

FDA Proposes Broadening Access to Drugs

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WASHINGTON -- Greater numbers of seriously ill patients could get experimental medicines under proposed federal guidelines released Monday that also would allow drug companies to charge for the medicines.

The guidelines would make the unapproved drugs available to patients with no other options to treat a life-threatening or serious disease or condition, the Food and Drug Administration said. The FDA would have to be satisfied that the potential benefit of the treatment justifies its potential risks. Both can be largely unknown at such a preliminary stage.

Since the 1970s, the FDA has made experimental drugs available to either individuals or large groups of patients under compassionate use programs. The new guidelines, subject to comment for 90 days, would further describe all the circumstances in which access would be allowed, including to small groups of patients.

"FDA hopes this proposal will increase awareness in the health-care community of the range of options available for obtaining experimental drugs for seriously ill patients," said Dr. Janet Woodcock, FDA's deputy commissioner for operations.

A drug also could be made available on a wider basis according to the seriousness of the disease it targets and the number of patients involved.

To defray the high costs of developing the treatments, drug companies in some cases would be able to charge patients for their drugs while under study. The FDA said doing so would encourage companies to provide early access to drugs by allowing them to recuperate some of their costs.

Next year, a federal court will rehear a 2003 case brought by the **Washington Legal Foundation** and the Abigail Alliance for Better Access to Developmental Drugs in seeking broader access to drugs that have undergone preliminary safety testing in as few as 20 people but have yet to be approved by the regulatory agency.

The issue has dogged the FDA for decades. In the late 1970s, terminally ill cancer patients and their spouses sought access to Laetrile, a then- and still-unapproved drug, eventually suing the FDA in a case that landed in the Supreme Court.

In 1979, the top Court ruled unanimously that there should be no exemption to the FDA's safety and effectiveness standards, which all drugs must meet, for medicines sought by terminally ill patients.

Sen. Sam Brownback, R-Kan., introduced legislation last year that would require the FDA to create a three-tiered approval system that would expand access to experimental drugs for patients with serious or life-threatening conditions and diseases.

On the Net:

Food and Drug Administration: <http://www.fda.gov/>