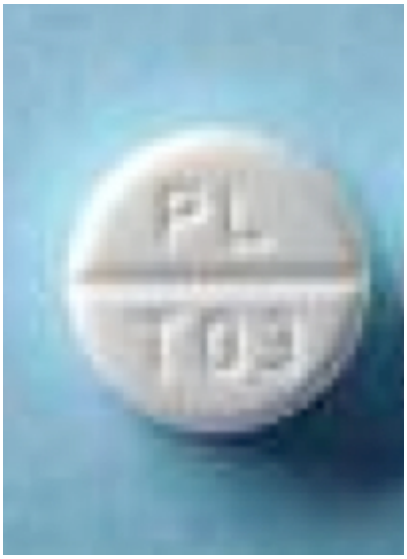
Written by **Michael Tennant** on September 4, 2010

Patients: 1, Bureaucrats: 0 — For Now



Consumers have won a rare, if possibly temporary, victory for their own freedom to take a drug that has worked for them even if its effectiveness has not been demonstrated to the FDA's satisfaction.

"Two weeks ago," writes the *New York Times*, "the Food and Drug Administration announced that it would remove the drug midodrine from the market because the drug's maker never confirmed that the medicine — approved in 1996 under an abbreviated process — actually worked against dizziness and fainting."

The medicine had been approved for sale under a process called accelerated approval, whereby drugs for severe or life-threatening conditions are approved so long as their manufacturers promise to perform post-approval studies to prove that their drugs are working as advertised.

Midodrine's manufacturer, Roberts Pharmaceutical, never did any studies once the drug was approved. Nonetheless, the nearly $257 million in sales the drug has generated might lead a reasonable person to believe that it has worked for quite a few people.

But this fact did not deter the FDA from deciding that the drug should be pulled. The *Times* indicates that this happened in part because of pressure from Congress, which did not like the idea that "more than a third of the 90 drugs approved under the [accelerated approval] program since 1992 never had studies done proving efficacy" — never mind that those drugs have been accepted by consumers and do not seem to have resulted in widespread illness or death. This is a matter of power.

What changed the FDA's mind, at least for the time being, is the large number of midodrine users — about 100,000 — who "flooded the agency with calls," according to the *Times*. The result: "Top F.D.A. officials announced that they had backtracked and would continue to allow midodrine to be sold."

The paper quotes Dr. Joshua Sharfstein, principal deputy commissioner of the FDA: "In a different situation, we might act differently. But in this case, it does not make sense to pull access to the drug while we get better data." That is, because of public outcry, the FDA will generously allow patients to get the drug they need; but if the manufacturer fails to satisfy the bureaucrats that the drug is efficacious, patients could be left high and dry again. (The report notes that users of Avastin, a drug for treating breast cancer, could end up in the same situation.)

The *Times* describes the predicament in which Congress has placed the FDA:

> The agency's flip-flop demonstrates the difficult choices regulators face in policing the nation's drug market. *Cracking down on drug makers sometimes means stranding desperate patients.* And now that Congress has given the Food and Drug Administration greater powers to insist on better information about life-saving medicines, such disputes may become more common. [Emphasis added.]

Therein lies the problem with the FDA and, indeed, with all government regulators: Bureaucrats charged with protecting the public from every conceivable danger have no choice but to substitute their judgment for the judgment of individual consumers. Even though 100,000 Americans find midodrine effective for controlling their health problems, their judgment is insufficient for the FDA to permit the drug to be sold unless the manufacturer jumps through the bureaucracy's hoops. Even if only one person were helped by midodrine, where would some government functionary get off telling that person he couldn't buy the drug?

How, exactly, is midodrine's maker (Shire Pharmaceuticals, which bought Roberts in 2000) supposed to prove that the drug is effective, anyway? A drug that works for one person may not work for another. A drug may work similarly for two patients, one of whom believes that the relief it provides is sufficient for his symptoms while the other thinks it's not. Similarly, a drug that is safe for one person may cause illness or death in another. Safety is relative, too: Person A may be willing to put up with some negative side effects of a drug while person B is not. Proving either efficacy or safety to the FDA always comes down to satisfying the arbitrary whims of bureaucrats.

Midodrine's users are fortunate that the drug was initially approved and that they were able to convince the FDA not to pull it from the market. Meanwhile, countless other patients go without helpful pharmaceuticals for years at a time, some of them dying from their illnesses, while the FDA delays approving new drugs. Those victims, of course, do not flood the FDA with phone calls or make the news since the not-yet-approved drugs are generally not known to the public.

Individuals should have the right to purchase and use whatever drugs they like. Each person's judgment about the safety and efficacy of particular products ought to be determinative. The FDA — unconstitutional and a menace to Americans' health — should be abolished.