REPS

Spring 2023

Research Ethics and Policy Series

The Burden of Uncertainty: Raising Regulatory Standards to Improve Health Equity

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Recently, the U.S. Food and Drug Administration (FDA) has been placing greater emphasis and implementing reforms focused on improving health equity. The focus of the reforms has been largely on increasing representation in clinical trials, enhancing transparency and access to available data on the effect of medical products on minority populations, and promoting health and safety communication to these populations. Concurrently, FDA continues to increasingly adopt regulatory flexibility in their review process, accepting less rigorous evidence as the basis of approval of novel medical products. In the case of accelerated approval, the agency allows for residual uncertainty at the time of approval, but then requires sponsors to complete additional studies that confirm clinical benefit in a timely manner; should these not be completed or if the studies yield negative results, FDA can withdraw these drugs from the market. However, the expanded and more flexible use of this pathway by the FDA has raised questions about which communities will bear the burden of such uncertainty and whether this may in fact exacerbate health disparities.

In this presentation, Dr. Ramachandran will discuss trends in FDA's adoption of regulatory flexibility in the approval of novel medical predicts, the implication of such policies, and proposals to center health equity in regulatory decision-making.

Co-sponsored by the Department of Family Medicine and Community Health at the Perelman School of Medicine

Penn Medicine
Department of Family Medicine & Community Health

Wednesday, June 14, 12:00–1:00 PM

RCH B102AB, Richards Building, 3700 Hamilton Walk
Register (for in-person and Zoom attendance): **REPS Ramachandran**
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