



How the FDA Impedes Innovation: A Case Study in Overregulation

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As the key gatekeeper for pharmaceutical and device innovation, the Food and Drug Administration (FDA) has a tough job. If it is too lenient, it will allow the sale of drugs and medical technology that could harm vulnerable Americans. Too tight, and the U.S. is being deprived of key innovations that could cut costs, increase health, and create jobs.

With this in mind, this paper addresses the question: Is the FDA unintentionally choking off cost-saving medical innovation? First, I discuss the difficulty of assessing whether the FDA is under-regulating or over-regulating new drugs and devices, given the desire for safety. I then show how the FDA is clearly applying “too-high” standards in the case of one noninvasive device currently under consideration—MelaFind, a handheld computer vision system intended to help dermatologists decide which suspicious skin lesions should be biopsied for potential melanoma, a life-threatening skin cancer. I then draw analogies to development of the early cell phones and personal computers.

In an upcoming paper, I will suggest possible remedies to the problem of FDA over-regulation of innovation.

Innovation in Medicine

If we look back at the economic history of the past 200 years, one pattern stands out clearly—new technologies start out expensive, but then end up cutting costs over time. For example, gasoline-driven tractors were initially much costlier and less reliable than horses. Over time, however, tractors were improved and made much less expensive, and the resulting shift to mechanized agriculture helped drive down the cost of producing food.

Similarly, when cell phones were first introduced in the 1980s, they were bulky, heavy devices which retailed for \$4000, provided terrible reception and could barely fit in a briefcase, much less a pocket. After 20 years of

evolution, iPhones and Android smartphones are slender, light, relatively cheap and far more capable than their ancestors.

One unfortunate exception to this historical pattern is healthcare. The United States devotes roughly one-third of its R&D spending, public and private, to the biosciences, so presumably we should be getting plenty of useful innovation.¹ Yet the cost of healthcare per person keeps rising, faster than the aging of the population would account for. As a result, the conventional wisdom is that healthcare technology, rather than holding down costs, has actually increased them.

This breakdown of historical precedent has generated plenty of finger-pointing. In no particular order, drug companies have been blamed for focusing too much on profit rather than on cost-saving advances; lawyers have been blamed for frivolous malpractice suits that have doctors practicing defensive medicine; physicians have been blamed for being too inflexible and focused on their own income; politicians have been blamed for setting up an entitlement system that encourages excess spending; and the government's main health research funding agency, NIH, has been blamed for overemphasizes academic research rather than product development.

FDA and Regulation

For the purposes of this paper, however, we will focus on the FDA, which has been criticized for imposing excessive requirements on the approval of new drugs and medical devices. Three facts are clear. First, the FDA's regulatory reach and intensity has increased over the past 10 years. FDA employment grew by 33 percent between 2000 and 2011, even as employment in the regulated industries—pharmaceuticals, medical devices, and biotech--only rose by 3 percent.

Second, in the wake of high-profile episodes such as the Vioxx case, the FDA has gotten stricter about requiring evidence of safety and effectiveness before approving new drugs. Third, the number of new drugs approved fell sharply over the past decade compared to the decade before.

Still, these three facts alone are not enough to show that the FDA is over-regulating today. Many would argue that the changes were necessary because the FDA was *under-regulating* previously. Indeed, few people would want the FDA to approve drugs or devices that carry potential safety risks for patients.

An Example of Overregulation

However, there is one ongoing example that suggests the FDA might have crossed the line into over-regulating and suppressing innovation. This is the case of MelaFind, which as noted above, is a handheld computer vision

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device intended to help dermatologists decide which suspicious skin lesions should be biopsied for potential melanoma. The device is pointed at a lesion, the visual image is rapidly compared to a computerized database, and the results are reported to the doctor.

A device such as MelaFind, if approved, could be a very useful tool, since melanoma is easy and cheap to treat when caught early, and expensive and difficult to treat if detection is delayed. MelaFind would provide an immediate second opinion for dermatologists, and a dermatologist working long hours in an inner city or rural clinic could use MelaFind's expert system to provide consistent advice. This availability of this tool is especially important as cost pressures force doctors to spend less time with each patient.

In order to get approval, Mela Sciences, the company that created MelaFind, did a multi-year study of the accuracy of the device compared to a panel of dermatologists. The company claims that it passed the test that the FDA had agreed to.² Indeed, on some dimensions of the study the device did better than the panel of dermatologists.

Nevertheless, the FDA staff deemed the device "not approvable," saying that MelaFind "puts the health of the public at risk."³ Despite the strong negative response from the FDA, the company requested that the device be assessed by a panel of dermatologists, statisticians, and other medical experts. The advisory panel met in November 2010 and voted narrowly to recommend approving MelaFind.⁴ Nevertheless, the FDA has not yet approved the device.

To understand why this is an example of overregulation, let's look at some of the medical background. The early detection process for melanoma has two steps: First, the dermatologist or other skilled physician checks the patient to identify potentially suspicious skin lesions. Second, the doctor decides which lesions to biopsy—remove in part or whole--and send to a lab to be checked for cancer.

There are two important points here: First, it's not feasible or desirable to biopsy all skin lesions. Biopsies are expensive and potentially disfiguring, depending on the location and the type of tool used. The goal, medically and financially, is to biopsy the fewest number of lesions consistent with catching the maximum number of melanomas.

Second, identifying which lesions to biopsy is more of an art than a science. Put five dermatologists in a room with a patient, and each of them might pick a somewhat different set of lesions to biopsy. And, of course, the chance of errors goes up when dermatologists with less experience or training are doing the screening.

Ideally, dermatologists could use a second opinion—another set of eyeballs—to help make a decision about which suspicious lesions to biopsy. That’s the role of MelaFind, which is a combination of computer vision linked to an expert system. The handheld device effectively takes a picture of the lesion, compares it to an internal database, and then indicates whether the lesion should be biopsied.

The FDA’s Rationale

There are two important points about MelaFind relevant to the topic of this paper. First, it is noninvasive. As a computer vision system, MelaFind stands at the low end of the spectrum of possible safety risks—less risky to patients than most drugs, implanted devices such as stents, pacemakers, and joint replacements, and devices that emit penetrating radiation.

Second, as an expert information technology system, the company has a clear path to improving the performance of the device over time, just like virtually every information technology device has improved its performance over time.

So why then did the FDA come out so strongly against MelaFind? In the briefing document for the November 2010 panel meeting, the agency made several arguments:⁵

- The device did not do better than the experienced dermatologists in the study (“the FDA review team does not believe this is a clinically significant difference between MelaFind and the examining dermatologist”)
- The device was tested on lesions identified by experienced dermatologists, not on the broader set of lesions that might be identified by “physicians less experienced than these dermatologists.”
- The device did not find every melanoma in the sample (“Since the device is not 100% sensitive, if use based on the device’s diagnostic performance reduces the number of biopsies taken, harm could ensue in the form of missed melanomas.”)
- The device was not demonstrated to make inexperienced physicians the equal of experienced dermatologists (“Currently, formal training is offered to physicians to become board certified dermatologist and thus be able to diagnose clinically atypical lesions. The FDA review team would have to compare this board certification training to that offered by the sponsor to those physicians operating MelaFind to determine if it is found adequate.”)

To summarize, the FDA seems to be saying that it cannot approve MelaFind unless the device can:

- Outperform experienced dermatologists
- Perform well on any lesion that an inexperienced doctor might find suspicious
- Never miss any melanomas
- Turn an inexperienced doctor into the equivalent of a board-certified dermatologist.

This is a standard that no first-generation device can ever reach. **If the FDA fails to approve, MelaFind, it would be the equivalent of rejecting the first cell phone on the grounds that callers might mishear important messages.**

Resetting the Standard

By not approving MelaFind, the FDA is clearly blocking innovation. The device is far from perfect, but it's a real-time system that by some measures does as well as an experienced dermatologist in identifying lesions to be biopsied.

What's more, the philosophy of the device is clearly pointing in the right direction—the use of information technology to improve medical decision-making and treatment, with the ultimate long-term goal of both improving health and lowering cost.

But beyond the approval or rejection of one particular device, the larger issue is whether the U.S. has unintentionally set up a system of approvals that are biased against cost-saving 'disruptive innovation'. A disruptive innovation, as identified by Clayton Christensen, starts out as less capable than existing technologies, but as the innovation evolves, it gets both cheaper and more powerful.

The first automobiles, for example, were both more expensive and less reliable than a horse. Similarly, the first personal computers were basically toys compared to the existing minicomputers and mainframes. But they got better and cheaper over time.

From that perspective, it's clear that a government regulatory body with "too-high standards" can have the effect of choking off innovation. Imagine how the history of computing would have been different if Steve Jobs and Steve Wozniak had to prove that the Apple I could meet government performances standards before it could be sold.

The question is how the FDA standards can be adjusted to encourage cost-saving innovation without compromising safety. In an upcoming paper, we

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will suggest a modest change to the FDA approval process that might help accomplish this goal.

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¹ “Where the U.S. is Building Knowledge Capital,” Innovation and Growth blog, December 21, 2010.

² More precisely, the company claims that it has a ‘binding protocol agreement’ that the FDA has violated. (see an explanation here). This is an exceptionally important point, but not germane to this paper.

³ FDA PMA P090012 Executive Summary, MELA Sciences, Inc., MelaFind, November 18, 2010.

⁴ “Mela Shares Surge After FDA Panel Vote,” Wall Street Journal (online), November 19, 2010.

⁵ FDA PMA P090012 Executive Summary, November 18, 2010.