COMMENTARY

Our Lawless FDA

By DAVID R. HENDERSON and CHARLES L. HOOPER
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The Food and Drug Administration spends your money and acts in your name to regulate medicines. It has been acting badly.

On April 27, the FDA rejected Arcoxia (etoricoxib), a new COX-2 inhibitor from Merck. The FDA explained that it didn't see the need for another drug like this. Robert Meyer, director of the FDA's Office of Drug Evaluation II, told reporters that, "simply having another drug on the market" wasn't "sufficient reason to approve the product unless there was a unique role defined."

The FDA is supposed to judge whether a drug is safe and efficacious and that's all. In its literature, the FDA even agrees with this role, saying that, "Once a new drug application is filed, an FDA review team -- medical doctors, chemists, statisticians, microbiologists, pharmacologists, and other experts -- evaluates whether the studies the sponsor submitted show that the drug is safe and effective for its proposed use." But the FDA slyly added a third requirement: Is Arcoxia better than what's currently on the market?

According to the law, this isn't part of the FDA's approval process and for three good reasons. First, it would be difficult and expensive to show, before it's marketed, that a new drug is better than all competing drugs. It already costs on average just shy of a billion dollars to get a new drug approved. A study by Joseph DiMasi, an economist at the Tufts Center for the Study of Drug Development in Boston, found that the cost of getting one new drug approved was $802 million in 2000 dollars ($956 million in 2007 dollars). Most new drugs cost much less, but his figure adds in each successful drug's prorated share of failures. And this $1 billion figure was before the FDA dreamed up this new requirement.

The fact that we're talking about drugs often causes us to forget what we know about other products whose safety and efficacy are important. We shouldn't. Imagine that Saturn had to prove that its new car, Aura, is safe, works well, and is better than Accord and Camry before a single Aura hits the showroom floor. If the evidence is too costly for Saturn to collect, Aura

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will be rejected regardless of the facts. To prove superiority, what manner of tests would Saturn run? How much would this cost and how long would it take? What if five years later Saturn presented its evidence and, on some attributes Aura was better, on some it was equal, and on some it was worse than Accord and Camry? Is it a better car?

There's no right answer. It would be better for some drivers and not as good for others. But there doesn't need to be a right answer. This is the second reason drug companies don't have to prove their drug is better than existing drugs. People are capable of choosing the cars that best meet their specific needs. Faced with this situation, however, the hypothetical federal agency regulating cars would probably say, as the FDA did with Arcoxia, "Why do we need Saturn's Aura when we've already got Honda's Accord and Toyota's Camry? The Camry and Accord are fine cars." Hasta la vista, Aura.

The non-steroidal anti-inflammatory (NSAID) class of products (including aspirin, naproxen, Aleve, ibuprofen, Motrin, diclofenac, Vioxx and Celebrex) have historically grown to their peak sales quickly because there is so much dissatisfaction with what's available. A lot of switching between products is taking place. Patients' switching behavior ensures that new products get tried quickly, unlike other therapeutic areas where doctors and patients adopt a wait-and-see approach. Take pretty much any product and ask around. You'll find that each product has its adherents and its critics.

One patient, Kathleen Slocum, said that her life without Vioxx or other COX-2 inhibitors was "misery." She also pointed out that while over-the-counter analgesics work well for pain relief, the main problem she has had with her severe arthritis is joint swelling and stiffness; OTC analgesics haven't helped her with these problems. Ms. Slocum knows more about her specific needs than the FDA does. Isn't it possible that at least some segments of the population would find that Arcoxia addresses their needs? And remember that the people choosing are self-interested patients and their highly educated and trained physicians.

The third reason drug companies don't have to prove their drug is better than existing drugs is summed up in one word: competition. Take the worst case and assume that Arcoxia is no better than any existing drug for anyone but is as good for some patients. In that "worst case," Arcoxia would compete with existing drugs. Two centuries of economic theory and evidence show that competition is good. A new drug that competes with existing drugs is likely to cause drug prices to fall and competitors to stay on their toes.

Don't be misled into believing that Arcoxia, which has been tested in over 34,000 patients, is a wildly dangerous drug. The FDA doesn't make that claim. According to Merck, "there is more long-term safety data from controlled clinical trials, in terms of patient-years on treatment, for Arcoxia than for any other NSAID, including traditional NSAIDs and COX-2 selective inhibitors." Do the German and English governments approve drugs carelessly? No, and those countries already allow patients to use Arcoxia, as do 61 other countries in Asia, Latin America and Europe. The FDA is being too cautious.

The FDA knows that it can make two types of errors. If it approves a drug later found to be dangerous, bad things happen. As one former FDA employee, Hoover Institution's Henry Miller, put it, "This kind of mistake is highly visible and has immediate consequences -- the media pounces, the public denounces and Congress pronounces." If the FDA fails to approve a good drug, few bad things happen -- to the FDA. One Arcoxia FDA advisory panel member, David Egilman, commented, "Fool me once -- Vioxx, shame on you. Fool me twice -- Arcoxia, shame on me." Arcoxia never had a chance because the FDA never gave it a fair trial.

Americans would protest a government agency that prevented the sale of Saturn's new Aura in favor of established competitors. Why should we let the FDA get away with such behavior?

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