Regulating Health Technologies in a Post-FDA World

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Overview

- Current events
- FDA's primary purposes
- Presenting hypothetical scenarios
- The institutional ecosystem for regulating healthcare technologies
- Reconstituting the functions of FDA

Mass Layoffs Hit Health Agencies That Track Disease and Regulate Food

The cuts were part of a Trump administration plan announced last week to dismiss thousands of employees and drastically overhaul the Health and Human Services Department under Secretary Robert F. Kennedy Jr.

Robert Califf · 2nd
Duke University
1h ·

OK, i'm on a coast to coast flight, but i'm overwhelmed with messages about the firings. The FDA as we've known it is finished, with most of the leaders with institutional knowledge and a deep understanding of product development and safety no longer employed. I believe that history will see this a huge mistake. I will be glad if I'm proven wrong, but even then there is no good reason to treat people this way. It will be interesting to hear from the new leadership how they plan to put "Humpty Dumpty" back together again.

FDA's Primary Purposes

- Consumer protection
- Efficient review of product applications
- Information generation

Getting to a "Post-FDA World"

- Decimating state capacity
- Moving to a "safety-only" approval standard
- Pure political control

FDA's Institutional Context

- International regulators
- Insurance companies and physicians
- Non-profit organizations

Where Do We Go From Here?

- What's the impact on insurers?
- What's the impact on evidence generation?
- What options are there for capacity building?
- What's the best – and worst – case scenario?

Additional Issues

- A world without FDA – or without other institutions as well?
- Approvals versus bans
- Dynamic effects

Questions?


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