Estimating the Cost of Industry Investment in Drug Research and Development: A Review of Methods and Results

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Abstract
Research and development (R&D) costs factor into considerations of the tradeoffs between prices, intellectual property protection, and incentivizing innovation, all of which can have implications for policy development. Yet, there is little consensus on the actual cost of R&D for new drugs. We review and synthesize papers estimating drug R&D costs incurred by industry. We find a substantial range of per-drug costs, from $113 million to just over $6 billion in 2018 dollars. This range includes estimates covering all new drugs, new molecular entities, and drugs in specific therapeutic classes. The range is narrower—$318 million to $2.8 billion—for estimates of the per-drug cost for new molecular entities. We discuss the data sources, methods, and assumptions used in each study to provide context for the wide range in existing estimates. Differences in definitions, methods, and assumptions lead to large divergences in the main estimates, and the combination of fragmented data sources and different assumptions across studies means that the resulting estimates that can rarely be directly compared. We suggest areas for future research and data collection that would result in more comparable and robust estimates to inform ongoing policy discussion.

Keywords
Drug costs, pharmaceutical preparations, policy making, data collection methods, research, industry, prescription drugs

What do we already know about this topic?
It is unclear whether current levels of investment in drug R&D and the resulting number of new drugs are close to socially optimal levels and uncertain how lower U.S. prices would affect R&D investment decisions.

How does your research contribute to the field?
There is a substantial range—from $113 million to just over $6 billion—in current estimates of drug R&D costs, resulting from different data sources, data samples, and methodologies used across studies.

What are your research’s implications toward theory, practice, or policy?
Future research should prioritize estimating key components where researchers currently have little information, including preclinical costs, cost of capital, and costs per specific R&D projects. Standardized data infrastructure for collecting R&D cost and activities could improve transparency and comparability of estimates across studies.

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**Introduction**

Investments in pharmaceutical research and development (R&D) lead to discovery of new drug candidates, progression of promising candidates through preclinical and clinical development, and, for drugs ultimately approved, post-approval studies. Firms investing in drug R&D weigh expected costs vs returns when making R&D investment decisions. Without the promise of sufficient returns, firms may invest too little in innovation from a social perspective or may not invest in the projects with the highest potential welfare gains. As a result, the U.S. and other governments invest directly in R&D and reward some successful R&D efforts—like those resulting in new drugs—with periods of monopoly pricing power through patents and regulatory exclusivity.

Discussion on the magnitude of investments in R&D vs returns to drug developers has intensified in the United States over the past year due to new policy proposals to regulate drug prices. Proponents of these proposals point to considerably lower drug prices in other countries compared to those in the United States, as well as the health and financial implications of expensive prescription drugs on patients, to justify the need for lower prices. Others argue that price controls will stymie investments in drug R&D, leading to fewer novel treatments in the future. Some recent policy proposals to regulate drug prices even argue that prices should be informed by the magnitude of investments in R&D.

However, it is unclear whether current levels of investment in drug R&D and the resulting number of new drugs are close to socially optimal levels. Furthermore, how lower U.S. prices would affect R&D investment decisions is uncertain and difficult to quantify. An accurate understanding of the current magnitude of R&D investments, overall and for specific drugs, is crucial to inform these discussions.

The trade-offs between the magnitude of resources invested in drug R&D and returns to manufacturers and society are also highly relevant given the current efforts through which the United States and other governments are directly financing the development of COVID-19 therapies and vaccines. The largest investments made by the Biomedical Advanced Research and Development Authority (BARDA) are cost-plus contracts where drug developers must estimate the cost and timelines for their development programs. Recent estimates on the amount of BARDA expenditures on COVID vaccine development range between $11 and $19.5 billion, not to mention additional public and philanthropic funds. Transparent information about the R&D costs and timelines involved to bring new drugs to market would be invaluable when there is an interest in financing drug development to respond to urgent public health needs or neglected disease areas.

We review extant studies estimating drug R&D costs incurred by industry. While government and academic entities play a critical role in laying the foundation for later drug development, our review focuses on industry costs to inform the policy discussion surrounding firm investments in R&D and drug prices. We present the substantial range in estimated industry per-drug R&D costs and discuss the main factors contributing to this range. While we aim to focus on estimates of novel R&D costs (eg, new molecular entities (NME) or new chemical entities (NCE)), many estimates cover a broader set of drugs, including reformulations or new indications. We use the term “novel” to refer to the broader set of drugs considered by all the studies, and specify “novel” when referring to the narrower set of studies analyzing NMEs or NCEs.

**Conceptual Framework for Industry R&D Costs**

Before discussing the extant estimates, we describe the inputs involved in the estimation of industry R&D costs. Novel drug R&D involves several stages, from basic research and drug discovery to preclinical studies, pre-approval clinical trials, and post-approval clinical trials. Each stage of R&D involves direct costs like materials, supplies, and labor; indirect costs like overhead expenses; and an opportunity cost reflecting the time value of money invested in R&D. The costs in all three categories and at each stage may be borne by industry, academic, government, and/or other sources. The starting point for industry involvement in drug R&D varies. Some drug companies invest in basic research and drug discovery, for example, bench research and high-throughput screening; others begin their involvement at the clinical trial stage. While this review focuses on industry contributions to drug R&D costs, this framework is also compatible with a broader consideration of total R&D costs by all entities.

Ideally, researchers would have, for all companies engaged in drug R&D activity, access to the complete accounting of direct and indirect costs related to drug R&D and firm-specific assumptions on the rate of return from alternative uses of capital to estimate opportunity costs. This hypothetical data would indicate the share of each cost that is attributable to each narrowly defined R&D project (such as the study of a specific active ingredient for a specific indication), including the costs of projects that were paused or abandoned for strategic reasons, or failed for scientific reasons. In some cases, for example, a Phase III clinical trial, the entire direct and allocated indirect costs are likely related to a single R&D project. In other cases, like investments in basic research or drug discovery, costs would have to be allocated to individual R&D projects using a transparent approach. Assuming cost data in this form, industry R&D costs for a given project would be the summation of the products of costs (including cost allocations for other abandoned and failed projects) and the share of costs attributable to the given project across all companies.

In practice, researchers do not have access to a complete accounting of R&D costs or abandoned drugs, nor do they have detailed information on how broader R&D costs should...
be allocated to specific R&D projects. Instead, researchers
make decisions about which R&D stages and costs to include,
and how to allocate these costs across partners, projects, and
over time. Differences in definitions, methods, and as-
sumptions lead to large divergences in the main estimates,
making it difficult for policymakers to point to any one study
or group of studies for the “right” estimate of the cost of novel
drug R&D.

Methods
We conducted a review and narrative synthesis of papers
estimating R&D costs per new prescription drug. The most
recent systematic review on R&D costs searched the literature
until 2009.20 We used this prior review and three other re-
views on related topics21-24 as the basis for identifying studies
published in or before 2009. We identified studies through
several rounds of reference mining, beginning with the se-
lected reviews and continuing with the bibliographies of other
relevant studies. We then reviewed the full text of each
reference. To identify papers published after 2009, we con-
ducted database searches on PubMed and Web of Science for
estimates of per-drug R&D costs published between January 1,
2009, and June 7, 2020. We searched titles, abstracts, and
MeSH terms/topics for the terms: (“pharmaceutical” OR
“biopharmaceutical” OR “drug”) AND “development” AND
“cost” AND “estimat*”. The search returned 947 unique
references. We flagged 32 articles for full-text review after
screening article titles and abstracts.

We included studies that met four criteria in our full-text
review. First, we included studies that estimated the costs of
clinical trials required for regulatory approval by the FDA.
Some included studies additionally considered costs of drug
discovery, preclinical research, or post-approval trials. Sec-
ond, we only included studies explaining their estimation
methods in detail, which allowed us to evaluate the study and
contextualize it in the wider literature. Third, we included
studies published after 1990 to focus on estimates that could
be relevant to the current policy debate. Finally, we only
included studies that measured R&D activity and costs over
the same set of drugs. For instance, a study comparing costs
of novel drugs with activities for novel and reformulated
drugs would be excluded.

After full-text review, we identified 8 studies that met our
criteria prior to 2009, and 9 studies that met our criteria from
the database search after 2009. The 17 final in-scope studies
included published original papers, “gray” literature self-
published by think tanks and nonprofits and re-analyses of
prior studies. We abstracted details from three categories: data
inputs, main results, design decisions. The detailed ab-
straction fields include data sources, drug sample definition,
cost attribution method, capitalization method, out-of-pocket
cost estimate, capitalized cost estimate, and methods for
estimating preclinical spending. We converted costs to 2018
U.S. dollars using the US GDP implicit price deflator from the
U.S. Bureau of Economic Analysis.25

Results
Estimates of Industry Drug R&D Costs

Figure 1 presents the wide range in estimates of the R&D per
new drug from the selected papers, from $113 million26 to
just over $6 billion.27 There is a significant increase in es-

timated R&D costs per new drug over time, particularly
among studies that estimate R&D costs for new, self-
or ganized drugs. Some earlier estimates are approximately
$450 million,28 while more recent estimates are over $2
billion.29,30 The cost estimates from studies focusing on
NMEs is narrower, ranging from $318 million31 to $2.8
billion.29 Analyses including both self-originated and li-
censed NMEs estimate lower costs than those focusing on
self-originated novel compounds.32-34 Self-originated drugs
make up an increasingly small proportion of novel drug
R&D: over 2000–2011, one-third of drugs were licensed-in,
and half had their development timeline interrupted by a
licensing agreement, merger with a larger firm, or co-
development agreement, and this share has decreased over
time.35 At the same time, studies for in-licensed drugs may
miss some costs if earlier phases of research were financed
by private firms where costs may be difficult to track once a
product is acquired by a new firm.

Cost estimates for specific drug types vary significantly.
Estimates for new vaccine and oncologic drug R&D are
below average costs.36-38 While the estimate for novel on-
cologic drugs uses a lower cost of capital, the estimate would
likely still remain within the range of estimates for NMEs if a
higher cost of capital estimate were used. The cost of de-
veloping a new Alzheimer drug is more than double that of
any other estimate.27 While this study used a similar cost of
capital as in other studies (11%), the costs are high due to the
lengthy estimated Phase II and Phase III trial durations and
the high risk of failure at each phase.

Two considerations affect the interpretation of the in-
creasing prices over time shown in Figure 1. First, studies
often collect data on R&D activity (wide pale lines) and cost
data (thin dark lines) from different sources and, in some
cases (eg, cases where the thin and wide lines do not overlap),
they are from different time periods.39 Many papers are
ambiguous about what time periods are covered, so Figure 1
reflects our best estimate based on available descriptions.

Second, the extent of cost increases over time depends on
the price deflator. Figure 1 uses a general GDP deflator, con-
sistent with prior studies.20,29 However, pharmaceutical
input prices, which have increased more rapidly than average
prices, are one main driver of the increased cost over time. An
alternative comparison based on a pharmaceutical input-
specific price deflator, such as the Pharmaceutical Producer
Price Index (PPI), would explain some of the increasing costs over time.

Methodological Choices in Existing Literature

The wide range in estimates in Figure 1 also results from differences in methodological choices, including data sources and how the data are used to attribute cost to specific drugs. Table 1 describes the different data sources and resulting estimates in each of the studies in our review. In our view, the highest quality studies within this group have transparent, replicable data sources that either directly attribute activity and costs to a single drug or have data at a granular level (eg, phase or component-level), enabling authors to build estimates based only on components required to bring a specific product to market.

Data Sources. Cost data. The data used for R&D cost estimates come in varying levels of detail. Some analyses use data on industry-level costs, but typically, studies use annual R&D costs reported at the firm level. Data on firm-level R&D costs are available in industry trade group reports, commercial databases, and SEC filings. Other studies measure R&D costs by development project and/or project-phase. Many studies taking this approach directly survey firms about their R&D expenditures by clinical trial phase for each project, or other development milestones. Other studies analyze data on the volume and costs of individual inputs used in drug R&D. Component-level costs are typically estimated by subject-matter experts, collected from contract research organization contracts, or derived from average estimates reported by industry.

R&D Activity. Depending on the level of detail contained in their cost data, studies may need to collect additional data on the number of trials, trial components (eg, number of enrolled patients), trial lengths, preclinical research, and attrition rates to allocate these costs to development projects. Some data sources can be used to obtain both R&D costs and inputs. For example, surveys of firms that elicit cost
| Study                        | R&D Activity Data Period | R&D Cost Data Period | Scope                              | R&D Activity Data Level (Source)               | R&D Cost Data Level (Source)      | Estimated Mean Capitalized Cost Per New Drug (Millions, $2018) |
|-----------------------------|--------------------------|----------------------|------------------------------------|------------------------------------------------|----------------------------------|----------------------------------------------------------|
| Adams and Brantner, 2006    | 1989–2006               | 1983–2000            | All drugs not new formulations of approved drugs | Phase level (PharmaProjects)                  | Phase level (DiMasi et al. 2003) | 1226.2                                                   |
| Adams and Brantner, 2010    | 1989–2001               | 1989–2001            | All drugs not new formulations of approved drugs | Phase level (PharmaProjects)                  | Firm level (CompuStat)           | 1753.3                                                   |
| Chit et al., 2014           | 2000–2011               | Hypothetical estimate, year not specified | Seasonal influenza vaccines         | Component level (Trialtrove)                  | Component level (Canadian Center for Vaccinology) | 539.2                                                   |
| DiMasi et al., 2003         | 1983–2000               | 1983–2000            | Self-originated new drugs          | Phase level (CSDD survey of 10 pharmaceutical companies) | Phase level (CSDD survey of 10 pharmaceutical companies) | 1133.0                                                   |
| DiMasi et al., 1991         | 1970–1987               | 1970–1987            | Self-originated new drugs          | Phase level (CSDD survey of 12 pharmaceutical companies) | Phase level (CSDD survey of 12 pharmaceutical companies) | 446.3                                                   |
| DiMasi & Grabowski, 2007    | 1990–2005               | 1990–2005            | Self-originated biopharmaceutical NCEs | Phase level (CSDD survey of 3 pharmaceutical companies and data from a separate biotech firm) | Phase level (CSDD survey of 3 pharmaceutical companies and data from a separate biotech firm) | 1565.8                                                   |
| DiMasi et al., 2016         | 1995–2013               | 1995–2013            | Self-originated new drugs          | Phase level (CSDD survey of 10 pharmaceutical companies) | Phase level (CSDD survey of 10 pharmaceutical companies) | 2772.7                                                   |
| Jayasundara et al., 2019    | 1981–2015               | 2013                 | All approved drugs in the FDA orphan Drug/Drugs@FDA databases. | Component level (ClinicalTrials.gov) | Component level (Batelle 2015, Hadjivasiliou 2017) | 447.0 (Non-orphan drugs) 315.8 (Orphan drugs) |
| Light & Warburton, 2011     | 1983–2000               | 1983–2000            | All drugs including reformulations | Phase level (DiMasi et al. 2003)               | Phase level (DiMasi et al., 2003) | 113.4 (median)                                            |
| Light et al., 2009          | 1987–2003               | Hypothetical estimate, 2005–2006 | Rotavirus vaccines                  | Component level (literature review)           | Component level (expert elicitation) | 800.6                                                   |
| Mestre-Ferrandiz et al., 2012 | 1998–2002              | 1998–2002            | Licensed and self-originated NMEs  | Phase level (CMRI survey of 16 pharmaceutical companies) | Phase level (CMRI Survey of 16 Pharmaceutical companies) | 1692.9                                                   |
| Paul et al., 2010           | 2000–2007               | 2000–2007            | Self-originated NMEs               | Phase level (pharmaceutical Benchmarking Forum (PBF) survey of 13 pharmaceutical companies and internal data from Eli Lilly) | Phase level (pharmaceutical Benchmarking Forum (PBF) survey of 13 pharmaceutical companies and internal data from Eli Lilly) | 2079.8                                                   |

(continued)
| Study                                  | R&D Activity Data Period | R&D Cost Data Period | Scope                                                                 | R&D Activity Data Level (Source) | R&D Cost Data Level (Source) | Estimated Mean Capitalized Cost Per New Drug (Millions, $2018) |
|----------------------------------------|--------------------------|----------------------|----------------------------------------------------------------------|----------------------------------|------------------------------|-------------------------------------------------------------|
| Prasad and Mailankody, 2017            | 1992–2015                | 1992–2015            | Oncologic NMEs developed by firms with no other drugs on the market. | Project level (FDA and literature review) | Firm level (SEC filings) | 927.3                                                       |
| Scott et al., 2014                     | Hypothetical estimate, 2013 | Hypothetical estimate, 2013 | Alzheimer’s disease new drugs                                        | Component level (expert elicitation) | Component level (expert elicitation) | 6170.8                                                      |
| The Global Alliance for TB Drug Development, 2001 | Hypothetical estimate, 2000<sup>a</sup> | Hypothetical estimate, 2000<sup>a</sup> | Tuberculosis NCE                                                      | Component level (expert elicitation) | Component level (expert elicitation) | 331.7 (maximum)                                             |
| Wouters et al., 2020                   | 1998–2018                | 1998–2018            | Self-originated and licensed in NMEs                                 | Phase level (ClinicalTrials.gov)   | Project level (SEC filings) | 1335.9                                                      |
| Young and Surrusco, 2001               | 1970–1987                | 1970–1987            | Self-originated NCE                                                   | Phase level (DiMasi et al., 1991)  | Phase level (DiMasi et al., 1991) | 317.9                                                       |

Note: Author descriptions based on data provided in each cited study.
Cost estimates adjusted to $2018 using U.S. GDP implicit price deflator from the U.S. Bureau of Economic Analysis.
<sup>a</sup>Dates provided in the study are ambiguous so start and end dates are estimated.
### Table 2. Methodological Decisions by Study.

| Study                                    | Preclinical Costs | Cost of Capital, % | Include Abandoned Projects? | Adjust for Tax Deductions/Credits? |
|------------------------------------------|-------------------|--------------------|-----------------------------|------------------------------------|
| Adams and Brantner, 2006                 | Yes — applied ratio of preclinical to clinical spending from DiMasi et al., 2003. | 11.0                | Yes — adjusted phase costs by the product of phase transition probabilities estimated from PharmaProjects | No                                  |
| Adams and Brantner, 2010                 | Yes — applied ratio of preclinical to clinical spending from DiMasi et al., 2003. | 11.0                | Yes — adjusted phase costs by the product of phase transition probabilities estimated from PharmaProjects | No                                  |
| DiMasi et al., 2003                      | Yes — applied ratio of preclinical to clinical spending estimated from survey responses | 11.0                | Yes — adjusted expected costs by overall clinical approval success rate estimated in CSDD database | No                                  |
| DiMasi et al., 1991                      | Yes — applied ratio of preclinical to clinical spending estimated from survey responses | 9.0                 | Yes — adjusted expected costs by overall clinical approval success rate estimated in CSDD database | No                                  |
| DiMasi and Grabowski, 2007               | Yes — applied ratio of preclinical to clinical spending estimated from survey responses | 11.0                | Yes — adjusted expected costs by overall clinical approval success rate estimated in CSDD and biotech firm data | No                                  |
| DiMasi et al., 2016                      | Yes — applied ratio of preclinical to clinical spending estimated from survey responses | 10.5                | Yes — adjusted expected costs by overall clinical approval success rate estimated in CSDD database | No                                  |
| Light and Warburton, 2011                | Yes — applied ratio of preclinical to clinical spending from DiMasi et al., 2003. | 5.0                 | Yes — followed DiMasi et al. (2003) | Costs reduced by estimated average marginal tax rate (50%). |
| Light et al., 2009                       | No                | 5.0                | No                          | No                                  |
| Mestre-Ferrandiz et al., 2012            | Data includes preclinical costs | 11.0                | Yes — adjusted phase costs by the product of phase transition probabilities from CMRI Industry Success Rates 2003. | No                                  |
| Paul et al., 2010                        | Data includes preclinical costs | 11.0                | Yes — adjusted phase costs by the product of phase transition probabilities estimated from PBF survey. | No                                  |
| Prasad and Mailankody, 2017              | Firm level costs include preclinical costs; preclinical period assumed to be two years. | 7.0                 | Bankrupt firms and abandoned projects concluded prior to the start of successful development not observed. | No                                  |
| The Global Alliance for TB Drug Development, 2001 | Experts are asked to estimate preclinical study costs. | 3.0                 | Yes — adjusted phase costs by the product of phase transition probabilities estimated by experts. | No. Adjusts for tax deductibility in later IRR calculations. |
| Wouters et al., 2020                     | Firm level costs include preclinical costs | 10.5                | Yes — adjusted phase costs by the product of phase transition probabilities estimated in Wong et al., 2019 | No                                  |
| Young and Surrusco, 2001                 | Yes — followed DiMasi et al. (1991) | 9.0                 | Yes — followed DiMasi et al. (1991) | Costs reduced by the average estimated marginal tax rate (34%). |
| Jayasundara et al., 2019                 | No                | 10.5                | Yes — adjusted phase costs by the product of phase transition probabilities estimated in Hay et al., 2014 | No                                  |

(continued)
information may also include the dates when a drug candidate entered and exited each development phase, whether development was abandoned, and preclinical R&D costs. Similarly, studies that rely on expert elicitation to estimate costs per patient often ask the same experts to estimate the number of patients required, trial lengths, and trials per phase. In other cases, the cost data source will not include all relevant information.

Existing studies rely on several publicly or commercially available databases for data on trial lengths, the number of enrolled subjects, and trials per phase including: Clinical Trials.gov, TrialTrove, and PharmaProjects. Studies also commonly rely on some estimates from prior analyses, particularly for estimates of preclinical research and phase failure rates. Preclinical costs. The challenges in accounting for preclinical costs vary with the study’s data sources and methodology. Approaches based on collecting component-level data must obtain estimates of the preclinical costs associated with the pipeline of interest. While approaches that start with total R&D spending likely include a firm’s expenditures of preclinical activities, researchers must attribute a portion of this total cost to preclinical spending by project.

Researchers take a variety of approaches to estimate preclinical costs. For example, DiMasi et al., 1991 estimated a ratio between total preclinical and total clinical R&D spending by surveying firms about both costs. Several other papers have relied on these estimates or developed models based on similar assumptions. One study found that, for the subset of firms that publicly reported preclinical costs, the median proportion of preclinical spending was less than one third of percentage estimated through the survey ratio method. Another study with firm-level cost estimates by year defines the preclinical period as two years before the first mention of a compound in the biomedical literature, attributing costs during that period as preclinical costs.

Attribution of Costs to R&D Components. To estimate R&D costs per drug, researchers must link cost data to specific development projects. The most common approach to estimating the total cost is to sum expected costs across each phase of clinical activity within a drug pipeline, usually with adjustment for the probability that the trial is successful and advances to the next stage of research. In this case, phase-level cost data are already explicitly linked to development projects and the drug sample defined through the data collection process. Another approach is to implement a linear regression of total R&D spending on measures of R&D activity. The resulting coefficients yield an estimate of the average marginal cost of each unit of R&D activity. Other studies focus on firms with narrow pipelines, such as firms with a single approved drug, or firms that report R&D expenditures separately by drug candidate in SEC filings.

Analyses using component costs must identify how many components are associated with each development project and then sum all required components by phase. This step requires additional assumptions including estimating how many trials are required per phase, the number of patients required in each trial, costs per patient enrolled, and fixed costs. Studies with trial component costs must define a sample of drugs, decide which components should be included in the estimate of total spending, and identify how many components apply to each drug in the sample. Studies relying on expert elicitation estimate the prospective cost of each component required to develop a drug. Other studies take a retrospective approach and combine trial component estimates with data from prior trials.

### Methodological Decisions

Each choice of data and attribution method requires researchers to additional decisions. We summarize key decisions in Table 2.

**Cost of capital.** In many cases, the estimated cost of capital can be substantial, representing almost half of total development costs in some recent estimates. While most studies do include a cost of capital, some authors argue that the cost of capital should not be considered at all, because firms “have no choice but to spend money on R&D.” Among studies that do include a cost of capital, there is disagreement on whether to use an estimated rate of return based on pharmaceutical bonds (1–5%), typical government investments

### Table 2. (continued)

| Study          | Preclinical Costs | Cost of Capital, % | Include Abandoned Projects? | Adjust for Tax Deductions/Credits? |
|----------------|-------------------|--------------------|-----------------------------|-----------------------------------|
| Scott et al., 2014 | Experts are asked to estimate preclinical study costs | 11.0                | Yes—adjusted phase costs by the product of phase transition probabilities estimated by experts. | No                                 |
| Chit et al., 2014 | Yes—applied ratio of preclinical to clinical spending from DiMasi et al. 1991 | 9.0                 | Yes—adjusted expected costs by overall clinical approval success rate estimated in TrialTrove data | No                                 |

Note. Author descriptions based on data provided in each cited study.
(3–7 percent), the Capital Asset Pricing Model (10–11%), or more flexible models that better account for systematic risk (10–13%). Others argue that costs of capital that account for risk should decrease over the development timeline as risks diminish.

**Abandoned development projects.** Pharmaceutical firms abandon or suspend development projects for many reasons, including safety concerns, low or no efficacy, or shifting market priorities. High attrition rates are touted as evidence of the difficulty of drug R&D but may also result from strategic choices to pursue high-risk, high-reward strategies or to mitigate risk through scale. Studies typically account for abandoned development projects by dividing average phase costs by an estimate of the probability that a drug in a given phase will ultimately reach approval.

**Tax credits and deductions.** Firms can also receive specific R&D tax deductions and credits, which may offer significant discounts to firms, with the value on the order of $1 billion. Most analyses in our review ignore the contribution of tax credits and deductions. Many argue that the value of tax credits are relatively small. Second, the value of tax deductibility changes as the tax code changes, which makes isolating the change in drug R&D costs over time more difficult. Finally, analyses claiming to estimate the cost of drug R&D to society, rather than to industry argue that credits and deductions are transfers that should not be deducted from the total cost.

**Discussion**

Some stakeholders in the ongoing discussion in the United States related to high drug prices invoke R&D costs as an argument against price regulation. Ideally, policymakers would have accurate estimates of R&D costs and welfare gains for a range of products that were and were not brought to market to understand whether refinements to policies are needed. Yet, our analysis demonstrates that existing estimates of the cost of drug R&D vary widely. While current data limitations prevent any study from reaching the ideal data and methodology we describe above, some design decisions can result in more plausible estimates.

Transparent and replicable data are essential. Data directly collected at a granular level, such as component or project, or from a firm with only one drug on the market, allow researchers the most flexibility in attributing only the activity and cost components required to bring a drug to market and excluding additional activity and costs incurred by the firm, such as post-marketing trials for other indications.

Some additional costs are reasonable to include in the estimate. Failed and abandoned projects are an inevitable and necessary part of the innovation process. Depending on the policy context, the cost of projects abandoned for strategic or profit-seeking reasons may need to be weighted differently than projects abandoned due to a lack of efficacy, safety concerns, or other medical and technological failures. Similarly, if the cost of failures has already been written off through tax deductions or credits, the amount deducted or credited should not be included in the cost estimate.

Including the cost of capital provides a fair way to account for the risks undertaken by the firm. Yet, there is little information on what rate of cost of capital is reasonable: while some say that the 11% estimate adopted by most of the literature is too high, others argue that it could be too low.

The best approach would be to present separate estimates of direct costs in every study, as well as a capitalized estimate with a clear justification of the rate chosen.

Further research and data collection efforts are needed to support researchers in conducting high-quality studies. There are little data available on several key components of drug R&D estimates, including preclinical costs, the true cost of capital, and factors that may make a trial more or less likely to succeed. As a result, while existing studies use varied data sources, the vast majority end up relying on the estimates of key components from one of the prevailing studies in this literature. For example, in the case of preclinical costs, the commonly used estimate is nearly three times as high as the median estimate from some publicly disclosed sources, meaning there is still room for debate on what true preclinical costs are. Future research should strive to provide updated estimates of these key components, to either substantiate existing work or to offer alternatives.

While researchers have been creative in using different data sources, the details vary significantly, resulting in estimates that are difficult to compare. A standardized data collection with a uniform format for reporting clinical trial and preclinical activities in the FDA’s New Drug Application (NDA) or Biologics License Application (BLA) could provide more comparable data. This could be achieved either by providing applicants with a more standardized form, or by FDA abstracting information in a consistent way when conducting reviews. Other standardized information could be included in clinicaltrials.gov, such as standardized measures of treatment duration or clinical trial costs. The SEC could also encourage large firms to report more detailed information on costs for various streams of work. Because much of these data are already collected in some format, the overall cost of such changes could be relatively lower than completely new data collection efforts.

**Conclusions**

Current estimates of the R&D costs required to bring a new drug to market vary, from $113 million to just over $6 billion. This wide range results from different data sources, data samples, and methodologies used to attribute costs to specific drugs. A standardized data infrastructure for reporting estimates of R&D costs by product in a way that can easily be compared and aggregated should be a priority for all working in this space. Future work in this area should prioritize estimating key components of the drug development process.
where researchers currently have little information, including preclinical costs, cost of capital, and costs per specific R&D projects. Policymakers and researchers can work together to develop more transparent estimates of drug R&D costs to inform policy discussions around prescription drugs.

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