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FDA Walls Do Not Encircle

by **Charles L. Hooper***

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hy do we need the U.S. Food and Drug Administration? Easy. Using unproven medicines is equivalent to playing Russian roulette, and profit-hungry drug companies may sell us harmful or unnecessary products.

Or at least I believed that when I was growing up. But then I got older and went to college and then graduate school, where I learned about the problems with government regulatory agencies and the benefits of freedom. Problems with regulation include good drugs that won't find their way through the FDA's hyper-expensive regulatory maze and good drugs that will, but years too late. And then there are the government bureaucrats who know nothing about your health status and preferences, but have the audacity to tell you and your physician which medicines you can and cannot use. Over time, I began to view the FDA in a new, more-negative light.

My perspective changed again, slowly and largely imperceptibly, when, after graduate school, I went to work in the pharmaceutical industry. I was so busy dealing with my new responsibilities that I virtually stopped thinking about public policy issues. Then, one day, I noticed that I had begun to believe in the FDA again. If we didn't have the FDA, I thought, what menagerie of dangerous and inefficacious drugs would be on the market? My thinking had come full circle.

That didn't mean that I liked or even respected the FDA. I had heard too many damning stories of the FDA's incompetence, arrogance, and capriciousness. However, my views were consistent with those of many employees in the pharmaceutical business: The FDA was a necessary evil.

Here's the mental model I had: The FDA has built a wall around us and stands vigilantly at the gate. The FDA lets in only friends and steadfastly keeps out foes. Sure, occasional problems arise; some foes get in and some friends are kept out. But, overall, the FDA does a pretty good job of protecting us.

Many of you probably accept this model, and you may be as surprised as I was to discover that the FDA's wall extends only partway around us. And, perhaps even more surprising,

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where the wall is missing, friends tend to get in and potential foes tend to stay out. In fact, the lack of a wall does not seem to be a big problem. What gives? Should the wall be extended completely around us to complete the job? Or should we consider having no wall at all?

Where the FDA's wall is intact, all new medicines are considered guilty until proven innocent. The sponsor of a new medicine, almost always a drug company, must run expensive and lengthy trials of the medicine in patients who are closely evaluated. This overall process takes a decade and costs a billion dollars.¹ Most new drugs cost less, but the one billion dollar figure adds in each successful drug's prorated share of failures. For example, if a drug company has to develop and test 100 compounds to find one winner, the total cost to the company would be, on average, one billion dollars. The truckload² of clinical data from these trials is then analyzed statistically and presented to the FDA, which gives either a thumbs up or a thumbs down to the drug's use for one specific, clearly defined disease or condition (an "indication"). No drug can be marketed until it is approved in such a manner.

Where there are gaps in the FDA's wall, products are considered innocent until proven guilty and are put on the market. As information and support structures develop, these products are used more wisely and widely. Consumers are free to use these products as they see fit. If a consumer is harmed, the manufacturer will likely be sued for damages and will suffer in other serious ways.

What is an example of this "wall-free" approach? Many products fit into this category: almost all foods, most natural and herbal medicines, older drugs, over-the-counter (OTC) drugs, and FDA-approved drugs that are used for non-FDA-approved diseases. These products touch every one of us, and we have done just fine with this approach, thank you.

Most foods need no FDA approval to be allowed on your grocer's shelves. But food has benefits and risks, just like medicines. If a prescription medicine caused life-threatening allergic reactions (anaphylaxis), the odds are high that it would be pulled off the market. But many foods do the same thing. Some people have adverse reactions to nuts, shellfish, eggs, wheat, soy, legumes, seeds, and dairy products. Approximately 30,000 people visit an emergency room and 125 people die each year in the United States from food-induced anaphylactic reactions. And yet these foods are still available for purchase.

The most common cause of food-induced anaphylaxis, peanuts, account for 80 percent of such fatal or near-fatal allergic reactions. Varying in severity, peanut allergy affects approximately 1.5 million Americans. Society's attitude toward foods like peanuts is to accept their existence and to learn to avoid them if necessary. In other words, foods aren't bad or good, but some people have a bad reaction to certain foods. This is completely different than the attitude expressed by the media, government, and public toward prescription drugs like Vioxx (rofecoxib). The press painted Vioxx as a bad drug because of the increased heart attack risk. Period. End of story. But some patients and doctors, even after they understood the risks, concluded that the benefits of Vioxx clearly outweighed the risks for some patients.

One such person is Kathleen Slocum, who says that her life without Vioxx or other drugs like it was "misery." She also points out that while OTC analgesics work well for pain relief, they do nothing for her severe joint swelling and stiffness.³ Hayes Wilson, a rheumatologist in Atlanta, put it this way: "If you live with intractable pain every day of your life, would you take a chance that you would have a heart attack? A lot of my patients would."

The FDA treats peanuts very differently than drugs like Vioxx, even though both have benefits but pose serious risks to some segment of the population. If peanuts were subjected to FDA approval, who would pay the bill to find out what we already know, namely that peanuts are nutritious for 99.5% of Americans and dangerous for 0.5%? The answer is that no one would pay. If peanuts were treated like drugs such as Vioxx, they would be kept off the market forever. Sorry, peanut butter and jelly lovers.

Another example of the wall-free approach is herbal and natural medicines. Almost none of these products has been evaluated and approved by the FDA. Why? The FDA categorizes these products as "dietary supplements," and their manufacturers don't make specific health claims. A specific health claim would be "lowers blood pressure," whereas a non-specific health claim would be "benefits cardiovascular health." The first statement can be measured and, therefore, proven or disproven. The second statement is too vague to measure and, thus, prove or disprove. The FDA allows these non-specific claims, usually followed by the disclaimer, "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease."

While natural medicines can cause side effects just as prescription drugs can, consumers are free to use them while we build real-world experience and scientific evidence. To remove a medicine from the market, the FDA must prove that it is unsafe. We can, however, predict with near certainty that natural medicines would disappear from the market if proof of safety and efficacy were required *prior* to marketing, as they are with prescription drugs. Why? Who will pay the billion dollars for a product without patent protection? Again, no one will.

I'm in great shape, but my father died of a heart attack at age 60. So, to be safe, my doctor recommended that I take an 81-mg "baby" aspirin each day to prevent the same thing from happening to me. Does that sound reasonable to you? It doesn't to the FDA. The FDA has approved aspirin for secondary prevention, not primary prevention. That means that the FDA believes that aspirin is safe and effective for preventing a second heart attack, but not a first heart attack. So, why am I allowed to take aspirin to help prevent me from ever having a heart attack? Simple. Aspirin has been on the market for 109 years and is available over the counter, so I can take it for whatever condition I deem reasonable. I could take aspirin for something absurd, like growing a new kidney, or something reasonable, like stopping a headache. It's my choice and the FDA has no control over my actions. I can even swallow the whole bottle at once. I won't, but there's no legal way to stop me.

While I'm on the topic of aspirin, I should note that this 1899 wonder drug was never tested

and approved by the FDA. How could it have been? The FDA didn't exist in 1899. Moreover, the FDA didn't get the power to prevent untested drugs from entering the market for another 39 years (the FDA required proof of safety in 1938 and proof of efficacy *and* safety starting in 1962, and drugs marketed before 1938 were grandfathered). So, if you have ever taken aspirin for a headache—and who of us hasn't—you have ingested a drug that was never formally evaluated and approved by the FDA. And if aspirin had been forced to run the FDA's gauntlet, you might never have had your desired headache relief. That's because while aspirin is a miracle drug, it does carry the risk of stomach ulceration and bleeding.

Vioxx and all the COX-2 inhibitors were specifically designed to be safer than drugs like aspirin. Aspirin, ibuprofen, and naproxen, all of which are non-steroidal anti-inflammatory drugs (NSAIDs), can cause gastrointestinal (GI) bleeding. Experts have estimated that in the United States, NSAID-induced GI complications result in 16,500 deaths and more than 100,000 hospitalizations per year. Vioxx and the other COX-2 inhibitors aren't perfect, but neither are the NSAIDs they tried to replace.

Even if the FDA had approved aspirin as a prescription drug, and only for headaches and secondary heart attack prevention, I could still take it for primary prevention if my doctor wrote me a prescription. This is yet another gap in the FDA's wall. Physicians can write prescriptions for uses (indications) that have not been evaluated and approved by the FDA. Such uses are called off-label because each drug's label, or prescribing information sheet, tells what the approved indications are. For example, Genentech's Avastin (bevacizumab) has been approved for other conditions, but not macular degeneration. Yet many physicians use Avastin for macular degeneration—without the FDA's (and Genentech's) blessing. Off-label usage is widespread and constitutes close to half of all drug uses—up to 90 percent in some therapeutic areas such as oncology and pediatrics.

Another specific example is electrical deep-brain stimulation (DBS). Although it has been used for Parkinson's disease since 1987, the FDA didn't get around to approving DBS for that indication until 2002. Today, approximately 95 percent of DBS procedures are for Parkinson's disease.

Off-label usage does not mean that physicians are making a mistake or are being duped. Physicians have eyes, ears, and brains and can see whether a medicine works based on published studies, talking to their colleagues, and their own experience. It's a case where the medical community thinks the drug works, but the FDA hasn't agreed, either because the FDA sees things differently or because the sponsor hasn't yet borne the cost of presenting that medicine to the FDA for that specific indication.

For my company, Objective Insights, I regularly talk to physicians to assess their likely use of new medicines. When asked about possible off-label usage, the physician will usually say that he doesn't care what the FDA says; he will use it if it works and won't if it doesn't. Here's what one infectious disease specialist said about off-label usage: "I would put an FDA indication at the bottom of the [priority] list, not at the top. We used propranolol for migraine for ten years before the FDA approved it. As long as there is literature to support a use, we can use anything we want."

If that part of the world not controlled by the FDA is so prevalent and works so well, a question arises: Is the FDA's partial wall necessary? The FDA's powers are predicated on fear: fear of the bad things that would happen in the absence of government regulation. However, if we have concrete and widespread examples of unregulated health care arenas that operate safely and efficiently, perhaps those fears have been greatly exaggerated.

When we consider foods, natural and herbal medicines, older drugs, OTC drugs, and prescription drugs that are used off-label, we see that the Food and Drug Administration, for its good intentions, legal power, and name, has evaluated only a small proportion of the foods and drugs we ingest. We Americans are living proof that the FDA is not essential.

Notes:

¹ A study by Joseph DiMasi, an economist at the Tufts Center for the Study of Drug Development in Boston, Ronald W. Hansen, an economist at the William E. Simon Graduate School of Business Administration at the University of Rochester, and Henry G. Grabowski, an economist at Duke University, found that the cost of getting one new drug approved was \$802 million in 2000 U.S. dollars, which is equivalent to \$1.01 billion in 2008 dollars. See the [full article](#).

² A single new drug application comprises up to 200,000 pages bound into 400 volumes. "[Generic drug flood headed our way.](#)" Aaron Smith, CNNMoney.com, August 3, 2005.

³ From *The Wall Street Journal Online*, November 26, 2004, regarding "The Truth About Vioxx? Ask an Arthritis Sufferer," November 22, 2004; Page A15.

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The cuneiform inscription in the logo is the earliest-known written appearance of the word "freedom" (amagi), or "liberty." It is taken from a clay document written about 2300 B.C. in the Sumerian city-state of Lagash.

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