GlobalResearch
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‘Independent’ Advisor Who Evaluated Pfizer Vaccine Safety Was Former Paid Pfizer Consultant

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Global Research, January 13, 2023
Children's Health Defense 12 January 2023
Region: USA
Theme: Intelligence, Law and Justice

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A member of a purportedly independent data monitoring committee charged with ensuring the safety and efficacy of the Pfizer-BioNTech COVID-19 vaccine previously worked as a paid consultant and advisor to Pfizer.

Dr. Kathryn Edwards’ apparent conflict of interest was revealed during a recent episode of “The Highwire with Del Bigtree.” Bigtree, an independent journalist and founder of Informed Consent Action Network (ICAN), interviewed Aaron Siri, ICAN’s lead attorney.

Siri, supported by ICAN, deposed and then cross-examined Edwards during Hazlehurst v. Hays, the first vaccine-related autism case to ever reach a jury in the U.S.

Edwards served as an expert witness in the Hazlehurst case for one of the defendants, a medical clinic in Tennessee that administered several childhood vaccines to Yates Hazlehurst in 2001. She testified that the vaccines Hazlehurst received “were not relevant or important” to Hazlehurst’s subsequent development of autism.

Court transcripts reviewed by The Defender reveal that Edwards’ conflict of interest involving Pfizer was just one of several revealed in her deposition and cross-examination.

The transcripts reveal that Edwards had, at times, served on government committees evaluating vaccine safety while maintaining concurrent affiliations with vaccine manufacturers whose products were being evaluated.

A review of Edwards’ August 2020 deposition and January 2022 cross-examination by Siri also reveals multiple instances where Edwards was apparently coached by others while her testimony was in progress. Edwards denied she was being coached, even when supporting evidence was presented.

Along with Edwards’ prior apparent conflicts of interest — many of which involve her parallel

association with vaccine manufacturers and with bodies evaluating candidate vaccines — the court transcripts raise questions about the broader impartiality of theoretically "independent" committees that evaluate vaccine safety.

As part of this investigation, The Defender reviewed video and transcripts from Edwards' deposition and cross-examination, and copies of her 2014 and 2019 curriculum vitae (CV) and other documentation relevant to her medical and professional background.

Who is Kathryn Edwards?

Edwards is viewed as a world-renowned vaccinologist, board-certified in pediatrics and pediatric infectious diseases, who has held professorships at Vanderbilt University in Nashville, Tennessee, since 1980 — the year she also joined the institution's Vaccine Research Program, which she previously directed and of which she remains a member.

According to one of her bios on Vanderbilt's website, 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.

Aside from her affiliation with Vanderbilt, Edwards is principal investigator of the Centers for Disease Control and Prevention's (CDC) Clinical Immunization Safety Assessment Network.

Another university bio for Edwards states she is "currently working with the CDC to address adverse events after immunization."

In Edwards' own words during her 2022 cross-examination, she said she has "directed and organized and conducted studies on vaccines. Some of those studies are the first times those vaccines are used in people and [I] have studied vaccines and their safety. I continue to work with the CDC in providing safety assessment for vaccines and work on research to make sure that the vaccines are safe and effective."

Yet another Vanderbilt bio for Edwards states she has received contracts from the CDC and National Institutes of Health (NIH), and served on several CDC, NIH, World Health Organization (WHO) and Infectious Diseases Society of America committees.

Edwards' participation in WHO-related endeavors includes a 2007 advisory role in the evaluation of pandemic influenza vaccines, an unspecified 1999 advisory role, and chairing a 1997 meeting on maternal and neonatal pneumococcal immunization, according to a publicly available 2014 version of Edwards' CV.

The same CV indicates that Edwards, between 1991 and 1995, was a member of the CDC's Advisory Committee on Immunization Practices (ACIP), and that between 1996 and 2000, she served as a member of the U.S. Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC).

Testimony Edwards provided during her 2020 deposition confirmed the above, plus a second tenure on the VRBPAC from 2016 to 2018. According to Edwards' 2022 testimony, ACIP "is a group of non-governmental experts in infectious disease vaccines and adult and child health that advise the CDC on vaccine policy."

According to the FDA, the VRBPAC "reviews and evaluates data concerning the safety, effectiveness, and appropriate use of vaccines and related biological products which are

intended for use in the prevention, treatment, or diagnosis of human diseases."

Edwards' 2014 CV also shows previous experience on the American Academy of Pediatrics' executive committee of the Section on Infectious Diseases and Committee on Infectious Diseases, prior membership on the National Academy of Science's Vaccine Priorities Committee and past membership on the council of the American Pediatric Society.

Edwards is also one of the associate editors of "Plotkin's Vaccines," widely viewed as one of the preeminent medical school textbooks on vaccines — which Bill Gates described as as "an indispensable guide to the enhancement of the well-being of our world."

Edwards co-authored the COVID-19: Vaccines section of UpToDate, an online point-of-care medical resource.

Edwards also was on the editorial board numerous well-regarded medical journals, including the New England Journal of Medicine (NEJM), Clinical and Vaccine Vaccine Immunology, and Clinical Infectious Diseases.

Edwards' conflicts of interest selectively — or reluctantly — disclosed

Edwards' online bios detail her many academic and government affiliations — however, conspicuously absent in those bios are details about her ties to pharmaceutical companies and vaccine manufacturers.

Edwards' Vanderbilt University Medical School and Infectious Diseases Clinical Research Consortium (IDCRC) bios focus on her prior leadership of government-funded studies and her prior consulting work with public agencies and the WHO.

Only the IDCRC bio makes a cursory mention of Edwards' prior participation in "industry-funded multicenter vaccine and surveillance initiatives," without providing further details.

Her 2014 CV notes her participation in studies funded by Novartis, GlaxoSmithKline and other Big Pharma companies, but these affiliations are not explicitly spelled out.

During her 2020 deposition, Edwards vehemently denied any conflicts of interest, past or present. She stated, for instance, that when she was a member of the VRBPAC, "it was imperative that I had no conflicts, and I had no conflicts."

However, those claims collapsed under further examination in 2020 and 2022.

Certain journal publications and academic activities with which Edwards has been associated reveal multiple conflicts of interest, though they fail to provide a full picture of the scope of those conflicts.

For instance, "Proposals to Accelerate Novel Vaccine Development for Children," an article Edwards co-authored in December 2021 for Pediatrics, a journal published by the American Academy of Pediatrics, notes under the "financial disclosure" section:

"Kathryn Edwards has received grant funding from the NIH and Centers for Disease Control and Prevention and is a consultant to Bionet and IBM. She is also a member of the Data Safety and Monitoring Board for Sanofi, X-4 Pharma, Seqirus, Moderna, Pfizer, Merck, and Roche."

Similar affiliations are listed in the "presenter info" provided as part of the online program for the April 2022 conference of the Pediatric Academic Societies (PAS), where Edwards delivered a presentation. However, the program listed her role for companies such as Pfizer and Moderna as "advisory committee."

Most other online bios for Edwards do not indicate any such Big Pharma affiliations, however — nor did at least some of the scientific presentations that Edwards has delivered in recent years.

Siri exposed these discrepancies when he deposed Edwards in 2020. For instance, he pointed out that in a July 2020 ACIP presentation on COVID-19 vaccine safety considerations, Edwards did not reveal her active affiliations with companies such as Pfizer and Moderna, and that this information is also absent from her CV.

These affiliations with Pfizer and other drugmakers became one of the main focus areas of her 2020 deposition and 2022 cross-examination.

Evaluating the 'safety' of Pfizer's COVID vaccine — while being paid by Pfizer

To understand Edwards' conflicts of interest related to drug companies it's important to understand the role of entities known as Data Monitoring Committees (DMCs), which are alternatively referred to as Data and Safety Monitoring Boards (DSMBs).

An April 25, 2022, presentation on Pfizer's COVID-19 vaccine trials, "Does It Work — and — Is It Safe?" — which Edwards co-presented at the Johns Hopkins Division of Infectious Diseases, provided an explanation of the role of such committees:

> "DMCs are considered to have 'stewardship' of the trial. The Board has responsibilities to monitor safety and efficacy, and to ensure the validity of results.
>
> "Board members are independent, are paid hourly consultants and are extensively vetted for conflicts of interest.
>
> "Unblinded data are 'Firewalled' from the study team(s)."

The presentation goes on to state that the composition of a DMC "should reflect the disciplines and specialties necessary to interpret the data and evaluate participant safety," and that they typically consist of three to seven members, depending on "the phase of the trial, range of medical issues, complexity of design and analysis, and potential level of risk."

These are the committees, according to the April 2022 presentation, that can issue recommendations to the pharmaceutical company for the study in question, including continuing, modifying or stopping the study or studies, or withholding a final recommendation until more data is provided.

An internal Pfizer document, dated Nov. 4, 2020, and released to the public as a result of the successful Freedom of Information Act (FOIA) request submitted by Public Health and Medical Professionals for Transparency, outlined the role of the DMC during the Pfizer-BioNTech COVID-19 vaccine trials:

> "This External Data Monitoring Committee (E-DMC) (hereafter referred to as 'the committee') is a single, external, independent, expert advisory group established to

oversee safety and efficacy data from the BNT162 Vaccine Program.

"The primary rationale for establishing the committee is to make certain that appropriate external safeguards are in place to help ensure the safety of subjects and to maintain scientific rigor and study integrity while the trial is on-going."

The same document, and the April 2022 Johns Hopkins presentation, note that Edwards was one of the five (later expanded to seven) members of the "independent" DMC for the BNT162 vaccine program that resulted in the development of the Pfizer-BioNTech COVID-19 vaccine.

In his 2022 cross-examination of Edwards, Siri raised the issue of Edwards' concurrent participation in the DMC for the Pfizer-BioNTech COVID-19 vaccine:

Siri: "And isn't it true that you've also been an advisor to Pfizer?"

Edwards: "Yes sir. I've been an advisor to Pfizer and I've been working very, very closely with Pfizer, particularly their COVID vaccines and going over lots of reactions and adverse [events] of that. So yes, I am working and being paid by Pfizer for my assessment of vaccine safety."

Siri: "You're part of the Data Safety Monitoring Board for Pfizer?"

Edwards: "That's correct."

Siri: "[For the] COVID vaccine, is that what you meant when you said that?"

Edwards: "That's correct. […]"

Siri: "And that's supposed to be an independent data safety monitor board, correct?"

Edwards: "It is an independent data safety monitoring board."

Siri: "That's the board that all of us in America are hoping on and relying upon is going to independently make sure that safety is properly assessed as the clinical trial for that Pfizer COVID-19 vaccine is ongoing, correct?"

Edwards: "That's true. And let me tell you that we have worked very hard to go over this and work very, very hard to do that indeed as comprehensively as we possibly can."

Siri: "And since it's supposed to be independent, it's critical that the members of that independent data safety monitor board are in fact independent of the pharmaceutical company. This product is being evaluated, correct?"

Edwards: "That's correct."

Siri: "Isn't it true that directly before becoming a member of the Independent Data Safety Monitor board of the Pfizer COVID-19 vaccine, you were an advisor to Pfizer?"

Edwards: "Pfizer pays me to evaluate the safety of their vaccines because I'm an expert. So I do get paid to do the work that I've been doing, but I've been doing the work conscientiously and comprehensively."

> Siri: “My question was, before you became a member of the Independent Data Safety Monitor board for the Pfizer COVID-19 vaccine, isn’t it true that you … separately, before you held that independent position, you were an advisor to Pfizer?”
>
> Edwards: “Yes sir. But I think what you’re presuming is that because I have been an advisor makes me on their dole or makes me going to say what they want me to say that … is not and has never been a part of my being. I say what I believe based on my expertise.”
>
> Siri: “You don’t think that financial incentives can sway people’s judgment at all?”
>
> Edwards: “It does not sway my judgment, sir.”
>
> Siri: “Why bother having an independent data safety monitor board? Why doesn’t Pfizer just have some of its employees on it?”
>
> Edwards: “Because we are independent … we are independent from Pfizer in this assessment.”

Later in the same exchange, Siri noted that at the same time Edwards sat on CDC and FDA committees providing recommendations for vaccine licensure, she maintained “relationships with a number of pharmaceutical companies” whose products were under consideration by those committees.

The Pfizer DMC on which Edwards sat appears to have overlooked numerous serious adverse events, including deaths, that occurred during the Pfizer-BioNTech vaccine trials.

Indeed, despite the FDA, in February 2022, opting to delay approval for the Pfizer-BioNTech COVID-19 vaccine for children under age 5, the April 2022 Johns Hopkins presentation stated, “The DMC found no safety issue, and after review of the data recommended to proceed with a 3-shot series (including boost the eligible children already enrolled in the study).”

The same presentation also claimed the Pfizer-BioNTech vaccine showed “high efficacy” for children ages 5-11 and provided “Effective neutralization of SARS-CoV-2 Omicron with three doses of BNT162b2,” the candidate vaccine that received an Emergency Use Authorization, and “Similar neutralization activity against BA.1 and BA.2 with three doses of BNT162b2.”

The FOIA-mandated release of the Pfizer documents, along with Pfizer’s hiring of extra staff to process vaccine injury claims related to the COVID-19 vaccine, later revealed the occurrence of serious side effects, including deaths, among trial participants.

Additionally, whistleblower Brook Jackson, who previously worked for Ventavia — which hosted some of the Pfizer-BioNTech COVID-19 vaccine trials — provided The BMJ a cache of internal company documents, photos and recordings highlighting alleged wrongdoing by Ventavia.

Jackson has since filed a lawsuit alleging Pfizer and others “deliberately withheld crucial information … that calls the safety and efficacy of their vaccine into question.”

Edwards’ role on the DMC was acknowledged in a November 2021 NEJM article, which found, “The data reported herein support vaccination of 5-to-11-year-old children with two 10-µg

doses of the BNT162b2 vaccine." The study was completed "with funding from Pfizer."

On Oct. 7, 2020, ICAN sent a demand letter to the U.S. Department of Health and Human Services, FDA, National Institute of Allergy and Infectious Diseases (NIAID) and the White House alerting them to the lack of independent members on the DSMBs for COVID-19 vaccines and specifically explaining the conflict with Edwards and another DSMB member.

ICAN later shared the FDA's Nov. 18, 2020, response letter, which according to ICAN, "fails to address a single one of the serious conflicts" and "would make any reasonable person even more concerned about the process for licensing a COVID-19 vaccine."

Edwards' relationship with Pfizer is also evident from her appearances in at least two episodes of "The Antigen," a Pfizer-produced podcast. In the inaugural episode of the podcast, Edwards explained "why vaccines are more relevant now than ever," while in episode four, Edwards discussed "vaccine hesitancy" and "everything anti-vax."

Edwards' 2020 deposition also revealed that between 1996 and 1998, she was paid $255,052 annually by pharmaceutical company Wyeth Lederle "to conduct a clinical trial for one of its vaccines," while being "a consultant and on the speakers' bureau" for the same company — and while being a member of the VRBPAC.

"When you voted to approve Wyeth Lederle's vaccine on VRBPAC, you also had a contract with Wyeth Lederle for $255,023 per year from 1996 to 1998 for the study of another of its vaccines," Siri said during the deposition — which after some hesitation, Edwards confirmed. In 2009, Pfizer acquired Wyeth Lederle.

Multiple conflicts of interest with other Big Pharma players

Edwards also maintained paid relationships with other pharmaceutical companies — often simultaneously with or in close proximity to her participation on the VRBPAC, ACIP and/or DMCs for vaccines produced by those very companies.

In her 2020 deposition, Edwards initially claimed she never was an advisor to any vaccine company. She later was obliged to admit, however, that in light of evidence produced, she had been both an advisor and consultant to Merck, including having received a "recent" $5,000 payment from Merck for services she provided.

It was further revealed during the 2020 deposition and 2022 cross-examination that Edwards served as a consultant for SmithKline Beecham (SKB) while conducting a vaccine trial for the same company. Edwards then remained as a consultant and on the advisory board for GlaxoSmithKline (GSK) after its merger with SKB, for whom Edwards claimed she "provided input in terms of the design of a flu study."

The 2022 cross-examination also revealed that Edwards received payments from GSK for her consulting services and for lectures she provided, while conducting clinical trials with some of the company's vaccines.

Similarly, in her 2020 deposition, Edwards initially testified she had never served on a speakers' bureau. In Edwards' own words, speakers' bureaus consisted of a "list of names that different people from [a] pharmaceutical company will say that people will give lectures, and so it's widely known that I will give lectures about vaccines."

She also claimed during her deposition not to remember having been on any speakers' bureaus or that she "misspoke," before admitting that while sitting on the VRBPAC, she was on the speakers' bureau of at least two companies — Connaught and Lederle-Praxis — and a consultant for one of them. This was not noted in her CV.

By the 2022 cross-examination, Edwards was more forthcoming, admitting that she participated in and received fees from speakers' bureaus. She also admitted such bureaus are "not very common now" and that "generally people don't want to be on those because they're felt to be perhaps more biased than they should be."

Despite telling Siri during the 2020 deposition that he "know[s] nothing about me," under cross-examination, Edwards qualified her involvement "in recent conflicts" on the basis that "we have a national pandemic … and we need people who know how to evaluate vaccine safety, and I spend a lot of time doing that."

Edwards also claimed that the CDC and FDA "did not feel" that her paid work for pharmaceutical companies, including conducting their clinical trials "were conflicts."

Notably, companies such as Merck, GSK and Sanofi, to whom she also provided paid services, produced childhood vaccines administered to Hazlehurst prior to the onset of his autism.

Siri further showed, during the 2020 deposition, that during Edwards' tenure on ACIP and VRBPAC between 1991 and 2000, numerous childhood vaccines were added to the CDC's ever-expanding childhood vaccine schedule. These included hepatitis A and B, dTaP (diphtheria, tetanus, pertussis) and Hib (Haemophilus influenza type B).

The end of Edwards' first tenure on VRBPAC, in 2000, was further marked by the release of a June 15, 2000, U.S. House of Representatives report highlighting conflicts of interest in VRBPAC and ACIP, noting:

> "How confident can we be in a system when the agency seems to feel that the number of experts is so few around the country that everyone has a conflict and thus waivers must be granted?
>
> "It almost appears that there is an 'old boys network' of vaccine advisors that rotate between the CDC and FDA, at times serving simultaneously."

The report also identified some of Edwards' conflicts of interest, noting, "Another member [of VRBPAC], Dr. Catherine [sic] Edwards, was receiving a grant for research on another vaccine of $163,000 from Wyeth Lederle."

Edwards coached during testimony — twice

Controversy involving Edwards also arose during the Hazlehurst trial when it appeared someone was coaching Edwards, seemingly guiding her toward providing specific responses to questions she faced from Siri, during both the deposition in 2020 and the cross-examination in 2022.

In at least two instances during the 2020 deposition, which as a result of COVID-19-related measures occurred online via Zoom, Siri asked Edwards if someone else was in the room with her, providing her with responses that she was then repeating.

Edwards denied she was being coached, claiming her husband "passe[d] through" or asked if she would "like some water." Multiple times, Siri had to ask Edwards to unmute her microphone.

This issue was then addressed during the 2022 cross-examination, when Siri played back video of the 2020 deposition — but with the volume amplified, revealing a voice, off-camera, that could be heard saying things that Edwards then repeated verbatim as her response to Siri. Despite the recording, Edwards continued to deny she was being coached.

During the same 2022 cross-examination, which took place in a Tennessee courtroom, Edwards' husband was ejected from the courtroom by the sheriff and by the judge presiding over the case, after he was seen communicating non-verbally with Edwards, apparently instructing her on how to respond. Again, Edwards denied this was the case.

At numerous other times during the deposition and cross-examination, Edwards' replies consisted of variations of "I don't know," "I don't remember," or "I couldn't hear that."

Notably, during the 2022 PAS conference, Edwards apparently drew upon her experience during the deposition and cross-examination — which she had testified was her first time as an expert witness — to deliver a presentation entitled "How to prepare and testify as an expert witness for vaccine-related litigation."

And, also of note, Edwards had, for a term spanning between 2012 and 2015, served as a member of the American Board of Pediatrics' Conflict of Interest Committee, according to her 2014 CV.

Close ties to Fauci and Gates-linked vaccine organization

Edwards also appears to be connected to Dr. Anthony Fauci, in part due to the funding she received from the NIH and the NIAID, one of the 27 institutes that together comprise the NIH and the one headed until recently by Fauci.

These ties were evident during a May 2021 question-and-answer session Fauci provided to Vanderbilt students "about lessons learned during the pandemic and to share career advice" — an event moderated by Edwards. This event was held just days before Fauci was awarded the university's Nichols-Chancellor's Medal, on the same day he delivered the university's commencement speech.

Edwards is also listed as a vaccine expert by the Sabin Vaccine Institute, which "recognizes that journalists and health workers play a vital role in public health by promoting fact-based media coverage," leading to the establishment of its "Immunization Advocates" program, with the support of GAVI, the Vaccine Alliance.

As previously reported by The Defender, GAVI proclaims a mission to "save lives and protect people's health," and states it "helps vaccinate almost half the world's children against deadly and debilitating infectious diseases."

GAVI describes its core partnership with various international organizations, including names that are by now familiar: the WHO, UNICEF, the Bill & Melinda Gates Foundation and the World Bank, and with the ID2020 Alliance, which supports the implementation of "vaccine passports."

ID2020's founding members include the Gates Foundation, Microsoft and Rockefeller Foundation.

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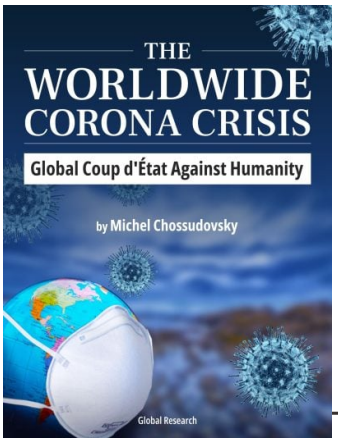

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