Top FDA Officials Accept Jobs with Moderna After Playing Key Roles in COVID-19 Vaccine Licensure

Two high-level regulatory officials with the U.S. Food and Drug Administration (FDA) involved in vaccine oversight accepted jobs at Moderna just months after signing off on the licensure of the company's COVID-19 vaccine, according to a British Medical Journal (BMJ) investigation.

The report by Dr. Peter Doshi, associate professor at the University of Maryland School of Pharmacy and senior editor at The BMJ, reveals a long-standing revolving door between the FDA and pharmaceutical companies whose products it regulates and raises questions about the impartiality and independence of top FDA regulators.

Dr. Doran Fink is a "physician/scientist experienced in regulation and clinical development/licensure of vaccines and related biological products" and was deeply involved with

vaccine regulation at the FDA for more than 12 years, according to his LinkedIn profile.

According to the BMJ report, Dr. Fink started his FDA career as a clinical reviewer in 2010 and "worked his way up" to Deputy Director of the Division of Vaccines and Related Product Applications within the FDA's Office of Vaccines Research and Review, where he led a team of medical officers focused on infectious diseases and related biological projects.

During the COVID-19 pandemic, Dr. Fink was a prominent voice on COVID-19 vaccines and which population groups should receive them. He spoke on behalf of the FDA at numerous meetings held by the agency's vaccine advisors who met to discuss whether to approve COVID-19 vaccines, change their composition, or authorize boosters.

Dr. Fink also presented at meetings held by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices—a group of health experts that develop recommendations on how to use vaccines—as the FDA's "principal FDA ex officio representative."

According to the BMJ report and Dr. Fink's LinkedIn profile, Fink also served on the senior leadership team for COVID-19 vaccine review and policy activities in response to the COVID-19 public health emergency.

As part of his role, he advised vaccine manufacturers on vaccine development throughout the pandemic and coordinated "expedited review of regulatory submissions," advised U.S. government stakeholders outside the FDA on COVID-19 vaccine science and development, and contributed to FDA guidance on the development, licensure, and emergency use authorization of COVID-19 vaccines.

Most notably, Dr. Fink engaged in a "senior level review" of the FDA's decision memoranda for emergency use authorization

and licensure of COVID-19 vaccines, including Moderna's.

According to Fink's LinkedIn profile, he left the FDA in December 2022 and started a job at Moderna as the head of "Translational Medicine and Early Clinical Development, Infectious Diseases" in February 2023.

Dr. Jaya Goswami has a similar history. Dr. Goswami began working as a medical officer at the FDA's Center for Biologics Evaluation and Research in March 2020 and had "broad oversight over vaccines and biologics clinical development," according to the BMJ report.

Goswami was responsible for determining whether Moderna's COVID-19 vaccine clinical data met regulatory standards for approval. Moderna's SPIKEVAX received FDA approval in January 2022. Goswami's LinkedIn profile said she left the FDA in June 2022 and began working for Moderna that same month as their director of clinical development in infectious diseases.

At Moderna, Goswami has been involved with the company's investigational mRNA vaccine against respiratory syncytial virus (mRNA-1345). The company announced in a press release on July 5 that it had submitted marketing authorization applications with the European Union, Switzerland, and Australia, as well as a "rolling submission of a Biologics License Application" to the FDA—which will be reviewed by the department within the FDA that employed Drs. Fink and Goswami.

According to Moderna, the company made $18.5 billion in 2021 from sales of its COVID-19 vaccine, more than $19 billion in 2022, and projects sales of its COVID-19 vaccine will reach at least $6 billion in 2023.

Dr. Doshi, writing for The BMJ, warns that this is another sign of the "revolving door" between pharmaceutical companies and the regulators entrusted with regulating their products.

Both FDA employees worked in vaccine regulation during the

COVID-19 pandemic and joined Moderna—whose only product was its COVID-19 vaccine.

“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,” Craig Holman, a government affairs lobbyist for Public Citizen, told The BMJ.

Holman was referring to the federal funding Moderna received as part of Operation Warp Speed that helped expedite the authorization of COVID-19 vaccines. Holman suggests a “cooling-off period” of at least two years to break down close relationships and networks that could present an ethical problem for employees who leave regulatory agencies for the companies whose products they regulate.

No Proof FDA Enforces Ethical Requirements for Employees

“The recurring issue of the revolving door culture between industry and regulators has long been a concern and raises questions about regulatory impartiality,” said Kim Witczak, a global pharmaceutical drug safety advocate and member of the FDA’s Psychopharmacologic Drugs Advisory Committee.

“A troubling trend is the intentional career move of making a stop at a regulatory agency, with the real payoff occurring when they transition to drug company roles. While this might benefit the pharmaceutical industry, it poses risks to public health. The worry arises about potential bias in regulating practices, including being lenient in criticism or overlooking safety concerns,” she added.

Witczak said the absence of strong measures leaves the FDA vulnerable to corruption, and implementing safeguards, such as a mandatory “cooling off period,” is important for maintaining regulatory integrity.

FDA press office Jeremy Kahn told the BMJ the agency has "more enhanced ethics restrictions than most other federal agencies" and "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."

Kahn also said the FDA provides "robust information and resources to employees regarding the steps that must be taken to fulfill these ethics obligations," however, the BMJ found the FDA doesn't keep records of where employees go when they leave the agency and doesn't require employees obtain approval or clearance before taking an industry job.

When the BMJ asked the FDA whether the health regulators sought direction from the FDA's Office of Ethics and Integrity before accepting positions with Moderna and whether they recused themselves from any FDA matters related to their employment search, the FDA told the BMJ to file a Freedom of Information Act Request.

Moderna's vice president of communications and media, Chris Ridley, said the company had "no comment" when asked the same by Dr. Doshi.

The FDA Has a Long History of 'Revolving Door' Culture

This is not the first time issues have been raised with the FDA's "revolving door"—a concept defined in an October 2005 paper by the Revolving Door Working Group (RDWG) as the "movement of individuals back and forth between the private sector and the public sector."

According to RDWG, the government-to-industry revolving door is where "public officials move to lucrative private-sector positions in which they may use their government experience to

unfairly benefit their new employer in matters of federal procurement and regulatory policy."

This may allow public servants to use their office for personal or private gain at the expense of taxpayers, cast doubts on the integrity of official actions, could influence a government employee's official actions through promises of a future high-paying job with the company benefits from the official's actions, could provide an unfair advantage or give the appearance of undue influence and impropriety.

In a 2016 study published in The BMJ, researchers followed 55 medical reviewers involved in drug approvals in the FDA's hematology-oncology division over several years. Of 26 medical reviewers who left the agency, 15 went to work for the biopharmaceutical industry, were consultants to it, or did both.

A search conducted in 2018 by the journal Science found that 11 of 16 FDA medical examiners involved with 28 drug approvals left the agency for new jobs or became consultants with companies whose products they recently regulated.

Another prominent example of a top regulatory official who left the FDA to work for the drug industry is former FDA commissioner Dr. Scott Gottlieb, who unexpectedly resigned in March 2019 after less than two years of serving in the position.

In June 2019, Pfizer announced that Dr. Gottlieb had been appointed to its board of directors "effective immediately" and joined the company's Regulatory and Compliance Committee and the Science and Technology Committee.

Dr. Gottlieb, who is also a CNBC contributor, was frequently consulted by news media outlets on COVID-19 vaccines, helped the company rake in more than $100 billion in sales of its vaccine and anti-viral, and flagged tweets that questioned COVID-19 vaccines for "X," formerly known as "Twitter," as

revealed by the Twitter files.

According to the BMJ investigation, Moncef Slaoui, a prominent member of Moderna's board of directors, was appointed by President Trump to co-lead Operation Warp Speed. Although he resigned from Moderna's board and sold his stake in the company, Moderna, which had never brought a product to market, received $4.94 billion in federal funding for 300 million doses of its COVID-19 vaccine.

The FDA Commissioner at the time, Stephen Hahn, authorized Moderna's COVID-19 vaccine on Dec. 18, 2020, and stepped down six months later when he accepted a job with Flagship Pioneering—"the venture fund that birthed Moderna."