



## Conflict of Interest Strikes Again at the FDA

January 24, 2012 by *Patrick A. Malone*

On his [GoozNews](#) website, journalist Merrill Goozner recently tackled the decision by Health and Human Services Secretary Kathleen Sebelius to overrule FDA scientists and ban the sale to minors of the over-the-counter morning-after contraception pill. He noted that opponents called it a blatant political move by the White House to woo social conservatives.

It's part of a pattern, Goozner suggests, that Capitol Hill pols might be influencing other FDA decisions. To wit: the agency's appointment last month of at least three scientists to a drug safety advisory committee charged with reviewing birth control products made by Bayer. The scientists, it seems, had financial ties to Bayer. The FDA did not disclose their connections, as reported in an investigation by [BMJ](#) and the [Washington Monthly](#).

The committee recommended that Bayer's problematic birth control pills (sold as Yaz and Yasmin) remain the market despite the FDA's own reports of dozens of deaths from blood clots. (We recently wrote about Bayer's questionable marketing efforts for the [troubled drug](#).) The tsunami of lawsuits filed against the company weren't compelling to the committee, which, Goozner reported, said the benefits of having another birth control option on the market outweighed the risks.

The committee vote was controversial from the start; we'd go as far as to call it hypocritical.

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Before the meeting, Goozner noted, the FDA ruled that the committee's usual consumer representative, Dr. Sidney Wolfe from Public Citizen, couldn't participate because he had publicly called for banning the drugs. The agency also refused to distribute a legal/scientific brief prepared for plaintiffs' attorneys by Dr. David Kessler, who once headed the agency, because it said he submitted it too late. Apparently, punctuality is more important than patient safety.

Goozner draws the smelly political connection in referring to U.S. senators who introduced legislation last year relaxing the FDA's conflict of interest policies. "The ostensible goal?" Goozner asks. "To speed up the review of medical products. That legislation followed statements by the FDA Commission[er] Margaret Hamburg that the agency was having difficulties finding people without conflicts of interest to serve on its 55 committees."

Conflict of interest laws can be suspended if the agency needs a particular person's expertise; it grants a waiver provided the conflict is disclosed to the public or if it is deemed too minor to affect someone's judgment. But the price of compromised judgment is not quantified.

Goozner says that U.S. universities, research institutes and private practices yield a large resource of nonconflicted experts who are "just as knowledgeable as people who sign consulting deals with industry. Moreover, eliminating the whiff of impropriety that appointing scientists with conflicts of interest brings would maintain the public's faith in the integrity of the process, even if the appointee swears up and down that is or she isn't biased by the relationship."

When political expedience compromises patient safety, it's no longer grist simply for Beltway chatter. As one practicing cardiologist quoted by Goozner said, "Lack of disclosure undermines the credibility of the advisory committee process and undermines public trust in the fairness of the regulatory process."

Goozner isn't the only prominent critic of the FDA's shady process. As noted on [AboutLawsuits.com](http://AboutLawsuits.com), the Project on Government Oversight wrote a [letter](#) requesting that a new meeting about Yaz/Yasmin be held.

We join this chorus of voices for competence and transparency in government -- especially when it concerns the public's health.

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