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by Jamie Young

ACCC members know firsthand that lifesaving new drugs take too long to reach the people who need them. Some say this delay occurs primarily because of impediments—namely, outdated federal regulations—placed in the paths of the emerging biotechnology companies that are developing these drugs. According to Carl Feldbaum, president of the Biotechnology Industry Organization (BIO), the problem is that new technology is progressing ever faster, while the federal agency charged with regulating its products is still governed by laws written generations ago. BIO is a trade association of more than 570 companies, state affiliates, and academic centers engaged in the research and production of biotechnology products.

In a *Washington Post* editorial, Feldbaum countered an earlier editorial by Congressman Ron Wyden (R-Oreg.) defending the Food and Drug Administration. Feldbaum wrote that Wyden's defense of the status quo at FDA ignored the real question that BIO and other organizations are trying to address, namely, has this "federal bureaucracy kept up with today's new technology?"

What may be surprising to many of us are the additional hurdles biotech companies face over and above the traditional drugs made from chemical compounds. Biotech drugs are regulated under two different laws, the most recent of which passed Congress nearly 60 years ago. This division results in biotech companies having to seek two specific FDA approvals, one for the process by which their drug will be produced and one for the drug itself.

"Every time the process is changed in almost any way, even when a piece of equipment is moved at the factory, the company must get a new approval. This increases the burdens on already overstretched resources at the FDA and takes reviewers away from their primary job of examining new products," Feldbaum wrote.

REORGANIZING THE CLINICAL TRIAL PROCESS

In July the National Kidney Cancer Association announced a proposal it has sent to FDA and several congressional committees. According to a NKCA press release, the proposal, entitled "Re-engineering the FDA Clinical Trial Process," would reorganize FDA's medical approval process, allowing the agency to meet its goals of assuring the public of safe and effective drugs while cutting the time and cost required to bring medical innovations to the public.

The changes proposed by NKCA include:

- doing away with Phase I, II, and III clinical trials
- initiating FDA certification of major clinical research centers
- establishing a Scientific Accounting Standards Board that would set standards for collecting and reporting clinical data to FDA
- encouraging real-time submission from research centers directly to FDA
- making clinical research data available to the public
- allowing inventors and makers of new drugs and devices to market new products directly to limited numbers of FDA-certified medical research centers until they achieve FDA approval.

NKCA "believes that FDA can meet its goal of controlling risk by limiting distribution of new products only to clinical research centers most qualified to evaluate them." Furthermore, the association expects the proposal can significantly affect industry and health costs as a result of early marketing of new products to FDA-certified centers, thereby eliminating the multiyear delays and enormous expense of bringing new drugs to the public. NKCA also writes that the public would receive more new drugs, particularly for rare diseases, by virtue of drugs becoming more profitable and viable for investment under a system that does not require a ten- to twelve-year clinical trials process. Lower prices could result by eliminating much of the drug development.

While NKCA has not proposed any specific legislative language, BIO and the Pharmaceutical Research and Manufacturers Association have been hard at work developing lengthy legislative language and hope to have sponsorship and introduction after Labor Day. Speedy passage is the goal of these groups in hope that the bill does not hit the wall next year when partisan presidential politicking prevails.

REFORMS AHEAD: PROCEED WITH CAUTION

Within the last few months, an offensive has been mounted to reform FDA. To be sure, some aspects of the reform proposals are appealing and would no doubt be beneficial to our members and cancer survivors, particularly provisions that address access to clinical trials, off-label uses, and speedier drug approval. ACCC will be involved in the ongoing debate over these proposals and will be looking to its membership for ideas on how to protect the best of the current system while removing regulatory barriers to improved cancer care and medical innovation. ■

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