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FORTUNE

FDA damned if it does, damned if it doesn't

Stung by criticism that it was too cozy with the industry, the agency got tougher after Vioxx. Now who's upset? Big Pharma. Fortune's John Simons examines an embattled regulator.

By [John Simons](#), Fortune writer

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(Fortune) -- The FDA just can't win. After years of public ridicule and congressional scrutiny, the Food and Drug Administration is taking a tougher stance against drugmakers in its review of new medicines. That new cautiousness, however, rankles its most powerful constituents: Big Pharma CEOs who charge that the agency is standing in the way of new medicines - and progress.

So is the FDA really to blame?

The agency's critics are vexed about recent reports that show FDA regulators have approved only 15 novel medicines so far this year - a pace that will likely match a 10-year low reached in 2002. Big Pharma CEOs contend that the FDA has become too anxious and hyper-vigilant about safety, requiring reams of additional data before it can make a decision.

"These developments have a negative impact on us," Novartis CEO Dan Vasella told *Fortune* recently. "Congress has been pressuring FDA reviewers - and it's extremely stressful for them. So, not making a decision becomes beneficial."

[Schering-Plough](#) ([Charts](#), [Fortune 500](#)) Chief Executive Fred Hassan echoed Vasella's sentiments in a recent interview with the *Wall Street Journal*. "When bureaucrats come under pressure, they tend to choose the path of asking for more data, as opposed to approving the drug."

Wyeth CEO Bob Essner lodged a more scandalous charge. He told the *Financial Times* earlier this week that the FDA's new safety-first attitude is "essentially establishing monopolies" to companies that are first to get a drug approved in a particular therapeutic class. Essner believes the FDA is now using the efficacy of existing drugs as a benchmark for whether a new drug gets approved in the same class. "If you're the first company to get approved in a certain area and competitors can't get on the market, the FDA is now establishing monopolies. And that's certainly not its mandate," noted Essner.

Wyeth has had three drugs delayed or rejected this year: bifeprunox, a treatment for schizophrenia, Pristiq, for depression and menopausal symptoms, and Viviant for osteoporosis. For its part, Novartis recently had its potential blockbuster diabetes treatment, Galvus, delayed by FDA for more testing, too.

Even so, FDA officials deny that there are new criteria in place for assessing new medicines. Some of the shift may be institutional. Until recently, the agency has lacked clear leadership for most of the decade. The commissioner's post was empty for nearly the first two years of the Bush Administration. Mark McClellan ran the FDA for 16 months starting in late 2002. After McClellan left to run Medicare and Medicaid in 2004, the FDA's top slot remained unfilled again until 2005, when Lester Crawford took the helm - for just two months before resigning. Bush named Andrew Von Eschenbach acting commissioner in

September 2005. Von Eschenbach didn't get the official title of commissioner until December 2006.

Ultimately, though, FDA Deputy Commissioner Janet Woodcock blames the industry for the dearth of new drugs coming through the agency. "I know the CEOs think we have become extremely conservative, but the standard for getting a drug approved has not changed," says Woodcock. "The number of new drug approvals is directly proportional to the number of applications we receive." The reason, then, for the downturn in new drugs approved in recent years? "It's because we're getting fewer submissions," says Woodcock.

The numbers support Woodcock's claim. It's no secret that Big Pharma has hit a research dry spell. Industry labs are churning out fewer novel discoveries and pipelines are virtually empty. The drop in new discoveries is reflected in the number of submissions sent to the FDA. Between 1996 and 2000, when the industry was still riding the wave of new lab finds, companies submitted an average of 38 new drug applications - technically "new molecular entity filings" - per year to the FDA. In turn, during the same period, the FDA granted an average of 36 approvals per year (see chart).

Beginning in 2001, new drug applications began to decline markedly. Between 2001 and 2006, the industry's annual average dropped to 29 applications per year, as the FDA averaged roughly 23 new drug approvals. Says Woodcock: "The percentage of drugs we reject has remained constant for years. But suddenly those empty pipelines make companies extremely conscious of drugs that don't get through."

To be fair, the FDA's new take on safety in recent years is not merely an industry hallucination. The agency says it doesn't keep a count of the number of times it asks companies to conduct additional studies or the frequency with which they order clinical tests with larger patient populations. But anecdotally, companies say this happens more than they would like. "There's no question that the FDA has shifted the risk/benefit ratio and is putting more demands on companies as they submit their applications," says Kenneth Kaitin, director of the Tufts Center for the Study of Drug Development.

Again, Woodcock blames the drugmakers. She says the research drought puts pressure on company researchers to push harder to get less efficacious drugs through the system. "Sometimes rather than tell their bosses that a drug isn't going to make it, researchers will submit it to the FDA and have us deliver the bad news," Woodcock notes.

If Big Pharma is feeling more put upon, there is one big change to which the FDA will admit. FDA has two main duties as it relates to medicines: pre-marketing evaluation and post-marketing observation, which includes, for instance, monitoring advertising practices and collecting ongoing safety data. FDA officials contend that in the wake of 2004's Vioxx recall, when Merck withdrew its wildly popular painkiller over concerns that it caused heart attacks, the FDA has become more vigilant in its post-marketing oversight of drugs.

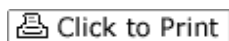
After the recall, Congress and consumer advocates questioned whether Merck had strong-armed the FDA into approving a questionable drug. Since 2004, the FDA has dramatically increased the number of public warnings it issues with regard to drug safety. Between 1997 and 2004, FDA released an average of 43 drug safety warnings each year, alerting patients to possible hazards (see chart). Since 2004, the annual average has more than doubled to 93 (which includes 92 warnings issued through October of this year).

Similarly, the FDA has become more aggressive about placing so-called "boxed warnings" on drug labels. In 2003, the year before Merck's Vioxx recall, the FDA slapped 20 warnings on drug packages. In 2006, that number jumped to 66. Label warnings through September of this year: 62 (see chart).

Even with its new stance, the FDA hasn't gained any new fans. A 2007 poll conducted by the Consumer Reports National Research Center found that 84 percent of consumers believe drug companies have too much influence over the government officials who regulate them. "Whatever action we take, someone's going to be unhappy. That's why it takes a special kind of person to work here," says FDA's Woodcock. "A masochist." ■

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