Investigation raises concerns over 'cozy relationship' between the FDA and Moderna

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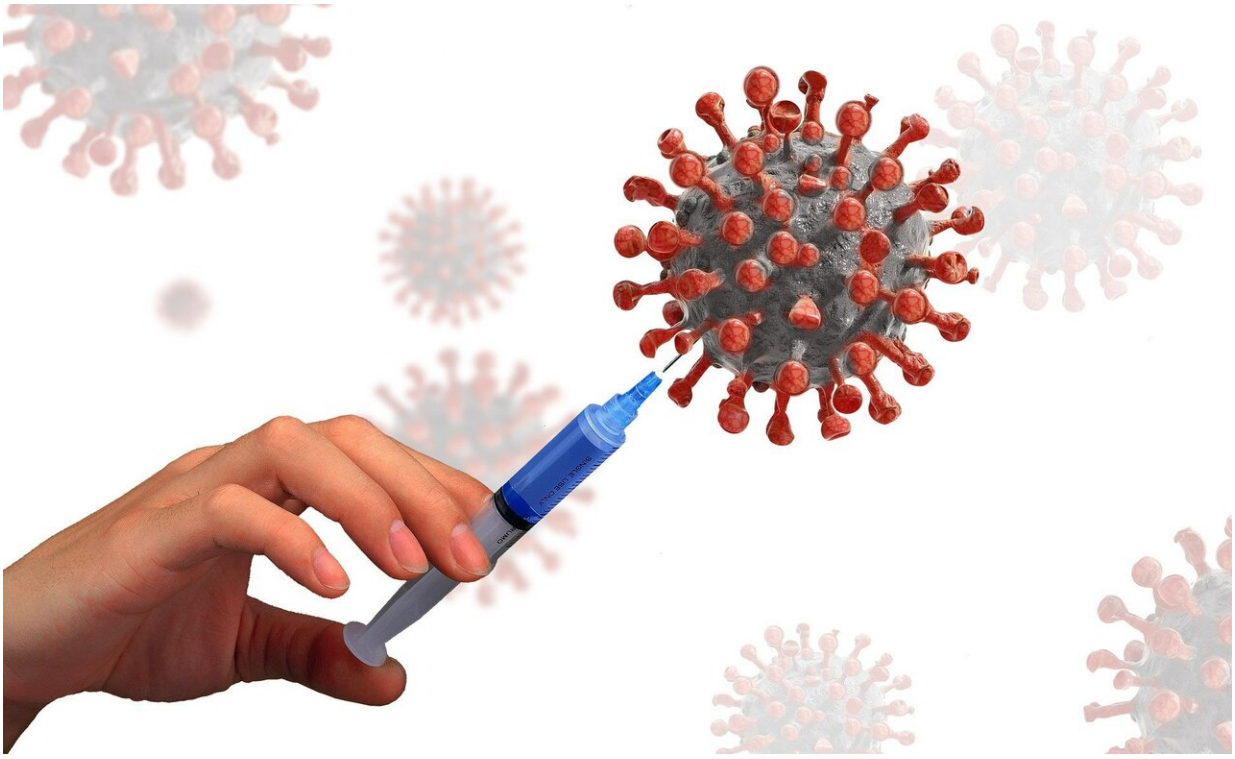

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An investigation published by *The BMJ* raises concerns about a revolving door culture between the US Food and Drug Administration (FDA) and Moderna after two regulators who held oversight roles for COVID vaccines went to work for the company.

During the COVID-19 pandemic, Doran Fink served on the FDA's senior leadership team for COVID vaccine review and policy activities and took part in the ultimate decision to license the Pfizer and Moderna vaccines, explains Peter Doshi, senior editor at The BMJ.

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 program in infectious diseases.

Similarly to Fink, Jaya Goswami started at the FDA in its Center for Biologics Evaluation and Research in March 2020 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.

Jeremy Kahn, FDA press officer, told The BMJ that the FDA has "more enhanced ethics restrictions than most other federal agencies" and "provides robust information and resources to employees regarding the steps that must be taken to fulfill 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 certain post-government employment restrictions, but as Doshi notes, adherence is inevitably self-enforced.

Craig Holman, government affairs lobbyist for the consumer advocacy organization Public Citizen, says safeguards are needed to make sure those in the public sector are serving the public interest. He suggests a "cooling-off" period of at least two years in which former FDA officials are prevented from lobbying their previous agency.

Studies also suggest that post-FDA industry employment is not uncommon.

For example, in a 2016 study published in *The BMJ*, researchers followed 55 medical reviewers involved in drug approvals in FDA's hematology-oncology division over several years. Of 26 officers who left the FDA, 15 later worked or consulted for industry.

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."

Goswami and Fink did not respond to requests for an interview and the FDA instructed The BMJ to file a Freedom of Information Act request for information on 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.

Meanwhile, at Moderna, Goswami has been involved in the company's efforts to bring to market an mRNA vaccine against respiratory syncytial virus (mRNA-1345). Doshi notes that Moderna's application for regulatory approval in the US is likely to be judged by the FDA's Office of Vaccines Research and Review, the group Fink and Goswami departed.

More information: Peter Doshi, The FDA and Moderna's cosy relationship: how lax rules enable a revolving door culture, *BMJ* (2023). DOI: 10.1136/bmj.p2486