The Elasticity of Pharmaceutical Innovation: How Much Does Revenue Drive New Drug Development?

Darren Filson, PhD
Karen Van Nuys, PhD
Darius Lakdawalla, PhD
Dana Goldman, PhD

USC Schaeffer
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AUTHOR AFFILIATIONS

Darren Filson is the James G. Boswell Professor of Economics and George R. Roberts Fellow at Claremont McKenna College.

Karen Van Nuys is executive director of the Value of Life Sciences Innovation program at the USC Schaeffer Center.

Darius Lakdawalla is chief scientific officer of the USC Schaeffer Center.

Dana Goldman is co-director of the USC Schaeffer Center and founding director of the USC Schaeffer Institute for Public Policy & Government Service.

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ABSTRACT

Pharmaceutical policy often affects the revenues of innovation-oriented firms. The Inflation Reduction Act of 2022 is the most prominent recent example: It allows Medicare to negotiate price discounts on selected prescription drugs using the overwhelming bargaining leverage of the federal government. These prices will go into effect in 2026. Economic theory suggests that reductions in revenue eventually translate into reduced rates of innovative effort—generally measured using some proxy for research and development (R&D). The question then becomes: How large is the impact? Researchers often measure this effect using the "elasticity" of innovation, which measures the percentage change in a measure of innovation—like Phase 1 trial starts or new drug approvals—that results from a percentage change in expected or actual revenues. We critically review the literature estimating this elasticity, along with alternative estimation strategies (including a study by the Congressional Budget Office). All the studies conclude that the elasticity is positive—i.e., lower revenues lead to less R&D—but estimates vary widely. However, we argue that a typical long-run elasticity associated with U.S. revenues lies within the range of 0.25 to 1.5, implying that for every 10% reduction in expected revenues, we can expect 2.5% to 15% less pharmaceutical innovation. Some caution is warranted, however, as a single elasticity does not apply to all contexts. The magnitude of the elasticity likely varies with time horizon, the magnitude of the price change, the size of the patient population and other marketplace factors.

POLICY IMPLICATIONS

Economic theory suggests that reducing drug spending by lowering drug prices—through regulation or other means—will reduce future medical innovation. A key policy question is: by how much? If the effects are large, price reductions by government fiat could have long-term negative impacts on population health, ultimately diminishing or outweighing the benefits of short-term spending reductions. This debate was pushed to the forefront by the 2022 Inflation Reduction Act's Medicare Drug Price Negotiation program.

We review the economic literature on this topic, with a focus on estimates of the elasticity of innovation, i.e. the percentage change in clinical trials or new drugs approved resulting from a percentage change in expected or actual revenues. We argue that a typical long-run elasticity associated with U.S. revenues lies within the range of 0.25 to 1.5, implying that for every 10% reduction in expected revenue, pharmaceutical innovation falls by 2.5% to 15%. We also review what this evidence means for assessments by the Congressional Budget Office of the Inflation Reduction Act. As policymakers evaluate their options to manage healthcare costs, significant care should be taken to balance reductions in health outcomes long-term with short-term access improvements.

KEY TAKEAWAYS

1. The study examines the "elasticity" of innovation, which measures how responsive innovation (e.g., the number of Phase 1 trials or new drug approvals) is to a change in expected or actual revenues.
2. Economic evidence demonstrates this elasticity is positive—meaning lower revenues lead to less R&D—but estimates vary widely.
3. The long-run innovation elasticity associated with U.S. revenues lies between 0.25 and 1.5, implying that a 10% reduction in expected revenues leads to a 2.5% to 15% decline in pharmaceutical innovation.
4. The magnitude of this elasticity likely depends on the time horizon studied, the size of the price change, cost of drug development, barriers to value-based pricing, and other marketplace factors.

INTRODUCTION

Policy interventions in the pharmaceutical industry often change the expected future revenues and current revenues of innovative firms. Such changes impact firms' anticipated and current profits, and firms respond by adjusting their research and development (R&D) efforts. These adjustments impact discovery research programs, drug-development decisions and, ultimately, the flow of new drugs. The elasticity of innovation with respect to revenues is an important metric that quantifies firms' responsiveness to such policy changes: It measures the percentage change in innovation—using the flow of new drugs approvals, or Phase 1, 2, or 3 starts—caused by a percentage change in revenues, typically expected future revenues. This paper evaluates alternative methods for estimating this elasticity and reviews existing estimates in the literature. Its goals are to distinguish credible methods from non-credible ones, evaluate studies that employ credible methods, and summarize what is known about the typical magnitude of elasticity and factors that impact the magnitude.

This white paper is aimed at PhD-level economists, policy analysts and similar professionals interested or involved in policymaking in the pharmaceutical industry. The paper assumes familiarity with the concept of an elasticity, the basic features of the process of drug development, and features of the industry such as therapeutic classes, on-patent periods and post-expiration generic entry (see Lakdawalla (2018) for a review of these features). We discuss the strengths and weaknesses of alternative estimation techniques in the context of estimating elasticities of innovation. Most of the paper is accessible to a broad audience of researchers and policy professionals, but we delve into technical details in some cases where necessary for interpreting results or guiding future research.

Three primary conclusions are reached:

1. Cross-sectional and aggregate time-series methods are poorly suited for estimating the elasticity of innovation. Credible methods involve panel-data analyses or parameterized computational models.
2. All existing studies employing credible methods have shortcomings that could make a reasonable skeptic question the resulting estimate(s) of the elasticity. Thus, while several studies exist, further work would be helpful.
3. All studies agree that the elasticity of innovation with respect to revenues is positive, but there is considerable variation in its magnitude (see table 1).[1]

However, we argue that it would be reasonable for policymakers to view the typical long-run elasticity associated with U.S. revenues as ranging from approximately 0.25 to 1.5.[2] Moreover, modeling exercises conducted by Abbott and Vernon (2007) and Filson (2012) suggest that the magnitude varies with the time horizon studied, the size of the price change studied, factors influencing the cost of drug development and barriers to value-based pricing (see table 2). Further work on such factors is warranted.

The paper proceeds as follows. Section 2 provides a simple version of a model introduced by Nordhaus (1969) that reveals how future expected profits and current ones are related to innovation. Given that profits cannot normally be observed and that policy changes of interest have more direct impacts on revenues, most empirical work examines data on revenues. We focus on the elasticity of innovation with respect to U.S.

1. While there is universal agreement in the economics literature that the elasticity is positive, some influential figures publishing in other venues seem to argue against a positive elasticity; see Angell (2005).

2. Throughout this paper, we use the term "short-run" elasticity to refer to the initial response that occurs once a response would be expected. Thus, the short-run elasticity of the flow of new drugs in response to an intervention might be measured several years after the intervention, and measuring a "long-run" elasticity might require decades. The long-run elasticity emerges from the initial intervention working its way through the market over a period of time that encompasses multiple generations of R&D projects: An initial intervention impacts revenues, which impacts innovation, which eventually impacts product market competition, which impacts expected profits, which has further impacts on innovation and so on.

revenues, and the model helps clarify why we focus on the U.S.: About 64% to 78% of worldwide pharmaceutical profits derive from the U.S. market (Goldman and Lakdawalla (2018)) and, as a result, we expect that the elasticity of innovation differs substantially in the two regions. Section 3 discusses the shortcomings of cross-sectional methods and aggregate time-series methods for estimating the elasticity of innovation. Sections 4 and 5 discuss panel-data analyses and computational models, respectively. Section 7 concludes with a summary of extant knowledge and recommendations for future work.

2. A SIMPLE MODEL AND ITS IMPLICATIONS FOR EMPIRICAL WORK

We provide a simple version of a model introduced by Nordhaus (1969) that reveals how a firm's R&D spending depends on its current and future expected profits; our exposition draws on Lakdawalla (2018). The model has two periods: The firm chooses how much to invest in R&D in the first period, and the outcome (introducing a new drug to the market or not) is determined in the second. Denote the level of spending by I and the probability of success by $p(I)$. Higher levels of I are associated with a higher probability of success and diminishing returns, so that $p'(I)>0$ and $p''(I)<0$. The firm solves

$$\max_I \left\{-\varphi(I) + \frac{1}{1+r}p(I)\pi\right\} \quad (1)$$

where $\varphi(I)$ represents the cost of investment (which might be lower or higher than I depending on factors such as tax incentives and costs associated with external financing), r is the discount rate ($r>0$) and π is the firm's expected future profit if R&D succeeds (for simplicity, we assume the future profit is zero if R&D is not successful). We assume that the marginal cost of R&D is positive and that it rises (or at least does not fall) with the level of investment ($\varphi'(I)>0$ and $\varphi''(I)\geq 0$); assuming otherwise would be unrealistic, because it would imply that real-world R&D investments could potentially grow without bound. Optimal R&D investment satisfies:

$$-\varphi'(I) + \frac{1}{1+r}p'(I)\pi = 0. \quad (2)$$

This condition implies the following relationships: (1) increases in future expected profits, e.g., from policies that increase pharmaceutical prices, result in higher R&D spending[3]; and (2) increases in *current* profits might also encourage more R&D spending, as long as external financing is costlier to access than internal funds.[4]

Since researchers typically lack good data on profits and since policy interventions of interest typically impact revenues, empirical work usually focuses on revenues rather than profits when estimating elasticities of innovation. Under the reasonable assumption that revenues impact innovation only through their impact on profits, the revenue elasticity of innovation $\frac{\partial I}{\partial R}\frac{R}{I}$ is equal to the profit elasticity of innovation $\frac{\partial I}{\partial \pi}\frac{\pi}{I}$ multiplied by the revenue elasticity of profit $\frac{\partial \pi}{\partial R}\frac{R}{\pi}$:

$$\frac{\partial I}{\partial R}\frac{R}{I} = \left(\frac{\partial I}{\partial \pi}\frac{\partial \pi}{\partial R}\right)\frac{R}{I}\frac{\pi}{\pi} = \left(\frac{\partial I}{\partial \pi}\frac{\pi}{I}\right)\left(\frac{\partial \pi}{\partial R}\frac{R}{\pi}\right) \quad (3)$$

where R is revenues (either expected or actual) and π is the corresponding profits. If marginal costs of production are small relative to prices, then profits and revenues will tend to move together: $\frac{\partial \pi}{\partial R}\frac{R}{\pi}$ will be close to 1,[5] and thus the revenue elasticity of innovation will be similar to the profit elasticity. Other circumstances can also lead to this outcome, such as a constant price elasticity of demand combined with constant marginal costs of production and profit-maximizing pricing decisions—modeling assumptions that are frequently employed when describing markets that are relatively free of intervention by governments (the U.S. in the case of pharmaceuticals).[6]

Three other issues need to be addressed before proceeding. First, the market for pharmaceuticals is global, and the relationship between profits and revenues varies substantially between U.S. and non-U.S. markets. Since most studies in the literature focus on estimating the effects of changes in U.S. revenues, we focus on this effect too. In one case (Dubois et al. (2015)), we need to convert the authors' elasticity to express

3. *The left-hand side of (2) is increasing in π, so if (2) holds initially and then π rises, I must rise to restore the equality.*

4. *Costly external capital is a standard assumption in the finance literature, and Krieger et al. (2022) provide empirical support for the assumption in the context of drug development. If so, current profits can influence φ′ (I). At low levels of I, the firm can rely on its current profit to cover its R&D spending, so φ′ (I) will be relatively low, but beyond some level of I, external financing will be required, and the extra financing cost will cause φ′ (I) to be relatively high. Suppose that, initially, (2) holds and that the firm is using external financing, so φ′ (I) is relatively high. An increase in current profits sufficient to pay for the firm's current level of I will reduce φ′ (I) by removing the need for external funds: The left-hand side of (2) rises, and I must rise to restore the equality. Thus, an increase in current profits can result in more R&D spending.*

5. *Specifically, define the net profit margin as $\eta = \frac{\pi}{R}$. If marginal costs are small relative to revenues, then $\frac{\partial \pi}{\partial R}\frac{R}{\pi} \approx \frac{1}{\eta}$. For instance, if firms retain 90% of revenues as profit, $\frac{\partial \pi}{\partial R}\frac{R}{\pi} \approx \frac{1}{0.9} \approx 1.11$.*

6. *Optimal pricing implies that $\frac{P-c}{P} = -\frac{1}{\varepsilon_p}$, where c is the marginal cost of production and ε_p is the own-price elasticity of demand. Multiply both sides by PQ (where Q is the output level) to obtain $PQ - cQ = -\frac{1}{\varepsilon_p}PQ$; this is $\pi = -\frac{1}{\varepsilon_p}R$. The latter equality (along with the constant-elasticity assumption) implies that $\frac{\partial \pi}{\partial R}\frac{R}{\pi} = 1$, which (using (3)) implies that the revenue elasticity of innovation equals the profit elasticity of innovation.*

it in terms of U.S. revenues; we explain how we do so when we discuss Dubois et al. (2015) in section 4. Second, policy interventions that impact revenues typically impact both expected future revenues and current ones, so an empirical analysis of how R&D spending responds to the policy change may often (although not always) mix the two effects. Thus, we typically refer to the elasticity of innovation "with respect to revenues" rather than distinguishing between expected future revenues and current ones. Third, some studies estimate the effect of price changes on innovation, while others estimate the effect of revenue changes. Studies that estimate price elasticities implicitly build in a prediction for how price will influence revenue. Where necessary, we convert price elasticities of innovation to revenue elasticities of innovation; we explain how we do so in section 5 in the context of the associated papers.

3. KEY SHORTCOMINGS OF CROSS-SECTIONAL METHODS AND AGGREGATE TIME-SERIES METHODS

Cross-sectional empirical methods attempt to exploit variation in revenues across therapeutic classes (or some other unit of analysis) to estimate the elasticity. Roughly speaking, researchers using this approach would compare innovation in "high-revenue" classes to innovation in "low-revenue" classes and infer the elasticity from this comparison. Cross-sectional analyses of pharmaceutical innovation include Lichtenberg (2005) and Civan and Maloney (2009). In contrast, aggregate time-series methods would attempt to exploit variation in industry-level revenues over time to estimate the elasticity; Giaccotto, Santerre and Vernon (2005) conduct a study of this type. We argue that panel-data analyses and parameterized computational models are better suited for estimating elasticities of innovation than these alternative approaches.

Cross-sectional methods have two primary shortcomings in this context. First, several hard-to-measure, nonrevenue factors contribute to different levels of innovation across classes, and many of these factors are correlated with revenues. Excluding these factors or mismeasuring them may bias the elasticity estimates. For example, some drug classes may feature more technological opportunities that make innovation easier, resulting in both more drug discoveries and higher revenues. Comparing a class like this to a counterpart with fewer technological advantages would mistakenly attribute differences in innovation to revenues, when in fact the cause is different technological possibilities. More generally, cross-sectional studies lack effective controls for differences in technological opportunities or other class-level characteristics that drive both innovation and revenues. Second, even when variables can be measured well, cross-class comparisons may not be meaningful. For example, Civan and Maloney (2009) explore the link between the number of drugs in development in a class and the average U.S. price of existing on-patent drugs treating those diseases, but it is not clear how to measure prices to facilitate comparisons across classes, and the estimates are wholly reliant on such comparisons.

In contrast, panel-data analyses can include drug-class "fixed effects" to absorb and net out hard-to-measure and persistent differences in class characteristics.[7] In effect, such an approach focuses on within-class revenue change as a driver of within-class innovation change. As long as technological opportunities and other class-level factors remain constant over time, this approach will properly net such factors out of the resulting estimates. Naturally, factors that vary over time within a class continue to pose problems— e.g., if some classes suddenly experience a burst of technological opportunity at a point in time, this approach will fail to net out this change within the class. For this reason, panel-data analyses are often combined with the use of "natural experiments" that change revenue differently across different segments of the market. Examples of such experiments are demographic trends like aging that raise demand for treatments of disease associated with old age (Acemoglu and Linn (2004); Dubois et al. (2015)) or policy changes like Medicare Part D (Blume-Kohout and Sood (2013)). Another approach to solving the problem of confounding cross-sectional variation is a computational model built upon explicit analysis of technological opportunities, the demand for new drugs, institutional features of the marketplace, and other variables that can plausibly drive both innovation and revenues. This approach is often referred to as "structural modeling" because it explicitly specifies and estimates the underlying structure of firms' profit functions and consumer preferences.

Aggregate time-series analyses fare little better than cross-sectional analyses for at least two reasons. First, there is no natural control group for interventions, making such analyses vulnerable to coincidental time trends. For example, if technological breakthroughs in drug-discovery methods happen to coincide with increases in the demand for drugs, an aggregate time-series analysis would mistakenly see these two unrelated trends solely as the effect of higher revenues on innovation rates. Panel-data analyses usually feature control groups and natural experiments to root out this problem. They

7. For estimating within-class impacts across time, price comparisons could potentially be meaningful (if prices could be measured well), but in cross-sectional analyses, different classes are associated with different health outcomes and production costs: Comparing prices across classes is comparable to comparing prices across different types of clothing (shirts, pants, shoes, etc.). Of course, issues can remain even in panel-data analyses if the analysis focuses on prices. Obtaining accurate pricing data is challenging for all types of empirical analyses because net prices (the prices actually paid) can differ substantially from list prices. Net prices for on-patent drugs are trade secrets and are difficult to estimate. This challenge helps explain why empirical work tends to focus on revenues.

focus on a well-understood and narrowly defined change in revenue for some classes of drugs. The causes of such a revenue change can be identified and shown to be plausibly unrelated to other trends in innovation. On the other hand, structural models address this problem by enumerating and modeling variables that cause trends in both revenue and innovation.

Second, in an aggregate time-series analysis, the only way to increase the sample size is to extend the sample to include earlier years, but then one needs to consider whether observations from 50+ years ago provide useful insights into empirical relationships in the current environment. Technologies, approaches to innovation, R&D tax incentives, Food and Drug Administration regulations and other business conditions have changed substantially over time.[8] In contrast, in a panel-data analysis, the sample size is determined partly by the number of therapeutic classes included: Following 100+ classes for a relatively short period of time yields a substantial sample size. Structural models also permit modeling different therapeutic classes and business environments.

4. PANEL-DATA ANALYSES

Panel-data analyses follow multiple therapeutic classes over time; the analyses combine a cross-sectional dimension (the classes) with a time-series dimension (the time period). Many contemporary panel-data analyses also feature a quasi-experimental design to identify the effects of interest. Panel-data analyses are well-suited for the pharmaceutical industry because classes are appropriate units of analysis: Most R&D programs and innovations focus on particular classes, and product-market competition occurs primarily within classes. Panel-data analyses permit including class fixed effects and across-class period effects in the model: The first control for persistent differences across classes in multiple hard-to-measure variables, including technological opportunities, production costs, distribution costs, marketing costs and other factors; and the second control for differences over time in the macroeconomic or industry-level business environment.

Acemoglu and Linn (2004)

Panel-data analyses also facilitate examining plausibly exogenous changes in revenues or related variables within classes over time by using quasi-experimental or natural experiment designs. For example, Acemoglu and Linn point out the challenge of reverse causality: Because innovations tend to expand the size of the market and thus expand revenues, too, this makes it difficult to estimate the elasticity of innovation with respect to market size. To address this challenge, Acemoglu and Linn exploit variation in market size driven by U.S. demographic changes to attempt to isolate exogenous changes in U.S. market size. They construct age profiles of users for each drug category, assume these profiles do not change over time, and then use changes in the age and income distributions over time to estimate changes in what they refer to as "potential market size."[9] They consider current potential market size and five-year leads of this variable. The panel includes 33 drug categories examined from 1970–2000. Innovation is measured using the flow of new drugs, and results are reported for all drugs (including generics), all nongenerics (including new indications) and new molecular entities (NMEs). The last category corresponds best to innovation. They find that the elasticity for all new drugs with respect to potential market size is approximately 6, the elasticity for nongenerics is approximately 4 and the elasticity for NMEs is 4–6 (Acemoglu and Linn, p. 1051); the reported values are based on point estimates. These elasticities imply that revenue changes have large effects. For example, an elasticity of 4–6 implies that when the potential market size decreases by 10%, the number of NMEs falls by 40%–60% (we discuss the plausibility of such effects shortly).

One aspect of the Acemoglu and Linn findings raises some questions: They find much stronger effects of current revenue on current innovation than of expected future revenue on current innovation. Compared to other studies that focus explicitly on expected future revenues, Acemoglu and Linn may be estimating effects along a different axis of variation.

Blume-Kohout and Sood (2013)

Panel data also facilitate data-driven approaches to measuring the impact of policy changes and other interventions: The extent to which a policy influences revenues in a class determines the extent to which the class can be viewed as belonging to a "treatment" group or a "control" group. For example, Blume-Kohout and Sood note that Medicare Part D increased prescription drug use among seniors and would have greater impact on classes such as Alzheimer's disease than on classes such as contraceptives. The introduction of Medicare Part D is a plausibly exogenous intervention (i.e., not driven by innovation) that impacts revenues, so it potentially facilitates estimating the elasticity of innovation with respect to revenues. The associated act—Medicare Prescription Drug, Improvement, and Modernization Act—was passed in 2003, and implementation began in 2006. Annual data from 49 classes during 1998–2010 is employed, and fixed effects are

8. Increasing the sample size by examining quarterly or higher-frequency data is inappropriate because pharmaceutical innovation takes years, not months or weeks.

9. The authors use the term "category" to refer to a collection of therapeutic classes.

employed to account for persistent differences across classes.

Blume-Kohout and Sood find that the passage and implementation of Medicare Part D is associated with significant increases in R&D (and new drug launches) for classes with high Medicare market shares. Time lags are relevant because of the time it takes to move through the phases of clinical trials. The estimated elasticity of Phase 1 clinical trials that starts with respect to revenues is 2.4–4.7 (Blume-Kohout and Sood, p. 335). The range of estimates corresponds to different time periods: The number of drugs entering Phase 1 increased 26% during 2004–2005 versus expected trends prior to the policy change. By 2006–2007, the increase was 33% versus expected trends and by 2008–2010 it was 51%. They also report an elasticity of global new drug launches with respect to revenues of 2.8 in the period 2008–2010 (Blume-Kohout and Sood, p. 334).

Dubois et al. (2015)

Turning to another panel-data analysis employing an instrumental-variables approach similar to the one used by Acemoglu and Linn, Dubois et al. find a lower elasticity: Their preferred point estimate is 0.23 (p. 844). Notably, they examine global revenues, and profit margins are substantially higher in the U.S. Therefore, a given change in global revenue may have more muted effects on innovation than a similar change in U.S. revenue. At the extreme, the elasticity of innovation with respect to non-U.S. revenues could be zero or close to zero. Their point estimate combines the U.S. and non-U.S. effects. They report that the U.S. accounts for approximately 40% of industry revenues. Using a 40% weight, the lower bound on the U.S. elasticity is .23 (under the assumption that the U.S. elasticity equals the non-U.S. one), and the upper bound is .58 (under the assumption that the non-U.S. elasticity is zero).

An additional aspect of the research design in Dubois et al. is notable as both a strength and a weakness. They compute the expected net present value of revenues to explicitly measure expected future revenues as the driver of current innovation. This may help explain, for instance, why their parameter departs from Acemoglu and Linn, who use a very similar natural experiment. However, this approach also has a downside: To compute long-run future revenues, they are forced to impute a meaningful amount of their data. Specifically, they observe revenues during the period 1997–2007, and they use available data to compute average yearly rates of change in revenues by product age. Then they use the average yearly rates of change to impute revenues out of sample backward in time for each drug to generate up to a 20-year life cycle for each drug; these data are employed to estimate expected market size over the period 1977–2007. Thus, estimating the elasticity of interest relies heavily on imputed data that pertain to 1977–1996 (for each drug, from nine to 19 of the 20 years of revenues data are imputed). If the measurement error associated with imputation is classically random, their imputation would not be cause for concern in a sufficiently large sample (the authors examine 630 active ingredients).[10] However, the analysis cannot assess whether the measurement error is random, and nonrandom measurement error could potentially bias the estimated elasticities toward zero.

Panel-Data Analysis Summary

Taken at face value, the estimates of Acemoglu and Linn and Blume-Kohout and Sood suggest the elasticity of innovation with respect to revenues is substantially higher than 1: The point estimates are approximately 5 and 2.8, respectively. Meanwhile, Dubois et al. offer a range of .23 to .58.

We can narrow the range somewhat by clarifying several differences among the studies. First, Acemoglu and Linn estimate the effect of "potential" market size (i.e., revenue), but their measure likely differs from the market size firms actually anticipated during the period of their study. Acemoglu and Linn note that a 1% increase in their measure of potential market size corresponds to a 4% increase in actual size. Thus, the implied elasticity with respect to actual market size is 1–1.5 rather than 4–6, which is substantially closer to Dubois et al., albeit still meaningfully different. Another potential concern is that Acemoglu and Linn do not include biologic drugs in their analysis. During the period they analyze (1970–2000), biologics became increasingly important in the flow of new drugs.

Blume-Kohout and Sood's results should also be interpreted in the proper context. Their elasticities represent short-run impacts in the sense that the timing of impact is associated with the first generation of Phase 1 starts and new drug introductions impacted by the policy change. As these projects and products mature (over the course of many years), there will be subsequent impacts on future generations of projects. As discussed in the next section, short-run impacts may be larger than long-run ones.[11]

Finally, it is worth noting that not all policy interventions that impact revenues lend themselves to estimating the elasticity of innovation. Examples from Finkelstein (2004), which involve vaccines rather than prescription drugs, provide useful illustrations. A 1991 recommendation from the Centers

10. The authors employ instrumental variables, so classically random measurement error would not introduce asymptotic bias into their estimates.

11. In contrast, Acemoglu and Linn (2004) and Dubois et al. (2015) focus on how firms respond to long-run actual and anticipated trends in market size; their estimates are reasonably interpreted as long-run elasticities.

for Disease Control and Prevention that all infants receive the hepatitis B vaccine resulted in vaccination rates jumping from essentially zero to 90% over a decade. While revenue clearly increased, the concept of an elasticity is of limited use because going from zero to anything positive is an infinite percentage increase. Hepatitis B vaccine clinical trial starts experienced a finite percentage increase (from 1.25 starts per year in 1983–1986 to 3.25 per year in 1996–1999), so the corresponding elasticity is zero. One can potentially compute an arc elasticity (the arc elasticity is .44 in this case), but arc elasticities are the subject of many criticisms (see Phillips (1993) for a discussion of the various critiques that have been levied), including the problem that the arc-elasticity concept admits many different possible elasticity calculations that cannot be tested against each other.[12] For another example, a 1993 decision that Medicare would cover 100% of the cost of the flu vaccine for Medicare recipients potentially impacted flu vaccination rates: Flu vaccination rates were approximately 50% prior to the policy change and increased from zero to 15 percentage points after the intervention. However, clinical trial starts per year experienced an infinite percentage increase (from zero starts in 1983–1986 to three in 1996–1999). Thus, once again, computing an arc elasticity is the only option: If we assume an increase in the vaccination rate from 50% to 57.5%, the arc elasticity is 14.33.

5. PARAMETERIZED COMPUTATIONAL STRUCTURAL MODELS

Panel-data analyses are clearly useful for estimating elasticities of innovation, but they have multiple shortcomings. Perhaps the most famous is the one attributed to Robert Lucas (the "Lucas critique") that changes to the policy environment can substantially alter the way firms and consumers respond, leading to different relationships among economic variables of interest (Lucas, 1976). Parameterized computational models (sometimes also referred to as structural models, as noted earlier) address the Lucas critique and facilitate insights that can be difficult or impossible to obtain any other way. Structural models specify firms' objective functions, strategy sets and features of the business environment, and when the model includes multiple firms, the model typically requires that the market is in equilibrium. The parameters are selected so that the key inputs and outputs of the model match facts such as the average R&D expenses associated with bringing a new drug to market and the average flow of new drugs. The impacts of policy interventions or other changes in the business environment are relatively straightforward to consider: The researcher can change one or more parameters and observe how firms' choices and market outcomes change in response.

Interventions that have no precedent in history (e.g., no matching "natural experiment") can be difficult to study using reduced-form approaches but are relatively straightforward to examine with an appropriate structural model. For example, suppose that revenues in a class during a sample period fluctuate between a lower bound of R_L and an upper bound of R_U. A researcher employing panel-data methods will use the available variation in revenues to estimate the elasticity of interest. Suppose the researcher is interested in examining the implications of an intervention that will reduce revenues well below R_L. This amounts to an out-of-sample projection, and it is well-known that regression coefficients need not remain stable out of sample. Given this, reasonable skeptics are unlikely to be persuaded by a regression-based analysis of the intervention. In contrast, parameterized computational models emphasize structural parameters that are less likely to depend on levels of revenues (parameters of cost functions and utility functions, technical probabilities of success in R&D and so on). The models also ensure that the responses of firms (and thus market outcomes) are compatible with the behavioral rules of the model (which can include an assumption that firms maximize their values along with a requirement that the market is in equilibrium). The models are potentially better suited than reduced-form regressions for evaluating the implications of substantial interventions that lack historical precedents.

Another key advantage of structural models is that they can easily incorporate forward-looking decision-making: Expected future values can drive choices. While it is possible to incorporate such values into reduced-form panel-data regressions, regression-based approaches typically model outcomes as functions of current or lagged values of the independent variables.

Abbott and Vernon (2007)

For an example of a structural approach, Abbott and Vernon use Monte Carlo techniques to model how U.S. price controls would impact Phase 1 starts. Firms base their decisions on net present value (NPV). Projects are heterogeneous, and the range of possible parameter values is determined using estimates from the literature of development costs by phase, probabilities of success by phase and future revenues (along with variation in these across projects).

Abbott and Vernon focus on the impacts of price reductions on Phase 1 starts. Price elasticities are smaller than revenue elasticities because demand is downward sloping: A given percentage change in price leads to a smaller percentage change in revenue because the output adjustment offsets the price change. Abbott and Vernon assume the price elasticity of

12. The arc elasticity uses two points to compute the elasticity of y with respect to x: $\{x_0, y_0\}$ and $\{x_1, y_1\}$. The typical formula is $\frac{y_1-y_0}{(y_1+y_0)/2} \Big/ \frac{x_1-x_0}{(x_1+x_0)/2}$.

demand (in the U.S. market) is -.3. They base this on Coulson and Stuart (1995), but more recent work finds similar point estimates: Duggan and Scott Morton (2010) estimate -.38 and Einav et al. (2018) estimate the elasticity of branded drugs is -.32 and class-level elasticities range from -.32 to -.26. Thus, a 10% U.S. price increase yields a roughly 3% decrease in U.S. demand, so U.S. revenues rise by 7%: U.S. price elasticities should be divided by .7 to convert them to revenue elasticities.

Abbott and Vernon's figure 6 shows the relationship between different percentage changes in prices and percentage changes in Phase 1 starts. Higher price reductions are associated with higher elasticities. Interpreting the figure suggests that the price elasticity for large price reductions (40%–50%) is close to 1, which suggests the revenue elasticity is 1.4. The price elasticity for small price reductions (10%–25%) is much lower; it is perhaps .4, which suggests a revenue elasticity of approximately .6.

Structural models require multiple assumptions about the structure of underlying incentives in an economy, and a reasonable skeptic could question several such assumptions. For example, Abbott and Vernon assume that R&D costs and the resulting revenues of products are uncorrelated, and it could be more realistic to allow nonzero correlations. However, there are good reasons to think that the basic conclusion that elasticities are increasing in the magnitude of the price reduction is robust. If future U.S. prices are initially expected to be profit-maximizing choices of price-setting firms, then small reductions in price should not affect future expected profits. Thus, a very low-impact price cap is likely associated with a low or zero price elasticity of innovation. Now consider a substantial price cap that is expected to drive future prices down to marginal cost: Expected profits go to zero, so innovation halts. Prices do not drop 100% (because marginal cost is positive), but innovation drops 100%, so the short-run price elasticity of innovation exceeds one.

Abbott and Vernon's results illustrate how the elasticity of innovation with respect to U.S. revenues depends on the size of the revenue reduction, but it also seems likely that—for large percentage changes in revenues—the elasticity depends on the direction of the revenue change: A less than 100% price reduction can potentially drive profits to zero, but a less than 100% price increase would not have as large a percentage impact on increasing profits.

Filson (2012)

While Abbott and Vernon focus on single-firm, single-project decision-making, Filson constructs an infinite-horizon, computable, dynamic, industry equilibrium model of pharmaceutical R&D and oligopoly product-market competition at the level of a therapeutic class. The model is parameterized so that equilibrium outcomes match facts such as the average R&D expenses and probabilities of success associated with bringing a new drug to market, the average flow of new drugs in a class and the distribution of new-product values (Filson, table 2). The resulting parameterized structural model is used to examine alternative price-control policies (price controls are modeled as upper bounds on prices firms can charge that might depend on product characteristics or features of the business environment).

In a base-case scenario, the long-run elasticity of innovation with respect to revenues is approximately one.[13] This long-run impact occurs over multiple decades. The analysis in Filson suggests that the short-run elasticity likely exceeds the long-run one. To understand why, consider a thought experiment where expected revenues rise. Firms initially respond by increasing their R&D efforts. Subsequently, however, this initial burst of activity discourages R&D, because rational firms will realize that the initial burst will lead to more competition and lower future profits (of note, firms in Filson's model forecast the degree of competition they will likely face). Thus, the subsequent response dampens the initial burst of R&D and thus lowers the long-run effect of the initial growth in revenue.[14]

When a policy change—such as the introduction of Medicare price negotiations—occurs in Filson's model, the preexisting number of drugs in development is likely far from the long-run mean levels associated with the post-

13. This conclusion emerges from Filson's table 6: A 10% increase in the patient population leads to a 10% increase in revenues in the long run, and this change is associated with an approximately 10% increase in the flow of new drugs over the long run.

14. Technically oriented readers might find some additional details helpful, and Filson provides further elaboration. The model is set in discrete time with six-year periods. Successful research programs during this period yield candidates in development during the next period, and successful candidates in development during this period yield marketable on-patent products during the next period. On-patent products engage in differentiated-products Bertrand competition for two periods before the patent expires, so the product market potentially contains "young" products in the first period of their market life and "old" ones in the second period of their on-patent market life. Firms are forward-looking value maximizers, so they look ahead to anticipate the competition from old products they will face when they enter the product market and adjust their research-project starts accordingly. Thus, if the number of drugs in development is currently above its long-run mean, forward-looking value-maximizing firms contemplating beginning research programs anticipate high competition from old products in future product markets and, in response, they pursue fewer new research projects (relative to the long-run mean). Outcomes are random, but pursuing fewer projects tends to eventually result in levels of drugs in development (and eventually, new drugs on the market) that are below the long-run average. Thus, a relatively high number of old products tends to be associated with a relatively low number of young ones. Similarly, if firms anticipate a relatively low number of old products when they enter the product market, there will likely be a relatively high number of young ones. Thus, over time, the levels of R&D spending, projects in development and new drugs move toward their long-run mean levels, but they do so through fluctuations around the long-run means that tend to diminish over time.

change environment, so research efforts adjust substantially in response: The initial short-run response exceeds the eventual long-run impact. An adjustment process of this sort has implications for studies such as Blume-Kohout and Sood: They are observing the short-run change in innovation that follows the passage of Medicare Part D; at the time of their paper, there was insufficient data to gauge the long-run response. In general, evaluating long-run responses requires an approach that facilitates examining projects that are well beyond the sample period because, in this industry, such responses take decades.

As an example of the short-run versus long-run magnitude, Filson considers a scenario in which all countries abandon price controls. The average number of research programs almost triples initially (a 200% increase) and then settles down to approximately 50% above its pre-intervention level (Filson, p. 124). Thus, in this case, the short-run elasticity is approximately four times the long-run one.

Filson's study also points to other factors that cause the elasticity of innovation with respect to revenues to vary by class. For example, in classes with small patient populations or fewer technological opportunities to develop new drugs, U.S. price controls can lead to a complete halt in innovation in the model. The intuition is that such classes attract relatively few R&D efforts even in the base case, so a revenue-lowering intervention can deter all efforts. This idea comports with the panel-data analysis of Dubois et al., who also find substantial variation in elasticities across therapeutic classes.

The Filson model also reveals the underlying forces that influence the magnitude of the innovation elasticity. First, barriers to entry in drug development reduce the elasticity. In the model, if there are high barriers to entry in R&D in a class (perhaps because of highly specialized know-how contained in only a few firms), firms earn abnormal profits (and achieve abnormal firm values) prior to U.S. price controls being imposed. In this case, relatively small price reductions need not impact R&D choices at all: All projects can remain viable even though expected revenues fall. Thus, the revenue elasticity of innovation in such cases would be zero. Of course, large price reductions could have substantial effects even in such cases. Whether such barriers to initiating R&D programs are empirically important—and which classes they impact—are questions future research could investigate.

Filson's analysis also suggests that nuances of the intervention could impact the elasticity: Different policies could yield different elasticities. For example, Filson compares U.S. price controls that permit higher markups on higher-quality products to controls that do not and concludes that the latter reduce innovation more.

Of course, no modeling effort can exhaust all possible scenarios, and models with different plausible assumptions could potentially generate different elasticities. While Filson's analyses reveal several nuances of impacts (such as short-run versus long-run ones), circumstances and other factors that future empirical work should consider, future modeling efforts could potentially reveal additional factors.

Adams (2021)

In more recent work, Adams describes a structural model employed by the Congressional Budget Office (CBO). Adams analyzes a policy that lowers the expected present value of drugs expected to be in the top quintile of the distribution of the expected present value of profits by 15%–25%; this intervention results in a persistent 18% reduction in expected industry profits.[15] The analysis concludes that there would be little immediate impact on the flow of new drugs (as altered R&D decisions take time to impact the flow of new drugs), but there would be an 8% annual reduction in the flow of new drugs by the third decade. The implied long-run elasticity with respect to expected product-market profits is approximately .45. For evaluating the impacts of U.S. price controls or comparable revenue-lowering policies, the elasticity with respect to profits provides a lower bound on the elasticity with respect to revenues.[16]

Other features of the CBO's model help explain why the estimated elasticity of innovation is lower than the ones obtained by Abbott and Vernon and Filson.[17] First, the CBO's model restricts attention to the decisions to begin Phase 1, Phase 2 and Phase 3 clinical trials, and policy changes are assumed to have no impact on preclinical discovery research. In contrast, in Filson's model, policies have their most substantial direct impacts on discovery research. Once discovery research has yielded a candidate for development (a potential Phase 1 start), the option to pursue the candidate is typically worth taking because discovery costs are sunk and initial hurdles have been overcome.[18] Thus, ignoring impacts

15. Adams uses the term "expected returns" to refer to product-market profits; we refer to profits to maintain consistency with the rest of this paper.

16. As we have already discussed, a 100% reduction in profits can be achieved with a less than 100% decrease in prices because marginal costs of production and distribution are not zero. Thus, a given profit elasticity of innovation is associated with a higher price elasticity of innovation, which implies a higher revenue elasticity.

17. Philipson and Durie (2021) provide related critiques of the CBO's work in this area.

18. Firms in Filson's model begin research programs until the NPV of the marginal research program reaches zero. Policies that reduce expected future revenues drive this NPV below zero, so fewer research programs are pursued. Candidates in development in Filson typically have NPVs substantially above zero, so only extreme reductions in expected future revenues make candidates unworthy of pursuit.

on discovery research results in a lower estimate of the elasticity of innovation; it essentially assumes that the flow of potential candidates that could begin Phase 1 is unaffected by the policy change.

Second, the policy considered by Adams is assumed to impact only those firms whose expected present values of product-market profits lie in the top 20% of the distribution of expected present values of profits. Real-world policies do not target firms this way because it is not feasible to do so: Real-world policies directly impact prices or revenues rather than profits, and they impact realizations rather than expectations. The distinction between realizations and expectations matters, because a policy that impacts the top 20% of the revenue distribution impacts the expected revenues of all firms with any chance of ending up in the top 20%, and this is a much larger set than those whose expected revenues lie in the top 20% (it includes all of this latter group but also includes many others whose expected revenues are not in the top 20% yet have some chance of ending up in the top 20%). A more plausible policy intervention would likely yield a higher estimate of the elasticity of innovation.[19]

Third, the model lacks rational expectations: When entering a new phase, firms obtain new random "draws" of expected future product-market profits and R&D costs that are independent of their prior draws, but firms' decision-making fails to take this sequence of random draws into account. For example, firms contemplating beginning Phase 1 base their decision on their current draws of expected profits and R&D costs without realizing their information will be invalid once they begin Phase 2. Rational forward-looking optimizers would realize that their current information will be invalid beyond Phase 1; they would anticipate new draws at the start of Phase 2.[20] Under more realistic assumptions, a policy that impacts any part of the revenue distribution would affect all firms' forecasts and hence their current decisions. The resulting elasticity of innovation would be higher.

Another issue worth raising about the policy analysis in Adams is associated with the challenges of measuring innovation using the flow of new drugs. Not all new drugs have equal impacts on welfare. Policies that target the top 20% of the distribution of expected present values of profits target the drugs that are mostly likely to be widely prescribed and have the most substantial impact on health. Reducing the flow of these drugs likely has a much larger welfare impact than reducing the flow of more typical drugs. Analyzing the impacts of a policy that targets the top 20% of the distribution by measuring innovation using impacts on the flow of new drugs without adjusting for quality of the drugs is inappropriate. Filson provides an analysis (within the context of his model) showing that policy interventions that fail to take quality into consideration can have particularly devastating impacts on innovation and welfare.

Summary of Structural Models

The elasticity estimates from the structural models in the literature are generally in the same range as the estimates from panel-data analyses. The rough concordance is encouraging and suggests that panel-data analyses may not be undermined by the Lucas critique.

Moreover, the structural models complement the panel-data analyses by revealing key factors that influence the magnitude of the elasticities observed. As summarized in table 2, Abbott and Vernon point out that large price reductions lead to larger elasticities of innovation and vice versa. Filson finds that the following factors increase the elasticity of innovation: high R&D costs, small patient populations (e.g., in orphan disease), low technological opportunities to develop new drugs, low barriers to entry in R&D, barriers to value-based pricing that allow firms with higher-quality drugs to be compensated accordingly and shorter time horizons.

SUMMARY OF THE LITERATURE AND NEXT STEPS FOR RESEARCH

Table 1 provides a summary of the elasticity estimates from credible studies. The table focuses on changes in U.S. revenues; we would expect non-U.S. revenue changes to be associated with lower elasticities. The table also briefly summarizes the method employed and the primary potential concerns associated with the study.

We argue that the weight of the evidence in table 1 (along with the interpretations of the studies we have provided) suggests that the typical long-run elasticity likely falls between 0.25 and 1.5. This conclusion results from characterizing Blume-Kohout and Sood as focusing on short-run effects (which Filson's analysis suggests are likely higher than long-run ones), interpreting Acemoglu and Linn's results using

19. A simplified model provides an illustration of how a more realistic policy could have a larger effect. Suppose there are two possible revenue levels: R_h and R_l, where $R_h > R_l$. Suppose some firms are sure to earn R_h, but others have an equal chance of earning R_h or R_l (their expected revenue is $\frac{R_h+R_l}{2}$). A policy that targets those with expected revenue of R_h would impact only the first group, but a (more realistic) policy that targets all those who end up earning R_h impacts the expected revenues of both groups.

20. If firms were rational optimizers, the conditional expectation in Adams' equation 2 (p. 6) would be an unconditional expectation. Under rational expectations, a firm contemplating beginning Phase 1 or 2 would know that its current information has no value for predicting its eventual product-market profits or the development costs associated with future stages.

actual market size rather than their measure of potential market size, and adjusting Adams' estimate upward to reflect our discussion in section 5 (the elasticities from Abbott and Vernon are centered around one, and Filson finds a typical long-run elasticity of one). The range of variation is not trivial, but it provides a useful interval for assessing the risks and benefits of public policy. Abbott and Vernon and Filson suggest that several factors impact the magnitude of the elasticity (see table 2).

Future work should employ careful research designs, critical evaluations of assumptions and intermediate findings, and multiple robustness checks. Parameterized computational models will likely remain useful complements to panel-data analyses. Parameters or relationships that are difficult to estimate or examine empirically can be explored in models through alternative assumptions, and appropriately designed models make it possible to consider both short-run and long-run impacts of interventions. The factors impacting the elasticity identified by Abbott and Vernon and Filson can help guide future work, and further work exploring such factors is warranted.

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Table 1. Implied Elasticities of Innovation With Respect to U.S. Revenues

The table restricts attention to studies that employ panel-data analyses or parameterized computational models. The elasticities are based on the point estimates reported in the studies cited; we report a range of point estimates when the study emphasizes a range. Where necessary, we have converted the estimates in the study to express them as an elasticity of innovation with respect to U.S. revenues.

Panel-Data Analyses

Study	Implied Elasticity	Method	Primary Potential Concerns
Acemoglu and Linn (2004)	4 -6 for "potential market size"; 1-1.5 for "actual market size"	A panel-data analysis attempts to control for endogeneity of market size using a measure of "potential market size."	Actual size and potential size are very different from each other, and this results in very different estimated elasticities.
Blume-Kohout and Sood (2013)	2.8; this is a short-run elasticity	The analysis assesses how Medicare Part D impacts R&D efforts in classes with high Medicare market shares.	The estimate is a short-run elasticity; the analysis in Filson (2012) suggests the long-run elasticity could be much lower. Also, results might not generalize beyond the Medicare Part D policy change.
Dubois et al. (2015)	.23-.58	A panel-data analysis attempts to control for endogeneity of market size.	A large amount of the data associated with estimating market size is imputed, and imputed data potentially introduces nonrandom measurement error that could bias the estimates toward zero. The study also does not focus on the U.S.; it uses global data.

Computational Models

Abbott and Vernon (2007)	1.4 for price reductions of 40%–50%; .6 for price reductions of 10%–25%	A parameterized model of firm-level NPV-based Phase 1 starts facilitates examining policy changes.	The model ignores competitive interactions, and key parameters that impact counterfactuals cannot be estimated (for example, development costs and revenues are assumed to be uncorrelated).
Filson (2012)	1 in a benchmark case; the short-run elasticity exceeds 1, and results depend on circumstances	A parameterized computational dynamic industry equilibrium model facilitates examining policy changes.	The model is more useful for revealing what can happen under different structural assumptions and hypothesized circumstances than for isolating a single representative elasticity.
Adams (2021; CBO study)	≥.45	A parameterized model of Phase 1, 2 and 3 starts facilitates examining a policy change that targets highly profitable drugs.	Several of the modeling assumptions bias the estimated elasticity toward zero.

Table 2. Factors That Structural Models Suggest Increase the Elasticity of Innovation With Respect to U.S. Revenues When U.S. Price Controls Are Imposed.

Source	Factors That Increase the Elasticity of Innovation
Abbott and Vernon (2007)	Large price reductions
Filson (2012)	High R&D costs Small patient populations Low technological opportunities to develop new drugs Low barriers to entry in R&D Controls that do not allow firms with higher quality to obtain higher markups The horizon being examined: The short-run response exceeds the long-run one

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Leonard D. Schaeffer Center
for Health Policy & Economics

Stephanie Hedt
Director of External Affairs
Schaeffer Center for Health Policy & Economics
University of Southern California
hedt@usc.edu
213.821.4555