

Integrity in Science Watch

Week of 3/03/06

FDA Puts Five Scientists with Conflicts of Interest On Committee Evaluating Controversial MS Drug

Five of the eleven scientists so far selected to judge the safety of the new multiple sclerosis drug Tysabri have financial ties to either the drug's sponsors, Biogen and Elan Pharmaceuticals, or their competitors. The Food and Drug Administration's Peripheral and Central Nervous System Drugs Advisory Committee will meet March 7 to reconsider Tysabri, which was pulled from the market last year after a handful of patients developed a rare brain disorder. Permanent committee member Lily Jung and Karl Kiebertz, special appointee, disclosed they earned between \$10,000 and \$50,000 from either Biogen and Elan by serving on their speakers bureaus or consulting. In addition, committee members Steven DeKosky, Larry Goldstein and Ralph Sacco consulted for or sat on the speaker bureaus of direct competitors. The FDA claims it cannot find experts without conflicts of interest to serve on advisory panels, whose advice it usually follows.

Source: FDA website, March 1, 2006.

(<http://www.fda.gov/ohrms/dockets/ac/06/waivers/2006-4208W1-index.htm>)

EPA To Get Suppressed Industry Chromium Study

The hidden industry study that showed chromium-6 poses a significant lung cancer risk will be submitted to the Environmental Protection Agency to become part of the permanent record on the dangerous chemical, the researchers who uncovered the study said. Without being able to consider the industry's incriminating data, The Occupational Safety and Health Administration this week adopted a feeble rule regulating workplace exposure to chromium-6. David Michaels, director of the Project on Scientific Knowledge and Public Policy (SKAPP) at George Washington University, called on federal agencies to require full disclosure of industry-funded studies during regulatory proceedings. Michaels and Public Citizen uncovered the industry study and recently published its findings in a report in the online journal *Environmental Health*, suggesting any organization participating in policy-setting proceedings should "certify that all relevant data have been submitted to the public record, whether published or not."

Source: Environmental Health 2006, 5:5 (February 2006).

(<http://www.ehjournal.net/content/5/1/5>)

Personal Communication, David Michaels, SKAPP Director, to CSPI, March 1, 2006.

SKAPP Website: <http://www.defending-science.org/>

P&G Issues Bill of Rights; Outside Researcher Still Without Data

Under fire from a British researcher denied access to data for his study, Proctor & Gamble this week issued a one-page "bill of rights" for scientists funded by the corporate giant. The company said researchers will have access to all relevant data and authors "will define and control any publications resulting from their work." Yet attorneys for UK scientist Aubrey Blumsohn said P&G is still withholding critical data from his study of P&G's osteoporosis drug, Actonel. The

Cincinnati-based consumer products company also submitted their version of the study's conclusions for publication under Blumsohn's name without his consent. "If P&G is acting in good faith, the place to start is releasing the necessary data to [Blumsohn] and to allow proper scrutiny," said Mark Cohen, an attorney with the Government Accountability Project, which is representing Blumsohn. P&G officials said there was no connection between Blumsohn's allegations and its new bill of rights.

Source: Revill, Jo. "Drugs Giant Promises Data Access," *The Observer*, Feb, 26, 2006.

(http://observer.guardian.co.uk/uk_news/story/0,,1718179,00.html)

Personal Communication, Tom Millikin, P&G Pharmaceuticals, to CSPI, March 1, 2006.

CSPI: New IP Rules Could Make Medical Innovation Cheaper

California should use its new \$3 billion stem cell research program to modernize the medical innovation system in a way that would both spur research and make its results affordable. In a major policy forum article in the open-source journal *Public Library of Science: Medicine*, Integrity in Science director Merrill Goozner said California should require researchers to donate intellectual property derived from stem cell research grants into a patent pool similar to the open-source patent pool that developed Linux, the computer operating system. Open-source patent pools allow anyone to use an invention as long as future patents that rely on patents already in the pool get donated into the pool. The pool would be coupled with large prizes for major breakthroughs, which would be distributed among the patent holders. The pool authority could then issue manufacturing licenses to generic manufacturers, Goozner asserts this reform would break down barriers between scientists and "eliminate the 30 to 40 percent of pharmaceutical industry revenue generated by wasteful marketing costs."

Source: Public Library of Science Medicine, Policy Forum, website, March 1, 2006.

(<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0030126>)

Politics Overrules Science at FDA, Former Top Staffer Says

In an op-ed piece this week, former assistant commissioner of women's health at the FDA, Susan Wood, continued her challenge to the federal health agency's "lack of independence." Wood resigned from the FDA six months ago after agency officials refused to approve over the counter status for Plan B for women 17 and older despite overwhelming scientific evidence indicating it should be approved. Wood said that acting Commissioner Andrew von Eschenbach, like his predecessor, is continuing to hide "behind a wasteful and pointless bureaucratic process" and damaging the FDA's credibility. She said the "American public does not want to -- nor should it - - have to think twice about the quality and reliability of information it is getting from the FDA."

Source: Wood, Susan. "When Politics Defeats Science," *Washington Post*, March 1, 2006.

(<http://www.washingtonpost.com/wp-dyn/content/article/2006/02/28/AR2006022801027.html>)

Senate Rejects Slowing the Revolving Door

The Republican-controlled Senate Rules Committee on Wednesday rejected legislation proposed by Sen. Mark Dayton (D-Minn) that would create a two-year waiting period before members of Congress could become "personally and substantially" involved in lobbying. Sen. Trent Lott (R-Miss), chair of the Committee, stated that Sen. Dayton's amendment to the lobbying reform bills did not "fall under the committee's jurisdiction." The Senate Committee approved modest curbs on earmarks and privately financed trips.

Sources: Gay Stolberg, Sheryl. "Lobbyist Turns Senator but Twists Same Arms" and "Senate Panel Approves Modest Curbs on Lobbyists," *New York Times*online, Feb 28 and March 1, 2006.

(<http://www.nytimes.com/2006/02/28/politics/28lobby.html> and <http://www.nytimes.com/2006/03/01/politics/01lobby.html>)

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