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RESEARCH SUMMARY

THE RIGHT TO TRY AND THE FUTURE OF THE FDA IN THE AGE OF PERSONALIZED MEDICINE

Do citizens have the right to determine their own courses of treatment and to use medicines and devices that they believe could improve their health? In other words, do patients have a "right to try" medicines and devices that can help them?

In a new study for the Mercatus Center at George Mason University, Mercatus Senior Research Fellow Adam Thierer offers a fresh perspective on the right to try. Rather than wading into the ethical debate, the study questions the practicality of government control over patient decision-making in an era of increasingly personalized medicine and decentralized technology.

Owing to the nature of technological innovation, a de facto right to try may already exist for some medical devices, such as 3-D–printed prosthetics. The practicality of government regulation matters, and the FDA's old command-and-control approach is increasingly ill-equipped to handle future medical developments. The FDA should reorient itself to focus on risk education, streamline its review processes, and improve consent mechanisms to keep pace with innovation.

To read the entire study and learn more about its author, please see "The Right to Try and the Future of the FDA in the Age of Personalized Medicine."

THE RIGHT TO TRY AND GOVERNMENT CONTROL

Two opposing viewpoints undergird the policy debate around the right to try: "precautionary principle" thinking and "permissionless innovation." The "precautionary principle" seeks to minimize any and all potential risks through regulation, whereas the "permissionless innovation" mindset argues for trial-and-error experimentation with minimal restraint.

- The information revolution has dramatically increased the costs of a precautionary system, as illustrated by the hypothetical case of limiting 3-D–printed prosthetics. These prosthetics, which often provide life-changing benefits to their users, are medical devices in a traditional regulatory sense, but few people are going to the FDA and asking for permission or

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a "right to try" new 3-D–printed limbs. Banning the printers, the materials, the blueprints, or the sale of these prosthetics would be highly impractical and costly to enforce.

- The rise of personalized medicine evidenced by the increasing use of genetic testing, wearable devices, and biohacking suggests that precautionary regulation will become increasingly impractical and undesirable as individuals seek to take advantage of these rapid technological developments.

A NEW ROLE FOR THE FDA

The FDA should adopt a role as a risk educator rather than risk regulator. The FDA currently tries to minimize any and all potential risks through a command-and-control system. Instead, the FDA should embrace a more educational role, enabling individuals to make well-informed decisions about the best medicines for them.

- Potential reform options for the FDA include ending the FDA's monopoly on drug and device approval by granting reciprocity to private bodies or foreign national drug and device certification agencies, developing a dual-access track that allows access to treatment before full FDA approval, clarifying and limiting the scope of the FDA's authority, or ideally, a combination of these reforms.

- Improved consent mechanisms and protection from excessive liability are necessary for a right-to-try system to function properly and continue to encourage innovation. Liabilities for innovators and healthcare providers must be defined so it's clear where the responsibility lies when things go wrong after a patient chooses a controversial path despite expert advice and information. All parties should understand that the fact that patients have gained a broader right to try alternative drugs and devices does not mean everyone else must pick up the tab for them should things go wrong.

CONCLUSION

Decentralized technology has increased the costs and decreased the practicality of preemptive regulation. Policymakers should reform the structure and role of the FDA to focus on risk education rather than regulation and improve consent mechanisms to ensure the FDA can keep pace with technological developments.