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CONFLICTS OF INTEREST

Covid-19: How independent were the US and British vaccine advisory committees?

Experts who sit on national vaccine advisory panels are asked to disclose any industry ties and other conflicts of interest. But **Paul D Thacker** finds that disclosure standards differ widely, often leaving the public in the dark

Paul D Thacker *investigative journalist*

In the wake of lightning fast authorisations of covid-19 vaccines in the UK and the US, public health officials have worked hard to maintain confidence in these new products. British and American officials have emphasised the independence of the experts who authorise vaccines and those who issue advice on them. But an investigation by *The BMJ* has found that some of these experts have significant industry ties that government agencies do not always disclose.

We looked at experts sitting on the covid-19 authorisation committees at the US Food and Drug Administration (FDA), as well as those on the UK's Joint Committee on Vaccination and Immunisation (JCVI), which advises the government on vaccines. It was not possible to repeat the exercise with the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), which licenses medicines and gave temporary authorisation for covid-19 vaccines, because the MHRA and its adviser, the Commission on Human Medicines, make almost none of their meetings or documents public.¹

Both the FDA and the UK government require panellists to disclose conflicts only from the previous 12 months, which can miss significant financial payments that occurred in recent years. We also found examples where panellists disclosed to committees their grants, patents, and other industry relationships in their publications, but it seems that the committees did not find these matters worth making public, and they remained undisclosed until now.

No conflicts registered

Most experts on the FDA and JCVI committees registered no conflicts of interest. From the JCVI's December meeting on 22 December 2020, the minutes report that 18 of 19 members had "no registered conflicts of interest," a pattern repeated in its eight other minuted meetings. Among FDA experts who were not industry or consumer representatives, the agency reported that 20 of 21 voting members had no conflicts at the 10 December advisory committee, as well as the same or a similar proportion at other covid vaccine meetings.

Adriane Fugh-Berman, professor of pharmacology and physiology at Georgetown University in Washington, DC, is not surprised at this low level of declarations. "Twelve months is too short. It's not going to give you a complete picture," she says. She

adds that it's preferable for government bodies to rely on experts who have had no financial ties for several years previously. The International Committee of Medical Journal Editors, for example, calls for disclosure of relationships going back 36 months.

In some cases, an expert has made a disclosure but the committee has not deemed it a conflict. For example, in the case of the UK's JCVI, the chair of the covid-19 meeting is Wei Shen Lim, a professor at the Nottingham Biomedical Research Centre, who JCVI says has "no registered conflicts of interest." The same document, however, further states that Lim's "institution has received unrestricted investigator-initiated research funding from Pfizer for a study in pneumonia in which Professor Lim is the chief investigator (non-vaccine related)." And in a preprint published only months before the JCVI's December meeting, Lim reported this Pfizer grant.

Similar matters exist with Adam Finn, professor at Bristol University, UK, as the JCVI reports him as having "no personal payments from manufacturers of vaccines" but adds that he is a local principal investigator for the Oxford-AstraZeneca covid vaccine. In disclosures for the *New England Journal of Medicine* in 2020 and in a disclosure the same year to *The BMJ*, Finn reported a study grant from GlaxoSmithKline (GSK). And in 2019 he published a study disclosing that his institution received funding from various drug companies and that he was president of a medical society whose annual meeting received sponsorship from vaccine manufacturers.²

For Maarten Postma of the University of Groningen in the Netherlands, the matter is rather complex. The JCVI reports no conflicts for his work on the covid-19 guidance, while he discloses board membership for two scientific consultancies on his website. And in a 2018 paper published in *JAMA Oncology* Postma disclosed grants and honorariums from more than a dozen drug companies, including AstraZeneca, Pfizer, and GSK. He also disclosed grants and personal fees from various pharmaceutical industries and financial support from the flu vaccine company Seqirus in studies he had published in recent months.^{3 4}

"I declare my conflicts of interest to JCVI in the field of vaccines," wrote Postma in an email to *The BMJ*. "They are indeed aware of those in the field of vaccines. Outside vaccines, I am happy to declare, but I think we decided we felt these are not relevant."

He also emailed *The BMJ* a list of his conflicts that JCVI reported for the main JCVI meeting, which was more expansive than what it reported for Postma for the covid meeting.

A spokesperson for Public Health England told *The BMJ* that for a single issue meeting of the JCVI such as for covid-19, conflicts of interest must be reported “only if they relate directly to that matter, rather than more widely.”

Transparency problems increase with the UK’s MHRA, which authorises vaccines after seeking advice from the Commission on Human Medicines, an independent expert scientific advisory body to government ministers. The commission does not make its advice public, publishes a scant record of meeting minutes, and has not disclosed its members’ declarations of financial interest since 2018.

Seeking the full picture

In the US, outside experts advise the FDA on whether to approve or authorise products. Only two members were reported to have conflicts of interest among several covid authorisation panels that met in late 2020. But *The BMJ* found panellists who had significant financial matters by looking at the Open Payments disclosure website and examining panellists’ published papers.

For example, Open Payments reported that Arnold Monto, professor at the University of Michigan School of Public Health and acting chair for the FDA’s covid vaccine authorisation meetings, had received over \$24 000 (£16 970; €19 650) in payments from drug companies in 2019. That same year, Open Payments reports that Myron Levine, a panellist from the University of Maryland School of Medicine, received about \$30 000, mostly in consulting fees.

In 2019, Open Payments reports, Robert Schooley of the University of California at San Diego received over \$25 000 in payments. It also reports that Ofer Levy at Boston Children’s Hospital received \$5500 in mostly travel expenses from GSK. And in a 2020 publication Levy disclosed that he was a named inventor on several patent applications related to vaccine adjuvants.

Ofer explained in an email that GSK was not a sponsor for either of the covid vaccine panels. He added that the pending adjuvant patents “were revealed to FDA in my disclosures and these were appropriately deemed by FDA as irrelevant to the subject matter being considered.”

In another email an FDA spokesperson explained that all potential candidates were required to report detailed financial matters to evaluate possible conflicts of interest. The email advised, “To protect the credibility and integrity of advisory committee advice, the FDA routinely screens members of all advisory committees carefully for potentially disqualifying interests or relationships and makes changes to committee meeting rosters as needed.”

However, a recent analysis by the *Pink Sheet*, an industry newsletter, found that the FDA had issued six conflict of interest waivers for experts who advised the agency on whether three oncology drugs should be withdrawn after failed clinical outcome studies.⁵ And a 2006 study published in *JAMA* found that conflict of interest disclosures were common at FDA advisory meetings but that they seldom resulted in recusals.⁶

The BMJ reviewed a blank copy of the FDA’s disclosure form and found that, as in the case of the JCVI’s disclosure policy, the FDA requires advisory members to disclose matters going back only 12 months.

Fugh-Berman says that these results reveal how confusing disclosure is and that common rules are needed. Few people realise that there’s

no common standard for what must be disclosed and how far back, she explains, nor that disclosure is a two step process. Experts disclose interests to an entity—such as a journal, university, or government agency—which then decides what to disclose to the public.

Fugh-Berman adds that she’s sometimes disclosed her own conflicts to editors when writing op-eds for newspapers, for example, and the outlets didn’t make them public. She says, “There needs to be standardisation of what should be disclosed and how it should be disclosed.”

Joel Lexchin of York University in Toronto, who publishes research on conflicts of interest, says, “Twelve months is really quite short. I think that’s not acceptable.” He also suggests that government agencies should publish everything that experts disclose to them, instead of picking and choosing what to make public. “The best policy is disclose everything,” he says. “Second best, pretty far down, is to have clear rules about why certain things don’t need to be disclosed.”

Schooley explains that the various time windows required by different disclosure policies can make it appear that an academic has reported financial interests in one case but not in another. More consistent disclosure policies are needed, he says—and universities, agencies, and journals should come together to normalise standards.

“If all of this were harmonised, it would improve transparency and reduce the time required for all involved,” he wrote to *The BMJ*. “In the meantime, we can try to answer each request as best we can based on how we interpret each query.”

Lexchin agrees that a standardised, universal disclosure form would make compliance easier for people and help avoid confusion about which financial matters should be disclosed and what the institutions should make public. As he explains, “People can legitimately follow whatever rules they encounter, but important things may get still get left out.”

NEJM editor had close ties with the FDA authorisation process when publishing covid-19 vaccine trials

The BMJ’s investigation into expert advisory committees for covid-19 vaccines has uncovered close ties between a leading medical journal and the FDA’s authorisation process.

The editor in chief of the *New England Journal of Medicine (NEJM)*, Eric Rubin, sat on the authorisation panels for and voted to recommend authorising the Pfizer,⁷ Moderna,⁸ and Johnson & Johnson⁹ covid-19 vaccines. After the panels authorised these vaccines, Pfizer¹⁰ and Moderna¹¹ published their clinical trials in *NEJM*.

Janssen, maker of the “one shot” Johnson & Johnson vaccine, had published its interim results¹² in *NEJM* on 13 January 2021, before seeking FDA authorisation.

Concentration of power

Rubin declared no conflicts of interest to all three vaccine panels. Asked by *The BMJ* whether he recused himself from the decisions on the *NEJM* submissions, he said, “Overall, we consider the deep involvement of editors in the medical and research communities to be a strength, not a problem.”

But this is “a concentration of power that should be questioned and debated,” says Charles Mehlman, a surgeon at Cincinnati Children’s Hospital Medical Center who has published several studies on journal editors¹³ and conflicts of interest.¹⁴

Joel Lexchin, an associate professor of medicine at the University of Toronto, says that a researcher’s involvement in a project that later gets published in a journal where they are editor is sometimes unavoidable. But he adds that Rubin should have recused himself from the FDA panels if he had an inkling that the companies would later publish their results

in *NEJM*. Lexchin explains, “By publishing, the journal stands to benefit in a number of ways: the impact factor of the journal might go up, or this type of high profile study might allow them to charge more for ads in the journal.”

Mehlman agrees that Rubin should have considered removing himself from the FDA process, and he points to research showing that physicians rarely think that they have a conflict of interest, while their colleagues often do.¹⁵ “People should have the common sense of knowing when to step away,” he says.

Lisa Cosgrove, professor at the University of Massachusetts in Boston, also studies conflicts of interest and found Rubin’s overlapping of roles troubling. When asked whether she would vote to authorise a product knowing that the company might later publish the clinical trial in a journal that she ran, she said, “Of course not. The obvious thing is that with this study everyone is going to read it, and it helps with their brand.”

Mixed views

The BMJ contacted several other journal editors and experts on conflicts of interest who gave a mixed review of the issue. One said that Rubin should have stepped aside from the FDA panel, while others saw no problem with his voting on the vaccine authorisation, as he had no financial conflict himself.

“I can’t get worked up about this,” says Jerome Kassirer, a distinguished professor at Tufts University School of Medicine in Boston. Kassirer spent a decade as editor of *NEJM* in the 1990s and has criticised corporate financial influence in medicine. “It represents a concentration of power, but I don’t get aggravated about this,” he says. “I would be deeply concerned about any direct financial interests.”

Fiona Godlee, editor in chief of *The BMJ*, says that she is most concerned about the concentration of power and lack of independent scrutiny, with Rubin being involved in both the regulatory and publication decisions for the vaccines. She says, “We don’t know whether Eric recused himself from the decision to publish, which would have been most important to do for the Pfizer and Moderna vaccine trials since these came to the journal after he had been part of their authorisation process.”

In a statement to *The BMJ*, Rubin confirmed that he had no direct financial interests in the vaccines and had even declined the FDA stipend to attend the advisory meetings. “Our editors are active clinicians, and almost all are actively involved in research,” he wrote. “They are experts in their fields and serve important roles as members of advisory boards and data and safety monitoring boards.”

He added that *NEJM* maintained a strict separation between business and editorial, so that he and other editors could not be influenced by the financial implications of reprints or advertising sales.

“That does mean that there are occasional non-financial conflicts, and editors are recused from discussions of some submissions because of their relationships with specific authors and studies,” he added. “Overall, we consider the deep involvement of editors in the medical and research communities to be a strength, not a problem.”

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