

THE ETHICAL ISSUES BEHIND EXPANDING THE RIGHT TO TRY PREAPPROVAL DRUGS AND MEDICAL DEVICES

The restrictions on the use of drugs and procedures not yet approved by the Food and Drug Administration (FDA) have long been a point of controversy, particularly when these restrictions affect individuals with terminal illnesses. In recent years a “right to try” movement has gained significant traction, arguing that terminally ill individuals should have access to experimental drugs.

In “[The Ethical Issues Behind Expanding the Right to Try Preapproval Drugs and Medical Devices](#),” professor Mark D. White of the College of Staten Island (part of the City University of New York) looks at the ethical issues concerned in the right-to-try debate and explores the arguments for and against government regulation of healthcare innovation in general. He finds that while both sides of the debate have made powerful arguments, the terminally ill should receive expedited access to experimental treatments—and the FDA would better serve the public by shifting its focus away from banning drugs and toward informing consumers.

CONTRASTING PRINCIPLES IN HEALTHCARE REGULATION

It is generally agreed that individuals have the right to control their own bodies, but there is disagreement about whether this right is absolute or whether exceptions exist that would open the door for state interference. The two principles in light of which people generally approach these questions can be described as follows:

- *Autonomy.* According to this principle, citizens know their interests better than policymakers do, and the government lets them make decisions in those interests. In terms of healthcare regulation, the government would be limited to, at most, assessing the safety of medical innovations and informing citizens of the results. Aside from this role, the government would leave it to individuals to make their own choices regarding whether or how to use medical innovations to further their own interests.

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- *Paternalism.* According to this principle, the government implements policies that it considers to be in people's best interests. This approach is explicitly paternalistic, involving a presumption on the part of policymakers that the relevant components of people's well-being are common and easily understood. Such policymakers believe that individuals, as victims of imperfections in human decision-making, will not make the best decisions in their own interests, which justifies openly coercive measures such as taxes and bans.

INTERESTS AND CHOICE

The most common justification for government interventions that restrict the use of unapproved treatments is that people may have difficulty making rational decisions about whether to use such treatments. It is true that individuals may contend with a lack of accurate information, well-documented cognitive biases that hamper risk assessment, or the emotional contexts in which medical decisions tend to be made. However, intervening policymakers also face several practical and ethical difficulties:

- Policymakers have no way of discovering or accounting for the true interests of individuals, which are multifaceted, complex, and subjective. Different people may value factors such as quality of life or preservation of wealth differently because of personal circumstances related to their family and friends, life goals, finances, and so on. Policymakers who prevent patients from experimenting with unapproved treatments do so blindly, without knowing how their intervention will affect individuals' interests.
- Policymakers and doctors who intervene in end-of-life decisions assume particular interests on the part of individuals. This betrays a lack of respect for individuals' interests at a time when those interests should be most respected. For the terminally ill, the benefits of experimental treatments are greater and their costs lower than for patients in other situations—especially if death is imminent.

REFORMING THE SYSTEM

Under current law, the FDA has the power to grant exceptions to its access restrictions and allow terminally ill patients to try treatments that are not yet approved. The application procedure for those wishing to take advantage of this opportunity is too burdensome, however. Policymakers should reform the FDA in the following ways in order to expand and expedite patients' access to potentially life-saving treatments:

- *Recognize foreign approval.* The approval of drugs or devices by parallel authorities in other countries should make domestic authorities more comfortable with allowing patients to try these medical innovations before they receive FDA approval.
- *Adopt a two-tiered system.* A system in which one level of approval is based largely on safety (corresponding to Stage I of the FDA's current process) while another level focuses on efficacy (corresponding to Stage II) could expand patients' access to treatments while maintaining the integrity of clinical trials. The government could require that drugs pass Stage I

before allowing terminal (and even nonterminal) patients to use them. Patients would be free to choose which level of approval best serves their interests.

- *Shift from banning to informing.* The FDA should shift the focus of its drug approval process from banning drugs and devices to informing consumers about their risks. Such a shift would promote consumers' health while allowing them to make the decisions they feel are best for them.