ARE REGULATORY HURDLES HURTING PATIENT CARE?

US approvals are slower than in Europe, without differences in safety.

BY MICHAEL P. JONES, MD

The FDA has a tough job. The administration is entrusted with approving medications and medical devices. These drugs and devices are designed to benefit patients, but the FDA regulators must make sure that these therapies and technologies are as effective as their makers say they are and that they do not cause harm. If regulators approve something too quickly, and a problem emerges, the FDA is accused of rushing the approval process. On the other hand, if the FDA takes its time to investigate a device, and meanwhile it has been approved in Europe or in Asia, then it is perceived as dragging its feet and is lambasted for taking too long. In other words, damned if they do, and damned if they don't.

Still, some aspects of the FDA's approval process could be improved. Like many other physicians, I am concerned that the FDA's regulatory hurdles are impairing patients' care in this country. This article concentrates on problems with device approval, but many of the same things could be said of drug approval as well.

A HOST OF PROBLEMS

It typically takes 4 to 5 years longer for medical devices to be approved in the United States than in Europe.[1] Studies have shown, however, that this difference in approval times does not translate to a difference in safety.[1] Clearly, European regulators are doing something right if products are approved more quickly than in the United States without sacrificing safety. The FDA, like most government agencies, has a tendency to become bloated over time. Bureaucratic processes multiply, and without periodic review, these processes can become too strenuous without resulting in additional benefit.

One issue is the FDA's one-size-fits-all approach. As with most government agencies, regulators want every process to work the same way, but clearly, it should not take the same length of time to approve every product. A simple medical device implanted under a flap on the surface of the eye, for example, should not have to undergo the same rigorous review as a new heart valve, a device that has the potential to kill a patient. With the FDA's one-size-fits-all approach, certain products take longer to approve than necessary. Because resources are being consumed scrutinizing potentially easier-to-review products, other more important products may be put on the back burner, and the backlog of products to be reviewed grows and grows.

Another roadblock is in the way the FDA collects data. The methods the FDA uses to collect data, the amounts of data, and the types of data that are required add up to about the most inefficient process one could imagine. The FDA is overdue for a review of the quantity of data collected and the format in which it is collected to see whether these processes could be more efficient and informative.

Finally, the FDA must adapt to the times—but nothing in government changes quickly. Some of the designations used for devices and for pharmaceuticals are based on definitions that may be decades old. For example, a health care app for use on a mobile phone is considered a device. Almost assuredly, that app does not need the same sort of scrutiny as a drug-eluting stent, yet the definition remains. Even addressing changes in definitions in a bureaucratic agency can be difficult.

A CASE EXAMPLE

For all of the aforementioned reasons, up-to-date patient care is being impeded by overly burdensome FDA regulations. European doctors have access to technologies that we do not and that we may not have for some time to come.

One glaring example in eye care is the AcrySof IQ Restor Multifocal Toric IOL (Alcon). I was an investigator in the clinical trial for the IOL. This lens often gives patients the ability to see at all ranges without correction, and it incorporates astigmatic correction. It has been available in Europe for 4 years and is available in Canada and many other countries—basically everywhere in the world except the United States.

We finished the first stage of that clinical trial 4 years ago. The data clearly showed that patients were pleased with their results (data on file with Alcon). The patients I implanted in the trial achieved great outcomes. Last year, the FDA's Ophthalmic Devices Advisory Committee unanimously recommended the lens' approval.[2] The FDA has yet to approve the device. In fact, it recently delayed its decision once again. That the FDA has taken this long to approve this lens is a disservice to patients. Many patients were under the impression that approval would be imminent and so are on waiting lists.

Granted, this would be the first multifocal toric IOL approved in this country, but toric-only and multifocal-only lens implants

TOP 5 REASONS US SURGEONS FELT ANNOYED AFTER ESCRS 2015

We asked four of our favorite frequent fliers, "When you attend international meetings, what bugs you the most about seeing what other surgeons have available to them?"

MITCHELL A. JACKSON, MD

No. 1. Lack of the complete gamut of presbyopia-correcting IOLs, specifically toric multifocals and trifocals

No. 2. Lack of the latest Visian ICLs (STAAR Surgical), especially a toric version to simultaneously correct astigmatism and the Centraflow version to avoid the need for preoperative iridotomies

No. 3. Continued FDA monitoring of safety and efficacy. For example, the FAA only monitors safety like the CE Mark. The FAA does not tell Boeing how to build airplanes. I wish the FDA would move to an FAA or European CE Mark safety concern-only level so more products could come to market faster. Surgeons will not use a product if it is not effective, so there is no reason for the FDA to continue to monitor efficacy.

No. 4. Lack of the Sulcoflex IOL (Rayner Intraocular Lenses) to be used as a piggyback IOL

No. 5. The Best DJs in the world and the best eletronic dance music shows are in Europe.

ROBERT J. WEINSTOCK, MD

No. 1. Everything is so expensive because of how poorly the US dollar has been performing.

No. 2. The IOL choices, including multifocals, are so much more extensive internationally than in the United States.

No. 3. Startup biotech companies are doing more clinical research outside the United States than inside due to the more conducive approval process.

No. 4. Electronic health record mandates and other governmental regulations are much less prevalent in most other countries, making them more enjoyable and financially viable practice environments.

No. 5. It is very difficult to find a Starbucks when you really need a cup of good, strong coffee.

JEFFREY WHITMAN, MD

No. 1. The time change—still no great way to avoid jet lag

No. 2. The lack of US-style air conditioning and heating, not to mention the difficulty of getting ice for a cold glass of anything

No. 3. Going to a symposium about the best lens implant ever only to find that it may never make it to the United States

No. 4. Finding out that technology that I do have access to in the United States has new and better software/hardware available that I will not get a hold of for years

No. 5. Colleagues who can speak foreign languages

COUNTERPOINT: WILLIAM B. TRATTLER, MD

European meetings do not depress me. They are a wonderful opportunity to learn about new technologies that may arrive in the United States in the future.

Certainly, there are some technologies that I am anxiously awaiting. Although it can be frustrating when the delay is on the order of many years, it is not uncommon for the most promising technologies being used in Europe to have further improvements before reaching the United States. A case in point is Kamra (AcuFocus), which was relatively successful when initially launched in Europe and Asia. However, over the few years that were required to achieve an FDA approval, the technology made significant improvements (such as switching from a flap to a pocket and enhanced femtosecond laser settings), which resulted in significant improvements in patient outcomes

Of course, one of the important reasons to attend European meetings is that there is top-level research that is presented by European clinicians. From corneal collagen cross-linking to presbyopia-correcting IOLs, international surgeons really make a difference in how we US surgeons will eventually be able to care for our patients.

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very similar to the AcrySof Restor Toric are used in cataract patients every day without problems. To my mind, this lens represents a change to an established product line, not a new product. Unlike other regulatory agencies elsewhere in the world, the FDA approached the IOL as a de novo lens, even though the materials, platform, and the dimensions are the same as those of other familiar AcrySof lenses. In my opinion, this should have been a fast-track approval, and it is hard to understand the reasons the FDA would delay it. To have it take this long to be approved is extremely frustrating for patients and physicians.

WORKING FOR CHANGE

There are efforts in both houses of Congress to speed up approvals at the FDA. There is a bill before the Committee on Health, Education, Labor, and Pensions in the Senate that would exempt some products, particularly low-risk medical software and apps, from regulation as a medical device.[3]

It is hoped that lobbying and engagement of legislators by health professionals, including eye care professionals, can help to move along this bill and other efforts to reform the regulatory process at the FDA. Our patients depend on us to have their best interests at heart, and one way to demonstrate our commitment is to fight for access to the latest, safest, most effective, and most efficient technologies. ■

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