Confronting Cancer:

FDA's Long Fight Against America's Bane

Few health hazards have blazed a trail as tragic as cancer, the second deadliest disease in the United States. And there is no public health hazard that the Food and Drug Administration has fought longer, more persistently, and on more fronts than this scourge, which currently affects 8 million Americans.

In the last nine decades, the agency has battled cancer by such means as exposing fraudulent panaceas, setting standards for radiation-emitting equipment, and proposing to regulate the use of tobacco.

After Congress passed the Mammography Quality Standards Act of 1992, the FDA launched a major program to facilitate the diagnosis of breast cancer by unifying and strengthening the standards for mammography facilities, their equipment and the qualifications of their personnel. The program helps ensure that every mammogram is of the highest quality.

In addition, the FDA has made great strides in making effective new drugs speedily available to patients. Here are two mechanisms developed by the agency for that purpose:

• **Accelerated approval:** The FDA has speeded up approval for major drugs whose effects on so-called "surrogate endpoints"—such as the size or number of cancer tumors—indicate the likelihood of extended survival or other long-term health benefits. Products that receive accelerated approval must subsequently undergo additional trials to provide clinical proof of the benefits suggested by the surrogate endpoints.

New Advances Against Cancer

Since 1996, the FDA has approved approximately 80 new cancer-related medications or new uses of already-available drugs. Some of these products treat the disease, some alleviate its pain and other symptoms, some help to diagnose it, and one reduces the risk of cancer in people who are considered at high risk.

Thirty-five of these products have been reviewed and marketed within six months of their submission to the agency; one of them—Gleevec, for the treatment of a rare chronic leukemia—was approved by the FDA in the all-time record time of 2.4 months.

According to a recent survey, the rate of new cancer cases in the United States declined an average of 1.1 percent a year from 1992 to 1998.

• **Priority drugs:** Medications that promise major advances in health care receive priority treatment to accelerate their testing and availability to patients. The FDA enhances the development process of these products by helping the sponsors design efficient clinical trials, and it speeds up the review of the resulting evidence by using additional resources.

The FDA also sponsors two programs that enable cancer patients or their family members to participate in the review and approval of cancer drugs. The Patient Representative program trains and supports patients who serve on the FDA's advisory committees that consider the safety and effectiveness of new cancer drugs. The Patient Consultant program enables cancer patients to participate in FDA meetings with sponsors of key clinical trials for cancer drugs.

For more information, call the FDA's office of special health issues at 301-827-4460 or visit *www.fda.gov/oashi/home.html*.

The National Institutes of Health lists studies that are testing new cancer treatments at *http://cancerTrials.nci.nih.gov*.

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