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pdoshi@bmj.com
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The FDA and Moderna's cosy relationship: how lax rules enable a revolving door culture

After holding oversight roles for covid vaccines, two regulators from the US Food and Drug Administration went to work for Moderna. Peter Doshi reports

Peter Doshi *senior editor*

The physician-scientist Doran Fink worked his way up at the Food and Drug Administration, with a focus on the regulation of vaccines. Starting as a clinical reviewer in 2010, he was promoted to lead medical officer in the FDA's Office of Vaccines Research and Review, overseeing a small team of medical officers responsible for infectious diseases and related biological products.

During the covid-19 pandemic Fink took on a public role, appearing in numerous FDA and Centers for Disease Control and Prevention advisory committee meetings to discuss covid vaccines and serving on the senior leadership team for covid vaccine review and policy activities. Part of his role was to engage vaccine manufacturers to advise on the development of vaccines during the pandemic. In mid-2020 Fink announced the FDA's expectations for any covid vaccine that the agency would consider authorising, and he took part in the ultimate decision to license the Pfizer and Moderna vaccines.

Fink's LinkedIn profile states that he finished his role at the FDA in December 2022. Two months later he was working at Moderna, heading the translational medicine and early clinical development programme in infectious diseases. He is one of two regulators *The BMJ* has found to have recently moved to Moderna from the FDA's Office of Vaccines Research and Review.

Concerns about a "revolving door"—movement of people between the government and the private sector—have persisted for decades, with public confidence in the balance over the integrity of government decision making.[1–3] Craig Holman, who serves as government affairs lobbyist for the consumer advocacy organisation Public Citizen, says that government service is fundamentally different from private sector work. Those in the public sector "are expected to serve the public interest," he says. "And so, we need safeguards to make sure they are serving the public interest."

Jeremy Kahn, FDA press officer, told *The BMJ* that the FDA has "more enhanced ethics restrictions than most other federal agencies. The FDA takes seriously its obligation to help ensure that decisions made and actions taken, by the agency and its employees, are not, nor appear to be, tainted by any question of conflict of interest. The agency provides robust information and resources to employees regarding the steps that must be taken to fulfil these ethics obligations."

But *The BMJ* has found that the FDA keeps no records on where employees go after they leave government service. Nor does it require employees to undergo an approval or clearance process before taking up an industry job. Employees are required to adhere to post-government employment guidance: restrictions include a permanent ban on "switching sides," defined as "a lifetime ban on communicating to or appearing before the government on behalf of their new employer or anyone else regarding specific party matters in which they participated personally and substantially during their entire government service." And those who have begun seeking or negotiating an industry job "must immediately recuse from participation in any official matter that involves the prospective employer as an identified party."[4] Adherence, however, is inevitably self-enforced.

Holman says, "The revolving door is particularly abusive in agencies that have a huge flood of money going in. That's a big problem with the FDA, especially with the pandemic and Operation Warp Speed"—referring to the public health-military-industrial partnership tasked with expediting a coronavirus vaccine to market.

Holman notes that the FDA could legally prohibit its employees from working for companies they had regulated, and those entering the FDA "could be required to sign an ethics pledge saying they will not take any official actions that affect their former employers or clients." He suggests a "cooling-off" period of at least two years: "You need a period of time where the close relationships and the networks kind of break down." Under President Obama, for example, all executive agency appointees were prohibited from lobbying the Obama administration after leaving their position.[5] Holman's research[6] has found that most US states have cooling-off laws that prevent former government officials from lobbying their previous agency for one to two years, and Florida recently extended its cooling-off period to six years.

The revolving door

The perils of a revolving door between the FDA and industry were vividly captured in the case of Curtis Wright and Purdue Pharma, a story now chronicled in books and on television.[7–10] At the FDA, Wright led the agency's 1995 approval of OxyContin, which came with specific labelling language that described the opioid as having less misuse potential—a centrepiece in Purdue's campaign to market the drug

for increasingly broad populations.[11] The book *Empire of Pain* states that, in a sworn deposition, "Wright allowed that he might have" written the key labelling passage.[7] Around a year after leaving the FDA he took up a $379 000 (£312 000; €360 000) a year position with Purdue.

While the case of Purdue Pharma is particularly egregious, studies suggest that post-FDA industry employment is not uncommon. In a 2016 study published in *The BMJ*, researchers followed the trajectories of 55 medical reviewers involved in drug approvals in FDA's haematology-oncology division over several years. Of 26 officers who left the FDA, 15 later worked or consulted for industry.[12] A separate investigation by *Science* magazine in 2018 similarly reported that "11 of 16 FDA medical examiners who worked on 28 drug approvals and then left the agency for new jobs are now employed by or consult for the companies they recently regulated. This can create at least the appearance of conflicts of interest."[13]

Similarly to Fink, Jaya Goswami started at the FDA in its Center for Biologics Evaluation and Research in March 2020. As a medical officer she had, in her words, "broad oversight over vaccines and biologics clinical development" and was responsible for evaluating whether the clinical data for Moderna's covid vaccine met regulatory standards for approval; licensure was granted at the end of January 2022. Goswami's LinkedIn profile states that she left the FDA in June 2022 and that same month started a new role as director of clinical development in infectious diseases at Moderna.

Goswami and Fink did not respond to requests for an interview. *The BMJ* asked Goswami, Fink, Moderna, and the FDA whether either of the former regulators sought guidance from the FDA's Office of Ethics and Integrity before moving to Moderna, as well as whether they recused themselves from any FDA matters related to their employment search. The FDA instructed *The BMJ* to file a Freedom of Information Act request for this information, which *The BMJ* has done, and Moderna's vice president of communications and media, Chris Ridley, replied, "We have no comment on your inquiry."

At Moderna, Goswami has been involved in the company's efforts to bring to market an mRNA vaccine against respiratory syncytial virus (mRNA-1345). In July this year the company announced that it had submitted applications for regulatory approval in the United States, the European Union, Australia, and Switzerland. In the US the review can be expected to be conducted by the FDA's Office of Vaccines Research and Review, the group Fink and Goswami departed.

Moderna's deepening connection with the government

Before the pandemic, Moderna had limited regulatory experience. The company, founded in 2010, had pursued a variety of mRNA platform products, but in its decade long history it had yet to bring a single product to market.

With covid, Moderna's fortunes changed. Moncef Slaoui, a career pharma executive and prominent member of Moderna's board of directors, was appointed by President Trump to co-lead Operation Warp Speed. With his appointment, Slaoui sold his whole shareholding of around $12m of Moderna stock and resigned from the Moderna board, but he kept an estimated $10m stake in GlaxoSmithKline, another recipient of Operation Warp Speed funds. Slaoui took the job as a contractor, which meant that he was not subject to the disclosure and divestiture ethical requirements of federal government employees.

On behalf of Public Citizen, Holman filed an ethics complaint against Slaoui, not upheld, urging him to be classified as a "special government employee" subject to federal conflict of interest code and disclosure requirements.

Under Slaoui's orchestration, Moderna quickly emerged as a frontrunner.[14] A phase 1 clinical trial commenced in March 2020, 66 days after the viral sequence was released, and by midsummer the US had pledged $955m towards a phase 3 trial, with an additional $1.5bn promised through an advance purchase agreement due on delivery of 100 million doses. (By March 2021 a congressional report estimated that Moderna had $4.94bn in federal funding for a total of 300 million doses.[15])

On 18 December 2020, under the leadership of FDA commissioner Stephen Hahn, the FDA granted a world first authorisation to Moderna's covid vaccine, mRNA-1273. Six months later, after resigning his post with the transition to the Biden administration, Hahn joined Flagship Pioneering—"the venture fund that birthed Moderna."[16]

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