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BMJ INVESTIGATION

Revolving doors: board memberships, hedge funds, and the FDA chiefs responsible for regulating industry

The US Food and Drug Administration says that it takes conflicts of interest seriously. But financial entanglements with the drug industry are common among its leaders. Peter Doshi reports

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At his public confirmation hearing in late 2021, Robert Califf, President Biden's nominee to lead the US Food and Drug Administration (FDA), faced pointed questions about his financial relationships with industry.

Bernie Sanders, the senator from Vermont, asked, "At a time when the American people are outraged by the high cost of prescription drugs, deeply disturbed about what happened with Purdue and Oxycontin, what kind of comfort can you give to the American people when you have been so closely tied to the pharmaceutical industry yourself?" He added, " How can the American people feel comfortable you're going to stand up to this powerful special interest?" Califf responded: "Senator Sanders, I have a history of doing that. But I'd also point out that this administration has the most stringent ethics pledge in the history of administrations."

Califf did not earn Sanders's vote, but he got the job. With it, the incoming FDA commissioner committed to sell his pharmaceutical stocks and sever his financial relationships with biotech companies such as Alphabet owned Verily Life Sciences, which paid Califf $2.7m as a senior adviser, according to his federal disclosure (see supplementary files on bmj.com).

The divestitures were not the product of an ethics pledge, nor were they optional. Criminal conflict of interest rules prohibit government employees from "participating personally and substantially in official matters where they have a financial interest."[1] Other regulations prohibit FDA employees from holding financial interests in any FDA "significantly regulated organisation" such as drug and medical device companies.[2]

Failure to comply can be costly. In 2007, a former FDA commissioner—Lester Crawford—was sentenced to three years of supervised probation and fined $89 377 for false reports about stocks that he and his wife owned in four FDA regulated companies.[3] Crawford, a pharmacologist and veterinarian who had served in the agency on multiple occasions before being nominated as commissioner, had been instructed to sell stocks in around a dozen regulated companies. But he did not sell shares in three of these companies: the food and drink multinationals Sysco and Pepsico, and Kimberly-Clark, a paper based consumer products company.[4]

2022 marked Califf's second time leading the FDA, having previously served during the Obama administration's final year. It was therefore his second time terminating a host of ties with the companies that the agency is meant to regulate, and his second time signing an ethics pledge.

The Trump administration, too, required that appointees sign an ethics pledge, committing not to lobby the agencies for five years after public service. But the requirement was rescinded on 19 January 2020, Trump's last full day in office. In addition, the ban only applied to lobbying activities, not employment in general, and within three months of vacating the FDA's top job, Scott Gottlieb, Trump's first nominee who led the agency from 2017 to 2019, was nominated to Pfizer's board of directors, subsequently gaining enormous public visibility through regular media appearances as a covid expert commentator. (While a medical student, Gottlieb interned at *The BMJ* as a Clegg scholar; he subsequently penned a number of BMJ news articles.)

The revolving door between the FDA and industry surprises few anymore, despite the widely acknowledged potential it has for undermining public trust in government. And stories about FDA commissioners' heavy ties to industry have become commonplace: nine of the FDA's past 10 commissioners went on to work for the drug industry or serve on the board of directors of a drug company.

But the story of Margaret Hamburg, Califf's predecessor who led FDA between 2009 and 2015, is less well known, apart from coverage in local press.[5] Like her colleagues, Hamburg had relationships with FDA regulated companies before and after her stint at the FDA's helm. But unlike her colleagues, Hamburg was allowed to hold financial interests in an exclusive hedge fund managed by her husband's company.[6] And in an analysis conducted by *The BMJ* (see table), the hedge fund consistently invested in FDA regulated drug companies during Hamburg's time at the FDA.

RenTec

The hedge fund, Renaissance Technologies, is one of the biggest and most profitable companies of its kind. It is also one of the most secretive and exclusive. Renaissance pioneered "quantitative trading," the use of statistical models to drive high frequency stock trading decisions, and became what some have called "the greatest modern day moneymaker,"[7] with almost

mythic status in the business community. Its flagship product, the Medallion Fund, has averaged annual gains of 39% after fees over three decades,[8] earning billions for its investors. But the lucrative fund is reportedly only open to the firm's employees, their families, and select friends.[9]

Hamburg was one of those fortunate investors, thanks to her husband Peter Brown, a senior employee at Renaissance. In 2010, the year after Hamburg was sworn in as the new head of food and drugs, Brown became Renaissance Technologies' co-chief executive officer, and in 2012, with $125m in earnings, was rated by *Forbes Magazine* as the 16th highest earning hedge fund manager.[10]

FDA policy—then and now—states that "FDA employees are prohibited from holding interests in certain investment funds that have a stated policy or practice of investing in companies that are SROs [significantly regulated organisations]."[11] And the law attributes the interests of spouses to the government employee.[1] An independent agency known as the Office of Government Ethics (OGE) reviews the financial disclosures of senior executive branch nominees to identify potential conflicts of interest.

Following the OGE's review and before becoming FDA commissioner, Hamburg pledged to resign from more than 10 non-profit organisations at which she held a senior position and from the board of Henry Schein, a massive healthcare products supplier company. Brown sold his stock in Johnson and Johnson and Merck, among others, and the couple divested from several fund holdings at Renaissance. But they were both allowed to keep their holdings in the Medallion Fund which, according to financial declarations, earned them more than $3m between 2009 and 2010. Brown kept his job at Renaissance, which shares its profits with employees, and apart from Medallion Fund income, he reported payments from Renaissance between 2008 and 2010 in excess of $1m each year. (The actual amounts earned while Hamburg led the FDA might be much larger as *The BMJ* only reviewed forms for Hamburg's first two years as commissioner, and spouses are not required to report in any specificity beyond "over $1 000 000.")

Why the OGE permitted these arrangements is unclear. The OGE does not make its deliberations public and, in response to a request from *The BMJ*, the office said that it "does not respond to questions about specific individuals."

The FDA also declined to provide any specifics of its evaluation of Hamburg's relationships with Renaissance. In an emailed statement, a spokesperson stated: "As part of the confirmation process, Dr Hamburg—like all FDA commissioners—underwent rigorous pre-approval and clearance procedures including review by the US Department of Health and Human Services Office of General Counsel Ethics Division, the US Office of Government Ethics, and the US Senate. Any potential conflicts were resolved with those entities prior to her confirmation."

According to an unnamed "administration official" that spoke with the *Wall Street Journal* in 2009, the couple were allowed to retain their holdings in Medallion because the fund is based on programming that "does not allow for human tracking or input except in rare instances," and trades rapidly, holding shares only briefly, "meaning that neither Dr Hamburg nor her husband would be in a position to direct their Medallion account to companies or areas affected by the FDA."[6]

Richard Painter, a professor of corporate law at the University of Minnesota and former chief ethics lawyer for President George W Bush, although not familiar with the details of Renaissance or Hamburg, commented that a lack of human involvement in Medallion might at least partially address the potential for insider trading, which can be criminally prosecuted as a felony. "If the computer's making the trades, I'm not too worried about government information getting into the company. I'm not as worried about the insider trading problem."

But the degree to which the algorithm controlling Medallion actually operated without human input was called into question by a 2014 Senate investigation into the abuse of structured financial products. In July 2014, the investigation's chairman, Senator Carl Levin questioned Brown, who was co-chief executive officer of Renaissance Technologies at the time.

Levin asked Brown: "You make it sound like the selections were made by a machine with no human intervention. Now, your scientists and your experts are continually looking for inefficiencies in the market, and when they find something new . . . they try to adjust the computer model and incorporate that into the algorithm, and that will affect the decisions that are generated. It could also have an impact on what positions are bought and sold. So there is a lot of ongoing human involvement in this process. Is that correct?"[12 13]

"That is correct," Brown responded.

Levin continued for eight minutes, identifying the number of employees involved in making those changes and the frequency of changes: "This algorithm wasn't just making changes by itself. It took human beings to make changes."

Brown: "Yeah sure, the human beings wrote the code."

Levin: "Good. And changed the code?"

Brown: "That's correct."

Levin: "Tweaked the code and once or twice every week changed . . . "

Brown: "On average."

The Senate report summarised the matter: "According to RenTec [Renaissance Technologies], its trading algorithms were dynamic and had to be updated and adjusted on a regular basis by its programmers. RenTec explained that the algorithm was frequently modified manually by programmers"—modifications that could be used "to direct trades to particular options to reduce or increase its portfolio size."[14]

The BMJ asked Brown to explain the discrepancy between his Congressional testimony indicating that RenTec employees regularly intervened in the algorithm and statements elsewhere that there was "no human intervention except in rare circumstances." But he did not respond to a request to be interviewed for this article, and his spokesperson, Jonathan Gasthalter, would only speak off the record.

High frequency trading with a proprietary algorithm partly explains why the Medallion Fund has been dubbed the "blackest box in all of finance." What, precisely, it is invested in, for how long, and how much are ever changing and unknown. But what is known is the overall holdings of the company and that the Medallion Fund is far and away the company's crown jewel.

Thanks to disclosure requirements, companies like Renaissance file quarterly reports with the Securities and Exchange Commission, which publicly posts them on its website. And a review by *The BMJ* found that, in every quarterly disclosure for the past 20 years, including the six in which Hamburg served as FDA commissioner, Renaissance Technologies held stock in FDA regulated companies.

In all 24 of the quarterly reports filed during Hamburg's tenure at FDA, Renaissance held stock in three major drug companies—Amgen, Novo Nordisk, and AstraZeneca—at an average value of $518m. Across 10 drug companies, the reports indicate average holdings of over $1bn (table).

The facts raise concerns over the adequacy of current rules governing financial holdings by FDA commissioners.

"This is something the OGE should have shut down right away," says Craig Holman, a government affairs lobbyist for the consumer advocacy organisation Public Citizen, who was not familiar with the details of Hamburg's case. "I've got a feeling they just didn't quite understand how these algorithms work—and were just inexperienced." He adds: "The OGE usually is quite good at moderating and mitigating conflicts of interest among the executive branch . . . I've always had quite a bit of respect for them."

Hamburg declined an interview request from *The BMJ*, but in response to questions about her private conversations with the OGE, emailed a response through her personal communications agent: "In my capacity as a physician and a government official, I have always taken my ethical obligations very seriously. Prior to my confirmation as FDA commissioner, the US Senate and the Office of Government Ethics (OGE) thoroughly evaluated any potential conflicts, including those that might arise as a result of my husband's position. Those potential conflicts were addressed in signed ethics agreements, and submitted financial disclosure reports were reviewed annually by the OGE during my tenure as commissioner."

Painter thinks that the OGE is mostly focused on assessing whether there is anything a government employee could do in their official position that would have a "direct and predictable effect" on their (or their spouse's) investments or salary. Although preventing such conflicts of interest is essential, Painter says that better protections against insider trading on government information are also urgently needed, something the OGE "has relatively little expertise in dealing with."

"Government leaks like a sieve," he adds, with routine unauthorised disclosure of non-public government information. Although RenTec's headquarters are in New York, "you have got a lot of hedge funds operating out of [Washington] DC, and I know exactly why they're there. They're trying to get non-public information out of the government."

In Holman's view, the OGE must be strengthened. Currently, the agency is small, with around 70 employees, and is focused on issuing advice, for example about divestiture, with limited ability to enforce its recommendations. In 2021, Holman helped draft legislation, introduced by Senator Richard Blumenthal of Connecticut, aimed at turning the OGE "into an actual ethics cop with enforcement authority and much greater transparency."[15]

Today Blumenthal leads the Senate Permanent Subcommittee on Investigations, the same panel that, 10 years ago, under Levin's leadership, investigated Renaissance Technologies, and concluded that Renaissance Technologies had avoided more than $6bn in taxes.

After fighting the tax evasion charge for years, in September 2021, Brown informed Medallion Fund investors that Renaissance had "resolved our longstanding dispute" with the government.[16] Current and former investors would be required to pay, with Renaissance's seven board members during 2005-2015 and their spouses "being subject to substantially more costly terms." The total cost of the settlement was not given but was reported in the press as up to $7bn.[17]

Brown and Hamburg did not respond to *The BMJ*'s query regarding how much of this penalty they are paying.

Table | Renaissance Technologies' holdings in 10 selected drug companies reported in ≥75% of quarterly public disclosure reports while Hamburg was FDA commissioner

Company	Average holding ($1000s)	No of quarters held (% of total reports)	Average quarterly holding while Hamburg was commissioner ($1000s)
Amgen	$75 808	24 (100%)	$75 808
Novo Nordisk	$349 690	24 (100%)	$349 690
Astra Zeneca	$92 745	24 (100%)	$92 745
Johnson and Johnson	$169 198	23 (96%)	$162 148
GlaxoSmithKline	$118 195	23 (96%)	$113 270
Baxter International	$62 057	20 (83%)	$51 714
WuXi PharmaTech (Cayman)	$2702	20 (83%)	$2252
Bristol-Myers Squibb	$212 421	19 (79%)	$168 167
Gilead Sciences	$86 080	18 (75%)	$64 560
West Pharmaceutical Services	$22 357	18 (75%)	$16 767
Total investment (weighted average)			**$1 097 121**

Hamburg was commissioner for six years, from 18 May 2009 to 6 April 2015. This analysis is based on 24 quarterly "13F-HR" reports that Renaissance Technologies filed with the US Securities and Exchange Commission during this period.

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Supplementary information: Robert Califf: certification of ethics agreement compliance

Supplementary information: Robert Califf: amendment to ethics agreement (1)

Supplementary information: Robert Califf: amendment to ethics agreement (2)

Supplementary information: Robert Califf: certificate of divestiture

Supplementary information: Robert Califf: public financial disclosure report (1)

Supplementary information: Robert Califf: public financial disclosure report (2)

Supplementary information: Robert Califf: public financial disclosure report (3)

Supplementary information: Scott Gottlieb: ethics agreement

Supplementary information: Scott Gottlieb: public financial disclosure report (1)

Supplementary information: Scott Gottlieb: public financial disclosure report (2)