BACK TO ALL NEWS

FDA's revolving door: Companies often hire agency staffers who managed their successful drug reviews

Job changes raise conflict of interest questions

5 JUL 2018 · BY CHARLES PILLER

The Food and Drug Administration (FDA) says its rules, along with federal laws, stop employees from improperly cashing in on their government service. But how adequate are those revolving door controls? *Science* has found that much like outside advisers, regular employees at the agency, headquartered in Silver Spring, Maryland, often reap later rewards—jobs or consulting work—from the makers of the drugs they previously regulated.

FDA staffers play a pivotal role in drug approvals, presenting evidence to the agency's advisory panels and influencing or making approval decisions. They are free to move to jobs in pharma, and many do; in a 2016 study in *The BMJ*, researchers examined the job histories of 55 FDA staff who had conducted drug reviews over a 9-year period in the hematologyoncology field. They found that 15 of the 26 employees who left the agency later worked or consulted for the biopharmaceutical industry.

FDA's safeguards are supposed to keep the prospect of industry employment from affecting employees' decisions while at the agency, and to discourage them from exploiting relationships with former colleagues after they depart. For example, former high-level employees can't appear before the agency on the precise issues they regulated—sometimes permanently, in other cases for a year or two.

Through web searches and online services such as LinkedIn, however, *Science* has discovered 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.

In 2009, for example, an FDA panel weighed whether the agency should approve AstraZeneca's widely prescribed antipsychotic drug quetiapine (Seroquel) for a wider range of conditions. The panel heard from health policy expert Wayne Ray of Vanderbilt University in Nashville, who described his research linking the drug to sudden cardiac death when used with certain other medications. Ray recalls "an FDA staff member who gave a very negative presentation on our paper." And according to the meeting transcript, the agency's then-Director of Psychiatric Products Thomas Laughren, who was instrumental in shepherding Seroquel and similar drugs through the review process and personally signed their FDA approvals, also challenged Ray's results and defended AstraZeneca's clinical trial findings in the discussion that followed. The company's "analysis should have been able to pick up a difference in sudden cardiac death, and they didn't find any difference between drug and placebo," he said.

Ray told Laughren and the panel that AstraZeneca had pooled data from all its trials as though the data were one data set, causing a well-known statistical error called Simpson's paradox. To take the company's conclusion "as definitive" would be "very dangerous," Ray said, according to the transcript. Laughren responded by calling sudden death "a pretty definitive event."

Ultimately, the committee voted overwhelmingly to advise approval of the drug for new indications and made no recommendation on labeling it to warn about sudden cardiac death. Later evidence showed that the cardiac problems Ray described are real, and in 2011, FDA required adding a warning on Seroquel's label.

Soon after, Laughren left the agency and formed a consultancy to help psychiatric drug makers, including AstraZeneca, navigate FDA approvals. He did not respond to repeated requests for comment.

In 2012 and 2013, data expert Joan Buenconsejo led FDA's analysis of medical statistics in drug reviews, including offerings from AstraZeneca. In 2014, she joined the company as a director and biometrics team leader. By 2015, Buenconsejo had already represented AstraZeneca before her former FDA colleagues as the company sought a drug's approval. In an email, Buenconsejo wrote that she strictly adhered to FDA's recusal rules "when considering employment with AstraZeneca." She added, "I do not believe there was any conflict of interest around my transition."

Former FDA employees, AstraZeneca spokesperson Karen Birmingham wrote in an email, "bring the perspective of seasoned regulators" who can assist current regulators with the "challenging decisions in approving innovative medicines to meet unmet medical needs."

Jeffrey Siegel, who was an FDA staff member specializing in reviews for arthritis drugs, oversaw the 2010 approval of Genentech's arthritis drug tocilizumab (Actemra). Months later, he left the agency to join the company and its parent, Roche, as director of the division that includes Actemra and related offerings. Siegel represented Roche before his former FDA colleagues when the company sought approval to promote Actemra for new conditions. Last year, he told *STAT* that the timing of his decision to join Roche and Genentech was coincidental.

Laughren, Buenconsejo, and Siegel apparently complied with existing federal laws and FDA requirements. And David Kessler, who led FDA under former Presidents George H. W. Bush and Bill Clinton, says such moves to industry by former FDA experts, steeped in "a culture of drug regulation," can benefit the public if they improve pharma practices. But "revolving door" rules need a fresh look, he adds, to ensure that "the tipping point, where that balance is," serves the public interest.

Vinay Prasad, a hematologist-oncologist at Oregon Health & Science University in Portland who co-wrote the 2016 study in *The BMJ*, contends that weak federal restrictions, plus an expectation of future employment, inevitably bias how FDA staffers conduct drug reviews.

"When your No. 1, major employer after you leave your job is sitting across the table from you, you're not going to be a hard-ass when you regulate. That's just human nature."

***Correction, 10 July, 6:10 p.m.:** An earlier version of this story stated that Thomas Laughren gave a negative presentation on Wayne Ray's paper. He was among FDA staff who critiqued that work at the advisory meeting, but he did not give the detailed presentation.*

doi: 10.1126/science.aau6841

RELEVANT TAGS:

FUNDING | HEALTH | SCIENCE AND POLICY | SCIENCE FUND FOR INVESTIGATIVE REPORTING

ABOUT THE AUTHOR

Charles Piller

Charles is a contributing correspondent based in Oakland, California.