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FEATURE

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CONFLICTS OF INTEREST

US opioid prescribing: the federal government advisers with recent ties to big pharma

With the US facing an epidemic of opioid deaths linked to overprescribing, **Tim Schwab** finds that the influential National Academies of Science, Engineering and Medicine has not disclosed that one of its presidents, and members of a panel it convened to advise on prescribing opioids, had recent links to the drug industry

Tim Schwab *independent journalist, Washington, DC, and 2019 Alicia Patterson Foundation fellow*

As lawsuits proliferate against members of the Sackler family, owners of Purdue Pharma, for allegedly downplaying the risks of Purdue's opioid painkiller Oxycontin (oxycodone), the family faces not only potentially bankrupting legal costs but also the end of its long history of philanthropy.[1 2]

Universities, museums, and civic institutions are sending a message to the billionaire Sacklers: your "blood money" is no longer good here.[3]

"It's like tobacco money at this point," Art Caplan, professor of bioethics at New York University, told *The BMJ*.

In 2007 Purdue pleaded guilty to criminal charges that it downplayed the addictiveness of Oxycontin.[4] The Sacklers' role in the opioid addiction crisis "makes any of their funding of research, either institutionally or to investigators, hyper-suspect," Caplan says.

Yet a scientific body that advises the US federal government on opioid policies, the National Academies of Sciences, Engineering and Medicine (NASEM), is staying quiet about at least $14m (£11.6m; €12.6) it has received from Raymond and Beverly Sackler since 2008.

And a new NASEM project commissioned by the US Food and Drug Administration will advise federal policymakers on clinical practice guidelines for prescribing opioids,[5] increased prescribing being one driver of the addiction crisis that is responsible for 50 000 US deaths a year.[6]

NASEM told *The BMJ* that the 15 academics it has appointed to the panel, serving pro bono for the 16 months of the project, are free of conflicts of interest. But *The BMJ* has found that seven panelists disclosed ties to the drug or healthcare industry in recent scholarly work on pain.

Additionally, *The BMJ* has discovered that the president of the National Academy of Medicine since 2014, Victor Dzau, had financial ties as recently as 2018 to Medtronic, which markets a device to deliver pain medicine. After inquiries from *The BMJ* Dzau published a letter of clarification about his financial interests in *JAMA*,[7] and the journal corrected two articles Dzau wrote about the academies' opioids work, disclosing his ties to Medtronic.[8 9] New financial disclosures have been or will be added to at least three other articles by Dzau on different topics, *The BMJ* has learnt, including in *JAMA*, the *Journal of the American College of Cardiology*, and *The BMJ*.[10-12]

The national academies have attracted concern before about their failure to disclose conflicts of interest. These new revelations draw attention to its unusual policies on conflicts and reflect problems coming to light elsewhere in US medical research. For example, last year the chief medical officer of New York City's Memorial Sloan Kettering Cancer Center, José Baselga, resigned after the media reported that he had not disclosed industry ties in his scholarly work.[13]

Recruiting panelists, disclosing conflicts

In November 2018 NASEM convened the first meeting of its new panel, declaring all panelists free of financial conflicts. But three months earlier *Pediatrics* had published a commentary about the "national opioid epidemic" by panelist Steven Weisman, medical director of pain management at the Children's Hospital of Wisconsin, in which he disclosed having "conducted trials involving opioid medication in children for [drug maker] the Medicines Company" and receiving "honoraria for lecturing on pain and analgesia."[14]

The year before, in the *Journal of Pain*, Weisman disclosed having worked with the drug companies Purdue, Pfizer Janssen, Grünenthal, the Medicines Company, Depomed, Cadence, and Mallinckrodt.[15] The federal Open Payments database of industry payments to physicians shows that Weisman's financial ties to drug companies have been significant and long standing, including more than $40 000 in research funding from Purdue between 2013 and 2015.[16]

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Weisman told *The BMJ* that he made financial disclosures to NASEM, adding that he ended all relationships with drug companies involved with drugs for pain before joining the panel.

"I am, as best as one can be, always squeaky clean," he said. "It's not my decision here how the National Academies defines . . . conflicts of interest . . . I would agree with you that transparency is of the utmost importance."

NASEM declined to tell *The BMJ* how it determined that Weisman, or any other panelist, was free of conflicts of interest. But it said that its policy considers only "current" interests, ignoring "past interests that have expired, no longer exist, and cannot reasonably affect current behavior."

Lisa Bero, who researches scientific integrity at the University of Sydney, expressed surprise at NASEM's focus on "current" interests, telling *The BMJ* that almost all medical research bodies require public disclosure of previous financial interests, usually going back three years. They also take the "duration of the financial tie into account, with longer standing relationships considered more severe and influential," she said. Bero sat on a 2009 NASEM panel on conflicts of interest that specifically highlighted these points.[17]

Consulting and speaker fees

Panelist Rosemary Polomano, associate dean for practice at the University of Pennsylvania school of nursing, has several times in the past decade disclosed industry ties in her scholarly publications related to pain management.[18,19] A January 2018 article about opioids she coauthored in *Pain Medicine* disclosed consulting and speaker fees from drug companies Salix, Mallinckrodt, and Shionogi.[20] AcelRx, which makes the prescription opioid Dsuvia (sufentanil), told *The BMJ* it had twice paid Polomano honorariums in the past four years. Polomano did not respond to inquiries from *The BMJ*.

Journalists have several times investigated the panelist Richard Payne's extensive history of industry ties.[21,22] He was professor emeritus at Duke University's divinity school but died in January 2019, after the panel began its work. Payne's biography on the NASEM website notes that he had been bioethics chair of the Center for Practical Ethics and past president of the American Pain Society but doesn't mention these groups' substantial funding from Purdue and other opioids makers in recent years.

A 2019 US Congressional investigation, unrelated to the National Academies, criticized these and other industry funded groups for "minimizing the risk of opioid addiction and promoting opioids for chronic pain."[23] In the biographies of several members of its new opioids panel, NASEM cites their work with groups identified by Congress.[24]

Andrew Kolodny, co-director of opioid policy research at Brandeis University, sees NASEM's recruitment of scientists with recent ties to opioid manufacturers as "inexcusable when one considers the history of our opioid addiction epidemic," he told *The BMJ* from Oklahoma, where he was serving as an expert witness in the state's civil litigation against the opioid maker Johnson and Johnson.

"The reason we wound up here is precisely because of a failure to regulate conflicts of interest," Kolodny told *The BMJ*. "We had doctors with financial ties to opioid manufacturers working on guidelines that call for much more aggressive prescribing."

Given the National Academies' own financial ties to the Sacklers, Kolodny noted, you might expect them to go "out of their way to exclude any member from this panel who would have a financial tie to an opioid manufacturer," whether current or previous. "I don't agree that if someone stopped taking money from Purdue yesterday they would be free of conflicts of interest," he said.

Four more panelists had links

Four other panelists have disclosed industry ties in recent scholarly work.

Cardinale Smith, professor of medicine at the Icahn School of Medicine at Mount Sinai in New York, disclosed in a 2019 article on palliative care having received an "honorarium" and playing a "consulting or advisory or role" for the drug company Teva.[25]

"I did disclose it [to NASEM] and it was deemed not to be a conflict of interest," she told *The BMJ,* declining to comment further. The Open Payments database shows that Smith was paid $5400 from Teva last August.

Johns Hopkins University professor of anesthesiology Mark Bicket disclosed in a 2019 article about opioids in the *American Journal of Surgery* that he "serves on the advisory board of and holds stock options in Axial Healthcare."[26] The journal received the article after the NASEM panel commenced. Bicket did not respond to inquiries from *The BMJ*.

The BMJ has no evidence that any panelist other than Bicket continued or started new commercial relationships since joining the panel and no evidence that any panelist withheld any information from NASEM.

The University of Pennsylvania professor of medicine Mucio Delgado disclosed in a 2019 *American Journal of Emergency Medicine* article having received an "honorarium" for participating in an "Expert Roundtable on opioid prescribing convened by United Health Group."[27] Delgado told *The BMJ* that this was for travel expenses related to the 2017 event. "I do not have any ongoing potential conflicts of interests," he told *The BMJ*.

In a December 2018 article Eric Sun, professor of anesthesiology at Stanford University, disclosed payment from the opioid maker Egalet.[28] He told *The BMJ* that this was for "a 1 hour talk I had with some of their staff a couple years ago for which I was paid a few hundred dollars." Sun did not answer *The BMJ*'s questions about whether he'd disclosed this to NASEM.

A history of missteps on transparency

The national academies have drawn previous scrutiny for not disclosing ties to opioid manufacturers and distributors. The *Milwaukee Journal Sentinel* in 2014 reported that nearly half the panelists who wrote a 2011 NASEM report had ties to opioid makers in the three years before the panel formed.[29] This report concluded that almost two Americans in five have chronic pain.[30]

But experts quoted in the *Milwaukee Journal Sentinel* called this number inflated and worried that it could be used to justify increases in prescriptions of opioid painkillers.[31] The FDA cited the two in five statistic in subsequent regulatory approvals of opioids.

In 2016 NASEM again faced public criticism for work on opioids, when Senator Ron Wyden criticized its recruitment of panelists with ties to advocacy groups funded by opioid makers.[32] After several investigations into undisclosed financial conflicts in its work, in 2017 NASEM announced that it was revamping its conflict of interest policies for panelists.[33] Two years later, its 2003 policy still stands.

"Potential updates to our . . . policy are under consideration," spokeswoman Dana Korsen told *The BMJ*.

Over the years NASEM has often dismissed allegations of conflicts of interest among its panelists. In an opinion article in *JAMA* in October 2014 it dismissed news reports of undisclosed conflicts in its opioids work, arguing that its panelists were "thoroughly vetted."[34]

Yet one of the article's authors, Victor Dzau, president of the National Academy of Medicine, did not disclose his own industry ties.

NAM president Victor Dzau

When Dzau joined the National Academy of Medicine (then called the Institute of Medicine) as its president in 2014, his history of private sector work—with Medtronic, Corgentech, PepsiCo, Alnylam, and Genzyme—made headlines. NASEM said it would forbid someone in Dzau's position from participating "in anything in which they have a financial conflict of interest" and that he would have to cut all industry ties before his tenure began, on 1 July 2014.[35]

NASEM confirmed this to *The BMJ*: "Prior to joining the Institute of Medicine/National Academy of Medicine, Dr Dzau ended his former relationships with corporations and has since taken on no new relationships or paid activities with any for-profit companies."

Likewise Dzau told *The BMJ* that he "ceased all activities with all commercial entities after I joined [the academy] to avoid any conflict." He also emphasized, "I have resigned from all relationships and divested the holdings since I became the president of NAM. I have no new relationship since 2014."

But this doesn't seem to tell the whole story.

In October 2014, the month *JAMA* published the opioids opinion article, Medtronic reported paying Dzau $220 000 in fees and stock that fiscal year for his previous service as a director.[36] Dzau resigned from Medtronic before joining the National Academy of Medicine, but the day before he took over as president, on 30 June, Medtronic reported that he owned more than 18 000 shares in the company, valued then at more than $1m.[37]

Medtronic sells many products that could be relevant to activities that Dzau is responsible for at the academy and discussed in his scholarly work, including an implant that delivers opioids to patients. The company reports more than $1bn in annual net sales related to "pain therapies,"[38 39] and its corporate materials on its pain products even cite the academies' work on opioids.[40]

When asked whether he held investments in Medtronic after joining the National Academy of Medicine, Dzau initially told *The BMJ*, "My bank manages my money and I keep at arm's length and do not get involved." He noted, "I have no financial interests in any companies that overlap with my work."

After requests for clarification, Dzau told *The BMJ* that he didn't fully divest from Medtronic—as well as other unnamed "pharma stocks"—until 2018, saying that he had received "deferred compensation" from Medtronic from which he could not immediately divest under US tax rules. Dzau did not directly respond to *The BMJ*'s further questions about whether he had other industry investments during his tenure at the academy. At various points in correspondence Dzau told *The BMJ* that his assets were "managed like a blind trust."

NASEM told *The BMJ* that it was aware of these ties: "As is common practice, for that board service [at Medtronic] he was compensated with shares, which were scheduled to be divested upon a predetermined vesting schedule."

Outside experts, when informed of Dzau's ties to Medtronic till 2018, raised concerns. "It's always been an important part of the national academies to be independent and objective. Having any industry ties compromises that objectivity, and for the head of the National Academy of Medicine to have financial ties to a pharmaceutical or medical device company is highly problematic," notes Adriane Fugh-Berman, a pharmacology professor at Georgetown University who serves as an expert witness on behalf of plaintiffs in cases related to opioids and medical devices.

Lack of public disclosure

Revelations of Dzau's financial ties to Medtronic during his first several years at the National Academy of Medicine raise questions about why it wasn't previously publicly disclosed, such as in his 2014 *JAMA* article about opioids.

"Frankly, I was new and within months of my new job, and it did not occur to me that there is a conflict with Medtronic," Dzau said.

When *The BMJ* initially asked Dzau for examples of disclosures he had made since joining the academy, he said, "None of the papers I wrote received financial support from commercial entities and my past financial relationships were not relevant to the published work or have any appearance of influence."

Later, Dzau told *The BMJ* that he had corresponded with unnamed journals in which he'd published, and "they agreed that my disclosures are in compliance."

When *The BMJ* asked *JAMA* about Dzau's disclosures, the journal said it would investigate. Shortly after, Dzau published a letter of clarification in *JAMA*,[7] disclosing his "having served previously as a member of the board of Medtronic Inc . . . and receiving compensation from that company." Dzau's letter also stated that he had "sold health care-related stocks to eliminate all potential financial conflicts of interest" before joining the academy on 1 July 2014—without mentioning that he did not fully divest from Medtronic until 2018.[7]

Dzau referred *The BMJ*'s questions to *JAMA,* which defended the new disclosures as "accurate," telling *The BMJ*, "There will be no further comment."

JAMA also published corrections to two of Dzau's publications on opioids, the 2014 opinion article and one from 2019, to disclose his Medtronic ties,[8 9] as well as a third article about precision medicine, disclosing Dzau's ties to Alnylam because of the company's interest in "targeted gene therapy."[10]

Dzau told *The BMJ* that its inquiries had "sensitized" him to the importance of financial disclosures, but he downplayed the corrections: "There was no sense from *JAMA* and its response that I was withholding information but we agreed that 'out of abundance of caution' to write a note of clarification," he said.

Dzau also sent a rapid response on bmj.com[12] to disclose his ties belatedly for two publications he coauthored in *The BMJ* about Ebola and the World Health Organization[41 42]—"in the spirit of transparency"—not because he believes they are conflicts of interest.

Like many medical journals, *JAMA* and *The BMJ* require authors to follow the guidelines of the International Committee of Medical Journal Editors. These ask authors to disclose "interactions with ANY entity that could be considered broadly relevant to the work" during the previous 36 months. "If there is any question, it is usually better to disclose a relationship than not to do so," the disclosure form notes.

Other recent publications by Dzau appear to cover topics relevant to Medtronic's interests, such as the more than $10bn in annual net sales the company reports for its cardiovascular products.[38] For example, a 2017 article Dzau coauthored in the *Journal of the American College of Cardiology* examined recommendations from a NASEM panel, co-sponsored by Medtronic.[43] The article favorably mentioned Medtronic twice; Dzau, a cardiologist, made no disclosures.[11]

After *The BMJ* made inquiries to Dzau, he contacted the *Journal of the American College of Cardiology*, offering to update his disclosures, but also saying he did not believe the article was "relevant to Medtronic . . . products, research or interests." Correspondence that Dzau shared with *The BMJ* shows that the journal agreed.

When contacted by *The BMJ*, however, the journal said it would update Dzau's disclosures, declining to discuss its decision.

An opioids and ethics leader at the academies

Though Dzau's scholarly work on opioids now discloses his ties to Medtronic, it is unknown how NASEM managed this relationship.

It told *The BMJ* that Dzau has disclosed all his financial interests to it privately and complies with its policy. But it declined to provide Dzau's disclosures, its staff conflict of interest policy, or any examples of its having publicly disclosed Dzau's industry ties or asking Dzau to recuse himself from its activities.

Dzau repeatedly distanced himself from the work of the current opioids panel, telling *The BMJ* he has no "direct oversight." He explained that the panel was not convened by National Academy of Medicine but by NASEM's separate National Research Council, on whose governing board Dzau sits.

Dzau's other work on opioids includes authoring scholarly articles about the national academies' work, such as those in *JAMA*, and currently chairing a NASEM led public-private partnership of over 55 groups to counter the opioid epidemic.[44]

According to a job description Dzau sent *The BMJ,* his duties at the National Academy of Medicine also include setting "a high standard of intellectual integrity, neutrality, and honesty in all that NAM does."

Dzau spoke about the importance of managing conflicts of interest at a NASEM workshop in 2015, co-sponsored by Medtronic. In a written summary of his presentation, NASEM did not disclose Dzau's ties to Medtronic and emphasized his independence, noting that he had stepped away from all commercial activities before joining the National Academy of Medicine. "In this capacity, there cannot be any real or perceived COI [conflict of interest]," it said.[45]

Dzau said that it "did not occur" to him to make disclosures. "In my mind I had already removed all competing interests out of my involvement. This is simply the fact," he told *The BMJ*.

Following the money

A private institution, NASEM publishes cumulative donations in bands instead of full financial details. In total, the Sacklers, one of its top donors, have given between $10m and $25m.

It declined to provide more details to *The BMJ* or to say whether it continues to receive Sackler funding. Dzau emphasized to *The BMJ* that no Sackler funding was endowed specifically to the National Academy of Medicine.

"I have no say whatsoever on how the other academies decide on the use of their endowment," he told *The BMJ*.

Annual financial reports provide a glimpse into the destination of at least some of the Sacklers' funding, none of which directly concerns opioids: $2m in 2008 to create a scientific forum between US and UK researchers, $2m in 2011 to support biomedical studies, and $10m in 2015 to fund a research prize.[46-50]

These reports also acknowledge NASEM having received millions of dollars from other drug companies that could have interests in its work, including beyond opioids. Merck has given between $5m and $10m in total. AstraZeneca, Bristol Myers Squibb, GlaxoSmithKline, Johnson and Johnson, Eli Lilly, Novartis, Pfizer, Sanofi-Aventis, and United Therapeutics have each given between $1m and $5m. Medtronic has given between $100 000 and $500 000.

Competing interests: I have read and understood BMJ's policy on declaration of interests and declare the following interests: in previous employment, at the public interest group Food and Water Watch, I gave an invited presentation to the National Academies on conflicts of interest in 2014, and reported undisclosed industry ties in the academies' agricultural work in 2017 (doi:10.1371/journal.pone.0172317).

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