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Peltzman Revisited: Quantifying 21st Century Opportunity Costs of FDA Regulation

Based on BFI Working Paper 2021-145, "Peltzman Revisited: Quantifying 21st Century Opportunity Costs of FDA Regulation," by Casey B. Mulligan, Professor, Kenneth C. Griffin Department of Economics, University of Chicago

FDA cost-benefit analysis is incomplete without accounting for substitution toward potentially unsafe and ineffective treatments that are both outside FDA jurisdiction and heavily utilized prior to FDA approval.

New medical products make important contributions to improved living standards, and both markets and regulators have the potential to contribute to, or detract from, the innovative process. On the market side there are concerns that competition may erode financial rewards to innovation, or that large, bureaucratic firms may not foster the innovation necessary to develop new products and methods. Meanwhile, government stands as a gatekeeper for new medical products for the stated purpose of protecting consumers.

Figure 1 • Entry and Price Changes in Drug Markets by Two-Year Period

	May 2015 - April 2017	May 2017- April 2019	May 2019 - April 2021
ANDAs Approved	1,286	1,754	1,475
NDAs Approved	184	229	202
Biosimilars Approved	4	16	15
New Biologics Approved	73	82	62
Rx CPI Change Relative to All Items	3.7%	-1.5%	-5.1%
Addendum: Inflation-Adjusted Changes in Unit Cost Between Calendar Years	-0.1%	-3.6%	N/A
Addendum: Medicaid/CHIP Enrollment Change, Per Capita	3.4%	-5.3%	12.8%

Note: CPI and Medicaid changes are from April to April. Unit cost is per- prescription consumer expenditure, including insurance plan expenditures net of rebates and discounts. Gottlieb was FDA commissioner May 2017 - April 2019. Biosimilars and new biologic approvals include Supplemental BLAs.

Sources: FDA Orange Book, FDA Purple Book, BLS CPI series CUSR0000SEMF01 and CUSR0000SA0, Express Scripts/Evernorth Drug Trend Reports

In terms of government protection, though, one question looms: What are the unintended costs associated with the introduction of regulations? For example, in 1962, Congress passed the "Drug Efficacy Amendment" (EA) to the Federal Food, Drug, and Cosmetic Act, which made proof of efficacy a requirement for the approval of new drugs by the Food and Drug Administration (FDA). Sam Peltzman, Chicago Booth emeritus professor, pioneered cost-benefit analysis of the EA in 1973 by estimating the consumer benefit (if any) of curtailing the sale of ineffective drugs and comparing it to the opportunity cost of effective drugs that were not introduced into the US market due to the additional approval costs created by the EA. Peltzman concluded that the EA imposed a net cost on consumers of magnitude similar to a "5-10 percent excise tax on all prescriptions sold."

Passage of the EA led to a post-1962 drop in the introduction of new drug formulas, and Peltzman was challenged to quantify the degree to which the foregone drugs would have been ultimately deemed ineffective by consumers and their physicians. In this new work, Casey B. Mulligan analyzes two drug market events between 2017 and 2021 to offer fresh perspectives on the consumer costs and benefits of the entry barriers created by the FDA approval processes.

In the first case, Mulligan employs a conceptual model of prices and entry to quantify the welfare benefits of the deregulation of generic entry that occurred since 2012, without restricting the values of the price elasticity of demand or the level of marginal cost. Mulligan's review

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Figure 2 • Vaccine-Delay Opportunity Costs According to the Excess Burden Method — Assumed Six-Month Delay

ASSUMED IMPACT OF VACCINE ARRIVAL, %		DELAY COSTS IN $ TRILLIONS		
Private Production	Mortality Cost	Of Reducing Exposure	Equilibrium Mortality	Sum
3	-33	0.51	0.17	**0.68**
3	-50	0.51	0.26	**0.77**
3	-67	0.51	0.35	**0.86**
5	-33	0.85	0.17	**1.02**
5	-50	0.85	0.26	**1.11**
5	-67	0.85	0.35	**1.20**
10	-33	1.70	0.17	**1.87**
10	-50	1.70	0.26	**1.96**
10	-67	1.70	0.35	**2.05**

Note: A full shutdown of nonessential activities is assumed to cost $4.3 trillion per 6 months, including nonmarket opportunity costs and the deadweight costs of relief packages, while reducing GDP by 25.4 percent. The "reducing exposure" column of the table rescales the $4.3 trillion. The full (100%) mortality cost is 250,000 deaths per six months valued at $2.1 million each.

of generic entry data suggests that easing generic restrictions discourages innovation, but that this cost is more than offset by consumer benefits from enhanced competition, especially after 2016.

In his second analysis, Mulligan views the timing of COVID-19 vaccine development and approval through the lens of an excess burden framework to better measure the opportunity cost of regulatory delays, including substitution towards potentially harmful remedies that need not demonstrate safety or effectiveness because they are outside FDA jurisdiction. He finds that the pandemic vaccine approval process, although accelerated during COVID-19, still had opportunity costs of about a trillion dollars in the US for just a half-year delay, and even more costs worldwide.

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ABOUT OUR SCHOLAR

Casey Mulligan
Professor in the College and the Kenneth C. Griffin Department of Economics
economics.uchicago.edu/directory/casey-mulligan

THE KENNETH C. GRIFFIN DEPARTMENT OF ECONOMICS