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Access to trial drugs expected to grow

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The Food and Drug Administration is expected to expand access to experimental medications for terminally ill patients later this year, but is resisting an attempt by a patient-advocacy group to make access to unapproved drugs a constitutional right.

Abigail Alliance, a nonprofit organization in Arlington that helps patients with life-threatening illnesses, and the Washington Legal Foundation are not satisfied with the extent of the FDA's proposed expansion of access to unapproved drugs and have taken the agency to court.

Experimental medications are drugs that are in clinical trials or at an early development stage and have not been approved by the FDA **to be sold on the market.**

The issue poses an ethical dilemma: Whether to consider an individual's need to have access to medications expected to help a condition or to give priority to the government's responsibility to ensure public safety.

"This is a classic ethics standoff case," said Arthur Caplan, director of the Center for Bioethics at the University of Pennsylvania in Philadelphia.

Mr. Caplan said he is siding with the government because experimental drugs have done more harm than good for some conditions. He pointed out that drugs in clinical trials exacerbated or inflicted new harm in patients with AIDS and Parkinson's disease.

"There is evidence that first-generation drugs will make people sicker. The history of drug development is littered with failures," he said. "A patient's hope is not grounded in experience."

Last month, the FDA proposed to expand patients' drug access by making it easier for physicians and other providers such as hospitals to understand when they can obtain unapproved medications.

"We feel the rules do not provide enough specificity about where and when one can apply for an unapproved drug," said Rachel Behrman, deputy director of the FDA's Office of Medical Policy.

In the U.S. Court of Appeals for the District of Columbia, a groundbreaking case is examining whether terminally ill patients have a right of due process to experimental drugs. If successful, the lawsuit would break the long-standing regulation that a drug must undergo three phases of testing before becoming available to the public.

"We are seeking access to investigational drugs for the terminally ill who have exhausted

every other FDA-approved treatment," said Scott Ballenger, counsel for the D.C. law firm Latham & Watkins LLP. "These are drugs that FDA has already approved for substantial human testing in a number of clinical trials."

Mr. Ballenger will argue that point on behalf of the Abigail Alliance and the Washington Legal Foundation before the appeals court March 1.

Currently, it is illegal for a drug company to sell an unapproved drug.

"We are asking for a transaction between a willing drug company and patient to be decriminalized," Mr. Ballenger said.

The drug industry is not backing the Abigail Alliance's case, observers said, because of the potential liability of an experimental drug causing harm to a patient. Mr. Ballenger emphasized that the lawsuit would allow drug companies to decide whether to sell the drugs.

The upcoming court date is the result of an FDA appeal of a ruling by a three-judge panel of the D.C. appeals court that terminally ill patients have a constitutional right to access to unapproved drugs. The FDA's proposed expansion of access to unapproved drugs came three months after the panel's ruling.

The panel's decision came as a surprise to Lawrence Gostin, a Georgetown University Law Center professor who specializes in bioethics and health policy law.

"I think it will be overturned. Despite the emotional aspect of the case, we have a Food and Drug Administration in place to protect patients," he said. "I can't see an abandonment of these rules."

The new rules are intended to give physicians clear directions on when to grant access to medications, even perhaps at the earliest stage of development, in cases in which the FDA deems the potential benefits outweigh the risks.

The goal, the FDA said, is to give "many more patients" access to unapproved medicines.

"In effect, FDA is telling doctors that if you have a patient that might need an unapproved drug, 'Here is the form, here is how to fill it out.' They are being proactive; right now, they are not reaching out to physicians," said Michael Levin-Epstein of the Food and Drug Law Institute, a nonprofit, nonadvocacy educational organization in the District. "At this point, that's how they intend to implement the new rule."

The FDA is reviewing public comments on the revised guidelines, and a final rule is expected in a few months.

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