

A new way of looking at drug discovery

February 17 2013

Garret FitzGerald, MD, FRS, chair of the Department of Pharmacology and Director of the Institute for Translational Medicine & Therapeutics, Perelman School of Medicine at the University of Pennsylvania, has long said the current drug-development system in the United States is in need of change, "representing an unsustainable model."

Even though the number of drugs approved has risen in the last three years, overall, roughly the same number of drugs have been approved by the Food and Drug Administration (FDA) each year since 1950 while the estimated cost, mostly because of the failure to bring new medicines all the way to market - has exploded.

As the dominance of large pharma erodes and the process of drug discovery and development moves to a more modular approach, initiatives such as the NIH's Clinical and Translational Science Awards are designed to enhance the ability of academia to play in this space.

Novel approaches to raising capital and to distributing intellectual property are also emerging.

However, most failures in [drug development](#) now occur during phase 2 clinical trials, when the mechanism of drug action is discovered and the factors that contribute to variability in drug response are parsed. We are challenged by a paucity of those individuals who integrate knowledge of preclinical science with an understanding of the complexity of drug action in humans. The relative absence of such individuals who serve as catalysts in drug development is apparent in big pharma, academia and at

the FDA.

A politically uncontroversial role for NIH's National Center for Advancing Translational Sciences would be to address this problem, giving academia incentives to couple initiatives in translational [medicine](#) and therapeutics and in regulatory science to create a cadre of such individuals. This interdisciplinary group could catalyze drug development by including strategies focused on a more personalized approach, improving prediction of efficacy and safety and becoming a source of information about therapy for prescribers and consumers that exceeds the "objectivity" of direct to consumer advertising.

FitzGerald will present "A New Paradigm for Therapeutics Discovery" at the 2013 American Association for the Advancement of Science Annual Meeting in Boston, Sunday, February 17.

Provided by University of Pennsylvania School of Medicine

Citation: A new way of looking at drug discovery (2013, February 17) retrieved 2 May 2024 from <https://medicalxpress.com/news/2013-02-drug-discovery.html>

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