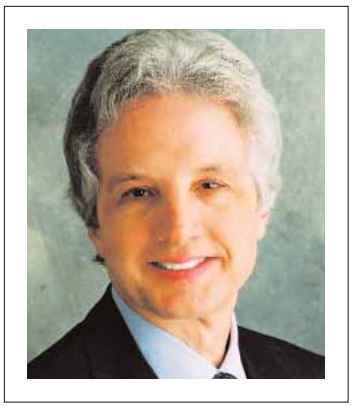
The FDA and Ophthalmology

News of a government investigation of the FDA by the Inspector General of the US Department of Health & Human Services caught my attention. The report reminded me that our practice of ophthalmology, including its business side as discussed in this issue, falls under the authority of the FDA.

And the news was not good. On September 28, 2007, *The New York Times* reported the investigation's results: "The Food and Drug Administration does very little to ensure the safety of the millions of people who participate in clinical trials."[1] In the report, the FDA was said to not know how many clinical trials were currently being conducted, had less than 1% of their clinical investigation sites audited by federal health officials, and typically then only conducted an audit of a trial site after the study was over. "In many ways, rats and mice get greater protection as research subjects in the United States than do humans," said Arthur L. Caplan, PhD, Chairman of the Department of Medical Ethics at the University of Pennsylvania in Philadelphia. The report includes several sensationalistic stories of study participants who were prevented from leaving trials after they were told they could exit at any time, sexual misconduct by investigators, and investigators who lost their license in one state only to move to another to conduct more clinical trials.



We often forget, perhaps intentionally, how important the FDA is to ophthalmologists. Our industry depends on technology, most of which must go through the agency before it can be used clinically. I have spent a lot of time at the FDA working with clinical investigations to try to get devices and techniques approved. At times, we were successful; other times, we were not. Whatever the outcome, however, I have always been impressed by the bright, hardworking physicians, scientists, and administrators who make up the FDA staff. They face enormous workloads and a system that punishes the negative far more than it rewards the positive. Have you ever heard a patient thank the FDA for making a new drug or device available? Yet, if an approved drug or device ever has issues, the FDA takes the blame—forever. They are not subject to a statue of limitations.

At the FDA's core, its system is a gamble. A drug that is approved by the FDA based on data compiled by a dozen physicians from a few hundred cases over a few years may not perform as expected when it is used as intended in the real world by tens of thousands of physicians in millions of patients over decades. We have all seen products that were approved for clinical use by the FDA but eventually failed to be commonly used in the real world, including conductive keratoplasty, laser thermal keratoplasty, Intacs (Addition Technology, Inc., Des Plaines, IL), etc.

Sure, I wish the FDA were less conservative than Europe's drug and device approval systems, but I think the agency does what the American people ask it to do—ensure their safety.

The report of this investigation concerns me. It simply does not seem to represent the FDA with which I have worked. In my experience, the FDA is doing its job. The FDA's staff members are open-minded, and they possess intellectual curiosity. I do not think this system is broken. ■

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1. Harris G. Report assails F.D.A. oversight of clinical trials. *The New York Times.* September 28, 2007. Available online at: http://www.nytimes.com/2007/09/28/health/policy/28fda.html?_r=1&oref=slogin. Accessed October 10, 2007.