Exhibit 216

Board Overseeing COVID-19 Trials Conflicted

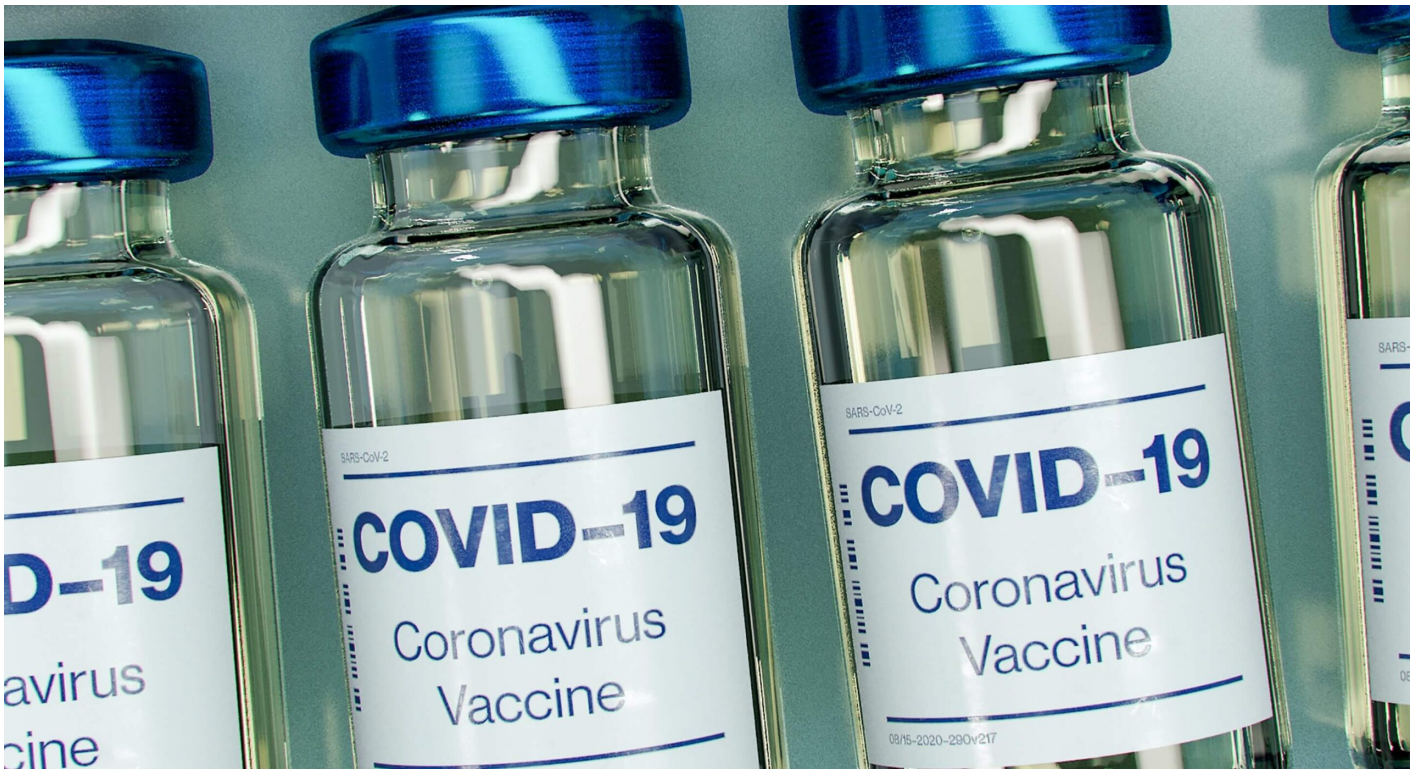
ICAN-Informed Consent Action Network

https://icandecide.org/article/board-overseeing-covid-19-trials-conflicted/

LEGAL ACTION

BOARD OVERSEEING COVID-19 TRIALS CONFLICTED

June 4, 2021



The boards overseeing the COVID-19 vaccine clinical trials are supposed to be independent of pharmaceutical companies. ICAN's intensive investigation into these boards has revealed conflicts of interest with pharmaceutical companies that are shocking to the conscience. ICAN, through its attorneys, has therefore filed a formal demand to remove these individuals from these boaerds.

The boards overseeing the COVID-19 vaccine trials are known as Data and Safety Monitoring Boards (**DSMBs**). As explained by pro-vaccine bioethicist, Art Caplan, regarding these DSMBs:

"They're very powerful. They're key guardians of science and safety and are as important if not more important than the FDA."

There are four potential COVID-19 vaccines that are currently in Phase III clinical trials in the United States. The clinical trials for three of these experimental vaccines – the ones to be sold by AstraZeneca, Moderna, and Johnson & Johnson – are being overseen by a DSMB created by the Dr. Fauci's National Institute of Allergy and Infectious Diseases (the **NIAID DSMB**). The clinical trial for Pfizer's experimental vaccine is being overseen by a different DSMB (the **Pfizer DSMB**).

The members of these DSMBs were selected in secret. They meet in secret. Their identities are supposed to remain a secret. This veil of secrecy has held with the exception of two members. The identity of the chairperson of the NIAID DSMB, Dr. Richard Whitley, was mistakenly revealed by his university in an announcement that has been scrubbed from its website. As for the Pfizer DSMB, made up of five individuals, one of its members, Dr. Kathryn Edwards, was apparently mistakenly revealed in a CBS article.

Selecting these individuals could only occur by turning a blind eye to their extremely troubling and blatant conflicts with pharmaceutical companies. For example, ICAN's investigation has revealed that one or both these two doctors have been, among other things, consultants for Gilead Science, AstraZeneca, GlaxoSmithKline, Merck, Sanofi, Sequirus, La Roche, Allergan, Moderna, and Novartis; advisors to Merck, Bionet, GSK, and Pfizer; paid speakers for Connaught, Lederle-Praxis, Wyeth Lederle, Glaxo, and Novartis; paid millions of dollars from these companies; and, on the tab of these companies, wined-and-dined to hundreds of meals and taken dozens of trips to exotic destinations. Meaning, they have had duties to these companies as consultants and advisors, have been personally financially supported by them, and have been their mouthpieces to the public.

Nonetheless, the American public is constantly assured by Dr. Fauci, Secretary Azar, and other public health officials that the DSMB members are independent of pharmaceutical companies. For example, Dr. Fauci recently told the public that: "[P]eople need to understand that **an independent body**, the Data and Safety Monitoring Board, is **beholden to no one**, not to the president, **not to the vaccine companies**, not to the FDA. Not to me."

Only those wearing blinders could give Dr. Whitley and Dr. Edwards the label "independent." To head the "independent" DSMB, Dr. Fauci could have selected from a sea of potential scientists, many of whom have never consulted for a pharmaceutical company, were never on a pharmaceutical company speakers' bureau, and have not had hundreds of meals and dozens of exotic trips paid for by pharmaceutical companies. Instead he chose Dr. Whitely as its head. Dr. Fauci makes a mockery of the term "independent" and calls into serious question his judgment and objectivity.

ICAN, through its attorneys, has therefore sent a demand letter to the Director of HHS, Director of NIAID, Director of the FDA's CBER, the White House Coronavirus Task Force, and POTUS. This letter lays out in detail: the conflicts of interest that Dr. Whitley and Dr. Edwards have with pharmaceutical companies; the litany of lies told by Dr. Fauci and other public health officials regarding the supposed independence of the DSMBs; and demands that they "**remove any member of the NIAID DSMB, including Dr. Whitley, who has ever been a consultant, has been on**

a speakers' bureau, or has had meals or travel paid for by any pharmaceutical company."

You can read the full demand letter here. When we receive notice that these and any other conflicts individuals have been removed from the COVID-19 vaccine DSMBs, we will update this webpage.

Update: November 18, 2020 – Click here to read the response letter from the FDA to the foregoing concerns of serious conflicts. As you will see, it fails to address a single one of the serious conflicts detailed in ICAN's letter regarding the members on the DSMB for the COVID-19 vaccines. This response would make any reasonable person even more concerned about the process for licensing a COVID-19 vaccine.

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October 7, 2020

VIA EMAIL AND FEDEX

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Re: *Lack of "Independent" Members on the Data and Safety Monitoring Boards for COVID-19 Vaccines Currently in Phase III Trials in the United States*

Dear Secretary Azar, Dr. Fauci, Dr. Marks, and Dr. Atlas:

We write on behalf of our client, Informed Consent Action Network ("**ICAN**"), to express serious issues it has uncovered regarding the Data and Safety Monitoring Boards ("**DSMBs**") that are overseeing the clinical trials for the four experimental COVID-19 vaccines currently undergoing Phase III clinical trials in the United States.

The clinical trials for three of these experimental vaccines – the ones to be sold by AstraZeneca, Moderna, and Johnson & Johnson – are being overseen by a DSMB created by the National Institute of Allergy and Infectious Diseases ("**NIAID**") (the "**NIAID DSMB**"). The clinical trial for Pfizer's experimental vaccine is being overseen by a different DSMB (the "**Pfizer DSMB**", and together with the NIAID DSMB, "**the DSMBs**"). Public health experts have repeatedly told the American public that these board members are independent of any influence from the pharmaceutical industry. However, ICAN has learned that two of the members that it could identify have significant ties to various pharmaceutical companies, which raises significant concerns regarding the independence of the DSMBs.

The members of the DSMBs were selected in secret. They meet in secret. Their identities are supposed to remain a secret. Indeed, the members of the DSMBs have remained a secret, with the exception of two members. The chairperson of the NIAID DSMB's identity was apparently mistakenly released by his university in an announcement that has now been scrubbed from its website. The article titled, *These Secret Safety Panels Will Pick the COVID Vaccine Winners*, reported about the announcement, which disclosed that Dr. Richard Whitley was appointed as chair of the NIAID DSMB.[1] As for the Pfizer DSMB, made up of only five individuals, one of its members, Dr. Kathryn Edwards, was apparently mistakenly revealed in a CBS article.[2] The names of the other members of the DSMBs have not been made public.[3]

ICAN's research regarding the two members of the DSMBs it could identify raises extremely troubling concerns regarding the selection of candidates for the DSMBs. The process for selecting these individuals certainly lacked transparency and their selection could only occur by turning a blind eye to their extremely troubling and blatant conflicts with pharmaceutical companies detailed in this letter. For example, one or both of these two doctors have been, among other things, consultants for Gilead Science, AstraZeneca, GlaxoSmithKline, Merck, Sanofi, Sequirus, La Roche, Allergan, SmithKline Beecham, Wyeth Lederle, Moderna, X4 Pharmaceuticals, Novartis, Fermavir, and Inhibitex; advisors to Merck, Bionet, GSK, Pfizer, and Gilead; and paid speakers for Connaught, Lederle-Praxis, Wyeth Lederle, Glaxo, and Novartis, among others. These scientists have had duties to these companies as consultants and advisors, have been personally financially supported by them, and have been their mouthpieces to the public. These conflicts raise serious ethical issues, render any decision by the DSMBs unreliable, and will undermine public confidence in this process.

Government Officials Assure the American Public that the DSMBs are Independent

The American public is constantly assured by Dr. Fauci, Mr. Azar, and other public health officials that the DSMB members are independent of pharmaceutical companies. They have provided repeated assurances that Americans can trust the COVID-19 vaccine trials because the members of the DSMBs overseeing these trials have no conflicts with pharmaceutical companies and can make objective decisions. For example, Dr. Fauci recently told the public that: "[P]eople need to understand that **an independent body**, the Data and Safety Monitoring Board, is **beholden to no one**, not to the president, **not to the vaccine companies**, not to the FDA. Not to me."[4]

In fact, Dr. Fauci has been loudly and vigorously beating the drum that Americans can have confidence in a COVID-19 vaccine since there is an "independent board," free of entanglements with pharmaceutical companies. The following are but a few examples from the last month, September 2020, in which Dr. Fauci repeated this assurance to the American public:

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[1] https://khn.org/news/these-secret-safety-panels-will-pick-the-covid-vaccine-winners/.

[2] https://www.cbsnews.com/news/covid-19-vaccine-when-will-be-available-ready/.

[3] As explained by Bioethicist Art Caplan, when speaking of the COVID-19 DSMBs, "They're very powerful. They're key guardians of science and safety and are as important if not more important than the FDA" and that while DSMB members are typically not disclosed, he explains that with regard to COVID-19 vaccines, "We need to know if we can trust the vaccine, so the more transparency the better." https://www.cnn.com/2020/10/03/health/dsmb-role-coronavirus-vaccine-trial/index.html.

[4] https://www.vox.com/21454359/fauci-rand-paul-covid-19-vaccine-trust-cdc-fda (emphasis added).

- On September 2, 2020, in a STAT News interview: "It's up to the DSMB, in their judgment, to balance the safety issue, the efficacy issue, and the duration of the trial issue…And that's the reason why **they're an independent group**. **They are not the company** because obviously the company is going to want to get their product approved as quickly as possible."[5]

- On September 11, 2020, in a *Newsweek* interview: "There are a number of checkpoints in that process [of releasing a vaccine] that would make it very difficult for politics to have an influence on whether a vaccine is approved for use before it was shown truly to be safe and effective. The accumulation of data and **the analysis of data is unbiased**. **An independent group** called a Data and Safety Monitoring Board is associated with every clinical trial that has NIH [National Institutes of Health] fingerprints on it."[6]

- On September 21, 2020, during a live townhall hosted by Navajo Nation President Jonathan Nez, addressing the safety of the Pfizer vaccine trials: "One of the assurances that you are dealing with something that is safe is that each vaccine that is tested has a Data and Safety Monitoring Board, which is **an independent group** that looks at the data to determine at which point you can say that the vaccine is effective."[7]

- On September 24, 2020, during a Facebook Live interview with New Jersey Governor Phil Murphy, when addressing the "mixed messages" that are being sent regarding whether a COVID-19 vaccine is safe and effective: "with every vaccine trial, there's a thing called a data and safety monitoring board which is **an independent group** of scientists, vaccinologists, ethicists and statisticians who are the only ones that are allowed to see the data from the [vaccine's clinical] trial."[8]

Secretary Azar has similarly recognized the issue of vaccine confidence and has provided the same assurance to the American people. On September 3, 2020, Secretary Azar acknowledged to CBS that, "We already have a significant challenge in this country with vaccine hesitancy, and efforts to undermine confidence in a vaccine that would come hurt in terms of people willing to take a vaccine once it comes through."[9] Secretary Azar further told the public that any vaccine data "will be reviewed by a Data and Safety Monitoring Board, that's **an independent board**, and then that data, at the appropriate time will go to the FDA."[10]

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[5] https://www.statnews.com/2020/09/02/experts-see-a-chance-for-a-covid-19-vaccine-approval-this-fall-if-its-done-right/.

[6] https://www.newsweek.com/dr-fauci-would-bet-10-cents-trump-having-covid-19-vaccine-november-december-1531370.

[7] https://navajotimes.com/coronavirus-updates/fauci-navajo-a-model-for-containing-coronavirus/.

[8] https://www.facebook.com/governorphilmurphy/videos/live-with-dr-anthony-fauci/631905121047750/.

[9] https://www.forbes.com/sites/carlieporterfield/2020/09/03/azar-denies-november-goal-for-vaccine-preparedness-is-tied-to-presidential-election/#57f9cec57f73.

[10] Secretary Azar then gave assurances that any decision to release a vaccine in the U.S. would be based on the data and the "FDA's gold standards." https://www.cbsnews.com/news/alex-azar-coronavirus-vaccine-distribution/. Even the National Institutes of Health's "Data and Safety Monitoring Board (DSMB) Guidelines" explain that "no member [of a DSM] should have financial,

Despite these assurances to the public and the clear principles underlying the need for an independent DSMB, the investigation conducted by ICAN into the chair of the NIAID DSMB and the one member it could identify for Pfizer's DSMB reveals that they have conflicts with pharmaceutical companies that are shocking to the conscience. They render the claims regarding a supposed "independent" DSMB for COVID-19 vaccines false. There are thousands of scientists in the world – choosing those that are pharmaceutical foot-soldiers undermines the purpose of a DSMB. There is still time to correct course by replacing these individuals with those free of all pharmaceutical company ties, past and present, and whose interests are not conflicted by the industry for whom they have acted – and will continue to act – as advisors, consultants, fiduciaries, advocates, and public speakers.

Dr. Richard Whitley

The NIAID DSMB's chairperson, Dr. Whitley, has long-standing and disqualifying financial and employment entanglements with many pharmaceutical companies, including those developing a COVID-19 vaccine.

In the last six years alone, Dr. Whitley has been a consultant for Gilead Science, AstraZeneca, GlaxoSmithKline, Merck, Sanofi, Sequirus, La Roche, and Allergan.[11] He personally was paid over $2.6 million for the work he performed for these companies during this period.[12] During the last six years, Dr. Whitley was also wined-and-dined on the tab of these companies to over 240 meals, for which these companies paid $15,597, including 42 meals with a bill above $100.[13] During the last six years, Dr. Whitley also took 281 trips around the country and the world, paid for by these companies – totaling $172,992.51 – including to Belgium, Bahamas, Japan, Canada, and South Africa.[14] Dr. Whitley has sat for well over a decade on the Board of Directors of a pharmaceutical company and is reported to own over 68,000 shares of the pharmaceutical company Gilead.[15] He has also received unknown amounts from Novartis and other pharmaceutical companies in consulting or lecture fees.[16]

As a final example, Dr. Whitley has been on the speakers' bureau for GlaxoSmithKline and Novartis, both of which are developing COVID-19 vaccines.[17] The Pew Charitable Trusts' guidance entitled *Conflict of Interest Policies for Academic Medical Centers* explains that: "Faculty who participate in speakers' bureaus are de facto 'marketers in academic robes' and lend a patina of academic endorsement to the promotional agenda of the sponsoring companies, which

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proprietary, professional, or other interests that may affect impartial, independent decision-making by the DSMB."[10] The FDA provides similar guidance, explaining that "[c]onflicts of interest deserve special consideration in choosing individuals to serve on a [DSMB]." https://www.fda.gov/media/75398/download.

[11] https://projects.propublica.org/d4d-archive/search?utf8=%E2%9C%93&term=Richard+James+Whitley&state%5Bid%5D=&company%5Bid%5D=&period%5B%5D=&services%5B%5D=; https://openpaymentsdata.cms.gov/physician/495549.

[12] *Id.*

[13] https://openpaymentsdata.cms.gov/physician/495549.

[14] *Id.*

[15] https://www.sec.gov/Archives/edgar/data/882095/000119312512123423/d317498ddef14a.htm.

[16] https://pubmed.ncbi.nlm.nih.gov/17143845/; https://jamanetwork.com/journals/jama/article-abstract/185429.

[17] https://jamanetwork.com/journals/jama/article-abstract/185429; https://cspinet.org/new/200701181.html.

compromises academic integrity. Furthermore, promotional speakers are poor role models for trainees."[18] Similarly, in an article published in the *Journal of Law, Medicine & Ethics* by professors and deans from the Tufts University School of Medicine – including the Dean and Professor of Public Health and Community Medicine and the Assistant Dean for Conflicts of Interest Administration – they explain regarding doctors, like Dr. Whitley, that serve on pharmaceutical company speakers' bureaus that:

> [N]umerous medical associations, such as the Association of American Medical Colleges (AAMC), the American Board of Internal Medicine (ABIM) and the Institute on Medicine as a Profession (IMAP), and government bodies such as the Institute of Medicine (IOM) have recommended that medical schools and teaching hospitals prohibit or strongly discourage faculty from participating in so-called industry "Speakers' Bureaus" …
>
> Pharmaceutical company Speakers' Bureaus are a marketing enterprise wherein physicians and other professionals are engaged and trained by one or more companies to give a lecture about a medical condition or drug treatment to an audience of prescribers toward the end of promoting the company's drug which treats that condition. These speakers are generally required to use company-created or company approved slides and are expected, prior to their presentation, to collaborate and review the slides with the company medical officers. This process is intended to focus the speaker on the most positive aspects of a drug, thus increasing the familiarity and appeal of that drug to the speaker — as well as the company's marketing message. It is widely argued that physicians who participate in Speakers' Bureaus are essentially just paid marketers or spokespersons for industry who use, indeed exploit, their roles as physician leaders to influence their colleagues to prescribe the sponsor's product. The sentiment that Speakers' Bureaus are promotional rather than educational is reinforced by the fact that the Bureaus are funded through pharmaceutical companies' marketing budgets. …
>
> In a recent study of physicians at continuing medical education conferences, 73 percent of physicians reportedly perceived that faculty members who participate in commercial Speakers' Bureaus are moderately-to-substantially biased in favor of the company's product. Indeed, numerous studies have shown that payments from a pharmaceutical company, even in the form of small gifts of minimal value, influence physicians' prescribing habits in favor of the company's drug. Even physicians who reportedly believe they are impervious to influence by gifts and fees, or who view themselves as educators and "thought leaders" when they are paid

[18] https://www.pewtrusts.org/-/media/legacy/uploadedfiles/phg/content_level_pages/reports/coibestpracticesreportpdf.pdf.

> to speak about a particular drug, have been shown to write more prescriptions for the drug after speaking about the product. …
>
> [P]harmaceutical companies' understanding of how gifts influence physicians has caused some of them to prohibit their own employees, including their physicians, from accepting even small gifts.[19]

Dr. Whitley also has a history of failing to disclose his conflicts of interest. He had to issue a public apology in 2010 for failing to disclose his extensive pharmaceutical company conflicts in an article he published in the Journal of the American Medical Association ("**JAMA**") where he had to publicly admit that he "truly regret[ted] [his] failure to report these disclosures in the articles and letter reply and apologize[d] to both the editors and the readers of JAMA for this."[20] In this apology, Dr. Whitley even said he is "a firm believer in transparency and believe[s] that it is mandatory in academic efforts."[21] He even thereafter stated that, "I think we need to teach people…how to interact with drug companies so everything is totally transparent...for patients, for colleagues, for administrators and to the community."[22]

Dr. Whitley has not learned from this "mistake" nor does it appear his apology was sincere since he has continued to fail to disclose his extensive conflicts thereafter. For example, on March 24, 2020, he gave a public presentation to the Bio Coronavirus Collaborative Initiative Summit, regarding COVID-19, including discussing treatments. While that presentation discloses that Dr. Whitley is a "distinguished Professor of Pediatrics, Vice Chair of the Department of Pediatrics, and Co-Division Director of Pediatric Infectious Diseases, University of Alabama at Birmingham," Dr. Whitley does not disclose a single conflict with any pharmaceutical company, including his conflicts with pharmaceutical companies developing products for COVID-19.

Only those wearing blinders could give Dr. Whitley the label "independent." To head the "independent" DSMB, Dr. Fauci could have selected from a sea of potential scientists, many of whom have never consulted for a pharmaceutical company, were never on a pharmaceutical company speakers' bureau, and have not had hundreds of meals and dozens of exotic trips paid for by pharmaceutical companies. Instead he chose Dr. Whitley. Compounding this debasement of the term "independent", Dr. Fauci misrepresented to the American people that "there's a thing called a data and safety monitoring board which is **an independent group** of scientists"[23] and that "an **independent body**, the Data and Safety Monitoring Board, is **beholden to no one**…**not to the vaccine companies**, not to the FDA. Not to me."[24] Dr. Whitley's numerous financial ties to pharmaceutical companies seriously raise questions regarding Dr. Fauci's definition of "independent."

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[19] https://pubmed.ncbi.nlm.nih.gov/22789048/.

[20] https://jamanetwork.com/journals/jama/article-abstract/185429.

[21] *Id*.

[22] https://www.al.com/news/birmingham/2015/07/some_uab_faculty_receive_hefty.html.

[23] https://www.facebook.com/governorphilmurphy/videos/live-with-dr-anthony-fauci/631905121047750/.

[24] https://www.vox.com/21454359/fauci-rand-paul-covid-19-vaccine-trust-cdc-fda.

Dr. Kathryn Edwards

Like Dr. Whitley, Dr. Kathryn Edwards has long-standing and disqualifying financial and employment entanglements with many of the companies developing a COVID-19 vaccine. Dr. Edwards is a professor of pediatrics in the division of infectious diseases at Vanderbilt University School of Medicine, where she is also vice-chair for clinical research.[25] CBS reported that Dr. Edwards is sitting on Pfizer's DSMB.[26]

Incredibly, Dr. Edwards was a paid advisor to Pfizer directly before joining its DSMB for the COVID-19 vaccine.[27] Meaning, she had duties to this company, in their employ, up until she then apparently relinquished this position to become a member of the "independent" DSMB overseeing Pfizer's clinical trial. This alone makes a mockery of the notion that this DSMB is "independent."

Dr. Edwards's other conflicts with pharmaceutical companies abound. Dr. Edwards has been an advisor and consultant to and has received personal fees from Merck.[28] She has received payments for giving lectures and research funding from GSK and has been on its advisory board.[29] She has been a consultant for and has received both tens of thousands of dollars in payments for lectures as well as research funding from Sanofi. [30] Sanofi has even paid for trips that Dr. Edwards has taken to, among other destinations: Paris, France; Dublin, Ireland; Amsterdam, Netherlands; and Cancun, Mexico.[31]

Dr. Edwards has also been a consultant for Connaught, Smith-Kline Beecham, Wyeth Lederle, Moderna, Roche, and X4 Pharmaceuticals.[32] She has been an advisor to Bionet[33] and has received research funding from Wyeth Lederle.[34] Like Dr. Whitley, she has also been on the speakers' bureaus for pharmaceutical companies, including Connaught and Wyeth Lederle.[35]

Dr. Edwards has also failed to disclose these incestuous conflicts with pharmaceutical companies. For example, on July 29, 2020, she provided the only presentation to date focused on the safety of COVID-19 vaccines given to the Advisory Committee on Immunization Practices ("**ACIP**") titled, "COVID-19 Vaccine Safety Considerations.[36] In her accompanying presentation materials, Dr. Edwards disclosed that she is the Principal Investigator of the CDC funded Clinical

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[25] https://www.vumc.org/viiii/person/kathryn-m-edwards-md.

[26] https://www.cbsnews.com/news/covid-19-vaccine-when-will-be-available-ready/.

[27] https://pubmed.ncbi.nlm.nih.gov/32338708/ ("K.E. serves as a scientific advisor for … Pfizer"); https://pubmed.ncbi.nlm.nih.gov/31971685/ ("Dr. Edwards reports … personal fees from Pfizer").

[28] https://pubmed.ncbi.nlm.nih.gov/30938299/.

[29] https://openpaymentsdata.cms.gov/physician/651167; https://academic.oup.com/jid/article/222/8/1413/5510417.

[30] https://www.nejm.org/doi/10.1056/NEJMoa050824; https://openpaymentsdata.cms.gov/physician/651167.

[31] https://openpaymentsdata.cms.gov/physician/651167.

[32] https://pubmed.ncbi.nlm.nih.gov/32753370/; https://pedsinreview.aappublications.org/content/19/2/68; https://pubmed.ncbi.nlm.nih.gov/10617749/.

[33] https://pubmed.ncbi.nlm.nih.gov/32753370/.

[34] https://pubmed.ncbi.nlm.nih.gov/10617749/.

[35] https://pedsinreview.aappublications.org/content/19/2/68.

[36] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2020-07/COVID-03-Edwards-508.pdf.

Immunization Safety Assessment Project.[37] Yet, she did not disclose any of her aforementioned conflicts with pharmaceutical companies, including those developing COVID-19 vaccines.[38]

Dr. Edwards also answered questions following her presentation and discussed the role of DSMBs. She stated that there would be an active effort by DSMBs to look at each adverse event as Phase III studies are rolled out and that these DSMBs are independent of manufacturers and investigators.[39] In discussing potential adverse reactions to a COVID-19 vaccine at the ACIP meeting, Dr. Edwards stated that, "people need to understand that if there is a signal, we want to see it" and that the DSMBs will investigate pre-licensure.[40] At no point in her presentation or discussion following the presentation did Dr. Edwards disclose that she has received payments and funds from numerous pharmaceutical companies throughout her career or that she currently sat on a DSMB.[41]

* * *

Dr. Fauci and other federal public health officials have repeatedly asserted in the national media that a coronavirus vaccine is critical to controlling infections and morbidity from SARS-CoV-2. They have also expressed that once a vaccine is licensed, its success will depend on the public's willingness to take the vaccine. But, recent polls reflect that a significant portion of Americans will not consent to this vaccine. Hence, more so than with other vaccines, overcoming vaccine hesitancy regarding a COVID-19 vaccine in the current climate demands that the process for evaluating its safety and efficacy during its clinical trials be transparent and that those involved in this process be free from financial and other conflicts of interest. This is especially true of a vaccine developed at "warp speed."

Addressing potential conflicts of interest is critical to assure the American public that decisions pertaining to any coronavirus vaccine are made with a sound, independent scientific basis, not for political reasons or for the financial benefit of any individual or company. We ask that you address the serious issue identified above forthwith in order to avoid further erosion of confidence in the NIH, in NIAID, and in Operation Warp Speed.

Dr. Fauci, as the head of NIAID and given your prior statements, you should remove any member of the NIAID DSMB, including Dr. Whitley, who has ever been a consultant, has been on a speakers' bureau, or has had meals or travel paid for by any pharmaceutical company. Secretary Azar, as the head of HHS, and as Dr. Fauci's boss, you have an obligation under 42 U.S.C. § 300aa-1-2 to assure safe vaccines, and hence, ICAN implores the same from you pursuant to 42 U.S.C. § 300aa-31(b). Dr. Peter Marks, as the head of the FDA's licensing division for vaccines, ICAN wanted to bring this to your attention so that in the event that the DSMB members are not removed, your office should refuse to consider any data released from these clinical trials.

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[37] *Id*.

[38] https://www.youtube.com/watch?v=vftiaq-yZBs&t=3963s.

[39] *Id.*

[40] *Id.*

[41] *Id.*

Dr. Atlas, as an advisor on the White House Coronavirus Task Force, we hope that you will take a close look at this issue and bring it to the attention of President Trump.

Very truly yours,

Aaron Siri, Esq.
Elizabeth Brehm, Esq.

cc: President Donald J. Trump

U.S. FOOD & DRUG ADMINISTRATION

November 18, 2020

Dear Mr. Siri and Ms. Brehm,

This is in response to your letter of October 7, 2020, regarding the composition of Data Safety Monitoring Boards overseeing clinical trials for COVID-19 vaccines. Thank you for sharing your comments.

FDA is a science-based regulatory agency and is focused on ensuring that vaccines that are approved or authorized for use are supported by the best available scientific and clinical evidence, and that the relevant statutory requirements for safety and effectiveness are met. In this regard, FDA is using all appropriate regulatory authorities and providing scientific and regulatory advice to expedite the development and availability of safe and effective therapeutics and vaccines to address COVID-19.

In general, a Data Monitoring Committee (DMC, also referred to as a Data Safety Monitoring Board or DSMB) is appointed by the study sponsor to evaluate the accumulating outcome data in one or more trials initiated by the particular sponsor. FDA's considerations regarding DSMB composition and operations are summarized in guidance (https://www.fda.gov/media/75398/download). The DSMB advises the sponsor regarding the continuing safety of trial subjects and those yet to be recruited to the trial, as well as the continuing validity and scientific merit of the trial.

We recognize that transparency around FDA's decision-making with respect to COVID-19 vaccines is likely to impact public confidence in these vaccines. We believe that the guidance documents issued in June (https://www.fda.gov/media/139638/download) and October (https://www.fda.gov/media/142749/download) 2020 provide insight into FDA's current thinking about the scientific data needed to support approval and authorization of COVID-19 vaccines. In addition to outlining our expectations for vaccine sponsors, we also hope both of these guidances help the public understand our science-based decision-making process that assures that any vaccine that is authorized or approved meets our high standards for safety and effectiveness. Please be assured that we are committed to principles of transparency, consistent with statutory authority and regulations.

Thank you again for sharing your comments.

Sincerely,

Peter Marks

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