Exhibit 347

Brief of Amici Curiae Medical and Scientific Professionals in Support of Defendant Appellant Joshua Nagel and Reversal

https://www.andrewbostom.org/wp-content/uploads/2023/03/Nagel-Brief-Amicus-Filed.pdf

No. SU2023-0066-A

IN THE SUPREME COURT OF THE STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Lauren Nagel
Plaintiff/Appellee

v.

Joshua Nagel
Defendant/Appellant

On Appeal from a Judgment Issued in the Family Court, Kent County no. F.C. No. K19-1687 (Lanni, J.)

BRIEF OF *AMICI CURIAE* MEDICAL AND SCIENTIFIC PROFESSIONALS IN SUPPORT OF DEFENDANT APPELLANT JOSHUA NAGEL AND REVERSAL

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INTEREST OF *AMICI CURIAE*[1]

Amici curiae are an international assembly of medical doctors, academic scientists, allied health professionals, and officers (past and present) of prestigious medical societies. Each maintains a keen professional interest in the unfolding research into the efficacy of the COVID vaccines and the documented risks of taking them, especially among children. Their shared interest is seeing to it that any professional recommendation about vaccinating minors, especially but not only those who have natural immunity from previous infection, be made according to the best scientific research and clinical experience available.

Amici include dozens of pediatricians and family practitioners, as well as a former President of the American Academy of Pediatrics and the former Executive Director of the American College of Pediatricians. Academic medical doctors from many universities, including Stanford, Brown, and Yale, are *amici.* Doctors from the United Kingdom, Canada,

[1] No counsel for a party authored this brief in whole or in part, and no party, party's counsel, or any person other than *amicus curiae* or his counsel contributed money intended to fund preparation or submission of this brief.

and Australia have joined their American colleagues. A former president of the American Heart Association is an *amicus*.

ARGUMENT

Amici are medical and scientific professionals with expertise in studying and treating COVID-19 viruses, the vaccines currently available for them, and the potential benefits and harms of vaccination for COVID. Many *amici* are pediatricians who treat daily children like the Nagel's healthy five- and eight-year-old girls. Based upon the best scientific studies available and abundant clinical experience, *amici* conclude that vaccinating children such as the Nagel girls would not be in their best interests. The potential benefits of vaccinating them are far outweighed by the certain risks of harm to them.

Amici recognize that some professional medical organizations (such as the American Academy of Pediatricians, to which many *amici* belong) recommend vaccination for all children over six months. But, in addition to overestimating the benefits and downplaying the risks of vaccinating children, these recommendations do not fully account for the effects of the natural immunity which the Nagel girls enjoy; are out-of-step with the recommended practices of professional medical organizations in other

countries; and fail to consider the presently unknowable long-term ill-effects of vaccines which have been, after all, approved for use as emergency measures under the duress of fighting a global pandemic.

I. The COVID-19 vaccine promises little if any benefit to healthy children like the Nagel girls.

The benefit of any vaccine typically consists in its ability to prevent the targeted illness and not to just to ameliorate its symptoms; thus, the epochally successful smallpox and polio vaccines practically eliminated those diseases from human experience. But the COVID-19 vaccines were not developed to prevent initial infection and were approved by the FDA mainly as protections against severely symptomatic cases of COVID. If these vaccines are to provide *any* benefit to children like the Nagel girls, then, it would be chiefly to decrease a child's chance of being hospitalized or experiencing serious illness.

Do they?

To date there is no clinical trial that has demonstrated COVID-19 vaccines reduce hospitalization in children. Instead, only *observational* studies are available. But observational studies are notoriously imprecise, even when measuring reliable metrics. They can form a basis only for educated guesses about whether COVID-19 vaccines are a net

benefit for minors. A review of the most recent data makes clear that the potential benefit of COVID-19 vaccination for children is, however, very small. The real uncertainty is just how small, particularly when it comes to reduced risk of hospitalization in previously infected children such as the Nagels.

A report published in January, 2023 by the United Kingdom's Health Security Agency ("UKHSA") evaluated the benefits of COVID-19 vaccination in children. UK HEALTH SEC. AGENCY, *Appendix 1* (2023) https://bit.ly/3mGDbpi. The UKHSA studied COVID-19 hospitalization of children aged five to eleven during the Omicron variant outbreak of July, 2022. The report used hospitalization and severe hospitalization rates to find the "number needed to vaccinate" ("NNV").[2] *Id.* at 2. The NNV is the number of people that must be vaccinated in order to prevent one hospitalization each year. The higher the NNV, the more people must be vaccinated in order to achieve the benefit, and the less beneficial the vaccine is. The NNV for five to eleven-year-old children is 34,000 for hospitalization and 110,000 for severe hospitalization. *Id.* at 4. Risk of death to any COVID-infected child is nowhere in the picture.

[2] Severe hospitalizations are ones requiring oxygenation.

The NNV in the UK study is likely even higher because the UKHSA made some methodological choices that affected the impartiality of the data employed. The UK Office of National Statistics acknowledged that their data set contains "healthy vaccine" bias. Ed Humpherson, *ONS Deaths by Vaccination Status Statistics*, OFF. FOR STAT. REGUL. (Jan. 23, 2023). It is difficult—if not impossible—to control for this bias, meaning that this study overestimated vaccine efficacy to an extent which cannot be precisely identified. This uncertainty is in itself ample reason for caution before vaccinating minors like the Nagels.

First, the UK study used hospitalization and illness rates from July, 2022 as the average for each month. UKHSA, *Appendix* at 1–2. However, no monthly surge has been as high as the one last July; twenty-nine of the thirty-one days in July recorded a case rate higher than any day since then. Edouard Mathieu, et al., *Coronavirus Cases*, OUR WORLD IN DATA, http://bit.ly/3T07Fyo. Thus, the hospitalization rate per month is now lower than the calculated 4.2 per million. The NNV is consequently much higher.

Second, the UK reported hospitalization rate and NNV is for all children including those with and without comorbidities. Considering

that the Nagel children have none, their hospitalization risk would be substantially lower than the UKHSA estimate. For instance, of four million children, only 0.11% were hospitalized with COVID-19. Lyudmyla Kompaniyets, et al., *Underlying Medical Conditions Associated with Severe COVID-19 Illness Among Children*, JAMA NETWORK: OPEN (2021); Rebecca C. Woodruff et al., *Risk Factors for Severe COVID-19 in Children*, 149 PEDIATRICS 37 (2022). But, if one narrows the group to children *without* underlying medical conditions, hospitalizations drop 65%. *Id.* Healthy children between the ages of five and eleven without medical conditions are, at least presumably, at a 65% lower risk of hospitalization than the UKHSA anticipated, making the real NNV higher than estimated.

A third concern is that the UK study does not account for prior infection and resulting natural immunity. Prior infection offers strong protection against all variants. COVID-19 Forecasting Team, *Past SARS-CoV-2 Infection Protection Against Re-Infection*, THE LANCET (Feb. 16, 2023). During Omicron, for example, prior infection reduced hospitalization by 89% and the robust protection endured for at least forty weeks. *Id.* Moreover, a study of nearly 900,000 North Carolina (U.S.) children aged

five to eleven found that prior infection was more robust and enduring than vaccination for prevention of COVID-19 hospitalizations. Dan-Yu Lin, et al., *Effects of Vaccination and Previous Infection on Omicron Infections in Children*, NEW ENG. J. MED. (2022).

Since the UKHSA does not report the number of children with prior infection, it is impossible to know exactly how inflated its hospitalization rate is. In any event, the small potential benefit of vaccination recorded in the UK study would quickly fade. Rapid waning of vaccine efficacy in children of this age has been observed in several studies. The New York Department of Health measured vaccine efficacy in children two weeks after the second dose and found it was only 50% effective. Vajeera Dorabawila, et al., *Effectiveness of the BNT162b2 Vaccine Among Children*, N.Y. DEP'T OF HEALTH (Feb. 28, 2022). By week five, the vaccine no longer prevented infection. *Id.* Other studies of children show similarly rapid reduction in vaccine efficacy, with minimal vaccine efficacy remaining in the range of 20–30%. Katherine E. Fleming-Dutra, et al., *Association of Prior BNT162b2 COVID-19 Vaccination with Symptomatic SARS-CoV-2 Infection*, JAMA (2022); Chiara Sacco, et al., *Effectiveness of BNT162b2 Vaccine Against SARS-CoV-2 Infection*, 400

THE LANCET 97 (2022). In fact: children who receive the vaccine may contract COVID infections requiring hospitalization at *greater* rates than unvaccinated children with a history of prior infection.

II. The COVID-19 vaccine puts children like the Nagel girls at statistically certain risk of harm, including serious harm.

Of course, whether a responsible physician should recommend COVID vaccination—or any vaccination—to healthy children like the Nagel girls depends only partly on the potential benefits. It also depends upon known risks. Reliable studies demonstrate that a *majority* of children who receive the COVID-19 vaccine experience systemic adverse symptoms including fatigue, fever, headache, chills, and myalgias. Atsuyuki Watanabe, et al., *Assessment of Efficacy and Safety of mRNA COVID-19 Vaccines*, JAMA PEDIATRICS (2023).

There are also much less common but much more severe risks to vaccinating children such as the Nagel girls. The two most serious adverse events caused by the COVID-19 vaccines are anaphylaxis (a life-

threatening allergic reaction)[3] and myocarditis (heart muscle inflammation and heart muscle cell death).

A. The COVID-19 vaccine causes anaphylaxis and myocarditis in children.

The AAP identified an anaphylaxis rate of 0.4 per million for children receiving the COVID-19 vaccine. Other estimates of anaphylaxis vary widely. Anne M. Hause, et al., *Safety of COVID-19 Vaccination in U.S. Children*, 150 PEDIATRICS 1 (2022). A different study tracking anaphylaxis from COVID-19 vaccination, independent of age, found an anaphylaxis rate of 10 per million, approximately 20-fold higher than the AAP's number. Helena C. Maltezou, et al., *Anaphylaxis Rates Associated with COVID-19 Vaccines*, 40 ELSEVIER 183 (2022). Both studies used "passive reporting surveillance," a method that consistently underestimates rates of harm. An *active* surveillance study found an anaphylaxis rate of approximately 200 per million, exponentially higher than the passive reporting studies. Takanao Hashimoto, et al., *High Anaphylaxis Rates Follow Vaccination*, 28 J. TRAVEL MED. 1 (2021). Given this range, the "NNH", or "number needed to harm" for

[3] While occasionally deadly, anaphylaxis is typically easily treated, as long as medical intervention is rapidly administered.

anaphylaxis could be anywhere from 4,000 to 2.5 million. (The NNH is the number of people who must be exposed to an intervention—here, the COVID-19 vaccine—for one of them to experience an adverse effect. The lower the number, the greater the risk of harm.)

A second harm caused by the COVID-19 vaccine is myocarditis. The frequency of vaccine-induced myocarditis in children aged five to eleven is uncertain, but it appears to increase as children grow older. An AAP study estimated the myocarditis rate for children in the five to eleven-year-old range was 5.4 cases per million after the first round of vaccination, an NNH of 185,000. Hause, *Safety of COVID-19 Vaccination*.

Two studies have examined subclinical myocarditis, in which all vaccine recipients have labs drawn to evaluate for myocarditis. These studies found evidence of subclinical myocarditis in up to 2.8% of children following vaccination. Suyanee Mansanguan, et al., *Cardiovascular Effects of the BNT162b2 mRNA COVID-19 Vaccine*, PREPRINTS.ORG (Aug. 7, 2022) http://bit.ly/3L5o2YE; Angelika Jacobs, *Temporary Mild Damage to Heart Muscle Cells After COVID-19 Booster*, UNIV. OF BASEL (Nov. 9, 2022) http://bit.ly/3F9Vs4A. This would represent an NNH of 35. While

these patients did not have symptoms or require hospitalization, myocarditis nonetheless kills cardiac cells. These cells never regenerate. Thus, the cardiac injuries are permanent. The long-term consequences of this myocarditis effect of the vaccine are unknown. Using the UKHSA data on NNV suggests, however, that approximately 950 children will experience subclinical myocarditis, with unknown long-term consequences, in order to prevent one COVID-19 hospitalization.

Unfortunately, there are good reasons to think that number is too optimistic.

As with anaphylaxis, myocarditis estimates are made using a passive surveillance system, the CDC's VAERS system. When an active surveillance system is used (as was used for older children and adults), the myocarditis rate is much higher. The NNH of myocarditis after boosters is around 11,000 with active surveillance, but is 450,000 when passively surveilled. Katie A. Sharff, et al., *Surveillance of Myopericarditis Following COVID-19 Booster* (Feb. 15, 2022) https://bit.ly/3yqIhbA. If children were actively surveilled for myocarditis following boosters, the rate would almost certainly be much higher than the AAP reports. Further, children who receive boosters will

be exposed to higher risks of myocarditis in the future since its chance of occurring increases after each booster.

In sum: approximately 700 children will suffer permanent damage to their heart muscle cells to prevent one COVID-19 hospitalization. Over 2,000 will suffer such heart damage to prevent one *severe* hospitalization.

B. The downstream effects of taking the COVID-19 vaccine are potentially harmful.

In addition to the known risks of administering the COVID-19 vaccine to the Nagels, *amici* are concerned with adverse events subsequent to vaccination which have not been proven to be *caused* by it. The causal link for these harms has not yet been definitively confirmed (or refuted). These associated harms are nonetheless additional reasons counseling against vaccinating children like the Nagels.

The CDC recently released a COVID-19 vaccine safety analysis based on their passive reporting system. The report identified safety signals for sixty-four different serious adverse events in children aged five to eleven including cardiac valve incompetency, appendicitis, Kawasaki disease, vitiligo, Bell's Palsy, and pleural effusion. Zachary Stieber, *CDC Finds Hundreds of Safety Signals*, EPOCH HEALTH (Jan. 3, 2023) http://bit.ly/3ZXRXGF. When the CDC flags safety concerns, its protocol

is to investigate the adverse events' validity. The CDC has not completed an investigation of these signals and, until it does, there is a real possibility that any number of them were caused by the COVID-19 vaccine.

Take appendicitis as an example. Not just one, but two passive surveillance systems flagged appendicitis as a safety concern. In addition to VAERS, the CDC's "V-safe surveillance system" (a passive, smartphone-based safety surveillance system) flagged appendicitis. The Pfizer clinical trials noted that appendicitis had a "non-significant" increased relative risk of 3.0 with an absolute increased rate of 2.7 per 10,000. Fernando Polack, et al., *Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*, 383 NEW ENG. J. MED. 2603 (2020); Robert Frenck, Jr., et al., *Safety, Immunogenicity, and Efficacy of the BNT162b2 COVID-19 Vaccine*, 385 NEW ENG. J. MED. 239 (2021); E.B. Walter, et al., *Evaluation of the BNT162b2 COVID-19 Vaccine*, 386 NEW ENG. J. MED. 35 (2022); Flor M. Muñoz, et al., *Evaluaion of BNT162b2 COVID-19 Vaccine in Children*, 388 NEW ENG. J. MED. 621 (2023). An observational study of over 1.6 million people observed a 40% increased risk of appendicitis after vaccination. Noam Barda, et al., *Safety of the*

BNT162b2 mRNA COVID-19 Vaccine, 385 NEW ENG. J. MED. 1078 (2021). If the COVID-19 vaccine *does* cause appendicitis, Pfizer's non-significant increase in risk would be an NNH of approximately 3,700.

It is certain that the COVID vaccines cause serious harm to some children. What is uncertain is how frequently that harm occurs. An AAP study of the passively collected VAERS data found that appendicitis was the fourth most commonly reported serious adverse event for children aged five to eleven. Hause, *Safety of COVID-19 Vaccination*, at 5. While it remains undetermined if the COVID-19 vaccine increases the risk of appendicitis, it represents one of multiple safety signals which further investigation will determine whether it is (or not) caused by the COVID-19 vaccine. These safety signals represent potential short-term harms, but since the COVID-19 vaccines have been used on children for less than 2 years, the potential for unknown, long-term consequences which have not yet been identified must be seriously entertained.

Vaccinated children also experienced seizure and multisystem inflammatory syndrome more frequently than appendicitis or even myocarditis. *All* of these could eventually be proven to result from

COVID-19 vaccination. Right now, they cannot be ruled out as harms caused by the COVID vaccines.

III. The AAP recommendation to vaccinate all children is based on faulty science.

A. The AAP fails to account for natural immunity as a reason not to vaccinate.

Citing a CDC study, the AAP recommends vaccines across-the-board, regardless of whether an individual has natural immunity. AM. ACAD. OF PEDIATRICS, *COVID-19 Vaccines in Infants, Children, and Adolescents* 150 PEDIATRICS 1 (2022). The AAP also recommends booster doses when the vaccine loses its efficacy as inevitably happens. *Id.* As explained above, studies into natural immunity show that it provides robust, long-term protection. The AAP does not refute the studies of natural immunity and remains silent on whether it is *more* effective than vaccination. While the AAP admits that vaccine efficacy wanes, it then recommends more vaccines rather than exploring natural immunity as a more effective protection.

B. The AAP's recommendation is out-of-step with vaccine recommendations in other countries.

The AAP is out of line with other respected health agencies and has not justified its position with respect to the risk of vaccination. Denmark,

Norway, Sweden, and France no longer recommend healthy children receive the COVID-19 vaccine. DANISH HEALTH AUTH., *Vaccination of People Aged Under 50* (Sept. 16, 2022), http://bit.ly/3JbTFyp; HELSE NORGE, *Covid-19 Vaccination in Norway* (NOV. 18, 2022), http://bit.ly/3ZlUN8j; *Sweden Decides Against Recommending COVID Vaccines For Kids Aged 5-12*, REUTERS (Jan. 28, 2022, 9:24 AM) http://bit.ly/3y9ABdB; *Covid-19: Primary Vaccination for General Population No Longer Recommended by the French Health Authority*, LE MONDE (Feb. 25, 2023, 8:46 AM) http://bit.ly/3Jm7I4F.

Norway's Minister of Health and Care Services, Ingvild Kjerkol, explained that "Children rarely become seriously ill, and knowledge is still limited about rare side effects or side effects that may arise at a distant time. There is little individual benefit for most children and the Norwegian Institute of Public Health has not recommended that all children aged 5-11 be vaccinated." MINISTRY OF HEALTH AND CARE SERV., *Vaccination of Children and Adolescents against COVID-19* (Jan. 14, 2022) http://bit.ly/3Yf0t2B. The UK does not even offer the COVID-19 vaccine to children below the age of twelve as a general matter. UK HEALTH SEC. AGENCY, *Covid-19 Vaccination: A Guide for Eligible*

Children and Young People (Feb. 1, 2022) http://bit.ly/3JbQEhm. Other countries do not recommend vaccination for children with prior infection.

C. The AAP fails to consider the long-term, potentially dangerous effects of COVID-19 vaccines.

The AAP does not sufficiently acknowledge the risks in its recommendations. Instead, the AAP tries to alleviate concerns by explaining that "the safety follow-up for COVID-19 vaccines is essentially the same that it is for all vaccine trials." AM. ACAD. OF PEDIATRICS, *About COVID-19 Vaccine: FAQ* (Dec. 8, 2022) http://bit.ly/3yR7AE8. Its website further states that pediatric vaccine studies involve investigation of all adverse events post-vaccination. *Id.* And yet the AAP (in a paper jointly published with the CDC) does not cite a single long-term study of the safety of COVID-19 vaccines in its recommendations. The AAP also does not mention that because COVID-19 vaccines are so new, long-term data is not available and that the investigations into adverse events have not been completed. The Moderna and Pfizer COVID-19 vaccines, for example, "[have] not been approved or licensed by FDA, but [have] been authorized for emergency use." FDA, *Emergency Use Authorization* (Dec. 8, 2022). The AAP fails to even acknowledge these safety concerns while providing its recommendation.

CONCLUSION

For the foregoing reasons, *amici curiae* urge the Court to reverse.

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