FDA's cancer-drug reviewers often join industry later: study

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(HealthDay)—Among federal employees who review new cancer-drug

applications for the U.S. Food and Drug Administration, about half who leave to work elsewhere end up working for the industry they once regulated.

That's what researchers at Oregon Health and Science University (OHSU) concluded after following the career paths of 55 FDA reviewers of new blood and cancer drugs.

The findings raise concerns about regulators' ability to make impartial decisions in the public interest, the researchers suggest.

"If you left the FDA, 57.7 percent of the time you worked for and consulted for the industry," said Dr. Vinay Prasad, a hematologist-oncologist and assistant professor of medicine.

"It's astonishingly high," added Prasad, a co-author of a letter that addresses the issue and was published Sept. 27 in the *BMJ*.

Concerns about the "revolving door" between government and industry aren't new.

According to Dr. Michael Carome, director of Public Citizen's health research group, "We've said for years ... that the FDA has grown too cozy with industry." Public Citizen is a nonprofit consumer rights advocacy organization.

"I doubt this is unique to the hematology-oncology division," Carome added.

Not that FDA cancer drug reviewers are doing anything illegal by taking industry jobs after leaving the government. As FDA employees, they must adhere to conflict-of-interest rules and violators may be subject to criminal prosecution, Carome noted.

The question, Prasad said, is whether drug reviewers are succumbing to subtle, even subconscious, pressures to approve drugs, thinking someday they might want to work for industry.

The reality is that cancer drug reviewers, whose starting pay at the FDA is "something like $170,000 to $190,000 a year," can earn substantially more in industry, Prasad said.

Perhaps that's so, but the FDA tries to stem that line of thinking, an agency spokesman said.

"The FDA has a strong set of rules in place to ensure that our employees are working in the public interest, not to the advantage of any company, organization or individual," said Jason Young, acting assistant commissioner for media affairs at the FDA.

Federal laws and FDA ethics rules cover a range of issues, including conflicts, disclosures and confidentiality of information they [former employees] worked on while employees, Young said. There's also a "cooling-off requirement" for senior employees and other "rules against switching sides, contacting former employees and contacting agency leaders," he said.

Using the FDA drug database, Prasad and co-author Jeffrey Bien, also of OHSU, identified 55 people who reviewed new applications for cancer and blood disease treatments from 2001 to 2010.

Then using publicly available information, they matched those individuals to the jobs they subsequently held.

Roughly half stayed at the FDA and half left, the investigators found. Of the 26 who moved on, 15 landed in jobs working or consulting for the biopharmaceutical industry.

In percentage terms, that means nearly 58 percent of those who left the FDA for another job took industry positions, the findings showed.

Researchers were unable to document the whereabouts of 30 percent of the former FDA employees except to say eight no longer worked for the U.S. Department of Health and Human Services, which oversees the FDA.

If anything, the study authors said, the extent of the government-to-industry phenomenon is underestimated since not all reviewers' future careers could be identified.

"They have a right to leave," Carome said. "I don't think that can ever be banned."

More information: The U.S. Food and Drug Administration has more about drug development and approval.