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Investigational therapies and patients' autonomy

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The growing demand for novel therapies has raised new ethical dilemmas to society. Vigorous debates have been initiated, especially after the recent *Right to Try Act*, which aims to facilitate access to new agents, even at an early stage of the investigation process. This article explores the concept of patient's autonomy in accessing investigational treatments, and discusses the implications of autonomy for patients, researchers and regulatory authorities. We propose that, in cases of adequate understanding of the anticipated risks and benefits, society should accept patients' autonomy in choosing to try new therapies, even in the absence of firm data. However, basic ethical principles should not be compromised, as the medical community and society as a whole retain the right to properly evaluate the accumulated experience from such cases. These thoughts may contribute to the ongoing discussions on ethical policies in clinical research.