Sidney Wolfe

Sidney Wolfe has been criticized as an anti-pharma zealot and thorn in the side of the US Food and Drug Administration (FDA). But his critiques and outspoken views increasingly resonate with a US public that is losing trust in the drug industry.

Sidney Wolfe is a man on a mission. "I despair for our country and the terrible leadership at the FDA," he says. Not only is there a "pitiful deficiency of Congressional oversight," but also the US public is being assaulted with "massive, comical public-relations efforts" from industry, he adds. "We have our work cut out for us."

Wolfe, who got his start studying chemistry at Cornell University, in Ithaca, New York, and earned his medical degree at Case Western Reserve University in Cleveland, has been director of the Public Citizen Health Research Group (a division of Ralph Nader's nonprofit Public Citizen) in Washington, DC, since 1971. Since his time working at the National Institutes of Health, his interest always has been research rather than doctoring, and Wolfe says he prizes the ability "to take data and evidence and convert it into some action."

Much of the work done by Wolfe's Public Citizen group has to do with secondary analysis of clinical data. This has propelled him to the fore in such recent debacles as Avandia (rosiglitazone maleate, the label of which now includes a 'black box' warning about heart complications) and Arcoxia (etoricoxib, rejected by an FDA advisory panel). Indeed, two-thirds of the marketed compounds Wolfe has asked the FDA to ban over the years are now no longer available, including phenformin, Oraflex (benoxaprofen), Tandearil (oxyphenbutazone) and suprofen, which suggests he's done the public a great service.

"We pick our targets carefully," Wolfe says, but his group does not distinguish between drugs that originate with biotech and those that come from pharma. "In terms of the volume of drugs [targeted by his group], way more are pharma drugs than the others, but if it happened to be a biotech drug, we would go after it," he says.

Although Wolfe acknowledges that the drug industry has "brought a number of drugs to market that are very useful," he devotes most of his time to brow beating companies. "I'm constantly teasing him about being Don Quixote," says psychiatrist Ted Rynearson, a friend since the mid-1960s, who attended medical school with Wolfe. "He has incredibly strong views about medicine, but he's never been a clinician. He hasn't had to give [drugs] to hundreds or thousands of people" and seen first-hand their positive effects.

Indeed, Wolfe's critics suggest the strength of his attacks can effectively blunt them. Ken Johnson, spokesman for the Pharmaceutical Research and Manufacturers of America (PhRMA) in Washington, DC, says that although Wolfe is "passionate in his beliefs," he's "incredibly biased. With respect to the pharmaceutical industry, there's never a middle ground. It's always his way or the wrong way."

But Wolfe's unease with the ethics of drug makers mirrors America's. He cites a Harris poll that found only industries like oil, tobacco and insurance are trusted less than big pharma, and Wolfe says that "no amount of Billy Tauzin [PhRMA] spin is going to convince the public that [we've] been unfair with the industry." The Harris poll of 2,010 adults in 2006 found only 7% believed statements made by companies in the pharmaceutical industry are "generally honest and trustworthy." Of the industries mentioned to respondents, only four yielded similarly bad trust scores: tobacco (2%), oil (3%), managed care (4%) and health insurance (7%).

How to repair this distrust? In the Harris poll, 48% of respondents believed the pharmaceutical industry should be more strongly regulated, and Wolfe agrees, so long as it is regulation without financial interest and is overseen by the US Congress. "There has never been less Congressional oversight," Wolfe says, blaming the passage of the Prescription Drug Fee User Act (PDUFA) in 1992, which gives Congress "an easy way out." Christopher Scott, senior research scholar at the Stanford Center for Biomedical Ethics in Palo Alto, California, differs with Wolfe about PDUFA, calling it a good interim solution that beefed up the FDA in order to relieve the backlog of drugs awaiting approval. But he agrees that more Congressional debate would help, as decision makers struggle with deeper, strategic problems regarding how drugs are reviewed. "It's always good to keep in mind that we're trying to do these things to help people who are suffereing, rather than focus on who's right or wrong," he says. "The world isn't black or white. It's gray."

Wolfe, though, insists the problem was clear but the solution was wrong. "No one disputes, including me, that FDA needed more staff," he says, adding that the US government should have appropriated more money for it. Instead, it created PDUFA, under which drug companies are paying $400 million in user fees to fund the FDA. A major improvement, Wolfe says, would be to "set it up the way it was for the first 86 years," with FDA funding earmarked by Congress.

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As for drug developers themselves, "a lot of the troubles companies are getting into are a result of desperate moves to try and keep the bottom line looking favorable," Wolfe ventures. Firms have no new products, so they aim to tweak older drugs and keep them viable. Wolfe cites Xenical (orlistat), the weight-loss drug from Basel-based Roche, which had "tanked" as a 120-mg prescription drug. "Sales had gone down 50% or more because of adverse effects" before Roche decided to find someone to sell it over the counter. London-headquartered GlaxoSmithKline now does so, with the FDA's blessing, in a lower dosage (60 mg). For Wolfe, it's one that got away.

Wolfe's critics suggest that instead of heckling from the sidelines, as a physician, he might do more good by actually treating patients. Others have suggested that he should consider leading the agency whose performance he attacks so regularly (during the Carter administration, for example, some tried to talk him into pursuing the post of FDA commissioner). But Wolfe scoffs at the possibility of heading one of the world's largest bureaucracies. "It's the last thing in the world I would want to do," he says.

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