# Why FDA recruitment of 'critics' is a problem

**To the Editor:**

The News article by Catherine Shaffer in the December issue[1] entitled "FDA recruits prominent critics" contends that the "the general response" to the appointment of anti-industry zealot Peter Lurie of Public Citizen "is positive, even among those who don't necessarily agree with Lurie's positions."

As a former US Food and Drug Administration (FDA) official myself (from 1979 to 1994), I find it difficult to comprehend how Shaffer came up with such a misrepresentation. But given the scant number of sources (a senior FDA staffer, a PR specialist and a representative of a nonprofit (anti-corporate) lobbying organization that she quotes in the rest of her piece), perhaps Shaffer's biased analysis and lack of balance simply reflect a low standard of reporting.

The vast majority of FDA employees are civil servants. Unlike at some other federal agencies, there are only a handful of political appointees, and contrary to the thrust of Shaffer's piece, most of President Barack Obama's choices for them have been woefully inappropriate rather than "positive." Apart from Meghan Scott (of the union-backed group WakeUpWalmart.com of Washington, DC) and Lurie, Shaffer fails to mention the dubious choices now brought into the fold:

Joshua Sharfstein, deputy FDA commissioner, who in effect directs all day-to-day operations of the agency, has a history of anti–drug industry bias that dates from his days in medical school. His fingerprints are already evident on various costly, anti-innovative and excessive regulatory actions taken by the FDA.

Ralph S. Tyler, newly appointed general counsel, whose main qualification seems to be that he is a crony of Sharfstein. Tyler, whose last job was insurance commissioner of Maryland, lacks any professional experience with FDA-related legal issues.

Lynn Goldman, as a part-time consultant to the FDA's lead scientist. While a senior Environmental Protection Agency official in the Clinton administration, Goldman never met a regulation she didn't like and oversaw some of the most radical, unscientific policy- and decision-making imaginable (including toward agbiotech)—another inside-the-Beltway illustration that no bad deed goes unrewarded.

Shaffer concludes her piece with a quote from Diana Zuckerman, president of the National Research Center for Women and Families, Washington, DC. Zuckerman, who claims that FDA employees are promoted for their "willingness to please" regulated industry and that "industry is getting their way more often than the science would merit," evidently believes that regulation is insufficiently stringent.

Nowhere in this piece is it acknowledged that recruitment of Lurie and company will further exacerbate what is generally considered to be the increasingly stringent and stultifying regulation that has been imposed on drug makers over the past decade and which has increased the time and costs of drug development, diminished competition and slowed approvals to a trickle. An increasingly risk-averse US Congress has granted the FDA additional powers that place new restrictions on the prescribing, distribution, sale and advertising of drugs; and at the same time, regulators have imposed new criteria in addition to the statutory requirements for safety and efficacy, in order for drug sponsors to obtain even those limited approvals.

**What are these new criteria?**

Seemingly arbitrarily, the FDA sometimes demands that new drugs are not merely effective but are actually superior to existing therapies, a new standard that is often difficult and extremely costly to meet. In April 2007, the agency announced what appears to be a landmark policy decision: although the law requires that to be marketed, a drug must simply be shown to be safe and effective, by denying approval of Merck's (Whitehouse Station, NJ, USA) new drug, Arcoxia (etoricoxib), a cyclooxygenase (COX)-2 inhibitor for the relief of arthritis pain, the FDA said that Arcoxia needed to be shown to be superior to existing drugs to obtain approval. Robert Meyer, director of the FDA office that oversees arthritis drugs [director of the Office of New Drug Evaluation II, Center for Drug Evaluation and Research], claimed that the agency's advisory committee had sent a clear message that "simply having another drug on the market…didn't appear to be sufficient reason" for approval[2]. But whether or not the advisory committee meant to convey that (and in any case, advisory committee recommendations are not binding), it is specious reasoning.

In addition, post-marketing studies as a condition of approval are tantamount to a new, fourth criterion for approval. Whereas they were once rare and the subject of discussions between FDA and drug sponsors, now they are required in more than three-quarters of approvals, and FDA dictates what shall be done.

In addition to the imposition of the new criteria to obtain approval to market new drugs, the FDA is now empowered to demand Risk Evaluation and Mitigation Strategies, some elements of which are so draconian that arguably they amount to limited approvals. They constrain physicians' prescribing practices, corporate advertising and pharmacy practices, and have the potential to reduce drastically the potential market for new drugs.

Finally, as measured by numerous metrics—number of clinical studies and patients to support a New Drug Application, number of black-box warnings on labels and the length of time required for and expense of clinical trials, for example—risk aversion at the FDA is high and escalating. If any of the above looks like "companies are still getting their way more often than the science would merit," then the industry should expect dire times ahead indeed.

COMPETING INTERESTS STATEMENT
The author declares no competing financial interests.

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1. Shaffer, C. *Nat. Biotechnol.* **28**, 7–8 (2010).
2. Richwine, L. FDA panel rejects Merck's Vioxx successor. http://www.reuters.com/article/idusn1234670420070413 (2007).

# Genetic exceptionalism

**To the Editor:**

September's Editorial[1] contained a fascinating contradiction that illustrates a basic problem with our attitudes to genetic information. Consider the following two quotes, from the end of the first paragraph and the start of the third. The context is Stephen Quake's publication of his own genome sequence in the same issue[2].

"Like scientific pioneers before him, Quake is heroically self-experimenting—testing the risks in publishing identifiable personal