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The New York Pharmaceutical Cost Transparency Act

HOW A NARROW VIEW OF THE PRESCRIPTION DRUG PRICING PUZZLE RENDERS A WELL-INTENTIONED BILL IRRATIONAL

INTRODUCTION

What is the cost of innovation? Is there a fixed dollar and cents amount for each instance in which a person is able to complete an everyday task pain-free, or with less pain than before? Can a numerical value be assessed for reducing the mental stress that often accompanies disease? There are no quick answers to these questions, and many people would instinctively answer the latter two in the negative, yet, pharmaceutical companies constantly attach a price to innovation and therapeutic value. Both these hypothetical figures, along with a multitude of other relevant factors,¹ are included in the ultimate pricing of a new drug. No one factor is dispositive of the overall value of a drug, and certain aspects can be more readily quantified and monetized than others. For instance, while patient benefit is an inherently elusive attribute on which to fix a price, research and development (R&D) expenditure is a far more tangible factor that informs pricing strategy. Much like the value of a drug's efficacy, however, a pharmaceutical company's R&D spend for a particular drug tells merely part of a far more complex pricing story.

Despite the intricate reality of pharmaceutical pricing, public furor has increasingly mounted over the rising cost of prescription drugs, reaching a fever pitch in recent years as a number of new drugs' prices per pill or treatment cycle have received especially intense criticism from patients,² media

¹ See *infra* Part I.

² The feeling of helplessness by the general public is apparently such that "a . . . [recent] poll shows that, overall, 87% of the public supports allowing the federal government to negotiate prices for the Medicare Part D program." Ed Silverman, *How High? The Backlash over Rising Prescription Drug Prices Gains Steam*, WALL ST. J. (July 21, 2015), <http://blogs.wsj.com/pharmalot/2015/07/21/how-high-the-backlash-over-rising->

pundits,³ and physicians.⁴ In response to such concerns, on May 13, 2015, New York State Senator Ruben Diaz introduced New York State Senate Bill 5338A⁵—coined the New York Pharmaceutical Cost Transparency Act (NYPCTA).⁶ The bill’s goal is to “bring transparency to an area of health care spending that for too long has been hidden from the public.”⁷ It would achieve that goal by requiring drug makers to disclose to the New York State Department of Health, for any drug with a “wholesale acquisition cost of ten thousand dollars (\$10,000) or more annually,”⁸ the total costs for:

production; research and development; clinical trials and other regulatory costs; materials, manufacturing and administration; costs paid by other entities, including federal, state or other governmental programs; other costs to acquire the drug; total marketing and advertising costs; a cumulative annual history of the average wholesale price; total profits derived from the sale of the drug; and the total amount of financial assistance provided by the manufacturer, if available.⁹

Prior to the final submission to the state health department, the requested figures must be audited by an independent third party at the expense of the submitting drug company.¹⁰ Through such transparency, the public would “have access to the information

prescription-drug-prices-gains-steam/ [https://perma.cc/UXP2-3PG7]. The poll spanned both political affiliations and generational age groups, indicating the widespread nature of the sentiment it uncovered. *Id.*

³ The New York Times, in particular, has been consistent in taking the pharmaceutical industry to task for perceived predatory pricing. See generally Ezekiel J. Emanuel, *I Am Paying for Your Expensive Medicine*, N.Y. TIMES (Nov. 7, 2015), <http://www.nytimes.com/2015/11/08/opinion/sunday/i-am-paying-for-your-expensive-medicine.html> [https://perma.cc/93GR-XHR8] (urging government intervention in drug price regulation because pharmaceutical companies are unlikely to self-regulate); *No Justification for High Drug Prices*, N.Y. TIMES (Dec. 19, 2015), <http://www.nytimes.com/2015/12/20/opinion/sunday/no-justification-for-high-drug-prices.html> [https://perma.cc/WK6R-ZKXT] (decrying various high-profile instances of egregious price hikes).

⁴ See Silverman, *supra* note 2 (In one recent instance of mounting physician anger, “a group of prominent doctors have gone public with complaints that Vertex Pharmaceuticals is overcharging for . . . ground-breaking medicines that combat cystic fibrosis. . . . [F]or the past three years, they held a private and largely fruitless dialogue . . . and are now airing their accusations out of frustration.”).

⁵ See S. 5338A, 2015–2016 Reg. Sess. (N.Y. 2015).

⁶ *Id.* Just over a month later, in June 2015, an identical bill, sponsored by Assemblyman Michael Blake, was introduced onto the floor of the New York State Assembly for debate and approval. See Assemb. A8265, 2015 Reg. Sess. (N.Y. 2015).

⁷ N.Y. S. 5338A.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.*

that supposedly justifies the cost”¹¹ of those prescription drugs with “outrageous price tag[s].”¹²

Senator Diaz’s proposal is just one of several exceedingly similar, if not identical,¹³ pieces of legislation introduced in various states across the country,¹⁴ further underscoring the sense that the nation is fed up with exorbitantly—and seemingly arbitrarily—priced drugs pressed upon a vulnerable populace only to line the pockets of greedy pharmaceutical companies. And while the NYPCTA’s ends are indeed admirable and important—since patients, payers, and physicians are certainly entitled to a better understanding of what drives a drug’s price tag—its means are problematic because the cost disclosures it requires are not representative¹⁵ of the true value of the vast majority, if any at all, of prescription pharmaceuticals being marketed and sold today. These limitations would implant a skewed assumption in the heads of an already uninformed public, and any ‘transparency’ the bill created would only serve to further vilify pharmaceutical companies, which, regardless of public backlash, would be unlikely to reconsider pricing strategies in the face of legislation that so wholly misrepresented the actual framework presently utilized to determine a new drug’s proper price point.

This note argues that the NYCPTA, while a noble consumer protection effort, is—or, at least, is perilously close to—an unconstitutional and impermissible regulation of economic activity by a state because its classification of pharmaceutical companies and subsequent transparency requirements are not rationally related to its legitimate goal of actually effecting drug price transparency.¹⁶ Part I of the note probes deeply into the

¹¹ *Id.*

¹² *See id.*

¹³ *See* H.B. 3486, 78th Legis. Assemb., Reg. Sess. (Or. 2015) (Oregon pharmaceutical price transparency bill presented to state House of Representatives on March 11, 2015); Assemb. B. 463, 2015–2016 Leg., Reg. Sess. (Cal. 2015) (Assembly bill introduced to California Legislature on February 23, 2015).

¹⁴ Ed Silverman, *Angry over Drug Prices, More States Push Bills for Pharma to Disclose Costs*, WALL ST. J. (Apr. 24, 2015), <http://blogs.wsj.com/pharmalot/2015/04/24/angry-over-drug-prices-more-states-push-bills-for-pharma-to-disclose-costs/> [<https://perma.cc/D3TF-UX3C>] (“Over the past several weeks, lawmakers in a handful of states stretching from California to Massachusetts have introduced bills in a bid to force the pharmaceutical industry to conduct an economic striptease.”).

¹⁵ “[T]he bill ‘only focuses on the medicines that make it to market, while completely ignoring the 90% that fail during testing, a costly yet vital part of discovering new treatments.’” Thomas Sullivan, *New York Introduces Pharmaceutical Cost Transparency Bill*, POLICY & MED. (May 18, 2015), <http://www.policymed.com/2015/05/new-york-introduces-pharmaceutical-cost-transparency-bill.html> [<https://perma.cc/97Y7-64BY>].

¹⁶ *City of Cleburne v. Cleburne Living Ctr., Inc.*, 473 U.S. 432, 440 (1985) (“The general rule is that legislation is presumed to be valid and will be sustained if

factors and influences that converge when setting a prescription drug's price to illustrate how, because the costs associated with bringing a drug to market tell only a fraction of that drug's true pricing story, pharmaceutical companies will be completely undeterred by any public outcry resulting from this enhanced "transparency." Ironically, while the bill purports only to educate an uninformed public,¹⁷ its implicit goal of shaming pharmaceutical companies into lowering prescription drug prices through negative publicity¹⁸ is its only truly transparent feature. Part II discusses the constitutional violation that could override the bill: it fails the rational basis standard applied to government regulation of businesses. Regardless of the NYPCTA's possible ulterior motive to serve as a "shame bill," its stated purpose is to provide the public with "access to the information that supposedly justifies the cost" of a drug.¹⁹ The bill's fundamental misunderstanding of the pharmaceutical pricing landscape, however, renders its purported solution to ever-rising pharmaceutical prices essentially toothless in this fight. Because its means are wholly insufficient to achieve its stated end, the legislation as proposed is an irrational attempt at prescription drug price reform. Finally, Part III will advocate some simple amendments to the NYPCTA that, if implemented, would more accurately represent the cumulative factors present within a drug's price, better educate the public on these elements of drug pricing, and bolster the legislation to a point at which it is a rational means of achieving its well-intentioned and legitimate goal.

I. PRICING PRESCRIPTION PHARMACEUTICALS

The New York Pharmaceutical Cost Transparency Act proffers the inference that pharmaceutical prices should be tied, more or less, directly to the R&D, manufacturing, marketing, and administrative costs associated with launching a new drug and maintaining yearly production and sales.²⁰ While R&D expenditure is arguably the factor most analyzed by and most

the classification drawn by the statute is rationally related to a legitimate state interest.").

¹⁷ See N.Y. S. 5338A.

¹⁸ "Such disclosures might shame companies into restraining their price increases and provide state officials with information to determine what action to take." *Runaway Drug Prices*, N.Y. TIMES (May 5, 2015), <http://www.nytimes.com/2015/05/05/opinion/runaway-drug-prices.html> [<https://perma.cc/W8HL-5TYA>].

¹⁹ N.Y. S. 5338A.

²⁰ See *id.*

compelling to companies in determining a drug's price tag,²¹ there are other, less visible aspects of both a drug itself and standard pharmaceutical industry practices that are pertinent to the pricing equation. These factors are hidden from the public by the NYPCTA's rigid disclosure requirements centered primarily on development costs. The result is that the bill seemingly views drug pricing with blinders rather than with the holistic inquisitiveness the issue merits. The following Section focuses on some of these ignored factors and highlights how their omissions render the NYPCTA deficient as a means to inject the drug pricing process with actual transparency.

A. "Pricing In" R&D Failures

Perhaps the most glaring and defined limitation to the NYPCTA is the simple fact that pharmaceutical companies factor far more than just the total production costs associated with a specific drug into its pricing.²² Drug companies must also recoup their expenditures on compounds that failed in clinical trials and will never reach the market.²³ For every drug that successfully gains approval by the Food and Drug Administration (FDA), its makers have incurred tremendous costs on numerous attempts to derive therapeutic value from other drugs where there either was none to extract or where the drug's dangers exceeded its benefits.²⁴ When this happens, the pharmaceutical company suffers a loss on most, if not all, of the resources expended on

²¹ "[T]he value of medicines, contrary to most other products and commodities, is in . . . the years of R&D that goes into them, rather than the substance itself," among other factors. Chris Lo, *Drug Prices: Profits Before Patients?*, PHARM.-TECH.COM (June 9, 2014), <http://www.pharmaceutical-technology.com/features/feature-drug-prices-profits-before-patients-4285101/> [<https://perma.cc/S79J-H7WX>].

²² See Ifrad Islam, *Rising Cost of Drugs: Where Do We Go From Here?*, HEALTH AFFAIRS BLOG (Aug. 31, 2015), <http://healthaffairs.org/blog/2015/08/31/rising-cost-of-drugs-where-do-we-go-from-here/> [<https://perma.cc/839K-GHRN>] ("While research and development can indeed carry large costs and span multiple years, there is simply more to pricing drugs.").

²³ See Barry Werth, *A Tale of Two Drugs*, MIT TECH. REVIEW (Oct. 22, 2013), <http://www.technologyreview.com/featuredstory/520441/a-tale-of-two-drugs/> [<https://perma.cc/BV6Z-CP86>] ("Drug companies insist that they need to make billions of dollars on their medicines because their failure rate is so high and because they need to convince investors it is wise to sink money into research.").

²⁴ "If a review by FDA physicians and scientists shows the drug's benefits outweigh its known risks and the drug can be manufactured in a way that ensures a quality product, the drug is approved and can be marketed in the United States." *What Is the Approval Process for a New Prescription Drug?*, U.S. FOOD & DRUG ADMIN. (May 12, 2016), <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194949.htm> [<https://perma.cc/YL94-QY5Y>].

testing the drug up until its failure.²⁵ For smaller companies with few, if any, approved products on the market, a clinical trial failure can have catastrophic effects on investor confidence and the firm's stock price.²⁶ The industry operates based upon the knowledge that "[m]ost new drugs don't succeed, and companies depend on the 'hits' to stay profitable."²⁷ By overlooking, or simply failing to mention, this fundamental reality of the pharmaceutical industry, the NYPCTA obscures to the public both the mammoth effort and price actually required to bring a drug from the lab to the market, which includes meeting the daunting regulatory standards of the FDA.

1. The Costs of Bringing a Drug to Market

The FDA has devised a stringent approval process that a drug must complete before it can be marketed, prescribed, and, ultimately delivered to a consumer in the United States.²⁸ An arm of the FDA, the Center for Drug Evaluation and Research (CDER), serves as the agency's primary "consumer watchdog"²⁹ to ensure the safety and efficacy of a new drug.³⁰ While the CDER is the ultimate gatekeeper over whether a drug is approved for sale, it does not oversee the various clinical trials that generate the data on which the center makes its ruling; that expense is borne directly by a drug's developers.³¹

²⁵ "A big pharmaceutical company carries that weight of failure, with both its successes and its failures on the books." Matthew Herper, *The Cost of Creating a New Drug Now \$5 Billion, Pushing Big Pharma to Change*, FORBES (Aug. 11, 2013), <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/> [<https://perma.cc/8AY5-C2T6>].

²⁶ A recent example of a clinical trial failure leading to near financial ruin can be found in the case of drug maker Chimerix. Following the Phase 3 clinical trial failure of brincidofovir, its candidate for FDA approval as a treatment for a variety of viruses, "Chimerix's stock plunged on the news, dropping more than 81 percent" by mid-afternoon after the trial results were announced. Frank Vinluan, *Chimerix Stock Plunges After Anti-Infection Drug Fails Phase 3 Trial*, XCONOMY (Dec. 28, 2015), <http://www.xconomy.com/raleigh-durham/2015/12/28/chimerix-stock-plunges-after-anti-infection-drug-fails-phase-3-trial/> [<https://perma.cc/MN37-D9D3>].

²⁷ Scott Gavura, *Legislators Want "Pharmaceutical Cost Transparency."* *Are They Asking the Wrong Question?*, SCL-BASED MED. (May 21, 2015), <https://www.sciencebasedmedicine.org/legislators-want-pharmaceutical-cost-transparency-are-they-asking-the-wrong-question/> [<https://perma.cc/D7MX-NY3M>].

²⁸ *Development & Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm> [<https://perma.cc/L53T-46JJ>] ("American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world.").

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

The process begins with a preclinical investigation of a drug's therapeutic capabilities. If—after preliminary laboratory analysis—the pharmaceutical company believes it has a potentially marketable drug on its hands, it will proceed to clinical trials,³² which mandate the drug's successful completion of three progressive trial phases—Phases 1, 2, and 3.³³ Each phase is designed to meet certain clinical endpoints generally related to the safety, efficacy, and proper dosing of the drug, and the population of enrolled patients increases, usually substantially, in each successive trial.³⁴ As the scope of each clinical trial phase grows, so too does the overall cost and duration of the development cycle.³⁵ Importantly, with the advent of each phase, the larger patient population carries heightened risk that adverse side effects previously undetected in the earlier, smaller cohort will be uncovered. There is also the possibility that the drug's preliminarily significant efficacy was merely the result of a statistical anomaly within the earlier sample and not transferable to a larger, more representative test group. Thus, the probability of the drug meeting the clinical endpoints required to continue its advance towards FDA approval declines.³⁶ These risks materialize simultaneously as the trial costs mount and the company's time investment in the drug grows ever longer.

The average cost of bringing a prescription drug to market is a controversial topic, and different, albeit interested, parties advance estimates that vary widely from one another.³⁷ In late 2014, the Tufts Center for the Study of Drug Development (CSDD) released a comprehensive report listing the projected total cost of obtaining FDA approval for a prescription

³² Prior to the initiation of human testing during the phased clinical trials, a drug's developer "must first file an investigational new drug application (IND) with the FDA." Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECONs. 151, 155–56 (2003).

³³ *Development & Approval Process (Drugs)*, *supra* note 28.

³⁴ *The Drug Development and Approval Process*, FDAREVIEW.ORG, http://www.fda.gov/oc/ohrt/development_and_approval_process.html [<https://perma.cc/PE83-H8C7>] (fig. 1).

³⁵ *Id.*

³⁶ *Id.*

³⁷ Compare Matthew Herper, *The Truly Staggering Cost of Inventing New Drugs*, FORBES (Feb. 10, 2012), <http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/2/> [<https://perma.cc/K3ZP-RZ6T>] ("The average drug developed by a major pharmaceutical company costs at least \$4 billion, and it can be as much as \$11 billion."), with Aaron E. Carroll, *\$2.6 Billion to Develop a Drug? New Estimate Makes Questionable Assumptions*, N.Y. TIMES (Nov. 18, 2014), http://www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html?_r=0 [<https://perma.cc/3H2C-HR4S>] ("In 2010, a systematic review of studies that looked at the cost of drug development was published in Health Policy. The review found thirteen articles, with estimates ranging from \$161 million to \$1.8 billion (in 2009 dollars).").

pharmaceutical at \$2.558 billion.³⁸ The report measured the total development timeframe during which these costs are incurred to be over a decade.³⁹ The last such major study done by the CSDD, in 2003, offered a figure less than half of its current estimate;⁴⁰ this cost difference has, predictably, inspired criticism of the study's methods and motivations. The study concludes that the two primary elements of a drug's developmental price tag "are average out-of-pocket outlays of \$1.395 billion and 'time costs' of \$1.163 billion, reflecting returns investors forgo while a drug is in development."⁴¹ Crucially, the CSDD also factored into its estimate the cost of therapies that failed at some point, either pre-trial or in one of the trial phases, during the development process.⁴² The study directly "links the costs of unsuccessful projects to those that are successful in obtaining marketing approval from regulatory authorities" and concludes that such R&D failures are a primary reason for rising drug costs.⁴³

Criticism of the CSDD's study centers primarily on the accusation that the exorbitant drug development cost estimate provides ample justification to pharmaceutical companies to price their products with impunity.⁴⁴ Advocates of the study seem to not expressly disagree with this assessment;⁴⁵ although, presumably, such proponents believe in the validity of the estimate and that drug pricing is an exercise in cost recoupment, not greed. Other charges leveled against the study hone in on its failure to account for "the impact of so-called orphan drug tax credits, in which the US government bankrolls half the cost of

³⁸ Robert Weisman, *Cost of Bringing a Drug to Market Tops \$2.5b, Research Finds*, BOS. GLOBE (Nov. 18, 2014), <https://www.bostonglobe.com/business/2014/11/18/cost-bringing-prescription-drug-market-tops-billion-tufts-research-center-estimates/6mPph8maRxcvftWjr7HUN/story.html> [<https://perma.cc/6SEJ-QCTS>].

³⁹ *Id.*

⁴⁰ *Id.* ("The center's projected cost of \$2.558 billion dwarfs the \$802 million figure in its last major study, done in 2003—the equivalent of \$1.04 billion in 2013 dollars.")

⁴¹ *Id.*

⁴² *Id.*; see also Rick Mullin, *Tufts Study Finds Big Rise In Cost of Drug Development*, CHEM. & ENG'G NEWS (Nov. 20, 2014), <http://cen.acs.org/articles/92/web/2014/11/Tufts-Study-Finds-Big-Rise.html> [<https://perma.cc/FJ4C-BPRU>] ("[T]he cost of unsuccessful projects is figured into . . . [the] group's analysis.")

⁴³ *Cost to Develop and Win Approval for a New Drug Is \$2.6 Billion*, TUFTS CTR. FOR THE STUDY OF DRUG DEV. (Nov. 18, 2014), http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study [<https://perma.cc/LX4Z-4YJ8>].

⁴⁴ The director of a DC-based non-governmental organization, Knowledge Ecology International, sniffed pretext in the study's findings, asserting that "[t]his estimate is not credible The only justification [it offers] for the high cost of new drugs is research and development, and this will be used by the drug companies to get people to accept higher prices." Weisman, *supra* note 38.

⁴⁵ Mullin, *supra* note 42 ("The value of the Tufts study is that it helps the public understand that . . . [pharmaceutical drug development] is a high-risk, expensive, and long-term endeavor.")

clinical trials that qualify.”⁴⁶ Additionally, critics have derided the CSDD’s exclusion of federally funded National Institute of Health (NIH) grants, which fund “early-stage research into drug compounds that are eventually sold,” from the study’s final calculation.⁴⁷ Subsidies on orphan drug development, however, are irrelevant in estimating the cost of therapies for diseases with large patient populations,⁴⁸ and standalone NIH grants represent a relatively small fraction of the pharmaceutical development cost landscape.⁴⁹ These criticisms are alone inadequate to discredit the CSDD’s findings, which focus on actual R&D costs borne by private manufacturers.⁵⁰ Allegations of bias and pretext are unsurprising in a study centered on such a fiercely debated topic. While a certain degree of healthy skepticism is merited,⁵¹ the study has nonetheless “been widely cited at industry forums,”⁵² and the CSDD as an organization has been generally accepted as credible by both the pharmaceutical industry and its observers.⁵³

Methodological and procedural controversies aside, perhaps the study’s most compelling case for the high cost of FDA approvals lies in its data on the failure rate of compounds in development. Figures for the success rate of drugs gaining FDA approval also vary, but even the industry’s critics agree that this

⁴⁶ Weisman, *supra* note 38.

⁴⁷ *Id.*

⁴⁸ The FDA designates as an orphan drug those “drugs and biologics . . . intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders that affect fewer than 200,000 people in the U.S., or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug.” *Developing Products for Rare Diseases & Conditions*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ForIndustry/DevelopingProductsforRareDiseasesConditions/ucm2005525.htm> [<https://perma.cc/L8KN-3FTM>] (last updated Oct. 17, 2016).

⁴⁹ “[L]ate-stage [drug] development . . . is funded primarily by pharmaceutical companies or venture capitalists with *some* collaborative support from government sources.” THERESA WIZEMAN ET AL., BREAKTHROUGH BUSINESS MODELS: DRUG DEVELOPMENT FOR RARE AND NEGLECTED DISEASES AND INDIVIDUALIZED THERAPIES: WORKSHOP SUMMARY 8 (2008) (emphasis added); see also DiMasi et al., *supra* note 32, at 157 (“[O]f 47 FDA-approved drugs that had reached at least US\$ 500 million in US sales in 1999, the government had direct or indirect use or ownership patent rights to only four of them.”).

⁵⁰ “This criticism distracts from the policy question, which concerns the actual dollars spent on R&D. If there were no corporate income tax, it would not really change what R&D contractors or drug company employees charge for their services. To improve R&D productivity, actual costs have to be addressed.” John R. Graham, *The Crisis in Drug Research and Development*, NAT’L CTR. FOR POLICY ANALYSIS (Mar. 3, 2015), <http://www.ncpa.org/pub/ib158> [<https://perma.cc/7UNC-55DV>].

⁵¹ “The Tufts Center is funded, to a large extent, by the pharmaceutical industry. It is in the pharmaceutical industry’s best interests to have the public believe that it is very expensive to develop a drug.” Carroll, *supra* note 37.

⁵² Weisman, *supra* note 38.

⁵³ Despite allegations of cronyism from its critics, the CSDD is “a bellwether figure in the drug industry.” Mullin, *supra* note 42.

percentage is extremely low.⁵⁴ The percentage is lower still for truly innovative medicines with new molecular entities⁵⁵ aimed at treating complex diseases. Understanding this, the CSDD study allocated “the cost of abandoned drugs . . . to successful ones.”⁵⁶ The abandoned drugs included in the report were not only those compounds that failed in human clinical trials, but also investigatory compounds discarded during pre-trial research, which accounted for 80% of the drugs that never made it out of development.⁵⁷ Costs incurred on preliminary research are especially hard to attribute to testing for any specific drug.⁵⁸ Nevertheless, these costs are expenditures by a pharmaceutical company that must be recouped by those products that do make it to market despite their decidedly amorphous relationship to the development of an ultimately approved product. Pharmaceutical companies should certainly not take pride in such high failure rates, and perhaps a higher degree of R&D efficiency could be achieved through a more strategic and selective decision-making process in the early stages of a drug’s development. The simple truth, however, is that science is an art of pure trial and error, and a high rate of failure is the price of innovation.⁵⁹ Furthermore, true innovation is what industry critics, and the public at large, commonly claim is lacking in the field, with companies too

⁵⁴ “The failure rate is high—but a successful new drug can . . . make[] up for a lot of failures.” Joe Nocera, *Is Valeant Pharmaceuticals the Next Enron?*, N.Y. TIMES (Oct. 27, 2015), http://www.nytimes.com/2015/10/27/opinion/is-valeant-pharmaceuticals-the-next-enron.html?_r=0 [https://perma.cc/UTY3-4DBG]. “[O]nly about one in ten drugs survives clinical trials to market.” Nick Stockton, *How Prescription Drugs Get So Wildly Expensive*, WIRED (Sept. 23, 2015), <http://www.wired.com/2015/09/prescription-drugs-get-wildly-expensive/> [https://perma.cc/JZS4-CPYR]. In an article arguing that the CSDD estimate is only representative of a specific subset of innovative pharmaceuticals and not all drugs, the author nonetheless admitted that “the road to approvals is littered with casualties.” *The Price of Failure*, THE ECONOMIST (Nov. 29, 2014), <http://www.economist.com/news/business/21635005-startling-new-cost-estimate-new-medicines-met-scepticism-price-failure> [https://perma.cc/DP5D-3P6A].

⁵⁵ Approximately 92% of biopharmaceuticals fail in oncologic clinical trials. ANASTASSIOS D. RETZIOS, WHY DO SO MANY PHASE 3 CLINICAL TRIALS FAIL?: PART 1: THE EFFECT OF DEFICIENT PHASE 2 TRIALS IN THERAPEUTIC AREAS WITH HIGH FAILURE RATES IN PHASE 3 STUDIES 3 (2010), http://www.adrclinresearch.com/Issues_in_Clinical_Research_links/Why%20Pivotal%20Clinical%20Trials%20Fail%20-%20Part%201_v12L_a.pdf [https://perma.cc/VKZ7-Z8DQ].

⁵⁶ Graham, *supra* note 50.

⁵⁷ *Id.*

⁵⁸ *See id.* (“[S]ubstantial expenditures incurred prior to clinical testing cannot be directly linked to work on specific compounds.”).

⁵⁹ “Compounds that appear to hit a designated target right between the eyes still often fail to be safe and effective in animal and human studies. Biology is just way too complicated.” Dan Hurley, *Why Are So Few Blockbuster Drugs Invented Today?*, N.Y. TIMES MAGAZINE (Nov. 13, 2014), <http://www.nytimes.com/2014/11/16/magazine/why-are-there-so-few-new-drugs-invented-today.html> [https://perma.cc/7RHP-LZRY].

often focused on developing branded ‘copycat’ drugs with fewer obstacles to clear on the path to FDA approval.⁶⁰ Innovation and scientific advancement are not achieved free of cost, and if drug makers are to serve the purpose that the public seems to expect from them, they must be allowed the opportunity, when it knocks, to see a return on the considerable investment innovation demands.

2. Why R&D Failures Must Be Included in Cost Calculations

The notion that pharmaceutical companies must make back their developmental losses through sales of approved products is fundamental to the successful functioning of the industry. Any field in which companies rely on R&D to stay relevant and afloat in the market must operate in such a manner. Quite simply, “[t]he road to blockbuster drugs . . . is paved in part by well-documented, very costly, pharmaceutical development failures.”⁶¹ In a recent post, Derek Lowe, a PhD in organic chemistry who has worked on the development of high-science therapies for Alzheimer’s disease, schizophrenia, and osteoporosis,⁶² offered the following pertinent real-world, hypothetical parallel to the R&D system of the pharmaceutical industry:

If only one out of every ten cars that Ford developed—assembly lines and all—ever made it to the showrooms, cars would be more expensive. If only one out of every ten movies—after shooting, production, and editing—ever made it to theaters, ticket prices would go up. We get one . . . out of every ten drugs in the clinic to market, and we’ve got to pay for it somehow.⁶³

As Lowe notes, baking past failures into a current product’s price tag is an entirely unavoidable economic reality of the R&D model under which many other industries, besides the

⁶⁰ Criticism of ‘me-too’ drugs commonly follows this line of reasoning: by introducing into a disease category competitors that are not compellingly superior alternatives to existing drugs, physician prescribing decisions may become more difficult, R&D resources are exhausted on a condition for which treatments already exist, and, “[e]ven at heavily discounted prices, brand-name drugs almost certainly cost more than generic medications.” See Joshua J. Gagne & Niteesh K. Choudhry, *How Many “Me-Too” Drugs Is Too Many?*, 305 J. AM. MED. ASS’N 711, 711 (2011).

⁶¹ Gavura, *supra* note 27.

⁶² *About Derek Lowe*, SCI. TRANSLATIONAL MED., <http://blogs.sciencemag.org/pipeline/about-derek-low> [<https://perma.cc/N4JX-Y8RD>].

⁶³ Derek Lowe, *Shkreli, Turing, and PhRMA*, SCI. TRANSLATIONAL MED. (Sept. 23, 2015), <http://blogs.sciencemag.org/pipeline/archives/2015/09/23/shkreli-turing-and-pharma> [<https://perma.cc/VQF6-AJEL>].

pharmaceutical sector, operate.⁶⁴ By ignoring this fact, the NYPCTA masks a fundamental aspect of drug pricing from the public in the name of transparency.

It is true that irresponsibly investing in compounds unlikely to ever see the daylight of FDA approval is an inefficient burden on the consumers who will ultimately shoulder such sunk costs.⁶⁵ When the approval rate of drugs in development is already so low, however, it becomes difficult for companies to objectively evaluate true therapeutic potential versus a virtual shot in the dark.⁶⁶ Ideally, drug companies would act “[l]ike good card players [and] . . . sit out many more hands than they play.”⁶⁷ But in an industry where continual innovation is necessary to remain competitive in the market, there is considerable risk in idleness as well. Efficiency conundrums aside, one thing is certain regardless of whether a company approaches R&D aggressively or conservatively: some drugs will fail in development, and those costs will have to be accounted for when another of that company’s drugs is granted FDA approval. Any acknowledgment of this basic industry totem is absent from the NYPCTA.

Regardless of the ultimate cost of bringing a drug to market,⁶⁸ the cost to the pharmaceutical company far exceeds merely the R&D associated with only the launched product. While the true pricing formula is a question of great contention, it is undeniable that the vast majority of drugs fails either in the laboratory⁶⁹ or in clinical trials⁷⁰ and will thus never turn a profit

⁶⁴ *Id.*

⁶⁵ “Sunk costs are fixed costs that firms incur to enhance the demand of its products, typically R&D and marketing expenditures.” *Market Size, Sunk Costs, and Entry in Pharmaceutical R&D*, SWITCH (Aug. 15, 2013), <http://www.theswitchproject.eu/market-size-sunk-costs-and-entry-in-pharmaceutical-rd/> [<https://perma.cc/5HT6-JLG3>].

⁶⁶ In describing how three major drug companies expended billions of dollars on a long-shot Alzheimer’s disease therapy that unsurprisingly failed in trials, Forbes’ Matthew Herper speculated on the corporate rationale for proceeding with clinical trials in the first place: “The logic behind going forward probably went something like this: Alzheimer’s is one of the world’s biggest health problems and any drug that can impact it would be simply huge. . . . It would be crazy not to try, right?” Matthew Herper, *How a Failed Alzheimer’s Drug Illustrates the Drug Industry’s Gambling Problem*, FORBES (Aug. 8, 2012), <http://www.forbes.com/sites/matthewherper/2012/08/08/how-a-failed-alzheimers-drug-illustrates-the-drug-industrys-gambling-problem/>.

⁶⁷ *Id.*

⁶⁸ Whether that cost is closer to \$2.6 billion, see *Cost to Develop and Win Approval for New Drug Is \$2.6 Billion*, *supra* note 43; or \$160 million, see Carroll, *supra* note 37.

⁶⁹ “Of five thousand compounds tested, approximately five will appear promising enough to induce the company to file an Investigational New Drug Application (IND).” *The Drug Development and Approval Process*, *supra* note 34 (fig. 1).

⁷⁰ “[T]he overall success rate for drugs moving from early stage Phase I clinical trials to FDA approval is about one in 10” Bill Berkrot, *Success Rates for Experimental*

for the private company whose investment in such drugs was lost. Accordingly, the pricing strategy of drugs that do make it to market must factor in the cost of the failures that came before it. The NYPCTA does not require that these sunk costs be included in its mandated development disclosures. Even if this exclusion reflects a fundamental misunderstanding of industry pricing norms or the bill knowingly seeks to educate the public on only the expenditures associated with the specifically approved drug, its implementation will not educate the public on the true costs of sustainable pharmaceutical development.

At the very least, a caveat to the bill's required disclosures is necessary to indicate that other basic principles of economics and corporate finance require companies to price drugs higher than the minimum at which its R&D price tag may be recouped. Without such a disclaimer, this important pricing factor is at risk of being completely obscured. If implemented as currently drafted, the bill would paint a simplistic and false picture of industry pricing strategy: specifically, that a new drug's price tag reflects only those dollars spent on its development. This image would likely further infuriate a public that, armed with its new 'knowledge,' must watch helplessly as drug makers continue to price drugs at levels that account for costs absent from the transparency bill.

B. International Pharmaceutical Pricing

While factoring clinical development failures into drug prices is the primary and most tangible culprit behind the inflation of pricing above merely what it costs to recoup R&D expenditures, there are additional considerations at play in setting a prescription drug's stateside price. Global health needs and international pharmaceutical consumption and cost often dictate U.S. drug pricing strategy.⁷¹ Americans, comprising "less than 5 percent of the world's population, buy[] more than 50 percent of its prescription drugs;"⁷² however, they "buy[] them at prices designed to subsidize the rest of the industrial world, where the same drugs cost much less."⁷³

Drugs Falls: Study, REUTERS (Feb. 14, 2011), <http://www.reuters.com/article/us-pharmaceuticals-success-idUSTRE71D2U920110214> [<https://perma.cc/DA95-K55L>].

⁷¹ See Werth, *supra* note 23.

⁷² *Id.*

⁷³ *Id.* Despite American subsidization, "most poor governments can't afford [prescription drugs] at even those lower prices." *Id.*; see also DIANA FARRELL ET AL., MCKINSEY GLOBAL INST., ACCOUNTING FOR THE COST OF US HEALTH CARE: A NEW LOOK AT WHY AMERICANS SPEND MORE 20 (2008), http://www.mckinsey.com/insights/health_

This reality stems from international regulatory schemes over which pharmaceutical companies have little to no control.⁷⁴ “The United States is the only major industrialized country in the world that does not currently regulate prescription drug prices,”⁷⁵ whereas, “[i]n Europe, drug prices are often set by government health systems and decline over time as countries demand additional price cuts.”⁷⁶ Such a state-run system is often the only buyer of large amounts of prescription drugs in the country it governs, which lends it massive leverage at the negotiating table with the pharmaceutical companies seeking to do business within its borders.⁷⁷ Accordingly, if a pharmaceutical company wants to compete in foreign markets, it must follow that nation’s established rules. This requires pricing its product in accordance with a government regulating body’s imposed price limit, which is often based on the state’s perceived worth of the drug’s therapeutic value.⁷⁸ In the United States, however,

systems_and_services/accounting_for_the_cost_of_us_health_care [https://perma.cc/Z3C N-9HTW] (“[P]rices in the United States need to be sufficient to subsidize R&D for the rest of the world.”); Rafi Mohammed, *It’s Time to Rein in Exorbitant Pharmaceutical Prices*, HARVARD BUS. REVIEW (Sept. 22, 2015), <https://hbr.org/2015/09/its-time-to-rein-in-exorbitant-pharmaceutical-prices> [https://perma.cc/7D4Y-TDQE] (“[C]onsumers in the U.S. are stuck footing most of the bill for developing new drugs, even as consumers throughout the developed world reap the benefits.”).

⁷⁴ Mohammed, *supra* note 73.

⁷⁵ John A. Vernon et al., *The Economics of Pharmaceutical Price Regulation and Importation: Refocusing the Debate*, 32 AM. J. L. & MED. 175, 176 (2006); *see also* Mohammed, *supra* note 73 (“[V]irtually every country regulates prices and the U.S. doesn’t.”).

⁷⁶ Robert Langreth et al., *The U.S. Pays a Lot More for Top Drugs Than Other Countries*, BLOOMBERG (Dec. 18, 2015), <http://www.bloomberg.com/graphics/2015-drug-prices/> [https://perma.cc/E7UU-U8DY].

⁷⁷ Jeanne Whalen, *Why the U.S. Pays More Than Other Countries for Drugs*, WALL ST. J. (Dec. 1, 2015), <http://www.wsj.com/articles/why-the-u-s-pays-more-than-other-countries-for-drugs-1448939481> [https://perma.cc/WY8F-6J84].

⁷⁸ For a western European example, the Norwegian government’s process of fixing drug prices, while disregarding the investment of the drug’s maker, is as follows:

The government controls costs in part by setting maximum prices. To do that, it reviews prices in nine neighboring countries and takes the average of the three lowest.

This system automatically holds prices low because the countries consulted also have government-controlled prices.

The Norwegian Medicines Agency, or NMA, then reviews patient data to decide whether a new drug is cost-effective. Its maker must request a reimbursement price at or under the maximum Norway has set and submit a detailed comparison of the drug’s cost and benefits versus existing treatments. Companies have teams of number crunchers to produce these comparisons, which can also prove useful in pitching products in the U.S.

Id.; *see also* Valerie Paris, *Why Do Americans Spend So Much On Pharmaceuticals?*, PBS NEWSHOUR (Feb. 7, 2014), <http://www.pbs.org/newshour/updates/americans-spend-much-pharmaceuticals/> [https://perma.cc/CZR9-8ZWA] (“[I]n many countries, government

“insurers typically accept the price set by the makers for each drug, especially when there is no competition in a therapeutic area, and then cover the cost with high copayments.”⁷⁹ The result is a paradoxical international health care market where, for example, prescription drug “[p]rices in Norway, the fourth wealthiest country in the world” are lower than those in the United States, the world’s sixth wealthiest nation.⁸⁰ Whether higher U.S. prices reflect the anticipation of losses due to lower-priced drugs abroad or are a response to losses already sustained in foreign markets, state-imposed price controls undeniably complicate a drug company’s attempt to reasonably price its product commensurate with R&D expenditures. With the knowledge that profits will be derived primarily from the domestic use of their products, American pharmaceutical executives set the stateside price for new drugs accordingly.

Price controls on prescription drugs in foreign countries result in burdens on the American consumer. “As millions of Americans [with poor] prescription drug coverage [well know] . . . , the ‘list prices’ they face for patented drugs when they walk into a drug store in the United States can be much higher than the price of drugs sold abroad.”⁸¹ Freed from the restrictions they face abroad, pharmaceutical companies will rationally recoup the ‘losses’ suffered internationally through higher prices on drugs sold in the United States.

Thus, even if drug makers were not already operating at a loss by the time a new drug hits the market due to failed therapies and forborne opportunity costs, pricing a drug based on the cost of its R&D alone, as the NYPCTA urges, would still result in the American public paying a price seemingly disproportionate to the costs of its full developmental lifecycle. This leads logically to the conclusion that even in a utopian health care landscape—where pharmaceutical companies operate benevolently and seek as payment for their innovation nothing more than those costs incurred to innovate—the NYPCTA would *still* obscure relevant factors that determine a drug’s price.

agencies essentially regulate the prices of medicines and set limits to the amount they will reimburse; they may only agree to pay for a drug if they feel that the price is justified by the therapeutic benefits.”).

⁷⁹ Paris, *supra* note 78.

⁸⁰ Mohammed, *supra* note 73.

⁸¹ *Cost of Prescription Drugs*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/NewsEvents/Testimony/ucm114800.htm> [<https://perma.cc/JG24-F7KQ>] (statement of Dr. Mark. B. McClellan before the Senate Committee on Commerce, Science, and Transportation).

C. *Therapeutic Value: The Cost of Efficacy*

Aside from global and domestic market economics and the profit and loss ratios of drug companies, the inherent therapeutic value of a prescription drug is another factor that pharmaceutical companies use to set its price.

1. Not All Drugs Are Created Equally: The Varying Degrees of Innovation Inherent Within Different Drug Classes

A common criticism of the industry rests on the assertion that companies increasingly focus more on producing ‘me-too’ drugs—“products that mimic existing treatments or offer only incremental improvements in outcomes”⁸²—than on developing novel therapies.⁸³ This allegation, however, rings hollow, especially when leveled against the biotechnology sector,⁸⁴ where many truly groundbreaking advances in medical science regularly occur and where more quantifiable therapeutic value can be found.⁸⁵

While in general, innovative medicines that are the most expensive to bring to market generate higher profits than drug makers’ other offerings,⁸⁶ it is not a uniform rule that the most efficacious therapies are the most expensive to develop. And it is not a foregone conclusion that piggybacking on existing products is a substantially cheaper endeavor since “the complexity of [new] molecules makes it more difficult to even make generic versions of these products.”⁸⁷ The NYPCTA makes no distinction between biotechnological products, which are more likely to

⁸² DAVID DRANOVE ET AL., *KELLOGG SCH. OF MGMT., PHARMACEUTICAL PROFITS AND THE SOCIAL VALUE OF INNOVATION* 9 (2014), http://www.kellogg.northwestern.edu/faculty/garthwaite/htm/medicare_pharma_innovation.pdf [<https://perma.cc/JL7U-4MKJ>].

⁸³ “Critics of the pharmaceutical industry love to attack ‘me-too.’” John LaMattina, *Impact of ‘Me-Too’ Drugs on Health Care Costs*, *FORBES* (Jan. 19, 2015), <http://www.forbes.com/sites/johnlamattina/2015/01/19/impact-of-me-too-drugs-on-health-care-costs/#7e7347692610>.

⁸⁴ Biotechnology firms differ from traditional pharmaceutical companies in that their products are primarily biologic and “far larger in size and more complex than traditional small molecule products and cannot reasonably be fully chemically synthesized. Instead, biologics are effectively grown from living organisms and therefore are almost certainly not likely to be simple copies or minor modifications of existing small molecule products.” DRANOVE ET AL., *supra* note 82, at 12.

⁸⁵ *Id.* at 30 (“[N]ew products emerging from this sector are more likely to represent some form of scientific advancement rather than only the me-too products cited by many critics of the pharmaceutical industry.”).

⁸⁶ Vernon, *supra* note 75, at 177 (“[T]he returns from pharmaceutical R&D come largely in the form of revenues generated by recently launched, patented new drugs . . .”).

⁸⁷ DRANOVE ET AL., *supra* note 82, at 30.

represent true innovation and should arguably be priced higher to account for this inherent value,⁸⁸ and drugs developed by more traditional, ‘small-molecule’ pharmaceutical firms.⁸⁹ In so doing, the bill either takes for granted that R&D cost correlates precisely with the therapeutic value of a drug, which is simply not the reality of the industry,⁹⁰ or it ignores therapeutic value entirely. By failing to expressly include therapeutic value in its regulatory framework, the NYPCTA again legislates broadly based on a sweeping industry generalization. Any chance at facilitating true pricing transparency is lost in the process.

2. Uncovering and Defining Therapeutic Value

In a free market system, private companies may price their products at whichever level they feel is appropriate, subject, of course, to whether or not the market will bear such cost. The NYPCTA, accordingly, does not explicitly impose price controls, but it does obscure relevant pricing factors. The bill recognizes that pure, unbridled capitalism in the realm of pharmaceuticals is an ugly, uncomfortable issue. And, to be sure, examples exist of predatory ‘entrepreneurs’ taking advantage of the industry’s unique ability to wholly sustain the lives of large subsets of its most loyal customers: the sick patients reliant on the company’s drugs.⁹¹ But a drug’s efficacy, as well as its tolerability, can

⁸⁸ “The efficacy and safety of biopharmaceutical products, combined with their ability to address previously untreatable conditions, allows pharma companies to command high prices for innovative drugs.” Ralf Otto et al., *Rapid Growth in Biopharma: Challenges and Opportunities*, MCKINSEY & CO. (Dec. 2014), <http://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/rapid-growth-in-biopharma> [<https://perma.cc/Q489-W9K9>].

⁸⁹ See S. 5338A, 2015–2016 Reg. Sess. (N.Y. 2015). The bill broadly reserves its cost disclosure requirements for those drugs with a “wholesale acquisition cost of ten thousand dollars (\$10,000) or more annually or per course of treatment.” *Id.* A drug’s chemical makeup is not a factor in defining the bill’s regulatory scope.

⁹⁰ The ultimate efficacy of a molecule in its intended patient population is still unknown during clinical trials. Therefore, this speculative efficacy cannot be the driving factor of the trials’ costs. Rather, “therapeutic area as well as number and types of clinical procedures involved are the key drivers of costs in [clinical trials].” AYLIN SERTKAYA ET AL., EASTERN RESEARCH GRP., INC., EXAMINATION OF CLINICAL TRIAL COSTS AND BARRIERS FOR DRUG DEVELOPMENT 3–7 (2014), https://aspe.hhs.gov/sites/default/files/pdf/77166/rpt_erg.pdf [<https://perma.cc/9DQS-FQAG>].

⁹¹ An especially egregious recent example is found in the near-universal condemnation of hedge fund manager-turned-chief executive officer of Turing Pharmaceuticals, and arguably the “most hated man in America,” Martin Shkreli. Janell Ross, *Martin Shkreli: A New Icon of Modern Greed*, WASH. POST (Sept. 23, 2015), <https://www.washingtonpost.com/news/the-fix/wp/2015/09/23/martin-shkreli-a-new-icon-of-modern-greed/> [<https://perma.cc/JG9P-K2FE>]. Shkreli was widely, and deservedly, skewered following his decision to raise the price of Daraprim, a more than six-decade-old drug, “from \$13.50 to \$750” shortly after Turing acquired it. *Id.* Daraprim is most commonly used to treat *Toxoplasma gondii* infections that afflict persons with severely

provide very real, tangible, and transformative benefits. Beyond the immediate value to the patient, there are also less instantly apparent, but nonetheless undeniable, social gains that result from a healthy populace. Pharmaceutical companies recognize this inherent value in their products, and, after investing in the R&D necessary to make such gains possible, are not per se greedy robber-barons for incorporating therapeutic value into a drug's price.

Pricing pharmaceuticals is a complex process that takes place within a unique market.⁹² On a basic level, and as opposed to the majority of consumer goods, "sales of most branded pharmaceuticals are not sensitive to prices or price changes. . . . [Therefore], [o]nce launched, prices are unlikely to decline in the face of new warnings or other information because of the presence of brand loyalty."⁹³ After this loyalty is attained, drug makers are hesitant to lower prices because "such a move could 'signal [to] the market or the courts that the manufacturer accedes . . . that the drug is worth less than was initially promised."⁹⁴ But the mere existence of brand loyalty is arguably indicative, wholly or in part, of either or both of a drug's clinical efficacy and its psychological healing component.⁹⁵ Thus, the question returns to how to quantifiably attach a figure to a drug's inherent value.

While a prescription drug's therapeutic value is highly relevant to its pricing strategy, "price and value are not always the same."⁹⁶ Price must reflect, in addition to clinical value,

compromised immune systems, including HIV/AIDS patients. See *Understanding Your Prescription*, DARAPRIM, <http://www.daraprimdirect.com/patients> [<https://perma.cc/39HB-KWJJ>].

⁹² See *In re Zyprexa Prods. Liab. Litig.*, Nos. 04-MD-1596, 05-CV-4115, 05-CV-2948, 06-CV-0021, 06-CV-6322, 2008 WL 2696916, at *31 (E.D.N.Y. July 2, 2008) (summarizing unique attributes of pharmaceutical pricing, including the relative inelasticity of the market).

⁹³ *Id.*

⁹⁴ *Id.*

⁹⁵ "Consumers who are brand loyal are not willing to compromise drug safety and efficacy for lower prices. A brand gives confidence to the physician regarding effectiveness. The physician who believes the effectiveness of a certain drug will have the tendency of prescribing it." Çağlar Macit et al., *Brand Loyalty as a Strategy for the Competition with Generic Drugs: Physicians Perspective*, 5 J. DEV. DRUGS 1,1 (2016) (footnote omitted).

⁹⁶ Jane Horvath, *Biopharmaceuticals: Pricing for Clinical Value and In-Market Risk*, HEALTH AFFAIRS BLOG (Aug. 20, 2015), <http://healthaffairs.org/blog/2015/08/20/biopharmaceuticals-pricing-for-clinical-value-and-in-market-risk/> [<https://perma.cc/PW7-WEU3>] ("It may be helpful . . . to think of a drug's value as the clinical performance and patient outcomes, while the price reflects both the value and the growing uncertainty around in-market risks of market consolidation and restricted access, branded therapeutic competition, mandatory discounts, and restrictive coverage policy.").

other “market risks [that] affect lifetime product revenue.”⁹⁷ But prescribing physicians are concerned primarily with a drug’s *efficacy* and not its price.⁹⁸ To entice doctors to prescribe their drugs, pharmaceutical companies must devise selling strategies demonstrating that its drug offers the maximum therapeutic value to the intended patient population and is, therefore, the best available treatment option.⁹⁹ Assuming that a drug’s efficacy is the main driver of its sales, and drug sales are a pharmaceutical company’s primary source of recouping R&D costs, it follows that a drug’s price must be based, at least in part, on its predicted sales necessary to recoup production costs using efficacy as a primary indicator of likely physician prescribing behavior.¹⁰⁰ If nothing else, therefore, therapeutic value aids drug makers in setting a floor price point at which they will, ostensibly, see a return on their investment. This element of the pricing strategy would be invisible to the public under the current version of the NYPCTA.

3. Social Gains Through Disease Eradication and a Healthy Populace

A drug’s efficacy may provide broader societal value, which, while impossible to definitively quantify in monetary terms, nonetheless justifies its consideration within the drug’s pricing formula. Effective—and partially or wholly curative—treatments today reduce or possibly nullify a patient’s medical costs that would accrue over time through an inferior, or merely symptom-treating, prior standard of care. These savings are also part of a drug’s total value, and it is not inappropriate to consider such long-term, net benefits in its price.¹⁰¹ True pharmaceutical innovation alleviates the burden that chronic treatments have on insurers, costs that are otherwise passed along to all consumers. A real-world application of this

⁹⁷ *Id.*

⁹⁸ See *Pfizer, Inc. v. Int’l Rectifier Corp.*, No. CV 73-58, 1983 WL 62442, at *6 (C.D. Cal. June 30, 1983).

⁹⁹ *Id.* (“The object, therefore, of every drug manufacturing company . . . is to sell the *physician* on the efficacy and safety of its particular drug.”).

¹⁰⁰ See DRANOVE ET AL., *supra* note 82, at 8 (A drug’s profit margin “is determined by a number of factors including the efficacy of the product compared to the next most effective treatment.”).

¹⁰¹ “[W]hen innovation leads to the discovery and development of an important new medicine, then its price, in turn, should be driven by the value that it brings.” John LaMattina, *Do R&D Costs Matter When It Comes to Drug Pricing?*, FORBES (May 20, 2015), <http://www.forbes.com/sites/johnlamattina/2015/05/20/do-rd-costs-matter-when-it-comes-to-drug-pricing/>.

hypothetical is conveniently embodied in Sovaldi, a Hepatitis-C treatment manufactured by Gilead Sciences and approved by the FDA in late 2013.¹⁰² Ever since the drug came to market, it has been the subject of much rancor for its high price tag.¹⁰³

Sovaldi is a once-a-day pill, taken in combination with one or two other drugs for twelve or twenty-four weeks, depending on the patient's genotype,¹⁰⁴ with extraordinary cure rates and mild, tolerable side effects.¹⁰⁵ Prior to Sovaldi's approval, the standard of care for Hepatitis-C patients was a combination therapy of four drugs that together embodied a treatment regimen lasting twenty-eight to forty-eight weeks, offering between a thirty to eighty percent cure-rate.¹⁰⁶ Moreover, the therapy produced miserable side effects,¹⁰⁷ which, when coupled with its long duration, prompted poor medication adherence, often leaving patients needing a liver transplant to save their lives.¹⁰⁸ Despite fierce and widespread outrage over the drug's \$1,000 per pill price tag,¹⁰⁹ "the price of Sovaldi is about the same as the combined prices of [the drugs that constituted the prior treatment method]; the cure rate is higher; the side effects are much milder; and the therapy takes less time."¹¹⁰ Sovaldi users, now in better physical

¹⁰² *U.S. Food and Drug Administration Approves Gilead's Sovaldi™ (Sofosbuvir) for the Treatment of Chronic Hepatitis C*, GILEAD (Dec. 6, 2013), <http://www.gilead.com/news/press-releases/2013/12/us-food-and-drug-administration-approves-gileads-sovaldi-sofosbuvir-for-the-treatment-of-chronic-hepatitis-c> [<https://perma.cc/Q7ZQ-BJ37>] [hereinafter *FDA Approves Gilead's Sovaldi*].

¹⁰³ Horvath, *supra* note 96.

¹⁰⁴ *FDA Approves Gilead's Sovaldi*, *supra* note 102; *How Do I Take SOVALDI?*, SOVALDI, <http://www.sovaldi.com/about-sovaldi/how-do-i-take-sovaldi> [<https://perma.cc/A PV2-X9TQ>].

¹⁰⁵ *See SOVALDI Combination Therapy Cure Rates in Clinical Studies*, SOVALDI, <http://www.sovaldi.com/about-sovaldi/study-results> [<https://perma.cc/LN3P-HUEH>].

¹⁰⁶ David R. Henderson, *In Defense of an "Expensive" Drug*, HOOVER INST. (Apr. 30, 2015), <http://www.hoover.org/research/defense-expensive-drugs> [<https://perma.cc/H6D G-34QK>].

¹⁰⁷ *Id.*

¹⁰⁸ Susan Heavey, *U.S. Drug Industry Group Defends Price of Gilead Hepatitis Drug*, REUTERS (Apr. 10, 2014), <http://www.reuters.com/article/us-hepatitis-gilead-pharma-idUSBREA391I220140410> [<https://perma.cc/3Q4K-M37B>].

¹⁰⁹ *See* Olga Khazan, *The True Cost of an Expensive Medication*, THE ATL. (Sept. 25, 2015), <http://www.theatlantic.com/health/archive/2015/09/an-expensive-medications-human-cost/407299/> [<https://perma.cc/SWK4-5VRL>] ("There's a drug called Sovaldi that works astonishingly well to cure people with the liver disease Hepatitis C. The rub? It costs \$1,000 per day for all 12 weeks of treatment."); Carolyn Y. Johnson & Brady Dennis, *How an \$84,000 Drug Got Its Price: 'Let's Hold Our Position . . . Whatever the Headlines.'* WASH. POST (Dec. 1, 2015), <https://www.washingtonpost.com/news/wonk/wp/2015/12/01/how-an-84000-drug-got-its-price-lets-hold-our-position-whatever-the-headlines/> [<https://perma.cc/L9EB-BV3U>] ("Gilead gained federal approval for . . . Sovaldi in late 2013 and ultimately settled on the price of \$84,000 for a 12-week course of treatment. . . . But they also got more than they bargained for: an outpouring of outrage from the public, a backlash from government and private payers, and political scrutiny.")

¹¹⁰ Henderson, *supra* note 106.

and mental shape, are able to again contribute to their families, workplaces, and communities unencumbered by the residual debilitating fatigue of a chronic condition. In this way, the therapeutic value of Sovaldi is undeniably higher to patients, and society at large, than the sum of its R&D investment.¹¹¹ And its potential to eradicate Hepatitis-C entirely¹¹² offers a value to society that exceeds all quantifiable bounds. Harvard health economist David Cutler¹¹³ frames the issue in frank terms: “Virtually every study of medical innovation suggests that changes in the nature of medical care over time are clearly worth the cost.”¹¹⁴ This larger social gain represents the true, full therapeutic value of Sovaldi, and Gilead is justified in including the drug’s transformative quality in its price. In the case of Sovaldi, and other breakthrough medicines,¹¹⁵ R&D expenditures are dwarfed by the therapeutic and social value inherent in the drug. This is not to imply that every drug approved by the FDA offers a cumulative value exponentially above its development costs,¹¹⁶ but it *is* disingenuous to overlook this factor in a drug price transparency effort. The NYPCTA ignores such therapeutic value as a pricing factor, and in so doing, its implementation could further skew the public’s already muddled understanding of how and why prescription drugs are priced.

¹¹¹ “The drug produced far better outcomes, faster, compared to the then-current standard of care without the severe side effects that accompany interferon therapy. Before Sovaldi, most Hep C patients weren’t treated or stopped treatment early.” *Price Bomb of Gilead*, WALL ST. J. (Dec. 6, 2015), <http://www.wsj.com/articles/price-bomb-of-gilead-1449447106> [<https://perma.cc/AUK9-P7FU>].

¹¹² Zoe Mintz, *The Cost of a Cure: New Drugs May Eradicate Hepatitis C But Are They Worth It?*, INT’L BUS. TIMES (Apr. 11, 2014), <http://www.ibtimes.com/cost-cure-new-drugs-may-eradicate-hepatitis-c-are-they-worth-it-1570671> [<https://perma.cc/BFN9-X3JQ>].

¹¹³ *David M. Cutler: Harvard College Professor, Otto Eckstein Professor of Applied Economics*, HARVARD UNIV., <http://scholar.harvard.edu/cutler/home> [<https://perma.cc/P4PB-WBSP>].

¹¹⁴ Peter J. Pitts, *AD Hoc*, MEDCITY NEWS (Jan. 31, 2011), <http://medcitynews.com/2011/01/ad-hoc/> [<https://perma.cc/2W3M-QBG4>].

¹¹⁵ “[A]dvances in HIV/AIDS therapies from 1987 to 2010 helped avoid a staggering 862,000 premature deaths in the United States and delivered \$615 billion in gains to the U.S. economy by enabling patients to lead productive lives.” Joel White, *Prescription Drugs: Innovative Medicines Are Worth the Price*, STAR TRIBUNE (Sept. 3, 2015), <http://www.startribune.com/prescription-drugs-innovative-medicines-are-worth-the-price/324234951/> [<https://perma.cc/U4WM-T5RU>]. In the oncology realm, while the scope and duration of treatment and patient outcomes provided by different cancer drugs vary widely, “[b]etween 1988 and 2000, treatment advances saved 23 million life-years and \$1.9 trillion in the United States.” *Id.*

¹¹⁶ Few drugs offer the absolute, curative relief of Sovaldi, and the FDA “has approved some pricey drugs based on clinical trials showing they extend life for just a matter of days.” Rebecca Robbins, *How Much Is an Extra Month of Life Worth? Drug Makers Face Pressure to Calculate*, STAT (Feb. 25, 2016), <https://www.statnews.com/2016/02/25/drug-prices-decisions/> [<https://perma.cc/AWN8-GFHS>].

4. The Power of Hope

Beyond the fairly tangible social value of curing the sick, new medicines may also provide intangible value through hope.¹¹⁷ This benefit does not even require an FDA approval to be unlocked, as the “innovation engine . . . laboring to produce new agents,” provides “great comfort” to the general population, especially those predisposed to certain medical conditions.¹¹⁸ Hope, and the knowledge that an entire industry devotes tremendous resources, both financial and intellectual, to curing disease, can extend benefits to all of society through efficiency gains and the general alleviation of the various psychological and social implications of living in fear of a hypothetical diagnosis.

Prescription drug prices are calculated based on a wide array of variables, only one of which is the R&D expended to bring a drug to market. Additionally, pharmaceutical companies occupy a unique niche in the American corporate landscape, operating under tremendous regulatory constraints to develop products that can provide value far beyond simply fixing what ails its customers. As a result, attaching an appropriate price to a drug requires an analysis deeper than simply determining at what margin above R&D expenditures executives would like to record a profit. The NYPCTA, aimed at educating the American public on the cost of bringing a prescription drug to market,¹¹⁹ overlooks the intricacies of the pricing equation by vastly simplifying the issue and proffering the disingenuous inference that a drug’s price should be based solely on the R&D costs directly associated with the drug’s path to FDA approval. While disclosure of company R&D would give the public a baseline at which it could begin to critically think about and debate drug pricing, the bill as written has no intention to truly educate on industry realities, and its fundamental mischaracterization of pharmaceutical pricing efforts ensures that no real change would result from its implementation.

¹¹⁷ Rena Conti et al., *New Cures Require New Pricing Policies*, HEALTH AFFAIRS BLOG (Apr. 16, 2015), <http://healthaffairs.org/blog/2015/04/16/new-cures-require-new-pricing-policies/> [<https://perma.cc/QF96-P8XA>].

¹¹⁸ *Id.*

¹¹⁹ See S. 5338A, 2015–2016 Reg. Sess. (N.Y. 2015).

II. A RATIONAL BASIS REVIEW OF THE NYPCTA: HOW A LEGITIMATE STATE PURPOSE IS FRUSTRATED BY THE VERY MEANS PROMULGATED TO ACHIEVE IT

States are afforded incredibly broad discretion in regulating the economic activities of commercial enterprises within its territories. A regulation of economic activity by a state is subject only to minimal scrutiny; it requires nothing more than that the challenged legislation be “rationally related to a legitimate state interest.”¹²⁰ By “rational,” the United States Supreme Court does not require that a given regulation be precisely proportional to whatever public injustice or inefficiency it seeks to correct,¹²¹ nor does it mandate the legislation even be particularly wise.¹²² Accordingly, businesses seeking the protections of the Constitution for a seemingly undue state burden on their ability to operate are rarely successful in such a challenge; however, “[r]ational basis review, while deferential, is not ‘toothless.’”¹²³ And, as currently drafted, the NYPCTA is particularly vulnerable to the fangs of minimal scrutiny given its mischaracterization of the pharmaceutical industry’s pricing strategies.

A. *Pharmaceutical Cost Transparency Is a Legitimate State Interest*

The constitutionality of economic regulation by a state or the federal government has historically been a topic ripe for debate and one that has been heavily litigated at all levels of courts throughout the United States. “Economic due process,” a laissez-faire system under which “the Supreme Court frequently struck down state laws¹²⁴ on the grounds that the *end* the state

¹²⁰ See *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985).

¹²¹ An economic regulation is not unconstitutional “merely because the classifications made by its laws are imperfect. If the classification has some ‘reasonable basis,’ it does not offend the Constitution simply because the classification ‘is not made with mathematical nicety or because in practice it results in some inequality.’” *Dandridge v. Williams*, 397 U.S. 471, 485 (1970) (quoting *Lindsley v. Nat. Carbonic Gas Co.*, 220 U.S. 61, 78 (1911)).

¹²² “[I]t is not within our authority to determine whether the Congressional judgment expressed . . . is sound or equitable, or whether it comports well or ill with the purposes of the Act. . . . ‘Our concern here, as often, is with power, not with wisdom.’” *Flemming v. Nestor*, 363 U.S. 603, 611 (1960) (quoting *Helvering v. Davis*, 301 U.S. 619, 644 (1937)).

¹²³ *Peoples Rights Org., Inc. v. City of Columbus*, 152 F.3d 522, 532 (6th Cir. 1998) (citing *Mathews v. Lucas*, 427 U.S. 495, 510 (1976)).

¹²⁴ See, e.g., *Adkins v. Children’s Hosp. (The Minimum Wage Case)*, 261 U.S. 525, 545 (1923) (“That the right to contract about one’s affairs is a part of the liberty of

sought to achieve with its economic regulation was itself illegitimate, regardless of the means or process chosen to achieve that end,”¹²⁵ reached its zenith at the turn of the twentieth century following the Court’s infamous decision in *Lochner v. New York*.¹²⁶ But by the late 1930s, the Court had “dispensed entirely with the *Lochner* doctrine”¹²⁷ in favor of the far more deferential rational basis framework still utilized today.¹²⁸ In seeking to overturn an economic regulation, challengers may allege the law violates the remnants of economic substantive due process via the Fifth Amendment’s Due Process Clause¹²⁹ or, if it creates a classification, that the resulting disparity between regulated and unregulated groups impinges upon equal protection liberties under the Fourteenth Amendment.¹³⁰ Regardless of which constitutional provision is alleged to be infringed, the stringency imposed upon the regulation by the rational basis standard is the same.¹³¹

While a state actor is not required to provide its actual purpose or rationale in enacting a regulation with the effect of creating a classification,¹³² the United States Supreme Court does mandate that “a purpose may conceivably or ‘may reasonably have been the purpose and policy’ of the relevant governmental decisionmaker.”¹³³ In regards to the NYPCTA, the bill’s purpose is stated fairly unequivocally: “It is the intent of

the individual protected by . . . [the Fifth Amendment’s due process] clause is settled by the decisions of this court and is no longer open to question. . . . Within this liberty are contracts of labor employment.”); *Coppage v. Kansas*, 236 U.S. 1, 21 (1915) (“To ask a man to agree in advance to refrain from affiliation with the union while retaining a certain position of employment is not to ask him to give up any part of his constitutional freedom.”); *Adair v. United States*, 208 U.S. 161, 190 (1908) (“There are rights which, when exercised in a private business, may not be disturbed or limited.”).

¹²⁵ Mark C. Christie, *Economic Regulation in the United States: The Constitutional Framework*, 40 U. RICH. L. REV. 949, 958 (2006).

¹²⁶ *Lochner v. New York*, 198 U.S. 45 (1905).

¹²⁷ Christie, *supra* note 125, at 959.

¹²⁸ See *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 440 (1985).

¹²⁹ This type of challenge would undoubtedly be an uphill battle, to say the least, as a plaintiff must “traverse ‘unusually inhospitable legal terrain’ because the Supreme Court has not invalidated an economic statute on substantive due process grounds since . . . 1935.” *In re Blue Diamond Coal Co.*, 79 F.3d 516, 521 (6th Cir. 1996) (internal citations omitted).

¹³⁰ “[R]estraints on judicial review have added force where the legislature must necessarily engage in a process of line-drawing.” *FCC v. Beach Commc’ns, Inc.*, 508 U.S. 307, 315 (1993) (quoting *U.S. R.R. Ret. Bd. v. Fritz*, 449 U.S. 166, 179 (1980)).

¹³¹ See Anthony B. Sanders, Comment, *Exhumation Through Burial: How Challenging Casket Regulations Helped Unearth Economic Substantive Due Process in Craigmiles v. Giles*, 88 MINN. L. REV. 668, 674 (2004) (“The Court uses virtually identical language to describe each test.”).

¹³² *Nordlinger v. Hahn*, 505 U.S. 1, 15 (1992) (citing *Fritz*, 449 U.S. at 179).

¹³³ *Id.* (quoting *Allied Stores, Inc. v. Bowers*, 358 U.S. 522, 528 (1959)).

the legislature to make information available to the public about the cost of ultra-high-priced pharmaceuticals, in order to make pharmaceutical pricing as transparent as the pricing in other sectors of the health care industry.”¹³⁴ Despite this purported intent, it is widely presumed that the real goal of the NYPCTA and other similar transparency bills is to “shame [drug] companies into restraining their price increases and provide state officials with information to determine what action to take.”¹³⁵

Both the stated and presumed purposes of the NYPCTA almost certainly serve what a court would consider legitimate state purposes. The bar a governmental actor must hurdle to prove its regulation serves a legitimate purpose is low; however, the Supreme Court has never explicitly “elaborated on the standards for determining what constitutes a ‘legitimate state interest.’”¹³⁶ Despite this silence, the Court has “made clear . . . that a broad range of governmental purposes and regulations satisfies these requirements.”¹³⁷ Further, a legislature is not required “to articulate its reasons for enacting a statute, [thus] it is entirely irrelevant for constitutional purposes whether the conceived reason for the challenged distinction actually motivated the legislature.”¹³⁸ While all that is required to pass constitutional muster is a conceivable purpose, however, “[t]he Supreme Court, employing rational basis review, has been suspicious of a legislature’s circuitous path to legitimate ends when a direct path is available.”¹³⁹ Thus, unless the NYPCTA’s path to lower drug prices was

¹³⁴ S.B. 5338-A, 2015–2016 Leg., Reg. Sess. (N.Y. 2015).

¹³⁵ See *Runaway Drug Prices*, *supra* note 18; see also Yevgeniy Feyman, *Vermont’s Wrongheaded Drug Price ‘Transparency’ Bill Misses the Mark*, FORBES (June 10, 2016), <http://www.forbes.com/sites/theapothecary/2016/06/10/vermonts-wrongheaded-drug-price-transparency-bill-misses-the-mark/#d3dbc845ed52> (“[L]egislators simply want *lower* drug prices across the board (with an added bonus of shaming drugmakers, of course.)”); Michael Olove, *High Drug Prices Prompt Demands for Transparency*, THE PEW CHARITABLE TRUSTS (Mar. 7, 2016), <http://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/03/07/high-drug-prices-prompt-demands-for-transparency> [<https://perma.cc/Z2F7-D6P8>] (“By talking about pricing and transparency . . . lawmakers may pressure the industry into talking with policymakers, health plans and others with a stake in health care about ‘how to make sure tomorrow’s breakthrough drugs are affordable and accessible to the patients who need them.’”); Emily Wasserman, *States’ Efforts to Fight Skyrocketing Costs Pose ‘Modest Risk to Pharma’: Report*, FIERCE PHARMA (Apr. 22, 2016), <http://www.fiercepharma.com/pharma/states-efforts-to-fight-skyrocketing-costs-pose-modest-risk-to-pharma-report> [<https://perma.cc/Z6H3-3A6B>] (“The ‘shame’ alone in sharing this information is not a strong enough mechanism for pharma to start to address prices . . .”).

¹³⁶ *Nollan v. Cal Coastal Comm’n*, 483 U.S. 825, 834 (1987).

¹³⁷ *Id.* at 834–35.

¹³⁸ *FCC v. Beach Commc’ns, Inc.*, 508 U.S. 307, 315 (1993).

¹³⁹ *Craigsmiles v. Giles*, 312 F.3d 220, 227 (6th Cir. 2002).

deemed too suspiciously meandering for a court's liking, it is irrelevant whether the bill's true intent is to merely educate the public on drug development costs or publicly shame pharmaceutical companies into lowering drug prices. It is highly likely a court would find that a state, armed with the power to preserve the public health,¹⁴⁰ is acting entirely within its powers to ensure that its citizenry is armed with knowledge of an industry vital to its health and has reasonable access to affordable medicines.

Recently, in *Sorrell v. I.M.S. Health, Inc.*,¹⁴¹ the United States Supreme Court overturned a Vermont regulation restricting the ability of pharmacies to sell physician prescribing information obtained from its customers' prescriptions to the marketing teams of pharmaceutical companies.¹⁴² Drug makers, in turn, used such information to personally tailor sales representatives' promotional messaging to physicians during sales calls in a process called "detailing,"¹⁴³ which has been found to increase health care costs.¹⁴⁴ The Court, in striking down the law, nonetheless held that "Vermont's stated policy goals [of, among other things, seeking to lower overall state health care costs] may be proper."¹⁴⁵ Thus, the named goal of the NYPCTA to simply educate the public on the cost of bringing a drug to market, without explicitly advocating for lower drug prices, is assuredly a proper state purpose. Moreover, the inquiry would likely end there because "a legislative choice is not subject to courtroom factfinding and may be based on rational speculation unsupported by evidence or empirical data."¹⁴⁶ In light of the great latitude afforded both states and the federal government by courts in determining whether a regulation's end is legitimate, especially in the public health domain where individual liberty is not impinged upon,¹⁴⁷

¹⁴⁰ See *Jacobson v. Massachusetts*, 197 U.S. 11, 25 (1905) ("[T]he police power of a State must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health.").

¹⁴¹ *Sorrell v. I.M.S. Health, Inc.*, 564 U.S. 552 (2011).

¹⁴² *Id.* at 557.

¹⁴³ *Id.* at 557–61.

¹⁴⁴ *Id.* at 561.

¹⁴⁵ *Id.* at 577.

¹⁴⁶ *FCC v. Beach Commc'ns, Inc.*, 508 U.S. 307, 315 (1993).

¹⁴⁷ "Public health seeks not merely the aggregation of individual satisfaction but, rather, the common good. Accordingly, individual rights are constantly in tension with communitarian interests." Elizabeth Weeks Leonard, *The Public's Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U. L. REV. 1335, 1344–45 (2009) (footnotes omitted).

the NYPCTA is likely well within constitutional bounds from a state policy perspective.

Regardless of which purpose is analyzed given that both are legitimate, it then becomes the function and practical effect of the bill that renders it irrational.¹⁴⁸ If the stated purpose of the NYPCTA is accepted, its means can hardly be said to accomplish its goal. By strictly tying R&D costs to drug price, it ignores the intricacies of the industry and pricing practices. And by so doing, the bill acts in seemingly direct contravention of its aim at educating the public. Further, if one accepts its hidden motive (shaming pharmaceutical companies) as the real driving force behind the bill, further irrationality within the NYPCTA is uncovered. This is so because it is exceedingly unlikely that pharmaceutical companies would adjust their pricing methods in response to a bill that creates a false inference about how drug prices are initially determined, all while in a quest to educate the public on the genesis of such prices.

B. The NYPCTA's Means Are Logically Disconnected from Its Intended End(s)

When viewed from beyond the specialized realm of a constitutional, economic due process framework and its accompanying rigor and relative predictability, the goals of the NYPCTA are indeed proper.¹⁴⁹ The seemingly ever-rising cost of prescription drugs and health care in general¹⁵⁰ is an issue that affects every American, regardless of political affiliation, and one that played a prominent role in the early stages of the 2016 presidential election.¹⁵¹ The NYPCTA, as well as the transparency

¹⁴⁸ See *Minnesota v. Clover Leaf Creamery Co.*, 449 U.S. 456, 461–63 (1981) (“[T]he purposes of the Act cited by the legislature . . . are legitimate state purposes. Thus, the controversy in this case centers on the narrow issue whether the legislative classification between plastic and nonplastic nonreturnable milk containers is rationally related to achievement of the statutory purposes.”).

¹⁴⁹ More than merely proper, the bill’s goals are admirable and important. While this note levies considerable criticism towards the bill, such criticism is directed squarely at only the means it uses to achieve a legitimate end.

¹⁵⁰ In 2014, national health care expenditures totaled \$3 trillion (or 17.5% of the United States’ GDP), and prescription drug expenditures comprised only 9.8% of that amount. *Health Expenditures*, CTR. FOR DISEASE CONTROL & PREVENTION, <http://www.cdc.gov/nchs/fastats/health-expenditures.htm> [<https://perma.cc/LMV2-MJW7>].

¹⁵¹ See, e.g., Linda Girgis, *Will a Healthcare Hero Rise Out of the Election of 2016?*, MEDCITY NEWS (Aug. 10, 2015), <http://medcitynews.com/2015/08/election-2016-healthcare/> [<https://perma.cc/26HP-HE8E>]; Jaimy Lee, *Pharma CEOs Defend R&D Model to Investors*, MED. MKTG. & MEDIA (Nov. 4, 2015), http://www.mmm-online.com/corporate/pharma-ceos-defend-rd-model-to-investors/article/451784/?DCMP=EMCMMM_Newsbrief&spMailingID=12869658&spUserID=MjMyNDE1NjYwNgS2&spJobID=660268706&spReportId=NjYwMjY4NzA2S0 [<https://perma.cc/3A3C-GB43>] (“The Turing controversy, as

bills introduced in other states after which New York's was modeled,¹⁵² understand this. The intentions of such legislation, while no doubt tainted to some degree by party politics, nonetheless appear generally pure. Unfortunately for the various drafters and proponents of pharmaceutical transparency bills, the constitutional analysis of their work does not end at the legitimacy of its purpose. Legitimate state goals must still be achieved by rational means, and the irrationality of the NYPCTA's regulations becomes apparent upon an examination of the bill's mechanics in the context of standard pharmaceutical industry pricing practices.

Because rational basis review is extremely deferential, instances of courts overturning a federal or state-based regulation of business are "by far the exception"¹⁵³ and, when one does occur, the legal community, as well as free-market, conservative, and libertarian commentators take notice.¹⁵⁴ Publicity surrounding a recent judicial determination of state regulatory overreach in the

well as fresh criticism of Valeant Pharmaceuticals' pricing practices, has turned what was once a fringe issue into a broad political topic."); Noam N. Levey, *How the Debate over Healthcare Is Changing—Just in Time for the 2016 Election*, L.A. TIMES (Oct. 7, 2015), <http://www.latimes.com/nation/politics/la-na-politics-healthcare-campaign-20151007-story.html> [https://perma.cc/EAL9-C34C]. Following the 2015–16 primary campaign season, the height of which coincided neatly with the public outcry against Martin Shkreli and his subsequent federal indictment, the issue of high pharmaceutical prices seemingly received less general election campaign trail lip service, likely due in no small part to Bernie Sanders's absence from the Democratic ticket. Interestingly, the pharmaceutical industry seemed to favor a Hillary Clinton presidency over a Donald Trump administration, at least based on campaign donations she received from the industry. Said one analyst in March 2016: "Hillary would probably be positive at this point because at least her policies are identifiable, understandable and likely to get toned down somewhat." Meg Tirrell & Leanne Miller, *Despite Her Rhetoric, Big Pharma Likes Hillary*, CNBC (Mar. 10, 2016), <http://www.cnbc.com/2016/03/10/despite-her-rhetoric-big-pharma-likes-hillary.html> [https://perma.cc/U5MT-U4E4]. Regardless of how industry insiders rationalized a Clinton administration's impact on the industry, biotechnology stocks suffered considerably during the protracted campaign season, a trend that reversed sharply in the days immediately following Trump's surprise election night victory. Nathan Vardi, *The Great Donald Trump Trade: Biotech Stocks*, FORBES (Nov. 9, 2016), <http://www.forbes.com/sites/nathanvardi/2016/11/09/the-great-donald-trump-trade-biotech-stocks/#1e9ccf957807>.

¹⁵² "New York is the latest state to introduce a 'pharmaceutical cost transparency act,' following five others—California, Oregon, Massachusetts, North Carolina, and Pennsylvania." Sullivan, *New York Introduces Pharmaceutical Cost Transparency Bill*, *supra* note 15.

¹⁵³ See Sanders, *supra* note 131, at 678.

¹⁵⁴ See Richard Epstein, *California Court Stunner: Something Fails the Rational Basis Test*, RICOCHET (June 11, 2010), <https://ricochet.com/archives/california-court-stunner-something-fails-the-rational-basis-test/> [https://perma.cc/MWY8-JL88] ("[A]ny decision that strikes down economic regulation under the rational basis test is as rare as the proverbial black swan."); George Leef, *Does Government Need a Good Reason for Restricting Your Freedom?*, FORBES (Oct. 26, 2015), <http://www.forbes.com/sites/georgeleef/2015/10/26/does-government-need-a-good-reason-for-restricting-your-freedom/> [https://perma.cc/6SKD-TZHJ].

hair braiding industry underscores this phenomenon, and the case itself serves as a stark reminder that, despite rational basis deference, the constitutional standard remains in place for a reason: to weed out truly irrational regulation and to protect businesses from unnecessary government interference.

In *Brantley v. Kuntz*,¹⁵⁵ a Texas statute that governed “barbering”—a blanket term for several follicular trades, including the practice of African hair braiding—mandated that any person wishing to perform these services must be licensed.¹⁵⁶ Certain licensing requirements for braiding had the actual effect of rendering compliance impossible and excluded the plaintiff entirely from the braiding market.¹⁵⁷ The statute required hair braiders to obtain a license specifically for that craft called a “Hair Braiding Specialty Certificate of Registration.”¹⁵⁸ The requirements necessary for a hair braiding license were considerably less rigorous than those required to become a licensed barber; however, the training curriculum required of would-be braiders could only be completed at licensed barber schools, which were mandated by law to “comply with a number of facility and equipment requirements in order to become licensed.”¹⁵⁹ These facility and equipment requirements naturally encompassed elements of the more rigorous prerequisites demanded of barbers by the state.¹⁶⁰ While rational and well-meaning in the context of ensuring that Texas’s future barbers were well-trained, the requirements were overbroad and potentially financially crippling when applied to the very same hair braiders already expressly exempted from such requirements. In the face of such statutory exemptions, the facility and equipment requirements were found to be wholly contradictory and irrelevant, and, based on this irrationality, the court concluded they served no legitimate purpose.¹⁶¹ Taken together, the “logical disconnect inherent in”¹⁶² the regulations constituted irrationality because “rather than logically connecting means and ends, [the regulations] shoehorn two unlike professions ‘into a single, identical mold, by treating hair

¹⁵⁵ *Brantley v. Kuntz*, 98 F. Supp. 3d 884 (W.D. Tex. 2015).

¹⁵⁶ *Id.* at 887.

¹⁵⁷ *Id.* at 894.

¹⁵⁸ *Id.* at 887.

¹⁵⁹ *Id.* at 888.

¹⁶⁰ *Id.* at 894.

¹⁶¹ *Id.*

¹⁶² *Id.* at 893.

braiders—who perform a very distinct set of services—as if they were [barbers].”¹⁶³

Brantley ultimately held that the regulations lacked “a rational connection with . . . fitness or capacity to engage in ‘hair braiding instruction,” and, furthermore, served no legitimate state purpose.¹⁶⁴ Thus, the principle that a ‘logical disconnect’ within some facet of a law can help defeat the rational basis standard is instructive in predicting how the NYPCTA would fare under a similar attack. The bill’s simplification of the pharmaceutical pricing paradigm is disconnected from the reality of standard industry practice. While compliance with the NYPCTA is not technically impossible, unlike the virtual impossibility of compliance with the licensing conditions in *Brantley*,¹⁶⁵ the bill’s mischaracterization of domestic pharmaceutical pricing contradicts its stated purpose of attempting to facilitate transparency in the prescription drug pricing process. By honing in on R&D and ignoring the totality of factors that converge to determine a drug’s price,¹⁶⁶ the NYPCTA would, in an attempt to open the public’s eyes to pharmaceutical cost strategy, actually misinform the populace. Thus, through its chosen means, the bill would effectively produce a result opposite of its stated goal.

The logical disconnect defect, or, at least, an analogue of it, was inherent in *U.S. Department of Agriculture v. Moreno*,¹⁶⁷ a prominent Equal Protection challenge to economic regulation heard by the United States Supreme Court in the early 1970s. In *Moreno*, a provision of the U.S. Food Stamp Act denied participation in the program to any household in which there resided a person unrelated to any other member of the dwelling.¹⁶⁸ The underlying legislative intent of this seemingly arbitrary classification was to exclude hippies, notorious for communal living, from receiving federal assistance;¹⁶⁹ however, the bill was deemed unconstitutional because it overlooked the fact that many poor families—the very population for whom the Food Stamp Act was enacted to assist—lived in shared housing arrangements to

¹⁶³ *Id.* (alteration in original) (quoting *Clayton v. Steinagel*, 885 F. Supp. 2d 1212, 1215 (D. Utah 2012)).

¹⁶⁴ *Id.* at 894 (quoting *Schware v. Bd. of Bar Exam’rs*, 353 U.S. 232, 239 (1957)).

¹⁶⁵ *Id.*

¹⁶⁶ *See supra* Part I.

¹⁶⁷ *U.S. Dep’t of Agric. v. Moreno*, 413 U.S. 528 (1973).

¹⁶⁸ *Id.* at 529.

¹⁶⁹ *Id.* at 537 (“It is my understanding that the Congressional intent of the new regulations are specifically aimed at the ‘hippies’ and ‘hippie communes.’”).

defray, or at least minimize, rental costs.¹⁷⁰ “Thus, in practical operation, the [regulation] exclude[d] from participation in the food stamp program, not those persons . . . likely to abuse the program,’ but, rather, only those . . . so desperately in need of aid that they [could not] even afford to alter their living arrangements so as to retain their eligibility.”¹⁷¹ Put simply, there was a logical disconnect between the program’s purported legislative intent and its ultimate effect.

If enacted, the NYPCTA would produce a similarly backward result. The practical application of the bill as written would misrepresent the prescription drug pricing process by implying that price is directly tied to only already-incurred R&D costs, despite the industry reality that decision makers involved in the drug pricing process must contemplate factors beyond merely R&D costs alone. While the stated goal of the bill is to inform consumers and shed light on a previously opaque process,¹⁷² the public would actually receive only selective information that lends itself to a misleading inference likely to accomplish little more than confusing the very citizens it purports to educate. Such a result is the opposite of the bill’s stated goal, and it is the only result the bill could possibly achieve because of its fundamentally flawed perception of prescription drug pricing policy. Surely, using ‘transparency’ to further obfuscate an already muddied issue is logically disconnected from the legitimate legislative goal of the NYPCTA.

Beyond the logical disconnect inherent in how its means would frustrate its purpose entirely, the NYPCTA is also wildly underinclusive when pharmaceutical costs are viewed as a fraction of total national health care expenditures. Underinclusiveness, on its own, is rarely dispositive of a finding of a regulation’s unconstitutionality because “[t]raditional equal protection analysis does not require that every classification be drawn with precise ‘mathematical nicety.’”¹⁷³ “[I]n practical effect,” however, a classification must nonetheless “operate so as rationally to further”¹⁷⁴ its goal. The NYPCTA, whether intentionally or not, creates a classification in imposing a requirement upon only one division of the expansive health care

¹⁷⁰ *Id.* at 537–38.

¹⁷¹ *Id.* at 538 (emphasis omitted).

¹⁷² See S.B. 5338-A, 2015–2016 Leg., Reg. Sess. (N.Y. 2015).

¹⁷³ *Moreno*, 413 U.S. at 538; see also *Metropolis Theatre Co. v. City of Chicago*, 228 U.S. 61, 69–70 (1913) (“The problems of government are practical ones and may justify, if they do not require, rough accommodations,—illogical, it may be, and unscientific.”).

¹⁷⁴ *Moreno*, 413 U.S. at 537.

sector. Yet in overall patient spending terms, prescription drugs in 2012 “accounted for just 9 cents of every [patient] dollar spent on health care.”¹⁷⁵ If the NYPCTA really sought to decrease the costs of the entire health care system, there are other areas within it with far costlier implications on total national health care spend, such as hospital, ambulance, and elder care services,¹⁷⁶ on which it could primarily focus its attention or, at least, impose similar cost disclosure obligations.

The fact that the NYPCTA is underinclusive by regulating the pharmaceutical industry while ignoring ample evidence showing that other health care providers impose far heavier costs on the public¹⁷⁷ would not prove persuasive to a judge analyzing the constitutionality of the bill.¹⁷⁸ The NYPCTA’s underinclusiveness, however, further highlights its limitations as currently drafted. And when considered in tandem with the paradoxically obfuscating effect this “transparency” bill would have on public perception of the factors included in the drug pricing analysis, the NYPCTA’s regulation of the pharmaceutical industry alone, in an ostensible consumer protection effort,¹⁷⁹ may tip the scales toward a judicial conclusion that there is no rational basis between the bill’s means and its end. Perhaps a more proportional, inclusive piece of legislation—one also regulating the other providers and professionals within the health care sector—would ensure that its required disclosures actually have the effect of educating the public on health care costs.

A judicial finding that the NYPCTA is unconstitutional is unlikely. But the fact that it is not inconceivable that the bill could join the constitutional short list of commercial regulations

¹⁷⁵ Robert Zirkelbach, *The Reality of Prescription Medicine Costs in Three Charts*, PHRMA (May 27, 2014), <http://www.phrma.org/catalyst/the-reality-of-prescription-medicine-costs-in-three-charts#sthash.VWh5aCAn.dpuf> [<https://perma.cc/FZ4X-MFGT>].

¹⁷⁶ Michael Mandel, *The Folly of Targeting Big Pharma*, WALL ST. J. (Dec. 10, 2015), <http://www.wsj.com/articles/the-folly-of-targeting-big-pharma-1449792625> [<https://perma.cc/STQN-KRDY>].

¹⁷⁷ “The single biggest driving force for increased health-care spending in the U.S. is the rising cost of labor, not drugs. . . . [T]otal labor compensation at hospitals, doctors’ offices, ambulatory care facilities and nursing homes has risen by roughly \$270 billion since 2007” *Id.*

¹⁷⁸ See *Williamson v. Lee Optical Co.*, 348 U.S. 483, 489 (1955) (“[T]he reform may take one step at a time, addressing itself to the phase of the problem which seems most acute to the legislative mind. The legislature may select one phase of one field and apply a remedy there, neglecting the others.” (internal citation omitted)).

¹⁷⁹ S.B. 5338, 2015–2016 Leg., Reg. Sess. (N.Y. 2015). The sponsor memo of the original version of the bill offered the following as justification for cost reporting: “Pharmaceutical companies have long maintained that the exorbitant prices are needed in order to cover the costs associated with research, development and clinical trials. However, . . . consumers who need these prescriptions . . . have [no] idea if what the . . . [companies] contend is actually true.” *Id.* (sponsor memo).

that have failed the rational basis standard (a dubious distinction) underlines the various shortcomings of the legislation. While minimal scrutiny is all that federal courts require an economic regulation to withstand to sustain its constitutionality, an effective pharmaceutical cost transparency effort should still aim higher. By regulating attuned to inexorable realities of the pharmaceutical industry, a revised bill could be more than just a rational business regulation that causes drug companies minor headaches; it could stand a reasonable chance of achieving its legitimate goals.

III. AMENDING THE NYPCTA

Despite its current deficiencies, the NYPCTA would require only relatively minor amendments to its disclosure requirements to pass constitutional muster without compromising the legislative intent behind the bill. The fatal flaw of the act as written is its oversimplification of the prescription drug pricing puzzle. By implying that R&D costs are the sole contributing factor to drug pricing, the bill falls far short of achieving its purported goal to educate the public on the investments made by pharmaceutical companies to develop and market innovative drugs.¹⁸⁰ Additionally, the bill as written sweeps broadly across the entire pharmaceutical sector, and it would benefit from granting exemptions to certain classes of drugs for whom the disclosure requirements make less practical sense. Finally, one area in which the NYPCTA could regulate *more* stringently is in situations where a company acquires an existing drug and promptly raises its market price. With these fairly simple amendments to the bill, the NYPCTA would regulate armed with a clear understanding of prescription drug pricing factors, and, through such knowledge, its means of regulation would represent a rational attempt to bring transparency to pharmaceutical costs.

A. *Disclosure of Investments into Failed R&D That Preceded a Newly Approved Drug*

If it were to truly educate the public, the NYPCTA must additionally require disclosure of, or at least a disclaimer, identifying or acknowledging the existence of, the less visible elements that comprise the prescription drug pricing scheme, including those costs incurred by the drug makers for failures

¹⁸⁰ See *supra* Part I.

during development. Determining a drug company's total expenditures on failed clinical trials or laboratory tests that nonetheless contributed incrementally to the innovation behind an approved drug is likely impossible to achieve with absolute precision. This is so because of the often-amorphous nature of preclinical expenses¹⁸¹ and the difficulty in assigning concrete scientific "credit" for the innovation associated with a drug's approval to various failures. But while the actual dollar amount may be ultimately elusive, pharmaceutical makers should have a sense of the general level of R&D invested during at least the past decade into efforts to produce a therapy for either the actual disease state for which a new drug is approved, similar disease states, or simply investments into the general disease category.¹⁸² Any of these R&D efforts could have resulted in data collection, trial and error, and minor breakthroughs that indirectly paved the way for an understanding and harvesting of the science behind a drug efficacious and tolerable enough to be granted FDA approval.

Reference to these efforts, whether or not absolute investment figures are available, would at a minimum signal to the general public that the process of innovation likely began well before the testing and development of only those molecules alive in a newly approved prescription medicine. Other large-scale or high-profile developmental failures in different disease categories that may not have any apparent causal nexus to the science behind a newly approved drug are also highly relevant to the price assigned to it; accordingly, an indication of such sunk costs is also appropriate in the context of a pricing transparency effort. This holistic representation of the full developmental lifecycle has the potential to truly educate the public on the expenses that justify the prices of new drugs.

B. Acquisition Cost Disclosure and Public Notice Period for Post-Acquisition Price Increases

A further provision to effect transparency would require—if a pharmaceutical company acquired a drug from a smaller

¹⁸¹ "[S]ubstantial expenditures incurred prior to clinical testing cannot be directly linked to work on specific compounds." Graham, *supra* note 50.

¹⁸² For example, an approval for a drug that treats a specific form of leukemia may have been made possible by insights gained in the earlier failure of a therapy that had been intended to treat the same type of leukemia, a different form of leukemia or other blood cancer, a different form of cancer, or another disease entirely. The costs associated with any such failure, regardless of the initial objective, are relevant in determining R&D spend.

developer or bought the developer itself either post-approval or during the development stage—not only public disclosure by the purchaser of the cost, to the penny, of that transaction, but also advanced public notice of any planned price raises of acquired drugs following the purchase. The NYPCTA could both educate and protect patients by imposing stringent reporting rules on firms looking for a quick payday in such a manner. This provision would result in far greater transparency than mandating only immediate R&D disclosure because the actual value of a drug to a company—what the company paid for the rights to manufacture and sell the drug—would be readily available. Based on existing prescribing patterns if the acquired drug is already FDA-approved, or the size of the prospective patient population for a drug still in clinical trials,¹⁸³ the public would have a snapshot of a drug maker's financial position following an acquisition, and an idea of at what price the drug must be made available for the company to profit off of its investment. Through such transparency, an informed debate as to how high these profit margins should be could ensue.

As currently drafted, the NYPCTA does include “costs for the purchase of patents, [and the] licensing or acquisition of any corporate entity owning any rights to the drug while in development” as expenses requiring disclosure.¹⁸⁴ Additionally, the bill accounts for disclosure of pre-acquisition R&D costs incurred by a target pharmaceutical company so that the buyer cannot simply point to the transaction costs (if the buyer believed its purchase was a bargain) plus the expenses associated with stewarding the drug to the FDA's finish line as the price of innovation.¹⁸⁵ Acquisition costs certainly merit heightened prominence in an effective pharmaceutical transparency bill, but the NYPCTA requires a more detailed drafting to fully protect consumers and ensure pricing transparency in a corporate combination scenario.

¹⁸³ Newsweek noted the intuitive relationship between patient population and price, especially in regards to specialty drugs, thus: “[D]ue to the smaller patient populations and higher development costs, the cost of creating the drugs must be spread over a smaller population of people needing the treatment, which increases the price.” Grace-Marie Turner, *Should Drug Prices Be Capped?*, NEWSWEEK (Dec. 19, 2015), <http://www.newsweek.com/should-drug-prices-be-capped-407045> [<https://perma.cc/7QBD-H5FE>].

¹⁸⁴ S.B. 5338A, 2015-2016 Leg., Reg. Sess. (N.Y. 2015).

¹⁸⁵ The bill requires disclosure of “the total costs of clinical trials and other regulatory costs paid by the manufacturer, and separately, the total costs of clinical trials and other regulatory costs paid by any predecessor in the development of the drug.” *Id.*

If an acquirer does intend to raise the price on a currently approved drug, that new, higher price should also be disclosed ahead of its implementation. The specifics of this advance notice period may be determined based on what a reasonable amount of time necessary to trigger public debate on, or at least awareness of, the price hike would require.¹⁸⁶ This type of disclosure would target truly predatory pricing schemes by ensuring they are exposed and served up to both the public and various enforcement mechanisms on a naked platter lacking the protections that previously enabled disingenuous executives to shield such parasitic efforts from condemnation and scorn.

Under such a rule, Turing Pharmaceuticals, and its CEO, Martin Shkreli, would have been taken to task by a diligent public for a “fifty-fold price increase”¹⁸⁷ of the newly acquired, but decades-old, drug Daraprim¹⁸⁸ before its new pricing scheme was ever implemented. In the case of Turing, Shkreli instituted a “gigantic overnight increase in the price of a 62-year-old drug that is the standard of care for treating a life-threatening parasitic infection.”¹⁸⁹ To both Shkreli’s dismay and surprise,¹⁹⁰ furor did

¹⁸⁶ Vermont recently enacted a transparency bill with similar consumer protection aims, although in practice it sweeps far more broadly and, seemingly, randomly than that of the hypothetical notice mechanism described above. This bill requires

state health care regulators to develop an annual list of fifteen drugs for which “significant health care dollars” are spent and where the wholesale acquisition costs (i.e., list prices) rose by fifty percent or more over the previous five-year period, or for which the list prices rose by fifteen percent or more over a twelve-month period. . . .

Select manufacturers will then need to disclose “all the factors that have contributed to a price increase” and justify the price increase to the Attorney General’s office, which could take companies to civil court if they decline to provide the requested information. Each violation also carries a \$10,000 penalty.

Thomas Sullivan, *Vermont Governor Signs Drug Price Transparency Bill*, POLICY & MED. (June 9, 2016), <http://www.policymed.com/2016/06/vermont-governor-signs-drug-price-transparency-bill.html> [<https://perma.cc/BQ8A-LK7H>]. Chief among the many differences between Vermont’s new legislative effort and a notice period on post-acquisition drug price hikes is that, in the latter case, the public is given a voice that it can choose to use or to remain on the sidelines, whereas in Vermont, state actors with unknown motivations are granted wide latitude to determine whether a drug’s price is, in their mind and based on an as yet undefined value proposition, justified. *See* Feyman, *supra* note 135 (“Based on Vermont’s prior legislative escapades—looking to allow the importation of drugs from Canada—it would seem that legislators simply want *lower* drug prices across the board (with an added bonus of shaming drugmakers, of course).”).

¹⁸⁷ Lowe, *supra* note 63.

¹⁸⁸ *See* Ross, *supra* note 91.

¹⁸⁹ Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), http://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html?_r=0 [<https://perma.cc/6A7D-83KY>].

eventually arise over his blatant cash grab. Under an amended NYPCTA, however, patients and physicians—having been made aware of the planned raise well before it took effect—would not have been blindsided and put immediately on the defensive by an instantaneous, crippling price increase.

Shkreli is an almost cartoonish villain and a convenient face for the industry’s detractors to personify as all that is evil and predatory about “Big Pharma.” The rise and fall of Martin Shkreli, however, will more likely be remembered as a cautionary Icarian tale of greed and hubris, serving as a warning for future entrepreneurs to not fly too closely to the sun on wings made of arbitrarily pumped-up pharmaceutical profits. His actions, moreover, represent an extreme case of corporate abuse of the pharmaceutical sphere in the private American health care market, and—given the extreme backlash that they generated—it is unlikely that another company will seek to replicate such an overt feat of greed in the near future.¹⁹¹

This does not change the reality that overnight drug price increases of any size pose a considerable danger to patients.¹⁹² When a price raise occurs solely as a result of a corporate acquisition, a notice period would arm the public, as well as its government representatives and advocates, with substantial leverage to attempt to block or delay its implementation rather than being forced to garner media attention and inspire grassroots condemnation of the new price after having already

¹⁹⁰ In justifying the price increase based on Daraprim’s relatively light usage and attempting to re-classify the drug as “specialty,” Shkreli contended that “[i]t really doesn’t make sense to get any criticism for this.” *Id.*

¹⁹¹ “If there’s a bright spot for those who think Shkreli’s actions are unconscionable, it’s that the attention paid to the Daraprim price increase may spell an end to the whole practice. ‘He basically ruined the concept for other companies,’ one biotech banker says.” Bethany McLean, *Everything You Know About Martin Shkreli Is Wrong—Or Is It?*, VANITY FAIR (Dec. 18, 2015), <http://www.vanityfair.com/news/2015/12/martin-shkreli-pharmaceuticals-ceo-interview> [<https://perma.cc/HP5Q-HK4F>]. This is made ever more likely by Shkreli’s December 2015 arrest by federal authorities for securities fraud. See Christie Smythe & Keri Geiger, *Shkreli, Drug Price Gouger, Denies Fraud and Posts Bail*, BLOOMBERG (Dec. 17, 2015), <http://www.bloomberg.com/features/2015-martin-shkreli-securities-fraud/> [<https://perma.cc/3S2H-DGW2>]. His arrest, unfortunately, was not an instance of karmic retribution, as the FBI had begun investigating Shkreli in 2014, well before he raised the price of Daraprim, on allegations of fraudulent activities he undertook in connection with a hedge fund he previously managed. *See id.*

¹⁹² “[W]hile more conventional companies do not typically triple or quadruple prices overnight, they do often raise them year after year at a rate far faster than inflation. . . . They now are concerned that innovation will be undermined by a reaction to price increases imposed by companies like Turing and Valeant.” Andrew Pollack & Sabrina Tavernise, *Valeant’s Drug Price Strategy Enriches It, but Infuriates Patients and Lawmakers*, N.Y. TIMES (Oct. 4, 2015), http://www.nytimes.com/2015/10/05/business/valeants-drug-price-strategy-enriches-it-but-infuriates-patients-and-lawmakers.html?_r=0 [<https://perma.cc/LZJ3-DCDJ>].

been subjected to its bite. Such leverage would take the form of the noise resulting from an angry public,¹⁹³ which could compel the seller to reconsider its new price point. If the prospect of poor public relations fails to force a price reduction, the ensuing outcry would still alert the manufacturers of branded competitor drugs to the opportunity to increase their own market shares and polish their images by undercutting a deeply unpopular price. In such a manner, a public educated on prescription drug costs through a transparency bill attuned to the inner-workings of the pharmaceutical industry could collectively act to facilitate sensible, proportional drug-pricing policy.

C. *“Innovation Exemption” from the NYPCTA for High-Science Molecules*

Finally, the NYPCTA would benefit from relaxing its disclosure requirements and offering exemptions to certain classes of drugs based on the likelihood of such treatments being the product of true innovation and scientific advance, and also conferring considerable patient benefit. Specifically, biologics, which, as opposed to traditional small-molecule compounds, “are more likely to represent some form of scientific advancement,”¹⁹⁴ are deserving of relief from the NYPCTA given that the bill’s limitations, particularly its failure to account for a treatment’s therapeutic value, are especially applicable to this class of drugs. Granting such exemptions would evince an understanding on the bill’s part of the complex differences that exist between various types of therapies, despite the uniform subjection of all new drug candidates to the FDA’s approval process.¹⁹⁵ By making these distinctions, the NYPCTA would indicate to the public that assigning a price to a new prescription drug requires an analysis

¹⁹³ Pharmaceutical executives are right to fear becoming the center of a Turing-like controversy, and are right to prevent *any* such scandal from occurring. “When scandals occur, they have a negative impact on companies that are doing things right. The subsequent public outcry tends to harm the committed, experienced companies, as politicians paint all health care companies with the same brush.” Bill George, *Meet Health Care’s Major Spoilers: Theranos, Valeant, and Turing Pharmaceuticals*, HUFF. POST (May 12, 2016), http://www.huffingtonpost.com/bill-george/meet-health-cares-major-s_b_9894126.html [https://perma.cc/K9VR-TYJQ]. Accordingly, the incentive would be high for companies to responsibly price recently acquired drugs such that the notice period does not generate negative publicity.

¹⁹⁴ See DRANOVE ET AL., *supra* note 82, at 30.

¹⁹⁵ “Since 1938, every new drug has been the subject of an [FDA]-approved NDA [New Drug Application] before U.S. commercialization.” *New Drug Application*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/drugs/developmentapprovalprocess/how-drugs-are-developed-and-approved/approval-applications/new-drug-application-nda/default.htm> [https://perma.cc/S4FN-M3WC] (last updated Mar. 29, 2016).

deeper than simply pricing according to R&D expenditure, thereby shedding more light on a very complicated process.

Biologics “are large and complex, often consisting of heterogeneous mixtures,”¹⁹⁶ and, thus, their development timelines are often more protracted and expensive than those of small-molecule drugs.¹⁹⁷ Since reproducibility of biologics is incredibly difficult, if not downright impossible “without intimate knowledge of and experience with the innovator’s process,”¹⁹⁸ there is minimal danger of a newly approved biologic being merely a “me-too” product representing either little or no innovation on the part of its developer. Therefore, it is likely that the inherent therapeutic value of biologics is, on the average, higher than that of small-molecule drugs being introduced into already crowded marketplaces.¹⁹⁹ By no means is this a universal rule; however, the NYPCTA’s failure to distinguish in any way between drug classes and types belies its misperception of pharmaceutical output as a homogenizing process.

If a blanket exemption for biologics were too broad, a slightly more pared-down proposal would seek a provision within the NYPCTA granting immunity to novel, first-in-class therapies²⁰⁰ or to drugs granted New Chemical Entity (NCE) status²⁰¹ upon

¹⁹⁶ *Small Molecule Versus Biological Drugs*, GABI ONLINE (June 29, 2012), <http://www.gabionline.net/Biosimilars/Research/Small-molecule-versus-biological-drugs> [<https://perma.cc/MAF6-NZK5>].

¹⁹⁷ “Manufacturing of biologics is more challenging than for traditional small molecule drugs. Even minor changes in manufacturing process can cause significant changes in efficacy or immunogenicity.” *Id.*; see also Lacie Glover, *Why Are Biologic Drugs So Costly?*, U.S. NEWS & WORLD REPORT (Feb. 6, 2015), <http://health.usnews.com/health-news/health-wellness/articles/2015/02/06/why-are-biologic-drugs-so-costly> [<https://perma.cc/TTJ9-Y4AG>] (“At the molecular level, . . . [biologics are] usually larger and much more complex than regular drugs. . . . It’s just not cheap to produce medicine from living cells with today’s technology.”).

¹⁹⁸ *How Do Drugs and Biologics Differ?*, BIOTECHNOLOGY, INNOVATION, ORG., <http://www.bio.org/articles/how-do-drugs-and-biologics-differ> [<https://perma.cc/6RY4-VUUT>].

¹⁹⁹ “[T]he big advantage of . . . [biologics] is their specificity: they do only what they are supposed to do, rarely causing the sort of side-effects that are frequently discovered in conventional, small-molecule drugs, and lead to them being abandoned.” *Going Large*, ECONOMIST (Jan. 3, 2015), <http://www.economist.com/news/business/21637387-wave-new-medicines-known-biologics-will-be-good-drugmakers-may-not-be-so-good> [<https://perma.cc/MM6Y-D9NC>].

²⁰⁰ “A first-in-class product is associated with the greatest risk [of clinical trial failure or FDA rejection] as it requires identifying a new target, and subsequently developing a therapeutic compound for that target and validating the target mechanism for disease intervention in human[s].” Herren Wu, *Balancing a Biologics Pipeline Portfolio*, DRUG DISCOVERY WORLD (Spring 2011), <http://www.ddw-online.com/drug-discovery/p142736-balancing-a-biologics-pipeline-portfolio-spring-11.html> [<https://perma.cc/9R5S-FDEE>].

²⁰¹ A new drug is entitled to an NCE designation if it “contain[s] no active moiety that has been approved in a prior application.” *Amarin Pharms. Ir. Ltd. v. FDA*, 106 F. Supp. 3d 196, 200 (D.C. Cir. 2015). The FDA defines ‘active moiety’ as “the

FDA approval. Since a first-in-class or NCE drug by its very nature represents some sort of innovation or breakthrough within its disease category,²⁰² it can be inferred that its development process was not aided by advances or knowledge already well established within its scientific niche. Thus, R&D expenditure was likely higher,²⁰³ and the risk of failure was likely greater;²⁰⁴ the end product of which provides a new treatment avenue for patients, likely filling an unmet need for greater efficacy and positive outcomes in the category.²⁰⁵ Relief from the NYPCTA is appropriate for these types of drugs as their developmental costs would be particularly obscured by the bill's disclosure mandates.

So as not to override other areas of necessary amendment to the NYPCTA, the "innovation exemption" should apply only to the forced disclosure of a new drug's actual R&D spend in the laboratory and during clinical trials; not to any acquisitions made during the development of the innovative therapy. If the compound was acquired from another company, or if that other company itself was acquired for purposes of obtaining the compound, these costs would still be subject to the bill's disclosure requirements and, if applicable, an advance public notice period, as discussed above. Prior to an FDA approval, acquisition costs would be disclosed publicly, and, based on the scope of the transaction, the public would have a sense of how the drug was valued by its purchaser at the stage of development at which it was acquired. If a compound were acquired on the cheap—prior to its being thoroughly investigated in a laboratory setting—but eventually progressed all the way to market, the purchaser would have shouldered the vast majority of the costs associated with the innovation.

Conversely, an investigatory drug already steeped in encouraging preliminary Phase 3 data would command a far

molecule or ion . . . responsible for the physiological or pharmacological action of the drug substance." *Id.* at 199.

²⁰² As a result of innovation, "[a] first in class drug provides the manufacturer with a period of market exclusivity free of competition from similar drugs" because none yet exist. *The Economics of Drug Discovery: 'First in Class' vs. 'Best in Class'*, SEEKING ALPHA (Aug. 22, 2010), <http://seekingalpha.com/article/221704-the-economics-of-drug-discovery-first-in-class-vs-best-in-class?page=2> [<https://perma.cc/NR8N-UVNB>].

²⁰³ "Companies [developing a first-in-class drug] face an extra burden of proof, more time and money to demonstrate product safety, as well as competition." Rachel MacDonald, *Biologic Copy-Cat Drug Development Is Rising, Bringing Pharmaceutical Companies Together*, MEDILL REPORTS CHI. (May 10, 2012), <http://newsarchive.medill.northwestern.edu/chicago/news-205418.html> [<https://perma.cc/5D69-L9GQ>].

²⁰⁴ Wu, *supra* note 200.

²⁰⁵ *Id.*

higher price so far along in development.²⁰⁶ Based on the drug's price tag in relation to where it was in the development cycle at the point of its purchase, the public could decide for itself whether this perceived value is reflected fairly in the drug's price tag or whether its owners are now seeking to profit many times over for the work of another. Therefore, the "innovation exemption" would not serve as a loophole for disingenuous firms. In this way, relaxing the sweeping nature of the NYPCTA would effect a greater transparency that could at least further the public's understanding of, if not solve, the pharmaceutical pricing puzzle.

CONCLUSION

The NYPCTA nobly seeks to force pharmaceutical companies to publicly justify the high costs of prescription drugs. In the face of the contentious current climate surrounding the motives and ethics of drug makers, bringing transparency to the drug pricing analysis is a legitimate legislative goal. But disclosure of only the types of information mandated by the NYPCTA would not provide an accurate justification of a drug's cost, and publicizing these costs completely devoid of any context of the other relevant pricing elements would only further embitter a frustrated public against the pharmaceutical industry. It would also obscure the true nature of the pharmaceutical pricing process, effectively using "transparency" to do nothing but precipitate more public confusion and mistrust of drug companies. An imperative constitutional check on government regulation of private businesses, while meek and rarely successful,²⁰⁷ nevertheless exists in the form of rational basis review, and the obfuscating effect the NYPCTA would likely have on the public enables this deferential, but "not 'toothless,'"²⁰⁸ standard to threaten the constitutionality of the bill. Hence, as drafted, the NYPCTA falls short of its admirable goal to arm the public with the information necessary to stimulate informed debate about prescription drug costs. One can only hope that in future discussions of the bill, the New York State Legislature views the NYPCTA with a more discerning

²⁰⁶ "[T]he more developed a product is, the more it has been derisked, and thus it is more valuable to pharma." Asiya Giniatullina et al., *Building for Big Pharma*, *BIOENTREPRENEUR* (Mar. 21, 2013), <http://www.nature.com/bioent/2013/130301/full/bioe.2013.3.html> [<https://perma.cc/Q5HZ-PK79>].

²⁰⁷ Aaron Belzer, *Putting the "Review" Back in Rational Basis Review*, 41 W. ST. U. L. REV. 339, 340 (2014).

²⁰⁸ See *Peoples Rights Org., Inc. v. City of Columbus*, 152 F.3d 522, 532 (6th Cir. 1998) (citing *Mathews v. Lucas*, 427 U.S. 495, 510 (1976)).

eye—one attuned to the complexities inherent in affixing a price to a product that engenders far more than the sum of its parts.

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