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The BMJ Press Release

Concern over “revolving door” between the US FDA and the biopharmaceutical industry

Experts writing in **The BMJ** this week raise concerns over the proportion of US Food and Drug Administration (FDA) reviewers who later work or consult for the industries they regulated.

Last month, the FDA said it may loosen conflict of interest rules because a shortage of independent experts means that its current rule (no more than 13% of advisers with industry ties) is delaying new drug approvals.

Vinay Prasad and Jeffrey Bien at Oregon Health and Science University say FDA medical reviewers “are vital to effective regulation, interpreting whether a drug’s harm-benefit balance is favourable.”

But they argue that, while the transition from regulator to advising companies seems logical, “it raises concern as to whether regulators indefatigably act in the public interest.”

Anecdotally, for years some of these reviewers after leaving the FDA were known to go on to work for the biopharmaceutical industry. So they set out to measure how often this “revolving door” occurs at the FDA.

Starting with the set of FDA haematology-oncology drug approvals (2006 to 2010), they used the FDA database (Drugs@FDA.gov) to compile a list of all medical reviewers for these drugs between 2001 and 2010.

They then searched publicly available information from the Department of Health and Human Services, LinkedIn, and PubMed, to ascertain subsequent jobs.

They identified 55 unique haematology-oncology medical reviewers who reviewed applications between 2001 and 2010. Nearly half, 27 (49%) continue to work exclusively at the FDA, and 2 (3.6%) work at the FDA but hold secondary appointments.

However, of the 26 who left the FDA, 15 (57.7%) later worked for the biopharmaceutical industry or consulted to it.

In addition, another 8 (30.8%) reviewers' subsequent employers could not be identified, only that they were not current government employees.

This analysis is the first to document the rate of the "revolving door" between the US FDA and the industry, and shows that a sizable percentage (57.7%) of FDA medical reviewers who leave the agency subsequently work for or consult for the biopharmaceutical industry.

The authors say they are concerned by these findings, and point out that, "if anything, we underestimate the extent of this phenomenon, as not all reviewers' future careers could be identified."

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Note to Editors

Letter: Future jobs of FDA's haematology-oncology reviewers
<http://www.bmj.com/content/355/bmj.i5055>

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