FDA Opens Door a Sliver to Gain Access to Investigational Drugs

New Policy’s Success Depends on Manufacturers

Stephen Barlas

We understand that some patients have run out of options and want to try something that is not fully tested, and we want to support them in these situations without exposing them to undue risks. But we also need to make sure that ultimately all patients get a treatment that has been shown to work. The clinical trial process gives everyone the full picture on the safety and effectiveness of a drug before it is used in the population at large.

Linah Lubin, spokeswoman for the National Coalition for Cancer Survivorship (NCCS), says much the same thing:

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The larger question: will pharmaceutical companies create more expanded access programs?

The answer probably depends in part on whether the companies find the FDA’s “fee-charging” rule suitable. If a pharmaceutical company meets the Treatment IND requirements, it can charge patients according to its “direct” costs, as specified by the FDA. When the FDA published the proposed rule on fees in 2006, the Pharmaceutical Researchers and Manufacturers of America (PhRMA), the brand-name industry trade group, criticized the direct-cost formula and instead asked the FDA to allow companies to charge based on “administrative” costs. In the final rule, the FDA rejected that request.

Asked about the final rule, a PhRMA spokesman provided a noncommittal statement from Ken Johnson, a senior vice president at PhRMA, and essentially said that individual companies would make their own decisions.
Meanwhile, Frank Burroughs and other members of the Abigail Alliance met with FDA Commissioner Margaret Hamburg, MD, and her top deputy, Joshua Sharfstein, MD, in September. The two final rules concerning expanded drug access were shaped by the FDA during the recent Bush administration. Mr. Burroughs hopes that he and others can convince the Obama FDA to widen access even more. He notes that Dr. Sharfstein, who headed the Obama FDA transition team, consulted him before the new administration took office.

“We have a good relationship with them,” Mr. Burroughs says. “I’m optimistic.”