall be filed not later than 90 days after the expiration of such 365-day period."

1988—Subsec. (a). Pub. L. 100–360 added Pub. L. 100–203, §4308(c), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4308(c), as added by Pub. L. 100–360, substituted "the court's final judgment" for "the entry of the court's judgment" in concluding provisions.

Pub. L. 100–203, §4307(8), substituted "the United States Claims Court" for "a district court of the United States" and "the court" for "a court" in three places.

Subsecs. (b), (c). Pub. L. 100–203, §4304(c), added subsec. (b) and redesignated former subsec. (b) as (c).

Statutory Notes and Related Subsidiaries

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by Pub. L. 102–168 effective as in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by section 5(f)(1) of Pub. L. 101–502 effective Nov. 14, 1986, and amendment by section 5(f)(2) of Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 420-day period prescribed in subsec. (b) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Effective Date

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa–23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

(July 1, 1944, ch. 373, title XXI, §2122, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3773; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

Codification

In subsecs. (b)(1), (c), "October 1, 1988" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsecs. (b)(1), (c). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

§300aa–23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa–11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa–22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

(July 1, 1944, ch. 373, title XXI, §2123, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §§4302(b)(1), 4307(9), Dec. 22, 1987, 101 Stat. 1330–221, 1330-225; Pub. L. 101–239, title VI, §6601(o), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (d)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

Codification

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1992—Subsec. (e). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" in two places.

1989—Subsec. (e). Pub. L. 101–239 substituted "finding of fact or conclusion of law" for "finding", "special master" for "master appointed by such court", and directed substitution of "the United States Claims Court and subsequent appellate review" for "a district court of the United States" which was executed by inserting "and subsequent appellate review" after "the United States Claims Court" the second place it appeared to reflect the probable intent of Congress and the amendment by Pub. L. 100–203, §4307(a), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e). Pub. L. 100–203, §4307(9), substituted "the United States Claims Court" for "a district court of the United States" in two places.

EFFECTIVE DATE OF 1992 AMENDMENT

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

EFFECTIVE DATE OF 1989 AMENDMENT

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

SUBPART C—ASSURING A SAFER CHILDHOOD VACCINATION PROGRAM IN UNITED STATES

§300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Editorial Notes

Codification

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsec. (b)(1), (3). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Statutory Notes and Related Subsidiaries

Effective Date

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–26. Vaccine information

(a) General rule

Not later than 1 year after December 22, 1987, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

(2) a concise description of the risks associated with the vaccine,

(3) a statement of the availability of the National Vaccine Injury Compensation Program, and

(4) such other relevant information as may be determined by the Secretary.

(d) Health care provider duties

On and after a date determined by the Secretary which is—

(1) after the Secretary develops the information materials required by subsection (a), and

(2) not later than 6 months after the date such materials are published in the Federal Register,

each health care provider who administers a vaccine set forth in the Vaccine Injury Table shall provide to the legal representatives of any child or to any other individual to whom such provider intends to administer such vaccine a copy of the information materials developed pursuant to subsection (a), supplemented with visual presentations or oral explanations, in appropriate cases. Such materials shall be provided prior to the administration of such vaccine.

(July 1, 1944, ch. 373, title XXI, §2126, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3775; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(p), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–531, title III, §312(d)(15), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103–183, title VII, §708, Dec. 14, 1993, 107 Stat. 2242.)

Editorial Notes

Codification

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1993—Subsec. (a). Pub. L. 103–183, §708(c), inserted "or to any other individual" after "to the legal representatives of any child".

Subsec. (b). Pub. L. 103–183, §708(a), struck out "by rule" after "revised" in introductory provisions and substituted "and 60" for ", opportunity for a public hearing, and 90" in par. (1).

Subsec. (c). Pub. L. 103–183, §708(b), inserted in introductory provisions "shall be based on available data and information," after "such materials", added pars. (1) to (4), and struck out former pars. (1) to (10) which read as follows:

"(1) the frequency, severity, and potential long-term effects of the disease to be prevented by the vaccine,

"(2) the symptoms or reactions to the vaccine which, if they occur, should be brought to the immediate attention of the health care provider,

"(3) precautionary measures legal representatives should take to reduce the risk of any major adverse reactions to the vaccine that may occur,

"(4) early warning signs or symptoms to which legal representatives should be alert as possible precursors to such major adverse reactions,

"(5) a description of the manner in which legal representatives should monitor such major adverse reactions, including a form on which reactions can be recorded to assist legal representatives in reporting information to appropriate authorities,

"(6) a specification of when, how, and to whom legal representatives should report any major adverse reaction,

"(7) the contraindications to (and bases for delay of) the administration of the vaccine,

"(8) an identification of the groups, categories, or characteristics of potential recipients of the vaccine who may be at significantly higher risk of major adverse reaction to the vaccine than the general population,

"(9) a summary of—

"(A) relevant Federal recommendations concerning a complete schedule of childhood immunizations, and

"(B) the availability of the Program, and

"(10) such other relevant information as may be determined by the Secretary."

Subsec. (d). Pub. L. 103–183, §708(c), (d), in concluding provisions, inserted "or to any other individual" after "to the legal representatives of any child", substituted "supplemented with visual presentations or oral explanations, in appropriate cases" for "or other written information which meets the requirements of this section", and struck out "or other information" after "Such materials".

1992—Subsec. (b)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1989—Subsec. (c)(9). Pub. L. 101–239 amended par. (9) generally. Prior to amendment, par. (9) read as follows: "a summary of relevant State and Federal laws concerning the vaccine, including information on —

"(A) the number of vaccinations required for school attendance and the schedule recommended for such vaccinations, and

"(B) the availability of the Program, and".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Statutory Notes and Related Subsidiaries

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–27. Mandate for safer childhood vaccines

(a) General rule

In the administration of this part and other pertinent laws under the jurisdiction of the Secretary, the Secretary shall—

(1) promote the development of childhood vaccines that result in fewer and less serious adverse reactions than those vaccines on the market on December 22, 1987, and promote the refinement of such vaccines, and

(2) make or assure improvements in, and otherwise use the authorities of the Secretary with respect to, the licensing, manufacturing, processing, testing, labeling, warning, use instructions, distribution, storage, administration, field surveillance, adverse reaction reporting, and recall of reactogenic lots or batches, of vaccines, and research on vaccines, in order to reduce the risks of adverse reactions to vaccines.

(b) Task force

(1) The Secretary shall establish a task force on safer childhood vaccines which shall consist of the Director of the National Institutes of Health, the Commissioner of the Food and Drug Administration, and the Director of the Centers for Disease Control.

(2) The Director of the National Institutes of Health shall serve as chairman of the task force.

(3) In consultation with the Advisory Commission on Childhood Vaccines, the task force shall prepare recommendations to the Secretary concerning implementation of the requirements of subsection (a).

(c) Report

Within 2 years after December 22, 1987, and periodically thereafter, the Secretary shall prepare and transmit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the actions taken pursuant to subsection (a) during the preceding 2-year period.

(July 1, 1944, ch. 373, title XXI, §2127, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(q), Dec. 19, 1989, 103 Stat. 2292.)

Editorial Notes

Codification

In subsecs. (a)(1), (c), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1989—Subsecs. (b), (c). Pub. L. 101–239 added subsec. (b) and redesignated former subsec. (b) as (c).

1987—Subsecs. (a)(1), (b). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Statutory Notes and Related Subsidiaries

Change of Name

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–28. Manufacturer recordkeeping and reporting

(a) General rule

Each vaccine manufacturer of a vaccine set forth in the Vaccine Injury Table or any other vaccine the administration of which is mandated by the law or regulations of any State, shall, with respect to each batch, lot, or other quantity

manufactured or licensed after December 22, 1987—

(1) prepare and maintain records documenting the history of the manufacturing, processing, testing, repooling, and reworking of each batch, lot, or other quantity of such vaccine, including the identification of any significant problems encountered in the production, testing, or handling of such batch, lot, or other quantity,

(2) if a safety test on such batch, lot, or other quantity indicates a potential imminent or substantial public health hazard is presented, report to the Secretary within 24 hours of such safety test which the manufacturer (or manufacturer's representative) conducted, including the date of the test, the type of vaccine tested, the identity of the batch, lot, or other quantity tested, whether the batch, lot, or other quantity tested is the product of repooling or reworking of previous batches, lots, or other quantities (and, if so, the identity of the previous batches, lots, or other quantities which were repooled or reworked), the complete test results, and the name and address of the person responsible for conducting the test,

(3) include with each such report a certification signed by a responsible corporate official that such report is true and complete, and

(4) prepare, maintain, and upon request submit to the Secretary product distribution records for each such vaccine by batch, lot, or other quantity number.

(b) Sanction

Any vaccine manufacturer who intentionally destroys, alters, falsifies, or conceals any record or report required under paragraph (1) or (2) of subsection (a) shall—

(1) be subject to a civil penalty of up to $100,000 per occurrence, or

(2) be fined $50,000 or imprisoned for not more than 1 year, or both.

Such penalty shall apply to the person who intentionally destroyed, altered, falsified, or concealed such record or report, to the person who directed that such record or report be destroyed, altered, falsified, or concealed, and to the vaccine manufacturer for which such person is an agent, employee, or representative. Each act of destruction, alteration, falsification, or concealment shall be treated as a separate occurrence.

(July 1, 1944, ch. 373, title XXI, §2128, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3777; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Editorial Notes

Codification

In subsec. (a), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Subpart D—General Provisions

§300aa–31. Citizen's actions

(a) General rule

Except as provided in subsection (b), any person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty under this part.

(b) Notice

No action may be commenced under subsection (a) before the date which is 60 days after the person bringing the action has given written notice of intent to commence such action to the Secretary.

(c) Costs of litigation

The court, in issuing any final order in any action under this section, may award costs of litigation (including reasonable attorney and expert witness fees) to any plaintiff who substantially prevails on one or more significant issues in the action.

(July 1, 1944, ch. 373, title XXI, §2131, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 100–203, title IV, §4305, Dec. 22, 1987, 101 Stat. 1330–224.)

Editorial Notes

Amendments

1987—Subsec. (c). Pub. L. 100–203, which directed that subsec. (c) be amended by substituting "to any plaintiff who substantially prevails on one or more significant issues in the action" for "to any party, whenever the court determines that such award is appropriate", was executed by making the substitution for "to any party, whenever the court determines such award is appropriate", to reflect the probable intent of Congress.

Statutory Notes and Related Subsidiaries

Effective Date

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–32. Judicial review

A petition for review of a regulation under this part may be filed in a court of appeals of the United States within 60 days from the date of the promulgation of the regulation or after such date if such petition is based solely on grounds arising after such 60th day.

(July 1, 1944, ch. 373, title XXI, §2132, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778.)

§300aa–33. Definitions

For purposes of this part:

(1) The term "health care provider" means any licensed health care professional, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities) under whose authority a vaccine set forth in the Vaccine Injury Table is administered.

(2) The term "legal representative" means a parent or an individual who qualifies as a legal guardian under State law.

(3) The term "manufacturer" means any corporation, organization, or institution, whether public or private (including Federal, State, and local departments, agencies, and instrumentalities), which manufactures, imports, processes, or distributes under its label any vaccine set forth in the Vaccine Injury Table, except that, for purposes of section 300aa–28 of this title, such term shall include the manufacturer of any other vaccine covered by that section. The term "manufacture" means to manufacture, import, process, or distribute a vaccine.

(4) The term "significant aggravation" means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(5) The term "vaccine-related injury or death" means an illness, injury, condition, or death associated with one or more of the vaccines set forth in the Vaccine Injury Table, except that the term does not include an illness, injury, condition, or death associated with an adulterant or contaminant intentionally added to such a vaccine.

(6)(A) The term "Advisory Commission on Childhood Vaccines" means the Commission established under section 300aa–19 of this title.

(B) The term "Vaccine Injury Table" means the table set out in section 300aa–14 of this title.

(July 1, 1944, ch. 373, title XXI, §2133, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3778; amended Pub. L. 107–296, title XVII, §§1714–1716, Nov. 25, 2002, 116 Stat. 2320, 2321; Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.)

Editorial Notes

Amendments

2003—Pars. (3), (5), (7). Pub. L. 108–7 repealed Pub. L. 107–296, §§1714–1717, and provided that this chapter shall be applied as if the sections repealed had never been enacted. See 2002 Amendment notes below.

2002—Par. (3). Pub. L. 107–296, §1714, which directed amendment of first sentence by substituting "any vaccine set forth in the Vaccine Injury table, including any component or ingredient of any such vaccine" for "under its label any vaccine set forth in the Vaccine Injury Table" and of second sentence by inserting

"including any component or ingredient of any such vaccine" before period at end, was repealed by Pub. L. 108–7.

Par. (5). Pub. L. 107–296, §1715, which directed insertion of "For purposes of the preceding sentence, an adulterant or contaminant shall not include any component or ingredient listed in a vaccine's product license application or product label." at end, was repealed by Pub. L. 108–7.

Par. (7). Pub. L. 107–296, §1716, which directed addition of par. (7), was repealed by Pub. L. 108–7, §102(a). Par. (7) read as follows: "The term 'vaccine' means any preparation or suspension, including but not limited to a preparation or suspension containing an attenuated or inactive microorganism or subunit thereof or toxin, developed or administered to produce or enhance the body's immune response to a disease or diseases and includes all components and ingredients listed in the vaccines's product license application and product label."

Statutory Notes and Related Subsidiaries

Effective Date of 2002 Amendment

Pub. L. 107–296, title XVII, §1717, Nov. 25, 2002, 116 Stat. 2321, which provided that the amendments made by sections 1714, 1715, and 1716 (amending this section) shall apply to all actions or proceedings pending on or after Nov. 25, 2002, unless a court of competent jurisdiction has entered judgment (regardless of whether the time for appeal has expired) in such action or proceeding disposing of the entire action or proceeding, was repealed by Pub. L. 108–7, div. L, §102(a), Feb. 20, 2003, 117 Stat. 528.

Construction of Amendments

Pub. L. 108–7, div. L, §102(b), (c), Feb. 20, 2003, 117 Stat. 528, provided that:

"(b) Application of the Public Health Service Act.—The Public Health Service Act (42 U.S.C. 201 et seq.) shall be applied and administered as if the sections repealed by subsection (a) [repealing sections 1714 to 1717 of Pub. L. 107–296, which amended this section and enacted provisions set out as a note under this section] had never been enacted.

"(c) Rule of Construction.—No inference shall be drawn from the enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296), or from this repeal [repealing sections 1714 to 1717 of Pub. L. 107–296], regarding the law prior to enactment of sections 1714 through 1717 of the Homeland Security Act of 2002 (Public Law 107–296) [Nov. 25, 2002]. Further, no inference shall be drawn that subsection (a) or (b) affects any change in that prior law, or that Leroy v. Secretary of Health and Human Services, Office of Special Master, No. 02–392V (October 11, 2002), was incorrectly decided."

§300aa–34. Termination of program

(a) Reviews

The Secretary shall review the number of awards of compensation made under the program to petitioners under section 300aa–11 of this title for vaccine-related injuries and deaths associated with the administration of vaccines on or after December 22, 1987, as follows:

(1) The Secretary shall review the number of such awards made in the 12-month period beginning on December 22, 1987.

(2) At the end of each 3-month period beginning after the expiration of the 12-month period referred to in paragraph (1) the Secretary shall review the number of such awards made in the 3-month period.

(b) Report

(1) If in conducting a review under subsection (a) the Secretary determines that at the end of the period reviewed the total number of awards made by the end of that period and accepted under section 300aa–21(a) of this title exceeds the number of awards listed next to the period reviewed in the table in paragraph (2)—

(A) the Secretary shall notify the Congress of such determination, and

(B) beginning 180 days after the receipt by Congress of a notification under paragraph (1), no petition for a vaccine-related injury or death associated with the administration of a vaccine on or after December 22, 1987, may be filed under section 300aa–11 of this title.

Section 300aa–11(a) of this title and subpart B of this part shall not apply to civil actions for damages for a vaccine-related injury or death for which a petition may not be filed because of subparagraph (B).

(2) The table referred to in paragraph (1) is as follows:

Period reviewed:	**Total number of awards by the end of the period reviewed**
12 months after December 22, 1987	150
13th through the 15th month after December 22, 1987	188
16th through the 18th month after December 22, 1987	225
19th through the 21st month after December 22, 1987	263
22nd through the 24th month after December 22, 1987	300
25th through the 27th month after December 22, 1987	338
28th through the 30th month after December 22, 1987	375
31st through the 33rd month after December 22, 1987	413
34th through the 36th month after December 22, 1987	450
37th through the 39th month after December 22, 1987	488
40th through the 42nd month after December 22, 1987	525
43rd through the 45th month after December 22, 1987	563
46th through the 48th month after December 22, 1987	600.

(July 1, 1944, ch. 373, title XXI, §2134, as added Pub. L. 100–203, title IV, §4303(f), Dec. 22, 1987, 101 Stat. 1330–222.)

Editorial Notes

Codification

In subsecs. (a) and (b), "December 22, 1987" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Part 2—National Vaccine Injury Compensation Program

subpart a—program requirements

§300aa–10. Establishment of program

(a) Program established

There is established the National Vaccine Injury Compensation Program to be administered by the Secretary under which compensation may be paid for a vaccine-related injury or death.

(b) Attorney's obligation

It shall be the ethical obligation of any attorney who is consulted by an individual with respect to a vaccine-related injury or death to advise such individual that compensation may be available under the program [1] for such injury or death.

(c) Publicity

The Secretary shall undertake reasonable efforts to inform the public of the availability of the Program.

(July 1, 1944, ch. 373, title XXI, §2110, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 101–239, title VI, §6601(b), Dec. 19, 1989, 103 Stat. 2285.)

Editorial Notes

Prior Provisions

A prior section 300aa–10, act July 1, 1944, §2111, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

A prior section 2110 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238g of this title.

Amendments

1989—Subsec. (c). Pub. L. 101–239 added subsec. (c).

Statutory Notes and Related Subsidiaries

Effective Date of 1989 Amendment

Section 6601(s) of Pub. L. 101–239, as amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–11 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] shall apply as follows:

"(A) Petitions filed after the date of enactment of this section [Dec. 19, 1989] shall proceed under the National Vaccine Injury Compensation Program under title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] as amended by this section.

"(B) Petitions currently pending in which the evidentiary record is closed shall continue to proceed under the Program in accordance with the law in effect before the date of the enactment of this section, except that if the United States Court of Federal Claims is to review the findings of fact and conclusions of law of a special master on such a petition, the court may receive further evidence in conducting such review.

"(C) Petitions currently pending in which the evidentiary record is not closed shall proceed under the Program in accordance with the law as amended by this section.

All pending cases which will proceed under the Program as amended by this section shall be immediately suspended for 30 days to enable the special masters and parties to prepare for proceeding under the Program as amended by this section. In determining the 240-day period prescribed by section 2112(d) of the Public Health Service Act [42 U.S.C. 300aa–12(d)], as amended by this section, or the 420-day period prescribed by section 2121(b) of such Act [42 U.S.C. 300aa–21(b)], as so amended, any period of suspension under the preceding sentence shall be excluded.

"(2) The amendments to section 2115 of the Public Health Service Act [42 U.S.C. 300aa–15] shall apply to all pending and subsequently filed petitions."

Effective Date

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, as amended, set out as a note under section 300aa–1 of this title.

[1] So in original. Probably should be capitalized.

§300aa–11. Petitions for compensation

(a) General rule

(1) A proceeding for compensation under the Program for a vaccine-related injury or death shall be initiated by service upon the Secretary and the filing of a petition containing the matter prescribed by subsection (c) with the United States Court of Federal Claims. The clerk of the United States Court of Federal Claims shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title.

(2)(A) No person may bring a civil action for damages in an amount greater than $1,000 or in an unspecified amount against a vaccine administrator or manufacturer in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, and no such court may award damages in an amount greater than $1,000 in a civil action for damages for such a vaccine-related injury or death, unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—

(i)(I) the United States Court of Federal Claims has issued a judgment under section 300aa–12 of this title on such petition, and

(II) such person elects under section 300aa–21(a) of this title to file such an action, or

(ii) such person elects to withdraw such petition under section 300aa–21(b) of this title or such petition is considered withdrawn under such section.

(B) If a civil action which is barred under subparagraph (A) is filed in a State or Federal court, the court shall dismiss the action. If a petition is filed under this section with respect to the injury or death for which such civil action was brought, the date such dismissed action was filed shall, for purposes of the limitations of actions prescribed by section 300aa–16 of this title, be considered the date the petition was filed if the petition was filed within one year of the date of the dismissal of the civil action.

(3) No vaccine administrator or manufacturer may be made a party to a civil action (other than a civil action which may be brought under paragraph (2)) for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988.

(4) If in a civil action brought against a vaccine administrator or manufacturer before October 1, 1988, damages were denied for a vaccine-related injury or death or if such civil action was dismissed with prejudice, the person who brought such action may file a petition under subsection (b) for such injury or death.

(5)(A) A plaintiff who on October 1, 1988, has pending a civil action for damages for a vaccine-related injury or death may, at any time within 2 years after October 1, 1988, or before judgment, whichever occurs first, petition to have such action dismissed without prejudice or costs and file a petition under subsection (b) for such injury or death.

(B) If a plaintiff has pending a civil action for damages for a vaccine-related injury or death, such person may not file a petition under subsection (b) for such injury or death.

(6) If a person brings a civil action after November 15, 1988 for damages for a vaccine-related injury or death associated with the administration of a vaccine before November 15, 1988, such person may not file a petition under subsection (b) for such injury or death.

(7) If in a civil action brought against a vaccine administrator or manufacturer for a vaccine-related injury or death damages are awarded under a judgment of a court or a settlement of such action, the person who brought such action may not file a petition under subsection (b) for such injury or death.

(8) If on October 1, 1988, there was pending an appeal or rehearing with respect to a civil action brought against a vaccine administrator or manufacturer and if the outcome of the last appellate review of such action or the last rehearing of such action is the denial of damages for a vaccine-related injury or death, the person who brought such action may file a petition under subsection (b) for such injury or death.

(9) This subsection applies only to a person who has sustained a vaccine-related injury or death and who is qualified to file a petition for compensation under the Program.

(10) The Clerk of the United States Claims Court [1] is authorized to continue to receive, and forward, petitions for compensation for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1992.

(b) Petitioners

(1)(A) Except as provided in subparagraph (B), any person who has sustained a vaccine-related injury, the legal representative of such person if such person is a minor or is disabled, or the legal representative of any person who died as the result of the administration of a vaccine set forth in the Vaccine Injury Table may, if the person meets the requirements of subsection (c)(1), file a petition for compensation under the Program.

(B) No person may file a petition for a vaccine-related injury or death associated with a vaccine administered before October 1, 1988, if compensation has been paid under this part for 3500 petitions for such injuries or deaths.

(2) Only one petition may be filed with respect to each administration of a vaccine. A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine.

(c) Petition content

A petition for compensation under the Program for a vaccine-related injury or death shall contain—

(1) except as provided in paragraph (3), an affidavit, and supporting documentation, demonstrating that the person who suffered such injury or who died—

(A) received a vaccine set forth in the Vaccine Injury Table or, if such person did not receive such a vaccine, contracted polio, directly or indirectly, from another person who received an oral polio vaccine,

(B)(i) if such person received a vaccine set forth in the Vaccine Injury Table—

(I) received the vaccine in the United States or in its trust territories,

(II) received the vaccine outside the United States or a trust territory and at the time of the vaccination such person was a citizen of the United States serving abroad as a member of the Armed Forces or otherwise as an employee of the United States or a dependent of such a citizen, or

(III) received the vaccine outside the United States or a trust territory and the vaccine was manufactured by a vaccine manufacturer located in the United States and such person returned to the United States not later than 6 months after the date of the vaccination,

(ii) if such person did not receive such a vaccine but contracted polio from another person who received an oral polio vaccine, was a citizen of the United States or a dependent of such a citizen,

(C)(i) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table in association with the vaccine referred to in subparagraph (A) or died from the administration of such vaccine, and the first symptom or manifestation of the onset or of the significant aggravation of any such illness, disability, injury, or condition or the death occurred within the time period after vaccine administration set forth in the Vaccine Injury Table, or

(ii)(I) sustained, or had significantly aggravated, any illness, disability, injury, or condition not set forth in the Vaccine Injury Table but which was caused by a vaccine referred to in subparagraph (A), or

(II) sustained, or had significantly aggravated, any illness, disability, injury, or condition set forth in the Vaccine Injury Table the first symptom or manifestation of the onset or significant aggravation of which did not occur within the time period set forth in the Table but which was caused by a vaccine referred to in subparagraph (A),

(D)(i) suffered the residual effects or complications of such illness, disability, injury, or condition for more than 6 months after the administration of the vaccine, or (ii) died from the administration of the vaccine, or (iii) suffered such illness, disability, injury, or condition from the vaccine which resulted in inpatient hospitalization and surgical intervention, and

(E) has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death,

(2) except as provided in paragraph (3), maternal prenatal and delivery records, newborn hospital records (including all physicians' and nurses' notes and test results), vaccination records associated with the vaccine allegedly causing the injury, pre- and post-injury physician or clinic records (including all relevant growth charts and test results), all post-injury inpatient and outpatient records (including all provider notes, test results, and medication records), if applicable, a death certificate, and if applicable, autopsy results, and

(3) an identification of any records of the type described in paragraph (1) or (2) which are unavailable to the petitioner and the reasons for their unavailability.

(d) Additional information

A petition may also include other available relevant medical records relating to the person who suffered such injury or who died from the administration of the vaccine.

(e) Schedule

The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition assessments, evaluations, and prognoses and such other records and documents as are reasonably necessary for the determination of the amount of compensation to be paid to, or on behalf of, the person who suffered such injury or who died from the administration of the vaccine.

(f) Maternal immunization

(1) In general

Notwithstanding any other provision of law, for purposes of this subpart, both a woman who received a covered vaccine while pregnant and any child who was in utero at the time such woman received the vaccine shall be considered persons to whom the covered vaccine was administered and persons who received the covered vaccine.

(2) Definition

As used in this subsection, the term "child" shall have the meaning given that term by subsections (a) and (b) of section 8 of title 1 except that, for purposes of this subsection, such section 8 shall be applied as if the term "include" in subsection (a) of such section were replaced with the term "mean".

(July 1, 1944, ch. 373, title XXI, §2111, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3758; amended Pub. L. 100–203, title IV, §§4302(b), 4304(a), (b), 4306, 4307(1), (2), Dec. 22, 1987, 101 Stat. 1330–221, 1330-223, 1330-224; Pub. L. 101–239, title VI, §6601(c)(1)–(7), Dec. 19, 1989, 103 Stat. 2285, 2286; Pub. L. 101–502, §5(a), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 102–168, title II, §201(h)(1), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–43, title XX, §2012, June 10, 1993, 107 Stat. 214; Pub. L. 105–277, div. C, title XV, §1502, Oct. 21, 1998, 112 Stat. 2681–

741; Pub. L. 106–310, div. A, title XVII, §1701(a), Oct. 17, 2000, 114 Stat. 1151; Pub. L. 114–255, div. A, title III, §3093(c)(2), (3), Dec. 13, 2016, 130 Stat. 1152.)

Editorial Notes

Codification

In subsecs. (a)(2)(A), (3), (4), (5)(A), (8), and (b)(1)(B), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 300aa–11, act July 1, 1944, §2112, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

A prior section 2111 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238h of this title.

Amendments

2016—Subsec. (b)(2). Pub. L. 114–255, §3093(c)(3), inserted at end "A covered vaccine administered to a pregnant woman shall constitute more than one administration, one to the mother and one to each child (as such term is defined in subsection (f)(2)) who was in utero at the time such woman was administered the vaccine."

Subsec. (f). Pub. L. 114–255, §3093(c)(2), added subsec. (f).

2000—Subsec. (c)(1)(D)(iii). Pub. L. 106–310 added cl. (iii).

1998—Subsec. (c)(1)(D)(i). Pub. L. 105–277 struck out "and incurred unreimbursable expenses due in whole or in part to such illness, disability, injury, or condition in an amount greater than $1,000" before ", or (ii) died".

1993—Subsec. (a)(10). Pub. L. 103–43 added par. (10).

1992—Subsec. (a)(1), (2)(A)(i)(I). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (a)(2)(A)(i), (ii). Pub. L. 102–168 realigned margins of cls. (i) and (ii).

1990—Subsec. (a)(2)(A). Pub. L. 101–502, §5(a)(1), substituted "unless a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death and—" and cls. (i) and (ii) for "unless—

"(i) a petition has been filed, in accordance with section 300aa–16 of this title, for compensation under the Program for such injury or death,

"(ii) the United States Claims Court has issued a judgment under section 300aa–12 of this title on such petition, and

"(iii) such person elects under section 300aa–21(a) of this title to file such an action."

Subsec. (a)(5)(A). Pub. L. 101–502, §5(a)(2), struck out "without prejudice" after "without prejudice or costs".

Subsec. (a)(5)(B). Pub. L. 101–502, §5(a)(3), substituted "plaintiff" for "plaintiff who".

Subsec. (d). Pub. L. 101–502, §5(a)(4), struck out "(d) except as provided in paragraph (3)," before "(d) Additional information".

Subsec. (e). Pub. L. 101–502, §5(a)(5), substituted "(e) Schedule" for "(e)(e) Schedule".

1989—Subsec. (a)(1). Pub. L. 101–239, §6601(c)(1), substituted "filing of a petition containing the matter prescribed in subsection (c)" for "filing of a petition" and inserted at end "The clerk of the United States Claims Court shall immediately forward the filed petition to the chief special master for assignment to a special master under section 300aa–12(d)(1) of this title."

Subsec. (a)(2)(A)(i). Pub. L. 101–239, §6601(c)(2), struck out "under subsection (b) of this section" after "section 300aa–16 of this title,".

Subsec. (a)(5)(A). Pub. L. 101–239, §6601(c)(3)(A), substituted "petition to have such action dismissed without prejudice or costs" for "elect to withdraw such action".

Subsec. (a)(5)(B). Pub. L. 101–239, §6601(c)(3)(B), substituted "has pending" for "on October 1, 1988, had pending" and struck out "does not withdraw the action under subparagraph (A)" after "vaccine-related injury or death".

Subsec. (a)(6). Pub. L. 101–239, §6601(c)(4), substituted "November 15, 1988" for "the effective date of this subpart" in two places.

Subsec. (a)(8). Pub. L. 101–239, §6601(c)(5), added par. (8). Former par. (8) redesignated (9).

Subsec. (a)(9). Pub. L. 101–239, §6601(c)(5), (7), redesignated par. (8) as (9) and realigned margin.

Subsec. (c)(1). Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(1)" in introductory provisions.

Subsec. (c)(2). Pub. L. 101–239, §6601(c)(6)(B), (C), added par. (2) and redesignated former par. (2) as subsec. (d).

Pub. L. 101–239, §6601(c)(6)(A), inserted "except as provided in paragraph (3)," after "(2)".

Subsec. (c)(3). Pub. L. 101–239, §6601(c)(6)(C), (D), added par. (3). Former par. (3) redesignated subsec. (e).

Subsec. (d). Pub. L. 101–239, §6601(c)(6)(B), redesignated former subsec. (c)(2) as subsec. (d), expanded margin to full measure, inserted subsec. designation and heading, substituted "A petition may also include other available" for "all available", struck out "(including autopsy reports, if any)" after "relevant medical records", and substituted "administration of the vaccine." for "administration of the vaccine and an identification of any unavailable records known to the petitioner and the reasons for their unavailability, and".

Subsec. (e). Pub. L. 101–239, §6601(c)(6)(D), redesignated former subsec. (c)(3) as subsec. (e), expanded margin to full measure, inserted subsec. designation and heading, and substituted "The petitioner shall submit in accordance with a schedule set by the special master assigned to the petition" for "appropriate".

1987—Subsec. (a)(1). Pub. L. 100–203, §4307(1), which directed that par. (1) be amended by substituting "with the United States Claims Court" for "with the United States district court for the district in which the petitioner resides or the injury or death occurred", was executed making the substitution for "with the United States district court for the district in which the petitioner resides or in which the injury or death occurred", as the probable intent of Congress.

Subsec. (a)(2)(A). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(2)(A)(ii). Pub. L. 100–203, §4307(2), substituted "the United States Claims Court" for "a district court of the United States".

Subsec. (a)(3). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(4). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(5)(A). Pub. L. 100–203, §4302(b)(2), substituted "after the effective date of this subpart" for "after the effective date of this subchapter".

Pub. L. 100–203, §4302(b)(1), substituted "who on the effective date of this subpart" for "who on the effective date of this part".

Subsec. (a)(5)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (a)(6). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part" in two places.

Subsec. (a)(7). Pub. L. 100–203, §4306, substituted "vaccine administrator or manufacturer" for "vaccine manufacturer".

Subsec. (a)(8). Pub. L. 100–203, §4304(a), added par. (8).

Subsec. (b)(1)(A). Pub. L. 100–203, §4304(b)(1), substituted "may, if the person meets the requirements of subsection (c)(1), file" for "may file".

Subsec. (b)(1)(B). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (c)(1)(D). Pub. L. 100–203, §4304(b)(2), substituted "for more than 6 months" for "for more than 1 year", "and incurred" for ", (ii) incurred", and "(ii)" for "(iii)".

Statutory Notes and Related Subsidiaries

Change of Name

References to United States Claims Court deemed to refer to United States Court of Federal Claims, see section 902(b) of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 2000 Amendment

Pub. L. 106–310, div. A, title XVII, §1701(b), Oct. 17, 2000, 114 Stat. 1151, provided that: "The amendment made by subsection (a) [amending this section] takes effect upon the date of the enactment of this Act [Oct. 17, 2000], including with respect to petitions under section 2111 of the Public Health Service Act [42 U.S.C. 300aa–11] that are pending on such date."

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Pub. L. 102–168, title II, §201(i), Nov. 26, 1991, 105 Stat. 1104, provided that:

"(1) Except as provided in paragraph (2), the amendments made by this section [amending this section and sections 300aa–12, 300aa–15, 300aa–16, 300aa–19, and 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title] shall take effect on the date of the enactment of this Act [Nov. 26, 1991].

"(2) The amendments made by subsections (d) and (f) [amending sections 300aa–12, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as if the amendments had been in effect on and after October 1, 1988."

Effective Date of 1990 Amendment

Pub. L. 101–502, §5(h), Nov. 3, 1990, 104 Stat. 1289, provided that: "The amendments made by subsections (f)(1) and (g) [amending section 300aa–21 of this title and provisions set out as a note under section 300aa–1 of this title and enacting provisions set out as a note under section 300aa–12 of this title] shall take effect as of November 14, 1986, and the amendments made by subsections (a) through (e) and subsection (f)(2) [amending this section and sections 300aa–12, 300aa–13, 300aa–15, 300aa–16, and 300aa–21 of this title] shall take effect as of September 30, 1990."

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] See Change of Name note below.

§300aa–12. Court jurisdiction

(a) General rule

The United States Court of Federal Claims and the United States Court of Federal Claims special masters shall, in accordance with this section, have jurisdiction over proceedings to determine if a petitioner under section 300aa–11 of this title is entitled to compensation under the Program and the amount of such compensation. The United States Court of Federal Claims may issue and enforce such orders as the court deems necessary to assure the prompt payment of any compensation awarded.

(b) Parties

(1) In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28.

(2) Within 30 days after the Secretary receives service of any petition filed under section 300aa–11 of this title the Secretary shall publish notice of such petition in the Federal Register. The special master designated with respect to such petition under subsection (c) shall afford all interested persons an opportunity to submit relevant, written information—

(A) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(B) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title.

(c) United States Court of Federal Claims special masters

(1) There is established within the United States Court of Federal Claims an office of special masters which shall consist of not more than 8 special masters. The judges of the United States Court of Federal Claims shall appoint the special masters, 1 of whom, by designation of the judges of the United States Court of Federal Claims, shall serve as chief special master. The appointment and reappointment of the special masters shall be by the concurrence of a majority of the judges of the court.

(2) The chief special master and other special masters shall be subject to removal by the judges of the United States Court of Federal Claims for incompetency, misconduct, or neglect of duty or for physical or mental disability or for other good cause shown.

(3) A special master's office shall be terminated if the judges of the United States Court of Federal Claims determine, upon advice of the chief special master, that the services performed by that office are no longer needed.

(4) The appointment of any individual as a special master shall be for a term of 4 years, subject to termination under paragraphs (2) and (3). Individuals serving as special masters on December 19, 1989, shall serve for 4 years from the date of their original appointment, subject to termination under paragraphs (2) and (3). The chief special master in office on December 19, 1989, shall continue to serve as chief special master for the balance of the master's term, subject to termination under paragraphs (2) and (3).

(5) The compensation of the special masters shall be determined by the judges of the United States Court of Federal Claims, upon advice of the chief special master. The salary of the chief special master shall be the annual rate of basic pay for level IV of the Executive Schedule, as prescribed by section 5315, title 5. The salaries of the other special masters shall not exceed the annual rate of basic pay of level V of the Executive Schedule, as prescribed by section 5316, title 5.

(6) The chief special master shall be responsible for the following:

(A) Administering the office of special masters and their staff, providing for the efficient, expeditious, and effective handling of petitions, and performing such other duties related to the Program as may be assigned to the chief special master by a concurrence of a majority of the United States Claims Courts [1] judges.

(B) Appointing and fixing the salary and duties of such administrative staff as are necessary. Such staff shall be subject to removal for good cause by the chief special master.

(C) Managing and executing all aspects of budgetary and administrative affairs affecting the special masters and their staff, subject to the rules and regulations of the Judicial Conference of the United States. The Conference rules and regulations pertaining to United States magistrate judges shall be applied to the special masters.

(D) Coordinating with the United States Court of Federal Claims the use of services, equipment, personnel, information, and facilities of the United States Court of Federal Claims without reimbursement.

(E) Reporting annually to the Congress and the judges of the United States Court of Federal Claims on the number of petitions filed under section 300aa–11 of this title and their disposition, the dates on which the vaccine-related injuries and deaths for which the petitions were filed occurred, the types and amounts of awards, the length of time for the disposition of petitions, the cost of administering the Program, and recommendations for changes in the Program.

(d) Special masters

(1) Following the receipt and filing of a petition under section 300aa–11 of this title, the clerk of the United States Court of Federal Claims shall forward the petition to the chief special master who shall designate a special master to carry out the functions authorized by paragraph (3).

(2) The special masters shall recommend rules to the Court of Federal Claims and, taking into account such recommended rules, the Court of Federal Claims shall promulgate rules pursuant to section 2071 of title 28. Such rules shall—

(A) provide for a less-adversarial, expeditious, and informal proceeding for the resolution of petitions,

(B) include flexible and informal standards of admissibility of evidence,

(C) include the opportunity for summary judgment,

(D) include the opportunity for parties to submit arguments and evidence on the record without requiring routine use of oral presentations, cross examinations, or hearings, and

(E) provide for limitations on discovery and allow the special masters to replace the usual rules of discovery in civil actions in the United States Court of Federal Claims.

(3)(A) A special master to whom a petition has been assigned shall issue a decision on such petition with respect to whether compensation is to be provided under the Program and the amount of such compensation. The decision of the special master shall—

(i) include findings of fact and conclusions of law, and

(ii) be issued as expeditiously as practicable but not later than 240 days, exclusive of suspended time under subparagraph (C), after the date the petition was filed.

The decision of the special master may be reviewed by the United States Court of Federal Claims in accordance with subsection (e).

(B) In conducting a proceeding on a petition a special master—

(i) may require such evidence as may be reasonable and necessary,

(ii) may require the submission of such information as may be reasonable and necessary,

(iii) may require the testimony of any person and the production of any documents as may be reasonable and necessary,

(iv) shall afford all interested persons an opportunity to submit relevant written information—

(I) relating to the existence of the evidence described in section 300aa–13(a)(1)(B) of this title, or

(II) relating to any allegation in a petition with respect to the matters described in section 300aa–11(c)(1)(C)(ii) of this title, and

(v) may conduct such hearings as may be reasonable and necessary.

There may be no discovery in a proceeding on a petition other than the discovery required by the special master.

(C) In conducting a proceeding on a petition a special master shall suspend the proceedings one time for 30 days on the motion of either party. After a motion for suspension is granted, further motions for suspension by either party may be granted by the special master, if the special master determines the suspension is reasonable and necessary, for an aggregate period not to exceed 150 days.

(D) If, in reviewing proceedings on petitions for vaccine-related injuries or deaths associated with the administration of vaccines before October 1, 1988, the chief special master determines that the number of filings and resultant workload place an undue burden on the parties or the special master involved in such proceedings, the chief special master may, in the interest of justice, suspend proceedings on any petition for up to 30 months (but for not more than 6 months at a time) in addition to the suspension time under subparagraph (C).

(4)(A) Except as provided in subparagraph (B), information submitted to a special master or the court in a proceeding on a petition may not be disclosed to a person who is not a party to the proceeding without the express written consent of the person who submitted the information.

(B) A decision of a special master or the court in a proceeding shall be disclosed, except that if the decision is to include information—

(i) which is trade secret or commercial or financial information which is privileged and confidential, or

(ii) which are medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of privacy,

and if the person who submitted such information objects to the inclusion of such information in the decision, the decision shall be disclosed without such information.

(e) Action by United States Court of Federal Claims

(1) Upon issuance of the special master's decision, the parties shall have 30 days to file with the clerk of the United States Court of Federal Claims a motion to have the court review the decision. If such a motion is filed, the other party shall file a response with the clerk of the United States Court of Federal Claims no later than 30 days after the filing of such motion.

(2) Upon the filing of a motion under paragraph (1) with respect to a petition, the United States Court of Federal Claims shall have jurisdiction to undertake a review of the record of the proceedings and may thereafter—

(A) uphold the findings of fact and conclusions of law of the special master and sustain the special master's decision,

(B) set aside any findings of fact or conclusion of law of the special master found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law and issue its own findings of fact and conclusions of law, or

(C) remand the petition to the special master for further action in accordance with the court's direction.

The court shall complete its action on a petition within 120 days of the filing of a response under paragraph (1) excluding any days the petition is before a special master as a result of a remand under subparagraph (C). The court may allow not more than 90 days for remands under subparagraph (C).

(3) In the absence of a motion under paragraph (1) respecting the special master's decision or if the United States Court of Federal Claims takes the action described in paragraph (2)(A) with respect to the special master's decision, the clerk of the United States Court of Federal Claims shall immediately enter judgment in accordance with the special master's decision.

(f) Appeals

The findings of fact and conclusions of law of the United States Court of Federal Claims on a petition shall be final determinations of the matters involved, except that the Secretary or any petitioner aggrieved by the findings or conclusions of the court may obtain review of the judgment of the court in the United States court of appeals for the Federal Circuit upon petition filed within 60 days of the date of the judgment with such court of appeals within 60 days of the date of entry of the United States Claims Court's [1] judgment with such court of appeals.

(g) Notice

If—

(1) a special master fails to make a decision on a petition within the 240 days prescribed by subsection (d)(3)(A)(ii) (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)), or

(2) the United States Court of Federal Claims fails to enter a judgment under this section on a petition within 420 days (excluding (A) any period of suspension under subsection (d)(3)(C) or (d)(3)(D), and (B) any days the petition is before a special master as a result of a remand under subsection (e)(2)(C)) after the date on which the petition was filed,

the special master or court shall notify the petitioner under such petition that the petitioner may withdraw the petition under section 300aa–21(b) of this title or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be.

(July 1, 1944, ch. 373, title XXI, §2112, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3761; amended Pub. L. 100–203, title IV, §§4303(d)(2)(A), 4307(3), 4308(a), (b), Dec. 22, 1987, 101 Stat. 1330–222, 1330-224; Pub. L. 100–360, title IV, §411(o)(2), (3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(d)–(i), Dec. 19, 1989, 103 Stat. 2286–2290; Pub. L. 101–502, §5(b), Nov. 3, 1990, 104 Stat. 1286; Pub. L. 101–650, title III, §321, Dec. 1, 1990, 104 Stat. 5117; Pub. L. 102–168, title II, §201(c), (d)(1), (h)(2), (3), Nov. 26, 1991, 105 Stat. 1103, 1104; Pub. L. 102–572, title IX, §902(b), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(c), Aug. 10, 1993, 107 Stat. 646.)

Editorial Notes

Codification

In subsec. (c)(4), "on December 19, 1989," substituted for "upon the date of the enactment of this subsection" and "on the date of the enactment of this subsection".

In subsec. (d)(3)(D), "October 1, 1988," substituted for "the effective date of this part".

Prior Provisions

A prior section 300aa–12, act July 1, 1944, §2113, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

A prior section 2112 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238i of this title.

Amendments

1993—Subsec. (d)(3)(D). Pub. L. 103–66 substituted "30 months (but for not more than 6 months at a time)" for "540 days".

1992—Subsecs. (a), (c) to (g). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" and "Court of Federal Claims" for "Claims Court", wherever appearing.

1991—Subsec. (d)(3)(D). Pub. L. 102–168, §201(c), (h)(2), realigned margin and substituted "540 days" for "180 days".

Subsec. (g). Pub. L. 102–168, §201(h)(3), made technical amendment to underlying provisions of original Act.

Pub. L. 102–168, §201(d)(1), substituted "or the petitioner may choose under section 300aa–21(b) of this title to have the petition remain before the special master or court, as the case may be" for "and the petition will be considered withdrawn under such section if the petitioner, the special master, or the court do not take certain actions" before period at end.

1990—Subsec. (d)(3)(D). Pub. L. 101–502, §5(b)(1), added subpar. (D).

Subsec. (g). Pub. L. 101–502, §5(b)(2), added subsec. (g).

1989—Subsec. (a). Pub. L. 101–239, §6601(d), substituted "and the United States Claims Court special masters shall, in accordance with this section, have jurisdiction" for "shall have jurisdiction (1)", ". The United States Claims Court may issue" for ", and (2) to issue", and "deems" for "deem".

Subsec. (b)(1). Pub. L. 101–239, §6601(f), substituted "In all proceedings brought by the filing of a petition under section 300aa–11(b) of this title, the Secretary shall be named as the respondent, shall participate, and shall be represented in accordance with section 518(a) of title 28." for "The Secretary shall be named as the respondent in all proceedings brought by the filing of a petition under section 300aa–11(b) of this title. Except as provided in paragraph (2), no other person may intervene in any such proceeding."

Subsec. (c). Pub. L. 101–239, §6601(e)(2), added subsec. (c). Former subsec. (c) redesignated (d).

Subsec. (d). Pub. L. 101–239, §6601(e)(1), redesignated subsec. (c) as (d). Former subsec. (d) redesignated (e).

Subsec. (d)(1). Pub. L. 101–239, §6601(g)(1), amended par. (1) generally. Prior to amendment, par. (1) read as follows: "Following receipt of a petition under subsection (a) of this section, the United States Claims Court shall designate a special master to carry out the functions authorized by paragraph (2)."

Subsec. (d)(2) to (4). Pub. L. 101–239, §6601(g)(2), added pars. (2) to (4) and struck out former par. (2) which prescribed functions of special masters.

Subsec. (e). Pub. L. 101–239, §6601(h), substituted "Action by United States Claims Court" for "Action by court" as heading and amended text generally. Prior to amendment, text read as follows:

"(1) Upon objection by the petitioner or respondent to the proposed findings of fact or conclusions of law prepared by the special master or upon the court's own motion, the court shall undertake a review of the record of the proceedings and may thereafter make a de novo determination of any matter and issue its judgment accordingly, including findings of fact and conclusions of law, or remand for further proceedings.

"(2) If no objection is filed under paragraph (1) or if the court does not choose to review the proceeding, the court shall adopt the proposed findings of fact and conclusions of law of the special master as its own and render judgment thereon.

"(3) The court shall render its judgment on any petition filed under the Program as expeditiously as practicable but not later than 365 days after the date on which the petition was filed."

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (d) as (e). Former subsec. (e) redesignated (f).

Subsec. (f). Pub. L. 101–239, §6601(i), inserted "within 60 days of the date of entry of the United States Claims Court's judgment with such court of appeals" after "with such court of appeals".

Pub. L. 101–239, §6601(e)(1), redesignated subsec. (e) as (f).

1988—Subsec. (c)(2). Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(a), see 1987 Amendment note below.

Subsec. (e). Pub. L. 100–360, §411(o)(2), made technical amendment to directory language of Pub. L. 100–203, §4307(3)(C), see 1987 Amendment note below.

Pub. L. 100–360, §411(o)(3)(A), added Pub. L. 100–203, §4308(b), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4307(3)(A), substituted "United States Claims Court" for "district courts of the United States" and "the court" for "the courts".

Subsec. (c)(1). Pub. L. 100–203, §4307(3)(B), substituted "the United States Claims Court" for "the district court of the United States in which the petition is filed".

Subsec. (c)(2). Pub. L. 100–203, §4308(a), as added by Pub. L. 100–360, §411(o)(3)(A), inserted ", shall prepare and submit to the court proposed findings of fact and conclusions of law," in introductory provisions and struck out subpar. (E) which read as follows: "prepare and submit to the court proposed findings of fact and conclusions of law."

Subsec. (e). Pub. L. 100–203, §4308(b), as added by Pub. L. 100–360, §411(o)(3)(A), inserted "within 60 days of the date of the judgment" after "petition filed".

Pub. L. 100–203, §4307(3)(C), as amended by Pub. L. 100–360, §411(o)(2), substituted "the United States Claims Court" for "a district court of the United States" and "for the Federal Circuit" for "for the circuit in which the court is located".

Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e) and struck out former subsec. (e) relating to administration of an award.

Subsec. (f). Pub. L. 100–203, §4303(d)(2)(A), struck out subsec. (f) which related to revision of an award.

Subsec. (g). Pub. L. 100–203, §4303(d)(2)(A), redesignated subsec. (g) as (e).

Statutory Notes and Related Subsidiaries

Change of Name

"United States magistrate judges" substituted for "United States magistrates" in subsec. (c)(6)(C) pursuant to section 321 of Pub. L. 101–650, set out as a note under section 631 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by section 201(d)(1) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 240-day period prescribed in subsec. (d) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Termination of Reporting Requirements

For termination, effective May 15, 2000, of provisions in subsec. (c)(6)(E) of this section relating to reporting annually to the Congress, see section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 13 of House Document No. 103–7.

Review by 3-Judge Panel

Section 322(c) of Pub. L. 99–660, as added by Pub. L. 101–502, §5(g)(2), Nov. 3, 1990, 104 Stat. 1288, and amended by Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516, provided that: "If the review authorized by section 2112(f) [42 U.S.C. 300aa–12(f)] is held invalid because the judgment of the United States Court of Federal Claims being reviewed did not arise from a case or controversy under Article III of the Constitution, such judgment shall be reviewed by a 3-judge panel of the United States Court of Federal Claims. Such panel shall not include the judge who participated in such judgment."

[Enactment of section 322(c) of Pub. L. 99–660 by section 5(g)(2) of Pub. L. 101–502, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

[1] So in original. Probably should be a reference to the United States Court of Federal Claims.

§300aa–13. Determination of eligibility and compensation

(a) General rule

(1) Compensation shall be awarded under the Program to a petitioner if the special master or court finds on the record as a whole—

(A) that the petitioner has demonstrated by a preponderance of the evidence the matters required in the petition by section 300aa–11(c)(1) of this title, and

(B) that there is not a preponderance of the evidence that the illness, disability, injury, condition, or death described in the petition is due to factors unrelated to the administration of the vaccine described in the petition.

The special master or court may not make such a finding based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.

(2) For purposes of paragraph (1), the term "factors unrelated to the administration of the vaccine"—

(A) does not include any idiopathic, unexplained, unknown, hypothetical, or undocumentable cause, factor, injury, illness, or condition, and

(B) may, as documented by the petitioner's evidence or other material in the record, include infection, toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death.

(b) Matters to be considered

(1) In determining whether to award compensation to a petitioner under the Program, the special master or court shall consider, in addition to all other relevant medical and scientific evidence contained in the record—

(A) any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death, and

(B) the results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions.

Any such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court. In evaluating the weight to be afforded to any such diagnosis, conclusion, judgment, test result, report, or summary, the special master or court shall consider the entire record and the course of the injury, disability, illness, or condition until the date of the judgment of the special master or court.

(2) The special master or court may find the first symptom or manifestation of onset or significant aggravation of an injury, disability, illness, condition, or death described in a petition occurred within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period. Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset or significant aggravation of the injury, disability, illness, condition, or death described in the petition did in fact occur within the time period described in the Vaccine Injury Table.

(c) "Record" defined

For purposes of this section, the term "record" means the record established by the special masters of the United States Court of Federal Claims in a proceeding on a petition filed under section 300aa–11 of this title.

(July 1, 1944, ch. 373, title XXI, §2113, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3763; amended Pub. L. 100–203, title IV, §4307(4), Dec. 22, 1987, 101 Stat. 1330–224; Pub. L. 101–239, title VI, §6601(j), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 101–502, §5(c), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Editorial Notes

Prior Provisions

A prior section 300aa–13, act July 1, 1944, §2114, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

A prior section 2113 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238j of this title.

Amendments

1992—Subsec. (c). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

1990—Subsec. (c). Pub. L. 101–502 inserted "the" after "special masters of".

1989—Subsecs. (a)(1), (b). Pub. L. 101–239, §6601(j)(1), substituted "special master or court" for "court" wherever appearing.

Subsec. (c). Pub. L. 101–239, §6601(j)(2), inserted "special masters of" after "established by the".

1987—Subsec. (c). Pub. L. 100–203 substituted "the United States Claims Court" for "a district court of the United States".

Statutory Notes and Related Subsidiaries

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–14. Vaccine Injury Table

(a) Initial table

The following is a table of vaccines, the injuries, disabilities, illnesses, conditions, and deaths resulting from the administration of such vaccines, and the time period in which the first symptom or manifestation of onset or of the significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths is to occur after vaccine administration for purposes of receiving compensation under the Program:

VACCINE INJURY TABLE

I.	DTP; P; DTP/Polio Combination; or Any Other Vaccine Containing Whole Cell Pertussis Bacteria, Extracted or Partial Cell Bacteria, or Specific Pertussis Antigen(s).	
	Illness, disability, injury, or condition covered:	Time period for first symptom or manifestation of onset or of significant aggravation after vaccine administration:
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	3 days
	C. Shock-collapse or hypotonic-hyporesponsive collapse	3 days
	D. Residual seizure disorder in accordance with subsection (b)(2)	3 days
	E. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above	Not applicable

	which illness, disability, injury, or condition arose within the time period prescribed	
II.	Measles, mumps, rubella, or any vaccine containing any of the foregoing as a component; DT; Td; or Tetanus Toxoid.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Encephalopathy (or encephalitis)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	C. Residual seizure disorder in accordance with subsection (b)(2)	15 days (for mumps, rubella, measles, or any vaccine containing any of the foregoing as a component). 3 days (for DT, Td, or tetanus toxoid).
	D. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
III.	Polio Vaccines (other than Inactivated Polio Vaccine).	
	A. Paralytic polio	
	—in a non-immunodeficient recipient	30 days
	—in an immunodeficient recipient	6 months
	—in a vaccine-associated community case	Not applicable
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable
IV.	Inactivated Polio Vaccine.	
	A. Anaphylaxis or anaphylactic shock	24 hours
	B. Any acute complication or sequela (including death) of an illness, disability, injury, or condition referred to above which illness, disability, injury, or condition arose within the time period prescribed	Not applicable

(b) Qualifications and aids to interpretation

The following qualifications and aids to interpretation shall apply to the Vaccine Injury Table in subsection (a):

(1) A shock-collapse or a hypotonic-hyporesponsive collapse may be evidenced by indicia or symptoms such as decrease or loss of muscle tone, paralysis (partial or complete), hemiplegia or hemiparesis, loss of color or turning pale white or blue, unresponsiveness to environmental stimuli, depression of consciousness, loss of consciousness, prolonged sleeping with difficulty arousing, or cardiovascular or respiratory arrest.

(2) A petitioner may be considered to have suffered a residual seizure disorder if the petitioner did not suffer a seizure or convulsion unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit before the first seizure or convulsion after the administration of the vaccine involved and if—

(A) in the case of a measles, mumps, or rubella vaccine or any combination of such vaccines, the first seizure or convulsion occurred within 15 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit, and

(B) in the case of any other vaccine, the first seizure or convulsion occurred within 3 days after administration of the vaccine and 2 or more seizures or convulsions occurred within 1 year after the administration of the vaccine which were unaccompanied by fever or accompanied by a fever of less than 102 degrees Fahrenheit.

(3)(A) The term "encephalopathy" means any significant acquired abnormality of, or injury to, or impairment of function of the brain. Among the frequent manifestations of encephalopathy are focal and diffuse neurologic signs, increased intracranial pressure, or changes lasting at least 6 hours in level of consciousness, with or without convulsions. The neurological signs and symptoms of encephalopathy may be temporary with complete recovery, or may result in various degrees of permanent impairment. Signs and symptoms such as high pitched and unusual screaming, persistent unconsolable crying, and bulging fontanel are compatible with an encephalopathy, but in and of themselves are not conclusive evidence of encephalopathy. Encephalopathy usually can be documented by slow wave activity on an electroencephalogram.

(B) If in a proceeding on a petition it is shown by a preponderance of the evidence that an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table. If at the time a judgment is entered on a petition filed under section 300aa–11 of this title for a vaccine-related injury or death it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table. In determining whether or not an encephalopathy is a condition set forth in the table, the court shall consider the entire medical record.

(4) For purposes of paragraphs (2) and (3), the terms "seizure" and "convulsion" include grand mal, petit mal, absence, myoclonic, tonic-clonic, and focal motor seizures and signs. If a provision of the table to which paragraph (1), (2), (3), or (4) applies is revised under subsection (c) or (d), such paragraph shall not apply to such provision after the effective date of the revision unless the revision specifies that such paragraph is to continue to apply.

(c) Administrative revision of table

(1) The Secretary may promulgate regulations to modify in accordance with paragraph (3) the Vaccine Injury Table. In promulgating such regulations, the Secretary shall provide for notice and opportunity for a public hearing and at least 180 days of public comment.

(2) Any person (including the Advisory Commission on Childhood Vaccines) may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

whichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the Federal Register a statement of reasons for not conducting such proceeding.

(3) A modification of the Vaccine Injury Table under paragraph (1) may add to, or delete from, the list of injuries, disabilities, illnesses, conditions, and deaths for which compensation may be provided or may change the time periods for the first symptom or manifestation of the onset or the significant aggravation of any such injury, disability, illness, condition, or death.

(4) Any modification under paragraph (1) of the Vaccine Injury Table shall apply only with respect to petitions for compensation under the Program which are filed after the effective date of such regulation.

(d) Role of Commission

Except with respect to a regulation recommended by the Advisory Commission on Childhood Vaccines, the Secretary may not propose a regulation under subsection (c) or any revision thereof, unless the Secretary has first provided to the Commission a copy of the proposed regulation or revision, requested recommendations and comments by the Commission, and afforded the Commission at least 90 days to make such recommendations.

(e) Additional vaccines

(1) Vaccines recommended before August 1, 1993

By August 1, 1995, the Secretary shall revise the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which are recommended to the Secretary by the Centers for Disease Control and Prevention before August 1, 1993, for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(2) Vaccines recommended after August 1, 1993

When after August 1, 1993, the Centers for Disease Control and Prevention recommends a vaccine to the Secretary for routine administration to children, the Secretary shall, within 2 years of such recommendation, amend the Vaccine Injury Table included in subsection (a) to include—

(A) vaccines which were recommended for routine administration to children,

(B) the injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines, and

(C) the time period in which the first symptoms or manifestations of onset or other significant aggravation of such injuries, disabilities, illnesses, conditions, and deaths associated with such vaccines may occur.

(3) Vaccines recommended for use in pregnant women

The Secretary shall revise the Vaccine Injury Table included in subsection (a), through the process described in subsection (c), to include vaccines recommended by the Centers for Disease Control and Prevention for routine administration in pregnant women and the information described in subparagraphs (B) and (C) of paragraph (2) with respect to such vaccines.

(July 1, 1944, ch. 373, title XXI, §2114, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3764; amended Pub. L. 101–239, title VI, §6601(k), Dec. 19, 1989, 103 Stat. 2290; Pub. L. 103–66, title XIII, §13632(a)(2), Aug. 10, 1993, 107 Stat. 645; Pub. L. 114–255, div. A, title III, §3093(c)(1), Dec. 13, 2016, 130 Stat. 1152.)

Editorial Notes

Prior Provisions

A prior section 300aa–14, act July 1, 1944, §2115, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

A prior section 2114 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238k of this title.

Amendments

2016—Subsec. (e)(3). Pub. L. 114–255 added par. (3).

1993—Subsec. (e). Pub. L. 103–66 amended heading and text of subsec. (e) generally. Prior to amendment, text read as follows: "The Secretary may recommend to Congress revisions of the table to change the vaccines covered by the table."

1989—Subsec. (a). Pub. L. 101–239, §6601(k)(1), substituted "(b)(2)" for "(c)(2)" in items I.D. and II.C. in table.

Subsec. (b)(3)(B). Pub. L. 101–239, §6601(k)(2), substituted "300aa–11 of this title" for "300aa–11(b) of this title".

Statutory Notes and Related Subsidiaries

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Revisions of Vaccine Injury Table

The Vaccine Injury Table as modified by regulations promulgated by the Secretary of Health and Human Services is set out at 42 CFR 100.3.

Pub. L. 103–66, title XIII, §13632(a)(3), Aug. 10, 1993, 107 Stat. 646, provided that: "A revision by the Secretary under section 2114(e) of the Public Health Service Act (42 U.S.C. 300aa–14(e)) (as amended by paragraph (2)) shall take effect upon the effective date of a tax enacted to provide funds for compensation paid with respect to the vaccine to be added to the vaccine injury table in section 2114(a) of the Public Health Service Act (42 U.S.C. 300aa–14(a))."

§300aa–15. Compensation

(a) General rule

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, shall include the following:

(1)(A) Actual unreimbursable expenses incurred from the date of the judgment awarding such expenses and reasonable projected unreimbursable expenses which—

(i) result from the vaccine-related injury for which the petitioner seeks compensation,

(ii) have been or will be incurred by or on behalf of the person who suffered such injury, and

(iii)(I) have been or will be for diagnosis and medical or other remedial care determined to be reasonably necessary, or

(II) have been or will be for rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(B) Subject to section 300aa–16(a)(2) of this title, actual unreimbursable expenses incurred before the date of the judgment awarding such expenses which—

(i) resulted from the vaccine-related injury for which the petitioner seeks compensation,

(ii) were incurred by or on behalf of the person who suffered such injury, and

(iii) were for diagnosis, medical or other remedial care, rehabilitation, developmental evaluation, special education, vocational training and placement, case management services, counseling, emotional or behavioral therapy, residential and custodial care and service expenses, special equipment, related travel expenses, and facilities determined to be reasonably necessary.

(2) In the event of a vaccine-related death, an award of $250,000 for the estate of the deceased.

(3)(A) In the case of any person who has sustained a vaccine-related injury after attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded, compensation for actual and anticipated loss of earnings determined in accordance with generally recognized actuarial principles and projections.

(B) In the case of any person who has sustained a vaccine-related injury before attaining the age of 18 and whose earning capacity is or has been impaired by reason of such person's vaccine-related injury for which compensation is to be awarded and whose vaccine-related injury is of sufficient severity to permit reasonable anticipation that such person is likely to suffer impaired earning capacity at age 18 and beyond, compensation after attaining the age of 18 for loss of earnings determined on the basis of the average gross weekly earnings of workers in the private, non-farm sector, less appropriate taxes and the average cost of a health insurance policy, as determined by the Secretary.

(4) For actual and projected pain and suffering and emotional distress from the vaccine-related injury, an award not to exceed $250,000.

(b) Vaccines administered before effective date

Compensation awarded under the Program to a petitioner under section 300aa–11 of this title for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—

(1) lost earnings (as provided in paragraph (3) of subsection (a)),

(2) pain and suffering (as provided in paragraph (4) of subsection (a)), and

(3) reasonable attorneys' fees and costs (as provided in subsection (e).[1]

(c) Residential and custodial care and service

The amount of any compensation for residential and custodial care and service expenses under subsection (a)(1) shall be sufficient to enable the compensated person to remain living at home.

(d) Types of compensation prohibited

Compensation awarded under the Program may not include the following:

(1) Punitive or exemplary damages.

(2) Except with respect to compensation payments under paragraphs (2) and (3) of subsection (a), compensation for other than the health, education, or welfare of the person who suffered the vaccine-related injury with respect to which the compensation is paid.

(e) Attorneys' fees

(1) In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover—

(A) reasonable attorneys' fees, and

(B) other costs,

incurred in any proceeding on such petition. If the judgment of the United States Court of Federal Claims on such a petition does not award compensation, the special master or court may award an amount of compensation to cover petitioner's reasonable attorneys' fees and other costs incurred in any proceeding on such petition if the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition was brought.

(2) If the petitioner, before October 1, 1988, filed a civil action for damages for any vaccine-related injury or death for which compensation may be awarded under the Program, and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed and to file a petition for compensation under the Program, in awarding compensation on such petition the special master or court may include an amount of compensation limited to the costs and expenses incurred by the petitioner and the attorney of the petitioner before October 1, 1988, in preparing, filing, and prosecuting such civil action (including the reasonable value of the attorney's time if the civil action was filed under contingent fee arrangements).

(3) No attorney may charge any fee for services in connection with a petition filed under section 300aa–11 of this title which is in addition to any amount awarded as compensation by the special master or court under paragraph (1).

(f) Payment of compensation

(1) Except as provided in paragraph (2), no compensation may be paid until an election has been made, or has been deemed to have been made, under section 300aa–21(a) of this title to receive compensation.

(2) Compensation described in subsection (a)(1)(A)(iii) shall be paid from the date of the judgment of the United States Court of Federal Claims under section 300aa–12 of this title awarding the compensation. Such compensation may not be paid after an election under section 300aa–21(a) of this title to file a civil action for damages for the vaccine-related injury or death for which such compensation was awarded.

(3) Payments of compensation under the Program and the costs of carrying out the Program shall be exempt from reduction under any order issued under part C of the Balanced Budget and Emergency Deficit Control Act of 1985 [2 U.S.C. 900 et seq.].

(4)(A) Except as provided in subparagraph (B), payment of compensation under the Program shall be determined on the basis of the net present value of the elements of the compensation and shall be paid from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26 in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner.

(B) In the case of a payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, the compensation shall be determined on the basis of the net present value of the elements of compensation and shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum. If the appropriations under subsection (j) are insufficient to make a payment of an annual installment, the limitation on civil actions prescribed by section 300aa–21(a) of this title shall not apply to a civil action for damages brought by the petitioner entitled to the payment.

(C) In purchasing an annuity under subparagraph (A) or (B), the Secretary may purchase a guarantee for the annuity, may enter into agreements regarding the purchase price for and rate of return of the annuity, and may take such other actions as may be necessary to safeguard the financial interests of the United States regarding the annuity. Any payment received by the Secretary pursuant to the preceding sentence shall be paid to the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26, or to the appropriations account from which the funds were derived to purchase the annuity, whichever is appropriate.

(g) Program not primarily liable

Payment of compensation under the Program shall not be made for any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to such item or service (1) under any State compensation program, under an insurance policy, or under any Federal or State health benefits program (other than under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.]), or (2) by an entity which provides health services on a prepaid basis.

(h) Liability of health insurance carriers, prepaid health plans, and benefit providers

No policy of health insurance may make payment of benefits under the policy secondary to the payment of compensation under the Program and—

(1) no State, and

(2) no entity which provides health services on a prepaid basis or provides health benefits,

may make the provision of health services or health benefits secondary to the payment of compensation under the Program, except that this subsection shall not apply to the provision of services or benefits under title XIX of

the Social Security Act [42 U.S.C. 1396 et seq.].

(i) Source of compensation

(1) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, shall be made by the Secretary from appropriations under subsection (j).

(2) Payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine on or after October 1, 1988, shall be made from the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(j) Authorization

For the payment of compensation under the Program to a petitioner for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, there are authorized to be appropriated to the Department of Health and Human Services $80,000,000 for fiscal year 1989, $80,000,000 for fiscal year 1990, $80,000,000 for fiscal year 1991, $80,000,000 for fiscal year 1992, $110,000,000 for fiscal year 1993, and $110,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B). Amounts appropriated under this subsection shall remain available until expended.

(July 1, 1944, ch. 373, title XXI, §2115, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3767; amended Pub. L. 100–203, title IV, §§4302(b), 4303(a)–(d)(1), (e), (g), 4307(5), (6), Dec. 22, 1987, 101 Stat. 1330–221 to 1330-223, 1330-225; Pub. L. 100–360, title IV, §411(o)(1), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(c)(8), (l), Dec. 19, 1989, 103 Stat. 2286, 2290; Pub. L. 101–502, §5(d), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(e), (f), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–531, title III, §314, Oct. 27, 1992, 106 Stat. 3508; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516; Pub. L. 103–66, title XIII, §13632(b), Aug. 10, 1993, 107 Stat. 646.)

Editorial Notes

References in Text

The Balanced Budget and Emergency Deficit Control Act of 1985, referred to in subsec. (f)(3), is title II of Pub. L. 99–177, Dec. 12, 1985, 99 Stat. 1038. Part C of the Act is classified generally to subchapter I (§900 et seq.) of chapter 20 of Title 2, The Congress. For complete classification of this Act to the Code, see Short Title note set out under section 900 of Title 2 and Tables.

The Social Security Act, referred to in subsecs. (g) and (h), is act Aug. 14, 1935, ch. 531, 49 Stat. 620. Title XIX of the Social Security Act is classified generally to subchapter XIX (§1396 et seq.) of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

Codification

In subsecs. (a), (b), (e)(2), (f)(4)(B), (i), and (j), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 300aa–15, act July 1, 1944, §2116, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

A prior section 2115 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238l of this title.

Amendments

1993—Subsec. (j). Pub. L. 103–66 substituted "$110,000,000 for each succeeding fiscal year" for "$80,000,000 for each succeeding fiscal year".

1992—Subsecs. (e)(1), (f)(2). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court".

Subsec. (j). Pub. L. 102–531 increased authorization for fiscal year 1993 from $80,000,000 to $110,000,000.

1991—Subsec. (f)(4)(A). Pub. L. 102–168, §201(e)(1)(A), (2), struck out "of the proceeds" after "portion" and substituted "Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "trust fund".

Subsec. (f)(4)(B). Pub. L. 102–168, §201(e)(1)(B), which directed substitution of "shall be paid from appropriations made available under subsection (j) in a lump sum of which all or a portion" for "paid in 4 equal installments of which all or portion of the proceeds" was executed by making the substitution for "paid in 4 equal annual installments of which all or a portion of the proceeds" to reflect the probable intent of Congress.

Subsec. (f)(4)(C). Pub. L. 102–168, §201(f), added subpar. (C).

1990—Subsec. (e)(2). Pub. L. 101–502, §5(d)(1), inserted "of compensation" before "limited to the costs".

Subsec. (f)(2). Pub. L. 101–502, §5(d)(2)(A), substituted "section 300aa–21(a)" for "section 300aa–21(b)".

Subsec. (f)(4)(B). Pub. L. 101–502, §5(d)(2)(B), substituted "subsection (j)" for "subsection (i)" and "the limitation on civil actions prescribed by section 300aa–21(a) of this title" for "section 300aa–11(a) of this title".

Subsec. (j). Pub. L. 101–502, §5(d)(3), inserted before period at end of first sentence ", and $80,000,000 for each succeeding fiscal year in which a payment of compensation is required under subsection (f)(4)(B)".

1989—Subsec. (b). Pub. L. 101–239, §6601(l)(1), substituted "may include the compensation described in paragraphs (1)(A) and (2) of subsection (a) and may also include an amount, not to exceed a combined total of $30,000, for—" and cls. (1) to (3) for "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000."

Subsec. (e)(1). Pub. L. 101–239, §6601(l)(2)(A), substituted "In awarding compensation on a petition filed under section 300aa–11 of this title the special master or court shall also award as part of such compensation an amount to cover" for "The judgment of the United States Claims Court on a petition filed under section 300aa–11 of this title awarding compensation shall include an amount to cover".

Pub. L. 101–239, §6601(l)(2)(B), (C), substituted "the special master or court may award an amount of compensation to cover" for "the court may include in the judgment an amount to cover" and "the special master or court determines that the petition was brought in good faith and there was a reasonable basis for the claim for which the petition" for "the court determines that the civil action was brought in good faith and there was a reasonable basis for the claim for which the civil action".

Subsec. (e)(2). Pub. L. 101–239, §6601(l)(2)(D), which directed amendment of par. (2) by substituting "the special master or court may also award an amount of compensation" for "the judgment of the court on such petition may include an amount", could not be executed because of the prior amendment by Pub. L. 101–239, §6601(c)(8)(B), see Amendment note below.

Pub. L. 101–239, §6601(c)(8), substituted "and petitioned under section 300aa–11(a)(5) of this title to have such action dismissed" for "and elected under section 300aa–11(a)(4) of this title to withdraw such action" and "in awarding compensation on such petition the special master or court may include" for "the judgment of the court on such petition may include".

Subsec. (e)(3). Pub. L. 101–239, §6601(l)(2)(E), substituted "awarded as compensation by the special master or court under paragraph (1)" for "included under paragraph (1) in a judgment on such petition".

Subsec. (f)(3). Pub. L. 101–239, §6601(l)(3)(A), inserted "under the Program and the costs of carrying out the Program" after "Payments of compensation".

Subsec. (f)(4)(A). Pub. L. 101–239, §6601(l)(3)(B), struck out "made in a lump sum" after "the Program shall be" and inserted "and shall be paid from the trust fund in a lump sum of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner" after "elements of the compensation".

Subsec. (f)(4)(B). Pub. L. 101–239, §6601(l)(3)(C), substituted "determined on the basis of the net present value of the elements of compensation and paid in 4 equal annual installments of which all or a portion of the proceeds may be used as ordered by the special master to purchase an annuity or otherwise be used, with the consent of the petitioner, in a manner determined by the special master to be in the best interests of the petitioner. Any reasonable attorneys' fees and costs shall be paid in a lump sum" for "paid in 4 equal annual installments".

Subsec. (g). Pub. L. 101–239, §6601(l)(4)(A), inserted "(other than under title XIX of the Social Security Act)" after "State health benefits program".

Subsec. (h). Pub. L. 101–239, §6601(l)(4)(B), inserted before period at end ", except that this subsection shall not apply to the provision of services or benefits under title XIX of the Social Security Act".

Subsec. (i)(1). Pub. L. 101–239, §6601(l)(5), which directed amendment of par. (1) by substituting "(j)" for "(i)", could not be executed because "(i)" did not appear.

Subsec. (j). Pub. L. 101–239, §6601(l)(6), struck out "and" after "fiscal year 1991," and inserted ", $80,000,000 for fiscal year 1993" after "fiscal year 1992".

1988—Subsec. (i)(1). Pub. L. 100–360, §411(o)(1)(A), substituted "by the Secretary from appropriations under subsection (j)" for "from appropriations under subsection (i)".

Subsec. (j). Pub. L. 100–360, §411(o)(1)(B), inserted "to the Department of Health and Human Services".

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Pub. L. 100–203, §4303(d)(1)(A), struck out last two sentences which read as follows: "Payments for projected expenses shall be paid on a periodic basis (but no payment may be made for a period in excess of 1 year). Payments for pain and suffering and emotional distress and incurred expenses may be paid in a lump sum."

Subsec. (a)(1). Pub. L. 100–203, §4303(c), struck out last sentence of subpars. (A) and (B) each of which read as follows: "The amount of unreimbursable expenses which may be recovered under this subparagraph shall be limited to the amount in excess of the amount set forth in section 300aa–11(c)(1)(D)(ii) of this title."

Subsec. (b). Pub. L. 100–203, §4303(e), substituted "may not include the compensation described in paragraph (1)(B) of subsection (a) of this section and may include attorneys' fees and other costs included in a judgment under subsection (e) of this section, except that the total amount that may be paid as compensation under paragraphs (3) and (4) of subsection (a) of this section and included as attorneys' fees and other costs under subsection (e) of this section may not exceed $30,000" for "shall only include the compensation described in paragraphs (1)(A) and (2) of subsection (a) of this section".

Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e)(1). Pub. L. 100–203, §4307(5), substituted "of the United States Claims Court" for "of a court" in two places.

Subsec. (e)(2). Pub. L. 100–203, §4302(b), substituted "effective date of this subpart, filed a" for "effective date of this subchapter, filed a" and "effective date of this subpart in preparing" for "effective date of this part in preparing".

Subsec. (f). Pub. L. 100–203, §4303(d)(1)(B), (g), added par. (4) and redesignated a second subsec. (f), relating to the Program not being primarily liable, as subsec. (g).

Subsec. (f)(2). Pub. L. 100–203, §4307(6), substituted "United States Claims Court" for "district court of the United States".

Subsecs. (g), (h). Pub. L. 100–203, §4303(g), redesignated a second subsec. (f), relating to the Program not being liable, as (g) and redesignated former subsec. (g) as (h).

Subsecs. (i), (j). Pub. L. 100–203, §4303(a), (b), added subsecs. (i) and (j).

Statutory Notes and Related Subsidiaries

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by section 201(f) of Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

Amendment by Pub. L. 101–239 applicable to all pending and subsequently filed petitions, see section 6601(s)(2) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

[1] So in original. Probably should be preceded by another closing parenthesis.

§300aa–16. Limitations of actions

(a) General rule

In the case of—

(1) a vaccine set forth in the Vaccine Injury Table which is administered before October 1, 1988, if a vaccine-related injury or death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury or death after the expiration of 28 months after October 1, 1988, and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine,

(2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the expiration of 36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury, and

(3) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a death occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such death after the expiration of 24 months from the date of the death and no such petition may be filed more than 48 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of the injury from which the death resulted.

(b) Effect of revised table

If at any time the Vaccine Injury Table is revised and the effect of such revision is to permit an individual who was not, before such revision, eligible to seek compensation under the Program, or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file a petition for such compensation not later than 2 years after the effective date of the revision, except that no compensation may be provided under the Program with respect to a vaccine-related injury or death covered under the revision of the table if—

(1) the vaccine-related death occurred more than 8 years before the date of the revision of the table, or

(2) the vaccine-related injury occurred more than 8 years before the date of the revision of the table.

(c) State limitations of actions

If a petition is filed under section 300aa–11 of this title for a vaccine-related injury or death, limitations of actions under State law shall be stayed with respect to a civil action brought for such injury or death for the period beginning on the date the petition is filed and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action or (2) an election is made under section 300aa–21(b) of this title to withdraw the petition.

(July 1, 1944, ch. 373, title XXI, §2116, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3769; amended Pub. L. 100–203, title IV, §4302(b)(2), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 101–239, title VI, §6601(m)(1), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(e), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(2), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 103–66, title XIII, §13632(a)(1), Aug. 10, 1993, 107 Stat. 645.)

Editorial Notes

Codification

In subsec. (a)(1) to (3), "October 1, 1988" and "October 1, 1988," substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Prior Provisions

A prior section 2116 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238m of this title.

Amendments

1993—Subsec. (b). Pub. L. 103–66 substituted "or to significantly increase the likelihood of obtaining compensation, such person may, notwithstanding section 300aa–11(b)(2) of this title, file" for "such person may file".

1991—Subsec. (c). Pub. L. 102–168 substituted "or (2)" for ", (2)" and struck out ", or (3) the petition is considered withdrawn under section 300aa–21(b) of this title."

1990—Subsec. (a)(1). Pub. L. 101–502, §5(e)(1), substituted "28 months" for "24 months" and inserted before comma at end "and no such petition may be filed if the first symptom or manifestation of onset or of the significant aggravation of such injury occurred more than 36 months after the date of administration of the vaccine".

Subsec. (c). Pub. L. 101–502, §5(e)(2), substituted "and ending on the date (1) an election is made under section 300aa–21(a) of this title to file the civil action, (2) an election is made under section 300aa–21(b) of this title to withdraw the petition, or (3) the petition is considered withdrawn under section 300aa–21(b) of this title" for "and ending on the date a final judgment is entered on the petition".

1989—Subsec. (c). Pub. L. 101–239 substituted "300aa–11 of this title" for "300aa–11(b) of this title".

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this subchapter" in pars. (1) to (3).

Statutory Notes and Related Subsidiaries

Effective Date of 1991 Amendment

Amendment by Pub. L. 102–168 effective as if in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

§300aa–17. Subrogation

(a) General rule

Upon payment of compensation to any petitioner under the Program, the trust fund which has been established to provide such compensation shall be subrograted [1] to all rights of the petitioner with respect to the vaccine-related injury or death for which compensation was paid, except that the trust fund may not recover under such rights an amount greater than the amount of compensation paid to the petitioner.

(b) Disposition of amounts recovered

Amounts recovered under subsection (a) shall be collected on behalf of, and deposited in, the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26.

(July 1, 1944, ch. 373, title XXI, §2117, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3770; amended Pub. L. 100–203, title IV, §4307(7), Dec. 22, 1987, 101 Stat. 1330–225; Pub. L. 101–239, title VI, §6601(m)(2), Dec. 19, 1989, 103 Stat. 2291.)

Editorial Notes

Amendments

1989—Subsec. (b). Pub. L. 101–239 substituted "the Vaccine Injury Compensation Trust Fund established under section 9510 of title 26" for "the trust fund which has been established to provide compensation under the Program".

1987—Subsec. (a). Pub. L. 100–203 struck out par. (1) designation before "Upon" and struck out par. (2) which read as follows: "In any case in which it deems such action appropriate, a district court of the United States may, after entry of a final judgment providing for compensation to be paid under section 300aa–15 of this title for a vaccine-related injury or death, refer the record of such proceeding to the Secretary and the Attorney General with such recommendation as the court deems appropriate with respect to the investigation or commencement of a civil action by the Secretary under paragraph (1)."

Statutory Notes and Related Subsidiaries

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

[1] So in original. Probably should be "subrogated".

§300aa–18. Repealed. Pub. L. 100–203, title IV, §4303(d)(2)(B), Dec. 22, 1987, 101 Stat. 1330–222

Section, act July 1, 1944, ch. 373, title XXI, §2118, as added Nov. 14, 1986, Pub. L. 99–660, title III, §311(a), 100 Stat. 3771, provided for annual increases for inflation of compensation under subsections (a)(2) and (a)(4) of section 300aa–15 of this title and civil penalty under section 300aa–27(b) of this title.

§300aa–19. Advisory Commission on Childhood Vaccines

(a) Establishment

There is established the Advisory Commission on Childhood Vaccines. The Commission shall be composed of:

(1) Nine members appointed by the Secretary as follows:

(A) Three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians.

(B) Three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death.

(C) Three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of Food and Drugs (or the designees of such officials), each of whom shall be a nonvoting ex officio member.

The Secretary shall select members of the Commission within 90 days of October 1, 1988. The members of the Commission shall select a Chair from among the members.

(b) Term of office

Appointed members of the Commission shall be appointed for a term of office of 3 years, except that of the members first appointed, 3 shall be appointed for a term of 1 year, 3 shall be appointed for a term of 2 years, and 3 shall be appointed for a term of 3 years, as determined by the Secretary.

(c) Meetings

The Commission shall first meet within 60 days after all members of the Commission are appointed, and thereafter shall meet not less often than four times per year and at the call of the chair. A quorum for purposes of a meeting is 5. A decision at a meeting is to be made by a ballot of a majority of the voting members of the Commission present at the meeting.

(d) Compensation

Members of the Commission who are officers or employees of the Federal Government shall serve as members of the Commission without compensation in addition to that received in their regular public employment. Members of the Commission who are not officers or employees of the Federal Government shall be compensated at a rate not to exceed the daily equivalent of the rate in effect for grade GS–18 of the General Schedule for each day (including traveltime) they are engaged in the performance of their duties as members of the Commission. All members, while so serving away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as such expenses are authorized by section 5703 of title 5 for employees serving intermittently.

(e) Staff

The Secretary shall provide the Commission with such professional and clerical staff, such information, and the services of such consultants as may be necessary to assist the Commission in carrying out effectively its functions under this section.

(f) Functions

The Commission shall—

(1) advise the Secretary on the implementation of the Program,

(2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table,

(3) advise the Secretary in implementing the Secretary's responsibilities under section 300aa–27 of this title regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions,

(4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of section 300aa–25(b) of this title, and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines, and

(5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out this part.

(July 1, 1944, ch. 373, title XXI, §2119, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3771; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221; Pub. L. 102–168, title II, §201(g), Nov. 26, 1991, 105 Stat. 1104; Pub. L. 102–531, title III, §312(d)(14), Oct. 27, 1992, 106 Stat. 3505.)

Editorial Notes

Codification

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1992—Subsec. (a)(2). Pub. L. 102–531 substituted "Centers for Disease Control and Prevention" for "Centers for Disease Control".

1991—Subsec. (c). Pub. L. 102–168 inserted "present at the meeting" before period at end.

1987—Subsec. (a). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part" in last sentence.

Statutory Notes and Related Subsidiaries

Termination of Advisory Commissions

Advisory commissions established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a commission established by the President or an officer of the Federal Government, such commission is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a commission established by the Congress, its duration is otherwise provided by law. See sections 3(2) and 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, §6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

References in Other Laws to GS–16, 17, or 18 Pay Rates

References in laws to the rates of pay for GS–16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, §101(c)(1)] of Pub. L. 101–509, set out in a note under section 5376 of Title 5.

subpart b—additional remedies

§300aa–21. Authority to bring actions

(a) Election

After judgment has been entered by the United States Court of Federal Claims or, if an appeal is taken under section 300aa–12(f) of this title, after the appellate court's mandate is issued, the petitioner who filed the petition under section 300aa–11 of this title shall file with the clerk of the United States Court of Federal Claims—

(1) if the judgment awarded compensation, an election in writing to receive the compensation or to file a civil action for damages for such injury or death, or

(2) if the judgment did not award compensation, an election in writing to accept the judgment or to file a civil action for damages for such injury or death.

An election shall be filed under this subsection not later than 90 days after the date of the court's final judgment with respect to which the election is to be made. If a person required to file an election with the court under this subsection does not file the election within the time prescribed for filing the election, such person shall be deemed to have filed an election to accept the judgment of the court. If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered. For limitations on the bringing of civil actions for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988, see section 300aa–11(a)(2) of this title.

(b) Continuance or withdrawal of petition

A petitioner under a petition filed under section 300aa–11 of this title may submit to the United States Court of Federal Claims a notice in writing choosing to continue or to withdraw the petition if—

(1) a special master fails to make a decision on such petition within the 240 days prescribed by section 300aa–12(d)(3)(A)(ii) of this title (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title), or

(2) the court fails to enter a judgment under section 300aa–12 of this title on the petition within 420 days (excluding (i) any period of suspension under section 300aa–12(d)(3)(C) or 300aa–12(d)(3)(D) of this title, and (ii) any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed.

Such a notice shall be filed within 30 days of the provision of the notice required by section 300aa–12(g) of this title.

(c) Limitations of actions

A civil action for damages arising from a vaccine-related injury or death for which a petition was filed under section 300aa–11 of this title shall, except as provided in section 300aa–16(c) of this title, be brought within the period prescribed by limitations of actions under State law applicable to such civil action.

(July 1, 1944, ch. 373, title XXI, §2121, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3772; amended Pub. L. 100–203, title IV, §§4304(c), 4307(8), 4308(c), Dec. 22, 1987, 101 Stat. 1330–224, 1330-225; Pub. L. 100–360, title IV, §411(o)(3)(A), July 1, 1988, 102 Stat. 808; Pub. L. 101–239, title VI, §6601(n), Dec. 19, 1989, 103 Stat. 2291; Pub. L. 101–502, §5(f), Nov. 3, 1990, 104 Stat. 1287; Pub. L. 102–168, title II, §201(d)(3), Nov. 26, 1991, 105 Stat. 1103; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Editorial Notes

Codification

In subsec. (a), "October 1, 1988," and "October 1, 1988" substituted for "the effective date of this part".

Amendments

1992—Subsecs. (a), (b). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" wherever appearing.

1991—Subsec. (b). Pub. L. 102–168 substituted "Continuance or withdrawal of petition" for "Withdrawal of petition" in heading, redesignated introductory provisions of par. (1) as introductory provisions of subsec. (b) and substituted "a notice in writing choosing to continue or to withdraw the petition" for "a notice in writing withdrawing the petition", redesignated subpars. (A) and (B) of former par. (1) as pars. (1) and (2), respectively, and realigned margins, struck out at end of former par. (1) "If such a notice is not filed before the expiration of such 30 days, the petition with respect to which the notice was to be filed shall be considered withdrawn under this paragraph.", and struck out par. (2) which read as follows: "If a special master or the court does not enter a decision or make a judgment on a petition filed under section 300aa–11 of this title within 30 days of the provision of the notice in accordance with section 300aa–12(g) of this title, the special master or court shall no longer have jurisdiction over such petition and such petition shall be considered as withdrawn under paragraph (1)."

1990—Subsec. (a). Pub. L. 101–502, §5(f)(1), in closing provisions, inserted after second sentence "If a person elects to receive compensation under a judgment of the court in an action for a vaccine-related injury or death associated with the administration of a vaccine before October 1, 1988, or is deemed to have accepted the judgment of the court in such an action, such person may not bring or maintain a civil action for damages against a vaccine administrator or manufacturer for the vaccine-related injury or death for which the judgment was entered." and inserted "for vaccine-related injuries or deaths associated with the administration of a vaccine after October 1, 1988" after "actions" in last sentence.

Subsec. (b). Pub. L. 101–502, §5(f)(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "If the United States Claims Court fails to enter a judgment under section 300aa–12 of this title on a petition filed under section 300aa–11 of this title within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title) after the date on which the petition was filed, the petitioner may submit to the court a notice in writing withdrawing the petition. An election shall be filed under this subsection not later than 90 days after the date of the entry of the Claims Court's judgment or the appellate court's mandate with respect to which the election is to be made. A person who has submitted a notice under this subsection may, notwithstanding section 300aa–11(a)(2) of this title, thereafter maintain a civil action for damages in a State or Federal court without regard to this subpart and consistent with otherwise applicable law."

1989—Subsec. (a). Pub. L. 101–239, §6601(n)(1)(A), amended introductory provisions generally. Prior to amendment, introductory provisions read as follows: "After the judgment of the United States Claims Court under section 300aa–11 of this title on a petition filed for compensation under the Program for a vaccine-related injury or death has become final, the person who filed the petition shall file with the court—".

Pub. L. 101–239, §6601(n)(1)(B), amended last sentence generally. Prior to amendment, last sentence read as follows: "If a person elects to receive compensation under a judgment of the court or is deemed to have accepted the judgment of the court, such person may not bring or maintain a civil action for damages against a vaccine manufacturer for the vaccine-related injury or death for which the judgment was entered."

Subsec. (b). Pub. L. 101–239, §6601(n)(2), substituted "within 420 days (excluding any period of suspension under section 300aa–12(d) of this title and excluding any days the petition is before a special master as a result of a remand under section 300aa–12(e)(2)(C) of this title)" for "within 365 days" in first sentence and amended

second sentence generally. Prior to amendment, second sentence read as follows: "Such a notice shall be filed not later than 90 days after the expiration of such 365-day period."

1988—Subsec. (a). Pub. L. 100–360 added Pub. L. 100–203, §4308(c), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4308(c), as added by Pub. L. 100–360, substituted "the court's final judgment" for "the entry of the court's judgment" in concluding provisions.

Pub. L. 100–203, §4307(8), substituted "the United States Claims Court" for "a district court of the United States" and "the court" for "a court" in three places.

Subsecs. (b), (c). Pub. L. 100–203, §4304(c), added subsec. (b) and redesignated former subsec. (b) as (c).

Statutory Notes and Related Subsidiaries

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1991 Amendment

Amendment by Pub. L. 102–168 effective as in effect on and after Oct. 1, 1988, see section 201(i)(2) of Pub. L. 102–168, set out as a note under section 300aa–11 of this title.

Effective Date of 1990 Amendment

Amendment by section 5(f)(1) of Pub. L. 101–502 effective Nov. 14, 1986, and amendment by section 5(f)(2) of Pub. L. 101–502 effective Sept. 30, 1990, see section 5(h) of Pub. L. 101–502, set out as a note under section 300aa–11 of this title.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, except that such suspension be excluded in determining the 420-day period prescribed in subsec. (b) of this section, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

Effective Date of 1988 Amendment

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

Effective Date

Subpart effective Oct. 1, 1988, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–22. Standards of responsibility

(a) General rule

Except as provided in subsections (b), (c), and (e) State law shall apply to a civil action brought for damages for a vaccine-related injury or death.

(b) Unavoidable adverse side effects; warnings

(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

(2) For purposes of paragraph (1), a vaccine shall be presumed to be accompanied by proper directions and warnings if the vaccine manufacturer shows that it complied in all material respects with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and section 262 of this title (including regulations issued under such provisions) applicable to the vaccine and related to vaccine-related injury or death for which the civil action was brought unless the plaintiff shows—

(A) that the manufacturer engaged in the conduct set forth in subparagraph (A) or (B) of section 300aa–23(d)(2) of this title, or

(B) by clear and convincing evidence that the manufacturer failed to exercise due care notwithstanding its compliance with such Act and section (and regulations issued under such provisions).

(c) Direct warnings

No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, solely due to the manufacturer's failure to provide direct warnings to the injured party (or the injured party's legal representative) of the potential dangers resulting from the administration of the vaccine manufactured by the manufacturer.

(d) Construction

The standards of responsibility prescribed by this section are not to be construed as authorizing a person who brought a civil action for damages against a vaccine manufacturer for a vaccine-related injury or death in which damages were denied or which was dismissed with prejudice to bring a new civil action against such manufacturer for such injury or death.

(e) Preemption

No State may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death if such civil action is not barred by this part.

(July 1, 1944, ch. 373, title XXI, §2122, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3773; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (b)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

Codification

In subsecs. (b)(1), (c), "October 1, 1988" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsecs. (b)(1), (c). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

§300aa–23. Trial

(a) General rule

A civil action against a vaccine manufacturer for damages for a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, which is not barred by section 300aa–11(a)(2) of this title shall be tried in three stages.

(b) Liability

The first stage of such a civil action shall be held to determine if a vaccine manufacturer is liable under section 300aa–22 of this title.

(c) General damages

The second stage of such a civil action shall be held to determine the amount of damages (other than punitive damages) a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(d) Punitive damages

(1) If sought by the plaintiff, the third stage of such an action shall be held to determine the amount of punitive damages a vaccine manufacturer found to be liable under section 300aa–22 of this title shall be required to pay.

(2) If in such an action the manufacturer shows that it complied, in all material respects, with all requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and this chapter applicable to the vaccine and related to the vaccine injury or death with respect to which the action was brought, the manufacturer shall not be held liable for punitive damages unless the manufacturer engaged in—

(A) fraud or intentional and wrongful withholding of information from the Secretary during any phase of a proceeding for approval of the vaccine under section 262 of this title,

(B) intentional and wrongful withholding of information relating to the safety or efficacy of the vaccine after its approval, or

(C) other criminal or illegal activity relating to the safety and effectiveness of vaccines,

which activity related to the vaccine-related injury or death for which the civil action was brought.

(e) Evidence

In any stage of a civil action, the Vaccine Injury Table, any finding of fact or conclusion of law of the United States Court of Federal Claims or a special master in a proceeding on a petition filed under section 300aa–11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.

(July 1, 1944, ch. 373, title XXI, §2123, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §§4302(b)(1), 4307(9), Dec. 22, 1987, 101 Stat. 1330–221, 1330-225; Pub. L. 101–239, title VI, §6601(o), Dec. 19, 1989, 103 Stat. 2292; Pub. L. 102–572, title IX, §902(b)(1), Oct. 29, 1992, 106 Stat. 4516.)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (d)(2), is act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Tables.

Codification

In subsec. (a), "October 1, 1988" substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1992—Subsec. (e). Pub. L. 102–572 substituted "United States Court of Federal Claims" for "United States Claims Court" in two places.

1989—Subsec. (e). Pub. L. 101–239 substituted "finding of fact or conclusion of law" for "finding", "special master" for "master appointed by such court", and directed substitution of "the United States Claims Court and subsequent appellate review" for "a district court of the United States" which was executed by inserting "and subsequent appellate review" after "the United States Claims Court" the second place it appeared to reflect the probable intent of Congress and the amendment by Pub. L. 100–203, §4307(a), see 1987 Amendment note below.

1987—Subsec. (a). Pub. L. 100–203, §4302(b)(1), substituted "effective date of this subpart" for "effective date of this part".

Subsec. (e). Pub. L. 100–203, §4307(9), substituted "the United States Claims Court" for "a district court of the United States" in two places.

Statutory Notes and Related Subsidiaries

Effective Date of 1992 Amendment

Amendment by Pub. L. 102–572 effective Oct. 29, 1992, see section 911 of Pub. L. 102–572, set out as a note under section 171 of Title 28, Judiciary and Judicial Procedure.

Effective Date of 1989 Amendment

For applicability of amendments by Pub. L. 101–239 to petitions filed after Dec. 19, 1989, petitions currently pending in which the evidentiary record is closed, and petitions currently pending in which the evidentiary record is not closed, with provision for an immediate suspension for 30 days of all pending cases, see section 6601(s)(1) of Pub. L. 101–239, set out as a note under section 300aa–10 of this title.

subpart c—assuring a safer childhood vaccination program in united states

§300aa–25. Recording and reporting of information

(a) General rule

Each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person shall record, or ensure that there is recorded, in such person's permanent medical record (or in a permanent office log or file to which a legal representative shall have access upon request) with respect to each such vaccine—

(1) the date of administration of the vaccine,

(2) the vaccine manufacturer and lot number of the vaccine,

(3) the name and address and, if appropriate, the title of the health care provider administering the vaccine, and

(4) any other identifying information on the vaccine required pursuant to regulations promulgated by the Secretary.

(b) Reporting

(1) Each health care provider and vaccine manufacturer shall report to the Secretary—

(A) the occurrence of any event set forth in the Vaccine Injury Table, including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,

(B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and

(C) such other matters as the Secretary may by regulation require.

Reports of the matters referred to in subparagraphs (A) and (B) shall be made beginning 90 days after December 22, 1987. The Secretary shall publish in the Federal Register as soon as practicable after such date a notice of the reporting requirement.

(2) A report under paragraph (1) respecting a vaccine shall include the time periods after the administration of such vaccine within which vaccine-related illnesses, disabilities, injuries, or conditions, the symptoms and manifestations of such illnesses, disabilities, injuries, or conditions, or deaths occur, and the manufacturer and lot number of the vaccine.

(3) The Secretary shall issue the regulations referred to in paragraph (1)(C) within 180 days of December 22, 1987.

(c) Release of information

(1) Information which is in the possession of the Federal Government and State and local governments under this section and which may identify an individual shall not be made available under section 552 of title 5, or otherwise, to any person except—

(A) the person who received the vaccine, or

(B) the legal representative of such person.

(2) For purposes of paragraph (1), the term "information which may identify an individual" shall be limited to the name, street address, and telephone number of the person who received the vaccine and of that person's legal representative and the medical records of such person relating to the administration of the vaccine, and shall not include the locality and State of vaccine administration, the name of the health care provider who administered the vaccine, the date of the vaccination, or information concerning any reported illness, disability, injury, or condition resulting from the administration of the vaccine, any symptom or manifestation of such illness, disability, injury, or condition, or death resulting from the administration of the vaccine.

(3) Except as provided in paragraph (1), all information reported under this section shall be available to the public.

(July 1, 1944, ch. 373, title XXI, §2125, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3774; amended Pub. L. 100–203, title IV, §4302(b)(1), Dec. 22, 1987, 101 Stat. 1330–221.)

Editorial Notes

Codification

In subsec. (b)(1), (3), "December 22, 1987" was substituted for "the effective date of this subpart" on authority of section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Amendments

1987—Subsec. (b)(1), (3). Pub. L. 100–203 substituted "effective date of this subpart" for "effective date of this part".

Statutory Notes and Related Subsidiaries

Effective Date

Subpart effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, set out as a note under section 300aa–1 of this title.

§300aa–26. Vaccine information

(a) General rule

Not later than 1 year after December 22, 1987, the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child or to any other individual receiving a vaccine set forth in the Vaccine Injury Table. Such materials shall be published in the Federal Register and may be revised.

(b) Development and revision of materials

Such materials shall be developed or revised—

(1) after notice to the public and 60 days of comment thereon, and

(2) in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care providers and parent organizations, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

(c) Information requirements

The information in such materials shall be based on available data and information, shall be presented in understandable terms and shall include—

(1) a concise description of the benefits of the vaccine,

Syllabus

NOTE: Where it is feasible, a syllabus (headnote) will be released, as is being done in connection with this case, at the time the opinion is issued. The syllabus constitutes no part of the opinion of the Court but has been prepared by the Reporter of Decisions for the convenience of the reader. See *United States* v. *Detroit Timber & Lumber Co.,* 200 U. S. 321, 337.

SUPREME COURT OF THE UNITED STATES

Syllabus

BRUESEWITZ ET AL. *v.* WYETH LLC, FKA WYETH, INC., ET AL.

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 09–152. Argued October 12, 2010—Decided February 22, 2011

The National Childhood Vaccine Injury Act of 1986 (NCVIA or Act) created a no-fault compensation program to stabilize a vaccine market adversely affected by an increase in vaccine-related tort litigation and to facilitate compensation to claimants who found pursuing legitimate vaccine-inflicted injuries too costly and difficult. The Act provides that a party alleging a vaccine-related injury may file a petition for compensation in the Court of Federal Claims, naming the Health and Human Services Secretary as the respondent; that the court must resolve the case by a specified deadline; and that the claimant can then decide whether to accept the court's judgment or reject it and seek tort relief from the vaccine manufacturer. Awards are paid out of a fund created by an excise tax on each vaccine dose. As a *quid pro quo,* manufacturers enjoy significant tort-liability protections. Most importantly, the Act eliminates manufacturer liability for a vaccine's unavoidable, adverse side effects.

Hannah Bruesewitz's parents filed a vaccine-injury petition in the Court of Federal Claims, claiming that Hannah became disabled after receiving a diphtheria, tetanus, and pertussis (DTP) vaccine manufactured by Lederle Laboratories (now owned by respondent Wyeth). After that court denied their claim, they elected to reject the unfavorable judgment and filed suit in Pennsylvania state court, alleging, *inter alia,* that the defective design of Lederle's DTP vaccine caused Hannah's disabilities, and that Lederle was subject to strict liability and liability for negligent design under Pennsylvania common law. Wyeth removed the suit to the Federal District Court. It granted Wyeth summary judgment, holding that the relevant Pennsylvania law was preempted by 42 U. S. C. §300aa–22(b)(1), which

Syllabus

provides that "[n]o vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side-effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings." The Third Circuit affirmed.

Held: The NCVIA preempts all design-defect claims against vaccine manufacturers brought by plaintiffs seeking compensation for injury or death caused by a vaccine's side effects. Pp. 7–19.

(a) Section 300aa–22(b)(1)'s text suggests that a vaccine's design is not open to question in a tort action. If a manufacturer could be held liable for failure to use a different design, the "even though" clause would do no work. A vaccine side effect could alway*s* have been avoidable by use of a different vaccine not containing the harmful element. The language of the provision thus suggests the design is not subject to question in a tort action. What the statute establishes as a complete defense must be unavoidability (given safe manufacture and warning) with respect to the particular design. This conclusion is supported by the fact that, although products-liability law establishes three grounds for liability—defective manufacture, inadequate directions or warnings, and defective design—the Act mentions only manufacture and warnings. It thus seems that the Act's failure to mention design-defect liability is "by deliberate choice, not inadvertence." *Barnhart* v. *Peabody Coal Co.*, 537 U. S. 149, 168. Pp. 7–8.

(b) Contrary to petitioners' argument, there is no reason to believe that §300aa–22(b)(1)'s term "unavoidable" is a term of art incorporating Restatement (Second) of Torts §402A, Comment *k,* which exempts from strict liability rules "unavoidably unsafe products." "Unavoidable" is hardly a rarely used word, and cases interpreting comment *k* attach special significance only to the term "unavoidably unsafe products," not the word "unavoidable" standing alone. Moreover, reading the phrase "side effects that were unavoidable" to exempt injuries caused by flawed design would require treating "even though" as a coordinating conjunction linking independent ideas when it is a concessive, subordinating conjunction conveying that one clause weakens or qualifies the other. The canon against superfluity does not undermine this Court's interpretation because petitioners' competing interpretation has superfluity problems of its own. Pp. 8–12.

(c) The structure of the NCVIA and of vaccine regulation in general reinforces what §300aa–22(b)(1)'s text suggests. Design defects do not merit a single mention in the Act or in Food and Drug Administration regulations that pervasively regulate the drug manufacturing process. This lack of guidance for design defects, combined with

Syllabus

the extensive guidance for the two liability grounds specifically mentioned in the Act, strongly suggests that design defects were not mentioned because they are not a basis for liability. The Act's mandates lead to the same conclusion. It provides for federal agency improvement of vaccine design and for federally prescribed compensation, which are other means for achieving the two beneficial effects of design-defect torts—prompting the development of improved designs, and providing compensation for inflicted injuries. The Act's structural *quid pro quo* also leads to the same conclusion. The vaccine manufacturers fund an informal, efficient compensation program for vaccine injuries in exchange for avoiding costly tort litigation and the occasional disproportionate jury verdict. Taxing their product to fund the compensation program, while leaving their liability for design defect virtually unaltered, would hardly coax them back into the market. Pp. 13–16.

561 F. 3d 233, affirmed.

SCALIA, J., delivered the opinion of the Court, in which ROBERTS, C. J., and KENNEDY, THOMAS, BREYER, and ALITO, JJ., joined. BREYER, J., filed a concurring opinion. SOTOMAYOR, J., filed a dissenting opinion, in which GINSBURG, J., joined. KAGAN, J., took no part in the consideration or decision of the case.

HRSA
Health Resources & Services Administration

Data & Statistics

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions.
In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a petition for compensation.

What does it mean to be awarded compensation?
Being awarded compensation for a petition does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Approximately 60 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded compensation by the Court, if certain minimal requirements are met. In those circumstances, attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee, including a contingency fee, for his or her services in representing a petitioner in the VICP.

What reasons might a petition result in a negotiated settlement?

- Consideration of prior U.S. Court of Federal Claims decisions, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a petition quickly

How many petitions have been awarded compensation?
According to the CDC, from 2006 to 2021 over 6 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 10,342 petitions were adjudicated by the Court, and of those 7,418 were compensated. This means for every 1 million doses of vaccine that were distributed, approximately 1 individual was compensated.

Since 1988, over 25,961 petitions have been filed with the VICP. Over that 30-year time period, 22,030 petitions have been adjudicated, with 9,664 of those determined to be compensable, while 12,366 were dismissed. Total compensation paid over the life of the program is approximately $4.9 billion.

VICP Adjudication Categories, by Alleged Vaccine for Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006 through 12/31/2021

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2021 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
DT	794,777	1	0	5	6	4	10
DTaP	119,588,927	27	23	124	174	140	314
DTaP-Hep B-IPV	89,690,234	7	8	32	47	67	114
DTaP-HIB	1,135,474	0	1	2	3	2	5
DTaP-IPV	35,717,741	1	0	5	6	5	11
DTap-IPV-HIB	85,135,961	5	4	9	18	41	59
DTaP-IPV-HIB-Hep B	464,070	0	0	0	0	0	0
DTP	0	1	1	3	5	4	9
DTP-HIB	0	1	0	2	3	1	4
Hep A-Hep B	19,067,612	3	1	19	23	8	31
Hep B-HIB	4,787,457	1	1	2	4	1	5
Hepatitis A (Hep A)	221,388,946	10	6	54	70	42	112
Hepatitis B (Hep B)	238,582,570	15	12	85	112	101	213
HIB	152,436,021	2	1	13	16	11	27
HPV	149,352,148	32	13	119	164	349	513
Influenza	2,231,400,000	1,761	237	3,432	5,430	964	6,394
IPV	83,134,982	1	1	5	7	5	12

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2021 (Source: CDC)	Compensable Concession	Compensable Court Decision	Compensable Settlement	Compensable Total	Dismissed/Non-Compensable Total	Grand Total
Measles	135,660	1	0	2	3	0	3
Meningococcal	140,401,298	16	5	46	67	28	95
MMR	127,871,467	26	16	105	147	148	295
MMR-Varicella	39,223,326	12	1	14	27	21	48
Mumps	110,749	0	0	0	0	0	0
Nonqualified	0	0	0	3	3	55	58
OPV	0	1	0	0	1	5	6
Pneumococcal Conjugate	303,138,568	47	3	77	127	76	203
Rotavirus	1,422,658,212	27	4	25	56	22	78
Rubella	422,548	0	1	1	2	0	2
Td	76,709,653	17	6	70	93	29	122
Tdap	335,133,138	205	21	442	669	149	818
Tetanus	3,836,052	20	2	55	77	22	99
Unspecified	0	1	1	5	7	597	604
Varicella	138,414,086	11	7	33	51	27	78
Grand Total	**6,020,731,677**	**2,252**	**376**	**4,789**	**7,418**	**2,924**	**10,342**

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2021 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation. Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The conceded "unspecified" petition was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the "unspecified" settlements were for multiple vaccines later identified in the Special Masters' decisions

Definitions

Compensable – The injured person who filed a petition was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the petition by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- **Concession**: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision**: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).
  For injury petitions, compensable court decisions are based in part on one of the following determinations by the court:
  1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
  2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement**: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Petitions may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- **Non-compensable/Dismissed**: The injured person who filed a petition was ultimately not paid money. Non-compensable Court decisions include the following:
  1. The Court determines that the person who filed the petition did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
  2. The petition was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
  3. The injured person voluntarily withdrew his or her petition.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 03/01/2023

Vaccines	Filed Injury	Filed Death	Filed Total	Compensated	Dismissed
DTaP-IPV	16	0	16	6	5
DT	69	9	78	26	52
DTP	3,288	696	3,984	1,273	2,711
DTP-HIB	20	8	28	7	21
DTaP	484	88	572	256	275
DTaP-Hep B-IPV	98	40	138	48	67
DTaP-HIB	11	1	12	7	4
DTaP-IPV-HIB	53	21	74	18	41
DTaP-IPV-HIB-HEPB	0	0	0	0	0
Td	239	3	242	139	80
Tdap	1,182	8	1,190	667	148
Tetanus	182	3	185	100	49
Hepatitis A (Hep A)	143	7	150	70	45
Hepatitis B (Hep B)	750	62	812	303	448
Hep A-Hep B	45	0	45	23	9
Hep B-HIB	8	0	8	5	3
HIB	50	3	53	23	21
HPV	734	20	754	163	384
Influenza	8,945	231	9,176	5,412	960
IPV	269	14	283	10	271
OPV	282	28	310	158	152
Measles	145	19	164	57	107
Meningococcal	121	3	124	66	28
MMR	1,045	62	1,107	429	609
MMR-Varicella	61	2	63	26	21
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	328	24	352	131	94
Rotavirus	115	6	121	76	33
Rubella	190	4	194	71	123
Varicella	117	10	127	71	39
Nonqualified[1]	118	13	131	3	124
Unspecified[2]	5,427	9	5,436	11	5,419
Grand Total	**24,564**	**1,397**	**25,961**	**9,664**	**12,366**

[1] Nonqualified petitions are those filed for vaccines not covered under the VICP.
[2] Unspecified petitions are those submitted with insufficient information to make a determination.

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	447
FY 2011	386
FY 2012	402
FY 2013	504
FY 2014	633
FY 2015	803
FY 2016	1,120
FY 2017	1,243
FY 2018	1,238
FY 2019	1,282
FY 2020	1,192
FY 2021	2,057
FY 2022	1,029
FY 2023	481
Total	**25,961**

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed.
On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	88	174
FY 2002	104	104	208
FY 2003	56	100	156
FY 2004	62	247	309
FY 2005	60	229	289
FY 2006	69	193	262
FY 2007	82	136	218
FY 2008	147	151	298
FY 2009	134	257	391
FY 2010	180	330	510
FY 2011	266	1,742	2,008
FY 2012	265	2,533	2,798
FY 2013	369	651	1,020
FY 2014	370	194	564
FY 2015	521	146	667
FY 2016	700	187	887
FY 2017	696	203	899
FY 2018	545	202	747
FY 2019	641	182	823
FY 2020	711	217	928
FY 2021	755	259	1,014
FY 2022	932	262	1,194
FY 2023	332	135	467
Total	**9,664**	**12,366**	**22,030**

Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	74	$2,531,394.20	2	$117,265.31	$83,556,982.40
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	59	$1,933,550.09	22	$1,978,803.88	$189,261,439.67
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,241,427.33	1,020	$8,649,676.56	37	$5,420,257.99	$186,803,360.70
FY 2013	375	$254,666,326.70	$13,543,099.70	704	$7,012,615.42	50	$1,423,851.74	$276,645,893.56
FY 2014	365	$202,084,196.12	$12,161,422.64	508	$6,824,566.68	38	$2,493,460.73	$223,563,646.17
FY 2015	508	$204,137,880.22	$14,464,063.71	118	$3,546,785.14	50	$3,089,497.68	$225,238,226.75

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 2016	689	$230,140,251.20	$16,298,140.59	100	$2,746,864.60	58	$3,398,557.26	$252,583,813.65
FY 2017	706	$252,245,932.78	$22,045,785.00	132	$4,454,379.49	52	$3,363,464.24	$282,109,561.51
FY 2018	521	$199,588,007.04	$16,689,908.68	113	$5,151,255.64	57	$4,999,766.30	$226,428,937.66
FY 2019	653	$196,217,707.64	$18,991,247.55	103	$5,292,700.23	65	$5,457,545.23	$225,959,200.65
FY 2020	733	$186,860,677.55	$20,165,188.43	113	$5,747,755.82	76	$5,090,482.24	$217,864,104.04
FY 2021	719	$208,258,401.31	$24,884,274.59	140	$6,942,253.81	53	$4,249,055.37	$244,333,985.08
FY 2022	927	$195,693,889.57	$22,992,062.07	102	$4,868,964.74	56	$6,329,886.09	$229,884,802.47
FY 2023	388	$54,900,354.60	$16,320,659.48	60	$3,411,942.57	33	$4,152,462.16	$78,785,418.81
Total	**9,608**	**$4,530,014,616.44**	**$290,547,393.97**	**5,872**	**$106,432,379.56**	**705**	**$57,807,489.68**	**$4,984,801,879.65**

NOTE: Some previous fiscal year data has been updated as a result of the receipt and entry of data from documents issued by the Court and system updates which included petitioners' costs reimbursements in outlay totals,

"Compensated" are petitions that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/petitions are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the petition, whether or not the petition/petition is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.