

Prologue

Big Scandals, Higher Prices

A PHARMA UNDER FIRE

Each January, the J. P. Morgan Healthcare Conference rolls into San Francisco, towing along hundreds of pharmaceutical and biotech companies and nearly 10,000 attendees looking to hear about the latest developments in one of the world's hottest industries. Suits hobnob with scientists, financial journalists breathlessly cover the proceedings, and, controversially, companies throw cocktail parties with women hired to attend and improve diversity numbers.¹ Deal making generally takes place behind closed hotel room doors at the glamorous Westin St. Francis in the heart of San Francisco's Financial District, but crowds still turn out for investor presentations and occasionally heated Q&As asking, "What drugs are in the pipeline?" or "How are clinical trials coming along?"

In January 2016, the mood was far less rosy. After years of hypergrowth in biotechnology and health care, stocks experienced a precipitous drop in the second half of 2015.² By the beginning of the annual conference, the NASDAQ's Biotechnology Index had lost more than 25 percent of its value in six months.³ *Bloomberg* reported that biotech stocks experienced their worst trading day for a J. P. Morgan conference opening day since the beginning of 2001's gathering.⁴ Statistical indicators of unease were certainly present. The number of initial public offerings (IPOs) had

¹ Sasha Damouni, Doni Bloomfield, & Caroline Chen, *At Biotech Party, Gender Diversity Means Cocktail Waitresses*, BLOOMBERG (Jan. 13, 2016), www.bloomberg.com/news/articles/2016-01-13/at-biotech-party-gender-diversity-means-cocktail-waitresses.

² NASDAQ Biotechnology Index, GOOGLE FINANCE, www.google.com/finance?q=INDEXNASDAQ%3ANBI&ei=TQHCV5CVE82NzAaopjYCw (click "Historical prices" and view prices from July 2015 to January 2016). The index peaked at an all-time high, 4,165.87, on July 20, 2015, before falling to 3,052.56 on January 11, 2016, the day the conference opened. That fall is equivalent to a 26.7% drop.

³ *Ibid.*

⁴ Drew Armstrong, Caroline Chen, & Sasha Damouni, *Worst Start to Health Conference Since 2001 Has Investors Glum*, BLOOMBERG (Jan. 11, 2016), www.bloomberg.com/news/articles/2016-01-11/worst-start-to-health-conference-since-2001-has-investors-glum.

fallen dramatically in the last year. Instead of raising money through IPOs, large pharmaceutical and biotech firms were looking to boost their cash flow through mergers and acquisitions, with deals totaling \$220 billion in 2014 compared to just \$65 billion in 2007.⁵

Yet perhaps the most salient problem at the 2016 conference was the public outcry over rising pharmaceutical prices. List prices for branded medications had climbed more than 12 percent in 2015 and more than 14 percent the previous year, with overall spending on medication up 8.5 percent.⁶ Even with insurance, these cost increases have the power to affect the health and well-being of patients directly. According to the Kaiser Family Foundation, almost one-quarter of people said their family chose not to fill at least one prescription in the last year, with numbers rising for those in poor or fair health.⁷ A similar survey from Kaiser found that people believe the government's top two health care priorities should be related to the price of medication.⁸

This rising concern was exacerbated by a number of national public scandals over dramatic, sudden price increases for existing drugs. Outside the Westin in San Francisco, a cadre of protesters railed against Gilead Science's pricing of Sovaldi, a breakthrough cure for hepatitis C that Gilead had priced at \$84,000 for the three-month course of treatment.⁹ Signs read, "Gilead = Greed" and "Don't Be Greedy! Treat the Needy!"¹⁰

In that respect, perhaps the biggest story at the J. P. Morgan Healthcare Conference was about who *wasn't* in attendance. And with that, we arrive at the story of Martin Shkreli – yes, that guy. The "Pharma Bro," who at the age of thirty-two became a global poster child for the excesses of Big Pharma, had long walked the hallways of the Westin in his time running hedge funds and pharmaceutical companies. When he led the hedge fund MSMB Capital Management in 2010, Shkreli entered the

⁵ Robert Weisman, *Drug Price Policies, China May Slow Biotech Bull Market*, BOSTON GLOBE (Jan. 10, 2016), www.bostonglobe.com/business/2016/01/10/biotech-bull-market-may-slow/PzzRRSFujEkiDntFtMT5IP/story.html.

⁶ Press Release, IMS Health, *IMS Health Study: U.S. Drug Spending Growth Reaches 8.5 Percent in 2015* (Apr. 14, 2016), www.imshealth.com/en/about-us/news/ims-health-study-us-drug-spending-growth-reaches-8.5-percent-in-2015; Katie Thomas, *Drug Prices Keep Rising Despite Intense Criticism*, N.Y. TIMES (Apr. 26, 2016), www.nytimes.com/2016/04/27/business/drug-prices-keep-rising-despite-intense-criticism.html?_r=0.

⁷ Bianca DiJulio, Jamie Firth, & Mollyann Brodie, *Kaiser Health Tracking Poll: August 2015*, KAISER FAMILY FOUNDATION (Aug. 20, 2015), <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/>.

⁸ Bianca DiJulio, Jamie Firth, & Mollyann Brodie, *Kaiser Health Tracking Poll: April 2015*, KAISER FAMILY FOUNDATION (Apr. 21, 2015), <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-april-2015/>.

⁹ Rebecca Robbins, *Drug Makers Dismiss Outrage over High Prices as 'Abomination'*, STAT (Jan. 12, 2016), www.statnews.com/2016/01/12/public-outrage-drug-prices/.

¹⁰ *Ibid.*

annals of the conference's history by peppering a pharma founder with questions during a public session. The founder's company, MannKind, was applying for FDA approval of an inhaled insulin product; Shkreli, as part of his hedge fund strategy, was shorting the company's stock.¹¹

That kind of behavior – in addition to brash missives on Twitter,¹² wunderkind status on the annual Forbes 30 under 30 list, all-day live streaming of his computer screen and office activities, and, more recently, his multimillion dollar purchase of the only copy of a new Wu-Tang Clan album, only to fight publicly later with the artists over the purchase – got Shkreli attention in biotech circles.¹³

Yet pharma's bad boy wasn't in California in January 2016, having just starred in the industry's biggest public relations disaster in years. In September 2015, Shkreli's latest company, Turing Pharmaceuticals, became the subject of intense scrutiny after raising the price of a drug by almost 5,500 percent overnight.¹⁴ Turing had bought the rights to Daraprim, an antimalarial drug also used for treatment of infections common in HIV-positive patients, for \$55 million. The company then immediately raised the price of the drug from \$13.50 a tablet to \$750 a tablet.¹⁵ A one-month course of the drug became \$20,000, up from just \$400 before the increase. The magnitude of the price increase for a potentially lifesaving drug led to immediate public outrage, particularly because the drug was originally approved in 1953 and had been off-patent for decades. In the midst of a heated 2016 presidential primary season, candidates including Hillary Clinton, Bernie Sanders, and Donald Trump denounced Shkreli's actions, and Daraprim soon became the most dramatic example of exorbitant price increases. Drug pricing had once again become a political issue and a core part of campaign messaging. Shkreli eventually promised, and then quickly walked back, a price decrease.

Shkreli was not alone in his tactics; the media's newfound villain just took the blunt of the criticism. Other companies, such as Valeant Pharmaceuticals, also

¹¹ Arlene Weintraub, *Gadfly Pharma Investor Shkreli Starts Anew after Ousting from Retrophin*, FORBES (Feb. 27, 2015), www.forbes.com/sites/ahlenweintraub/2015/02/27/gadfly-pharma-investor-shkreli-starts-anew-after-ousting-from-retrophin/#5303e3e5359d; Allie Conti, *Why Is Martin Shkreli Still Talking?* VICE (Jan. 27, 2016), www.vice.com/read/why-is-martin-shkreli-still-talking.

¹² Examples of interesting Twitter behavior: Martin Shkreli (@MartinShkreli), TWITTER (Jun. 10, 2016, 7:48 PM), <https://twitter.com/MartinShkreli/status/741431768247640064>; Martin Shkreli (@MartinShkreli), TWITTER (Jun. 10, 2016, 7:47 PM), <https://twitter.com/MartinShkreli/status/741431597761736704>.

¹³ Devin Leonard & Annmarie Hordern, *Who Bought the Most Expensive Album Ever Made?* BLOOMBERG BUSINESSWEEK (Dec. 9, 2015), www.bloomberg.com/features/2015-martin-shkreli-wu-tang-clan-album/.

¹⁴ Andrew Pollack, *Drug Goes from \$13.50 a Tablet to \$750, Overnight*, N.Y. TIMES (Sept. 20, 2015), www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html. The price of the drug was as low as \$1 in 2010, before a series of acquisitions. *Ibid.*

¹⁵ *Ibid.*

came under fire in the fall of 2015. In one example, Valeant sold a drug called Duexis that simply combined the active ingredient in Motrin with the active ingredient in Pepcid, but charged \$1,500 for the privilege of a monthly prescription.¹⁶ Prescribing the two drugs separately would cost no more than \$40, but Valeant had increased the price of its combination drug by about 1,000 percent in the four years since the drug was introduced.¹⁷ Notably, Valeant also pushed its main competition out of the market. According to the *New York Times*, Valeant acquired Vimovo – a simple combination of naproxen (Aleve) and esomeprazole (Nexium) – and then immediately raised the price to make it equal to that of Valeant’s drug.¹⁸ Around the same time as these stories broke, federal prosecutors announced an investigation of Valeant, for reasons discussed later in this book.

Criminal investigations were numerous that fall, with the most notable being the arrest of Shkreli early in the morning of December 17, 2015. Federal authorities charged Shkreli with multiple counts of securities fraud and conspiracy, reaching back to his tenure at MCMB Capital and Retrophin, a previous pharmaceutical company.¹⁹ Allegedly, Shkreli had taken money from Retrophin to pay back investors who lost money at MCMB.²⁰ (The FBI also made sure to inform the public that the Wu-Tang Clan album had not been seized – sorry, Clan fans.)²¹ Shkreli resigned from Turing the next day, and then made a famous appearance testifying in front of the House Committee on Oversight and Government Reform in February 2016. With charges pending against him, Shkreli answered every question, no matter how trivial, with a knowing smirk and the same response: “On the advice of counsel, I invoke my Fifth Amendment privilege against self-incrimination and respectfully decline to answer your question.”²² The spectacle lasted no more than ten minutes.

While Shkreli smirked his way through his congressional hearing, attendees at the 2016 J. P. Morgan Conference were far more worried. Big Pharma and its perceived excesses were back in the spotlight, and attention was shifting to a core pharma revenue strategy – simply raising prices. Price increases had occurred across the board, on everything from gallstone treatments to, stunningly, the drug used for

¹⁶ Andrew Pollack, *Drug Makers Sidestep Barriers on Pricing*, N.Y. TIMES (Oct. 19, 2015), www.nytimes.com/2015/10/20/business/drug-makers-sidestep-barriers-on-pricing.html?smid=pl-share&_r=0.

¹⁷ *Ibid.*

¹⁸ *Ibid.*

¹⁹ Stephanie Clifford & Matthew Goldstein, *Shkreli Indictment Portrays Small-Time Fraud*, N.Y. TIMES (Dec. 17, 2015), <http://nyti.ms/1mbrPVh>.

²⁰ Additional charges were made in June 2016. Dan Mangan, ‘Pharma Bro’ Martin Shkreli Pleads Guilty to New Charges, CNBC (Jun. 6, 2016), www.nbcnews.com/business/business-news/pharma-bro-martin-shkreli-pleads-not-guilty-new-charge-n586676.

²¹ FBI New York (@NewYorkFBI), TWITTER (Dec. 17, 2015, 3:12 PM), <https://twitter.com/NewYorkFBI/status/677597263540191232>.

²² U.S. House Committee on Oversight and Government Reform, *Developments in the Prescription Drug Market: Oversight*, YOUTUBE (Feb. 4, 2016), www.youtube.com/watch?v=BPPerZLjp4M.

physician-assisted suicide.²³ A shocking *Wall Street Journal* piece revealed that between 2010 and 2014, U.S. prices for the thirty best-selling drugs rose four times faster than prescription volume, and eight times faster than inflation.²⁴ Put another way, 80 percent of the growth in profits of the twenty largest drug companies in 2015 resulted from price increases.²⁵ Put still *another* way, customers of CVS Health spent 12.7 percent more on drugs in 2015 than in the previous year, and more than 80 percent of that additional spending was the result of price increases.²⁶ U.S. President Barack Obama even got into the academic mix, publishing a paper in the *Journal of the American Medical Association* that, in part, called attention to rising spending on prescription medication.²⁷ And in the days before his 2017 inauguration, the next U.S. president, Donald Trump, sharply criticized the pharmaceutical industry. “We have to . . . create new bidding procedures for the drug industry because they’re getting away with murder. . . . Pharma, pharma has a lot of lobbies and a lot of lobbyists and a lot of power.”²⁸

The brunt of the pain is felt by U.S. citizens – one drug that costs less than \$400 a year in some countries has a list price around \$300,000 in the United States.²⁹ The rest of the world, however, has not been immune to the plague of skyrocketing prices, and some governments have taken dramatic action. In a popular story, the *New York Times* reported on an unprecedented deal the Egyptian government struck with Gilead, in which Gilead provides its \$84,000 hepatitis C treatment, Sovaldi, to the Egyptian government for \$900, in exchange for strict distribution requirements to prevent black market sales, particularly to countries where the price

²³ Examples: Ed Silverman, *Mylan Raised Prices for Some Drugs by Huge Amounts*, STAT (Jun. 10, 2016), www.statnews.com/pharmalot/2016/06/10/mylan-drug-prices-increase/ (describing the price increase for gallstone medication); April Dembosky, *Drug Company Jacks Up Cost Of Aid-In-Dying Medication*, NPR (Mar. 23, 2016), www.npr.org/sections/health-shots/2016/03/23/471595323/drug-company-jacks-up-cost-of-aid-in-dying-medication (discussing price increases for physician-assisted suicide medication).

²⁴ Joseph Walker, *For Prescription Drug Makers, Price Increases Drive Revenue*, WALL ST. J. (Oct. 5, 2015), www.wsj.com/articles/for-prescription-drug-makers-price-increases-drive-revenue-1444096750. The *Wall Street Journal*’s coverage of pharmaceutical price increases was later a finalist for a Pulitzer Prize. 2016 Pulitzer Prizes, The Pulitzer Prizes – Columbia University, www.pulitzer.org/prize-winners-by-year/2016.

²⁵ Walker, *For Prescription Drug Makers, Price Increases Drive Revenue*, *supra* note 24.

²⁶ *Ibid.*

²⁷ Barack Obama, *United States Health Care Reform: Progress to Date and Next Steps*, J. AM. MED. ASS’N E1, E5 (Jul. 11, 2016), http://jama.jamanetwork.com/article.aspx?articleid=2533698&utm_campaign=articlePDF&utm_medium=articlePDFlink&utm_source=articlePDF&utm_content=jama.2016.9797.

²⁸ Donald Trump’s News Conference: Full Transcript and Video, N.Y. TIMES (Jan. 11, 2017), https://www.nytimes.com/2017/01/11/us/politics/trump-press-conference-transcript.html?_r=0.

²⁹ Bethany McLean, *The Valeant Meltdown and Wall Street’s Major Drug Problem*, VANITY FAIR (Jun. 5, 2016), www.vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem.

is dramatically higher.³⁰ Egypt then provides the medication free to its citizens, a country so ravaged by hepatitis that it spends one-third of its national health budget on the disease.³¹ Similarly, in 2016, Colombia's health minister forced Novartis to lower the price of its Gleevec leukemia treatment, a medication that costs \$15,000 per year in Colombia, where the average annual income is approximately \$8,000.³²

With this information about global pricing scandals out in the open, everyone at the conference buzzed about pharmaceutical pricing. Presenters dismissed concerns and talked strategically about price increases. At the Borgia Room in the Westin St. Francis, Biogen's CEO answered questions about why the price of its multiple sclerosis therapies had only risen 3.9 percent in the previous year. (One of these multiple sclerosis medications, Avonex, had experienced a 93 percent price increase between 2000 and 2014, rising to more than \$60,000 annually.)³³ Biogen's CEO responded: "We're trying not to put a target on our foreheads ... [Don't want] to wave the red flag in front of the bull, whatever you want to call it." Later: "It's unlikely there will be any official government action on drug pricing this year. ... Right now, it's possible to take a price increase. But it's wise to be prudent."

A member of Sanofi's executive committee was more blunt: "Everybody has to make money. Should it be surprising? We do serve different stakeholders."³⁴ Expressing similar frustration on an earnings call, the CEO of Alnylam decried the scrutiny as "political demagoguery," but admitted that companies would now need to "think about their growth based on productivity not based on artificial price increases."³⁵ During its J. P. Morgan conference presentation, AbbVie revealed projections that its operating margin would increase to 50 percent by 2020 compared to a 36 percent margin in 2014.³⁶ That improvement would occur as part of a \$17 billion revenue increase in the same time frame, with only \$4 billion of that increase

³⁰ Donald G. McNeil Jr., *Curing Hepatitis C, in an Experiment the Size of Egypt*, N.Y. TIMES (Dec. 15, 2015), www.nytimes.com/2015/12/16/health/hepatitis-c-treatment-egypt.html?smid=pl-share.

³¹ *Ibid.*

³² Ed Silverman, *Colombia Plans to Unilaterally Lower the Cost of a Novartis Cancer Drug*, STAT (Jun. 9, 2016), www.statnews.com/pharmalot/2016/06/09/colombia-novartis-gleevec/; Ed Silverman, *Novartis, Colombia Face Off Over Cancer Drug Cost*, STAT (Jun. 14, 2016), www.statnews.com/pharmalot/2016/06/14/novartis-colombia-drug-costs/.

³³ Ed Silverman, *Multiple Sclerosis Drug Prices Rose at an 'Alarming' Rate: Study*, WALL ST. J. (Apr. 24, 2015), <http://blogs.wsj.com/pharmalot/2015/04/24/multiple-sclerosis-drug-prices-rose-at-an-alarming-rate-study/>.

³⁴ Ed Silverman, *Sanofi on Rx Pricing: 'Everyone Has to Make Money,'* STAT (Jan. 13, 2016), <https://embed.scribblelive.com/Embed/v7.aspx?Ibid=1755036&Page=4&overlay=false>.

³⁵ Lee Fang, *Pharma Executives Worry about Presidential Candidates Demanding Reform*, INTERCEPT (Feb. 2, 2016), <https://theintercept.com/2016/02/02/goldman-sachs-pharma/>.

³⁶ Presentation, AbbVie, 2016 J. P. Morgan Healthcare Conference (Jan. 13, 2016), www.abbvieinvestor.com/phoenix.zhtml?c=251551&p=irol-presentations. One should note that operating margin is not directly equivalent to profit margin, as it does not include fixed costs such as research and development.

attributable to newly introduced drugs from the development pipeline.³⁷ On the basis of current trends, most of the remaining \$13 billion would be generated by price increases, not increased sales volume.

Of course, Shkreli and other pharmaceutical executives would tell a different story about high prices. New treatments have immense value in improving quality of life, extending life spans, and eliminating the need for invasive medical procedures to be used instead.³⁸ The hefty price for some of these pharmaceuticals reflects the value they offer to patients.

There is certainly some truth to these statements, as well as an obvious counter-argument: Why would prices of existing drugs, some of which have been available for decades, increase when constantly improving medical care would suggest that their relative value should decrease or remain stagnant? The routine price bumps suggest that pharmaceutical companies are taking advantage of price inelasticity and minimal competition to push pricing to its limit.

All of this begs the question: How *do* these price increases go unchallenged? Shouldn't other drug makers step in to provide competition in the marketplace? That is where generic drugs enter the picture. Always looming in the back of the minds of pharma executives is the threat of generic competition. Nothing has more power to shift the all-important bottom line. A United Therapeutics executive at the J. P. Morgan event referred to a generic launch as a generic intrusion.

In a way, generics are quite an intrusion. Brand-name drug companies, who enjoy a monopoly in the market for a drug until generic entry, face a nearly instantaneous plummet in market share and price. Within a year of entry by the first generic, a brand-name drug generally loses an average of 80–90 percent of its market share.³⁹ As multiple generic competitors enter the market, the price of most drugs eventually falls to 15–20 percent of the original brand-name cost.⁴⁰

For companies that rely on just one or two patent-protected drugs for the majority of their revenues, generic competition can be a rude awakening. Considering that generic entry often coincides with the expiration of a brand-name company's patents

³⁷ *Ibid.*

³⁸ Victoria Colliver, *Biotech Execs Talk "Value" in Backlash against High Drug Prices*, S.F. CHRON. (Jun. 9, 2016), www.sfchronicle.com/business/article/Biotech-execs-talk-value-in-backlash-7974134.php; Rebecca Robbins, *With Tens of Millions on Hand, Drug Makers Fight State Efforts to Force Down Prices*, STAT (Jun. 9, 2016), www.statnews.com/2016/06/09/drug-companies-fight-back/.

³⁹ See *ibid.*; see also Henry G. Grabowski *et al.*, *Evolving Brand-Name and Generic Drug Competition May Warrant a Revision of the Hatch-Waxman Act*, 30 HEALTH AFF. 2157, 2163, exhibit 4 (2011). In fact, for the period between 2004 and 2008, Grabowski *et al.* found that the average drug with more than \$1 billion in annual sales had more than ten generic competitors one year after first generic entry. See *ibid.* at 2160 exhibit 1.

⁴⁰ See *Facts about Generic Drugs*, U.S. FOOD & DRUG ADMIN., www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm167991.htm (last updated June 28, 2016).

or FDA exclusivities, it is no surprise that looming generic competition is often referred to as the “patent cliff.” Channeling his best eulogist, Shkreli once tweeted about the brand-name view of the patent cliff:

Every time a drug goes generic, I grieve. Let us not mourn the dearly departed, instead celebrate the profits and new assets it has brought us. – @MartinShkreli, April 10, 2012, 7:46 A.M.⁴¹

Hold your sympathy for drug makers, however – this humbling event of patent expiration is supposed to happen! As citizens, in fact, we actually bestow limited-time rights on drug companies in the form of patents. Society gives companies the opportunity to make billions, and with good reason. The hope is that the promise of that opportunity will incentivize companies to innovate in ways that will benefit all of us. Patents are not the type of inalienable rights to life and liberty one might think. Nor are patents the same as core rights in our homes and land.⁴² Rather, patents are time-limited government grants that exist for a specific purpose only: that is, to incentivize innovation for the benefit of society.⁴³

In the pharmaceutical space, the prevailing explanation for strong patent rights is the following: given the astronomical cost of drug research and development, patents provide a necessary period for pharmaceutical companies to recoup their costs and profit from their invention. In return, society benefits from new treatments, and we hope some of the earnings are returned to future research and development. Celebrate the profits, celebrate the assets, and then return to research!

Pharmaceuticals have long served as a prototypical example, sharing the pedestal with blockbuster movies, for the continuing benefits of intellectual property, because of their high initial fixed costs along with the multiple research failures and dead ends that occur on the way to producing one medication that receives market approval.⁴⁴ (Researchers disagree vehemently about the costs of getting a medication to market, but most research puts the expense somewhere in the high hundreds of millions or even billions of dollars.)⁴⁵ In designing those rights, society strives to strike the proper

⁴¹ Martin Shkreli (@MartinShkreli), TWITTER (Apr. 10, 2012, 7:46 AM), <https://twitter.com/MartinShkreli/status/189695905790832640>.

⁴² For an explanation of why patents are not core property rights, see Robin Feldman, *Federalism, First Amendment and Patents: The Fraud Fallacy*, 18 COLUM. SCI. & TECH. L. REV. 30, 71–72 (2015).

⁴³ U.S. CONST., art. I, § 8, cl. 8 (“The Congress shall have power ... To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries”).

⁴⁴ See Mark Lemley, *IP in a World without Scarcity*, 90 N.Y.U. L. REV. 460, 464–65 (2015), www.nyulawreview.org/sites/default/files/pdf/NYULawReview-90-2-Lemley.pdf, for a fascinating discussion of this issue.

⁴⁵ See Steve Morgan et al., *The Cost of Drug Development: A Systematic Review*, 100 HEALTH POLICY 4 (2011), www.ncbi.nlm.nih.gov/pubmed/21256615 (discovering estimates of drug development cost ranging from \$161 million to \$1.8 billion); see also Aaron E. Carroll, *\$2.6 Billion to*

balance, giving pharmaceutical companies the opportunity to recoup investment without blocking the incentive for others to innovate further in the future.

That balance means all good things must come to an end – maybe. When a drug's patents or exclusivities expire or are found invalid, in theory, anyone who can obtain FDA approval becomes eligible to sell the medication, and thus generic competition begins. The expectation is that the brand-name pharma company, having likely enjoyed more than a decade of unimpeded sales, heads back to the lab bench, ready to discover new treatments with improved therapeutic benefits for patients. R&D activity, however, is expensive and difficult – mergers, acquisitions, and obstruction are cheaper and simpler. As a result, it has become far too easy to spend time and resources exhausting legal and regulatory options, pushing the patent cliff as far away as possible.

The temptation to avoid the impact of the patent cliff can be overpowering when even a few months of additional monopoly profits can be worth hundreds of millions of dollars or more.⁴⁶ For example, Gilead's previously mentioned hepatitis C drug, Sovaldi, earned \$7.9 billion in sales in 2014, making it the top-earning drug in the United States. Three additional months of sales at that rate would be worth \$1.98 billion. Similarly, Pfizer's Nexium took in \$5.9 billion in revenue in the same year – three additional months would be worth \$1.48 billion.

These enormous and precariously fleeting revenue streams encourage companies to expend tremendous energy blocking generic entry by any means possible, with companies using ever more clever and complicated strategies. As a result, many pharmaceutical firms may no longer compete solely on the basis of innovation, but rather on their ability to manipulate policy mechanisms and pathways to extend monopoly and duopoly terms. The lure of the easy way out means that many companies fail to follow the advice of their colleague Mr. Shkreli and instead prolong the generic mourning period.

Of course, this behavior undermines the goals of intellectual property and can provide less than optimal innovation and pricing effects. As an example, let us return to Mr. Shkreli and his actions at Turing. While Daraprim was already off-patent at the time Turing purchased distribution rights for the drug, Shkreli's company used a modified version of an emerging generic delay strategy to keep all competition off the market, allowing the eye-popping price increase to occur.

Develop a Drug? New Estimate Makes Questionable Assumptions, N.Y. TIMES (Nov. 18, 2014), www.nytimes.com/2014/11/19/upshot/calculating-the-real-costs-of-developing-a-new-drug.html (describing the conflict in determining how much it costs to develop a drug).

⁴⁶ Lacie Glover, *Here Are the Top-Selling Drugs in the US*, TIME (June 26, 2015), http://time.com/money/3938166/top-selling-drugs-sovaldi-abilify-humira/?xid=soc_socialflow_twitter_money. Fifty-five drugs earned more than \$1 billion in revenue in 2013. *U.S. Pharmaceutical Sales – 2013*, DRUGS, www.drugs.com/stats/top100/2013/sales (last updated Feb. 2014).

Specifically, when Turing acquired the rights to Daraprim, it maintained a restricted distribution system originally put in place by Impax, the previous owner.⁴⁷ In fact, Turing requested that a restricted distribution system be established before the sale occurred. As we will discuss later, restricted or controlled distribution systems are mandated by the FDA as part of safety protocols when a drug presents special concerns regarding safety, administration, or storage. Yet Impax (and later, Turing) instituted its restricted distribution system without the FDA and for no apparent safety reason at all, making the drug only available through Walgreen's Specialty Pharmacy.⁴⁸ Along with creating access problems for hospitals,⁴⁹ the move in part may have been designed to make it difficult for generics to gain access to the samples needed to gain approval for a generic version of the drug.⁵⁰

Comments from Turing executives support this implication. In response to the Daraprim pricing controversy and the potential for generic competition, the director of patient access at Turing said the following: "Most likely I would block that purchase [by a generic]. We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make generics], no matter what. But I'm certainly not going to make it easier for them."⁵¹ The comments suggest a concerted effort to block generic competition, and a failure to accept the intent of the generic drug system. Although Turing executives may have spoken more directly than others, actions in many corners of the pharmaceutical industry reflect a similar mind-set. Turing's actions, specifically the use of restricted distribution to block competition, are now under investigation by the New York attorney general, and U.S. lawmakers have also called on the FTC to look into the Turing business model.⁵²

As other academics have detailed, the Daraprim system was not the first time a Shkreli-led company implemented a restricted distribution system.⁵³ Notably,

⁴⁷ Michael Carrier & Aaron Kesselheim, *The Daraprim Price Hike and a Role for Antitrust*, HEALTH AFF. BLOG (Oct. 21, 2015), <http://healthaffairs.org/blog/2015/10/21/the-daraprim-price-hike-and-a-role-for-antitrust/>.

⁴⁸ *Ibid.*

⁴⁹ Letter from Stephen B. Calderwood, President, Infectious Diseases Soc'y of Am., and Adaora Adimora, Chair, HIV Medicine Ass'n, to Tom Evigan, Head of Managed Markets, Turing Pharm., and Kevin Bernier, Nat'l Dir. of All. Dev. & Pub. Affairs, Turing Pharm. (Sept. 8, 2015), www.hivma.org/uploadedFiles/HIVMA/HomePageContent/PyrimethamineLetterFINAL.pdf.

⁵⁰ Michael A. Carrier, Nicole L. Levidow, & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECH. L.J. (2016), <http://ssrn.com/abstract=2724604>.

⁵¹ Ed Silverman, *How Martin Shkreli Prevents Generic Versions of His Pricey Pill*, STAT (Oct. 5, 2015), <http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/>.

⁵² Andrew Pollack, *New York Attorney General Examining Whether Turing Restricted Drug Access*, N.Y. TIMES (Oct. 12, 2015), www.nytimes.com/2015/10/13/business/new-york-attorney-general-examining-if-turing-restricted-drug-access.html.

⁵³ See Carrier, Levidow, & Kesselheim, *Using Antitrust Law*, *supra* note 50, at *20–21.