Oncology Issues

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ISSN: 1046-3356 (Print) 2573-1777 (Online) Journal homepage: https://www.tandfonline.com/loi/uacc20

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To cite this article: Jamie Young (1996) Pushing for FDA Reform, Oncology Issues, 11:3, 6-6, DOI: 10.1080/10463356.1996.11904607

To link to this article: https://doi.org/10.1080/10463356.1996.11904607

Pushing for FDA Reform

by Jamie Young

At long last the Food and Drug Administration has announced new rules that anticancer drugs may be given early approval to go to market—before it is conclusively proven they are effective—if drug companies can show they work in shrinking tumors. The initiative expands existing FDA programs for accelerated approval and access to drugs, programs that have long been available to patients with serious or life-threatening diseases. Recently, the agency has given such approval for various AIDS treatments.

President Clinton announced the new rules in an East Room ceremony held on March 29. In attendance were a number of cancer survivors and executives from major oncology organizations, including ACCC Executive Director Lee Mortenson and ACCC Director Carol Kirkland.

This new announcement comes at a time when a call for FDA reform has been heating up. The FDA has warned Congress that proposed legislative changes to the drug-approval process, such as third-party review of drug applications and other measures, would lead to an erosion of the safety standards that have protected the public from unnecessary harm. FDA argued that, in the face of tighter deadlines, reviewers would not have the time to resolve the more time-consuming drug approval applications. Most likely, according to the agency, the difficult cases would be rejected, only to enter into additional cycles in the review process. Conversely, the pharmaceutical industry and some consumer groups have argued that FDA's data requirements, which far exceed those required in many European countries, have delayed patient access to needed therapies and have contributed to the loss of countless numbers of lives.

ACCC supported a letter to educate members of Congress about the need for timely legislative reform of FDA. The National Coalition for Cancer Survivorship and the American Society of Clinical Oncology requested our cooperation in demonstrating the cancer community's support of legislative reform of FDA. In the letter we asked that Congress require FDA to give priority to products for the prevention, diagnosis, and treatment of life-threatening diseases like cancer. In addition, we advocated that FDA be:

1) held accountable for speeding the approval process for drugs, biologics, and devices
2) required to explain its actions or failure to take action
3) restricted in its ability to limit dissemination of accurate information about off-label drug uses
4) required to streamline review of supplemental new drug applications.

This position is consistent with some of the more reasonable legislative proposals currently under consideration, most notably Senate bill S. 1477, sponsored by Sen. Nancy Kassebaum (R-Kan.). The bill also includes provisions related to the dissemination of off-label information. The language of the off-label provisions comes from a bill sponsored by Senators Connie Mack (R-Fla.) and William Frist (R-Tenn.) that has received ACCC support. This proposal would allow companies to send physicians off-label information if that information appeared in a peer-reviewed journal. This is less restrictive than FDA-proposed guidelines, which would also require, in addition to appearing in a peer-reviewed journal, that the off-label information be developed during a clinical trial for an FDA-approved drug. ACCC's support of off-label drug reimbursement legislation is well known.

While FDA has been under fire, the National Cancer Institute, its sister agency, has been making progress in its attempts to negotiate with insurers concerning access to clinical trials. A recent memorandum of understanding between NCI and the Department of Defense will grant members of the military and DOD employees insured through CHAMPUS access to phase II and III trials. Flush from this successful agreement with DOD, NCI has continued to meet with private insurers and has created a Clinical Trials Review Committee as part of its overall emphasis on current threats to clinical trials. Both David K. King, M.D., chairman of ACCC's Ad Hoc Reimbursement Committee, and James L. Wade III, M.D., ACCC's president-elect and chairman of the Governmental Affairs Committee, have accepted NCI's invitation to serve on this committee.

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