



# Killer Profits:

*How Big Pharma Takeovers Destroy Innovation and Harm Patients*



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## Foreword by Congresswoman Katie Porter

I hear it all the time from Orange County families: **the cost of prescriptions is too high**. This rings true across the country: **Nearly 1 in 5 Americans reported skipping a dose** because of costs, and nearly 1 in 4 Americans didn't fill a prescription for the same reason.<sup>1</sup> Meanwhile, **Big Pharma's profits are higher than ever**. One study found that Pharma would still be the most profitable industry sector—even if it lost \$1 trillion in sales.<sup>2</sup>

Yet, moving drug pricing reform through Congress remains nearly impossible. Last year, the House of Representatives passed the *Elijah E. Cummings Lower Drug Costs Now Act*, but the Senate has failed to move this legislation forward. Pharmaceutical companies, and the Members of Congress to whom they donate millions, decried the bill as “socialist” and claimed that price negotiation would “kill innovation.”<sup>3</sup>

Anyone who has ever purchased a car can tell you that negotiation is central to capitalism. So is price transparency, competition, and consumer choice. By any metric of a healthy market, the prescription drug industry fails. **Pharmaceutical companies have little incentive to invest in innovative new medicine without the threat of competition. Instead, they are free to devote their considerable resources to merging with or acquiring companies that might otherwise force them to compete.** This consolidation has destroyed scientific cultures that once celebrated creativity and transformed them into places that cater to the whims of shortsighted shareholders.

Rather than producing breakthrough, lifesaving drugs for diseases with few or no cures, most companies focus on small, incremental changes to existing drugs in order to kill off generic threats to their government-granted monopoly patents.

The rapid breakthroughs that we have seen in response to the COVID-19 pandemic highlight that innovation is possible. But without taxpayer funded research, we likely would not see these signs of hope. Companies with billions in profits have relied on our dollars to support research, unwilling to assume risk themselves. It's no different in the rest of the market, where **Big Pharma relies on the creativity of academic researchers and small biotechnology firms, only to acquire them after they've discovered a blockbuster drug.**

One episode of this story is the merger between Immunex, a small biotechnology firm, and Amgen, a pharmaceutical giant. My office's investigation has peeled back the harmful effects on innovation that result from this kind of acquisition. But our investigation also shows us how **we can chart a new path forward, increasing competition and saving lives.**

Very Truly Yours,



Katie Porter

<sup>1</sup> Poll: Nearly 1 in 4 Americans Taking Prescription Drugs Say It's Difficult to Afford Their Medicines, KFF, Retrieved at: <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>

<sup>2</sup> A Comparison of Returns Between Pharmaceutical & Other Industries, WHPC, Retrieved at: [https://www.westhealth.org/wp-content/uploads/2019/11/WHPC\\_White-Paper\\_How-Much-Can-Pharma-Lose\\_FINAL-November-2019.pdf](https://www.westhealth.org/wp-content/uploads/2019/11/WHPC_White-Paper_How-Much-Can-Pharma-Lose_FINAL-November-2019.pdf)

<sup>3</sup> McConnell warns Pelosi's drug-pricing plan is DOA, POLITICO, Retrieved at: <https://www.politico.com/story/2019/09/19/mcconnell-pelosi-prescription-plan-1504496>

## Consolidation in the Pharmaceutical Industry

In just 10 years, the number of large, international pharmaceutical companies decreased six-fold, from 60 to only 10.<sup>4</sup> The number of mergers and acquisitions (M&A) involving one of the top 25 firms in the pharmaceutical industry more than doubled from 2006 to 2016,<sup>5</sup> and the practice doesn't seem to be abating.<sup>6</sup> The major companies in the industry now include Johnson & Johnson, Roche, Pfizer, Novartis, Merck, GlaxoSmithKline, Sanofi, Abbvie, Bristol Myers Squibb, AstraZeneca, Amgen, Gilead, and Teva.<sup>7</sup>

Pharmaceutical company CEOs attempt to frame these deals as simply efforts to improve company structure and diversify product offerings. **However, digging a level deeper “exposes a troubling industry-wide trend of billions of dollars of corporate resources going toward acquiring other pharmaceutical corporations with patent-protected blockbuster drugs instead of putting those resources toward” discovery of new drugs.**<sup>8</sup> The pattern tends to look like this: a small firm will develop a breakthrough drug, and then will be acquired by a slightly larger firm, which will later be acquired by one of the giants discussed before, or will be acquired outright by one of these megafirms.<sup>9,10</sup>

**“In just 10 years, the number of large, international pharmaceutical companies decreased six-fold, from 60 to only 10.”**

The reasons for the M&A deals are highly varied: some are done to **boost stock prices**, while others are done to **stop competitors**, and many are done to acquire an innovative blockbuster drug with an enormous prospective revenue stream.<sup>11,12</sup> Instead of spending on innovation, **Big Pharma is hoarding its money for salaries and dividends,<sup>13</sup> all while swallowing smaller companies, thus making the marketplace far less competitive.**<sup>14</sup>

This behavior has an overall negative effect on investments in research and development. The Düsseldorf Institute for Competition Economics found that “patenting and R&D of the merged entity and its non-merging rivals declines substantially,” indicating that the merger pattern has, on average,

<sup>4</sup> High Drug Prices and Monopoly, Open Markets Institute, Retrieved at: <https://www.openmarketsinstitute.org/learn/drug-prices-monopoly>

<sup>5</sup> Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals, Government Accountability Office, Retrieved at: <https://www.gao.gov/products/GAO-18-40>

<sup>6</sup> Pharmaceutical mergers and megamergers stifle innovation, STAT, Retrieved at: <https://www.statnews.com/2019/07/10/pharmaceutical-mergers-stifle-innovation/>

<sup>7</sup> The top 20 pharma companies by 2019 revenue, Fierce Pharma, Retrieved at: <https://www.fiercepharma.com/special-report/top-20-pharma-companies-by-2019-revenue>

<sup>8</sup> Ibid.

<sup>9</sup> The Roles of Academia, Rare Disease, And Repurposing in the Development of the Most Transformative Drugs. Health Affairs, Retrieved at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1038>

<sup>10</sup> Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem, Journal of Health Care Law and Policy, Retrieved at: <https://digitalcommons.law.umaryland.edu/cgi/viewcontent.cgi?article=1356&context=jhclp>

<sup>11</sup> Pharmaceutical M&A: A New Kind of Drug Deal, Health Trust, Retrieved at: <https://healthtrustpg.com/thesource/pharmacy-services/pharmaceutical-ma-new-kind-drug-deal/>

<sup>12</sup> What's behind the pharmaceutical sector's M&A push, McKinsey & Company, Retrieved at: <https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/whats-behind-the-pharmaceutical-sectors-m-and-a-push>

<sup>13</sup> Profit Over Patients: Americans are Paying for a Financialized Pharmaceutical Industry, Roosevelt Institute, Retrieved at: <https://rooseveltinstitute.org/publications/profit-over-patients-americans-are-paying-for-a-financialized-pharmaceutical-industry/>

<sup>14</sup> Pharmaceutical mergers and megamergers stifle innovation, STAT, Retrieved at: <https://www.statnews.com/2019/07/10/pharmaceutical-mergers-stifle-innovation/>

reduced innovation industrywide.<sup>15</sup> A Harvard Business Review study found that in mergers of companies who may be perceived as competitors, “R&D and patenting within the merged entity decline substantially after a merger...”<sup>16</sup> In other words, **the less competition that exists in the pharmaceutical industry, the less likely the industry will actually focus on innovation and new cures that can save lives.**<sup>17</sup>

The Pharmaprojects database, which allows researchers to track the progress of drugs from early development through market launch, tells a similar story: One analysis of the database found that during this era of consolidation, **from 2000 to 2008, nearly 2,000 drugs in discovery were discontinued and the vast majority of these decisions were made not because of any issues with the science but for “strategic” or “financial” reasons.**<sup>18</sup> Speaking with one of the researchers who worked on the study, he explained that it was “clear that business incentives had trumped the need for innovation or failures in research” in decisions regarding discontinuation.<sup>19</sup>

In recent years, some of the biggest mergers and acquisitions provide examples of this behavior: Bristol-Myers Squibb acquired Celgene in 2019.<sup>20</sup> Celgene is well known for its cancer drug, Revlimid, which has garnered attention in recent years for aggressive and unexplained price hikes.<sup>21</sup> Celgene had recently acquired Juno, an innovative young biotechnology firm from Seattle. The acquisition gave Celgene, already a leader in cancer therapies, access to Juno’s pipeline of CAR-T blood cancer drugs.<sup>22</sup>

In 2019, AbbVie, the producer of Humira, acquired Allergan, the producer of botox.<sup>23</sup> Humira is a blockbuster drug, which brings in billions a year for AbbVie.<sup>24</sup> The company has abused the patent system to delay a generic option from coming to market.<sup>25</sup> Just as these patents started to run out, and there were few choices left to defend their profits, the company acquired Allergan in order to increase its funding streams.

Together AbbVie and Bristol-Myers Squibb are responsible for nearly 10% of all M&A deals over the last decade.<sup>26</sup> Five of the six largest acquisitions in the study took place from 2017-

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<sup>15</sup> "How mergers affect innovation: Theory and evidence from the pharmaceutical industry," DICE Discussion Papers 218, University of Düsseldorf, Düsseldorf Institute for Competition Economics (DICE), Retrieved at: <https://ideas.repec.org/p/zbw/dicedp/218.html>

<sup>16</sup> Research: Innovation Suffers When Drug Companies Merge, Harvard Business Review, Retrieved at: <https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge>

<sup>17</sup> Drug Mergers Hurt in Every Direction (Save One), Science Mag, Retrieved at: <https://blogs.sciencemag.org/pipeline/archives/2016/08/24/drug-mergers-hurt-in-every-direction-save-one>

<sup>18</sup> Vertical disintegration: a strategy for pharmaceutical businesses in 2009?, Nat Rev Drug Discov, Retrieved at: <https://pubmed.ncbi.nlm.nih.gov/19483701/>

<sup>19</sup> Conversation with Laurent Galibert, October 16, 2020.

<sup>20</sup> Pharmaceutical mergers and megamergers stifle innovation, STAT, Retrieved at: <https://www.statnews.com/2019/07/10/pharmaceutical-mergers-stifle-innovation/>

<sup>21</sup> Celgene repeatedly raised Revlimid’s price to hit aggressive sales targets, congressional probe finds, Fierce Pharma, Retrieved at: <https://www.fiercepharma.com/pharma/celgene-repeatedly-raised-revlimid-s-price-to-meet-aggressive-sales-targets-congressional#:~:text=Celgene%20launched%20Revlimid%20in%202005,R%26D%20investment%20or%20rebate%20pressure>.

<sup>22</sup> Bristol-Myers Squibb’s \$7.4B acquisition of Juno parent Celgene puts Seattle biotech world on alert, GeekWire, Retrieved at: <https://www.geekwire.com/2019/bristol-myers-squibbs-74b-acquisition-juno-parent-celgene-puts-seattle-biotech-world-alert/> and Celgene Buys Juno Therapeutics: A Risky \$9B Bet, Forbes, Retrieved at: <https://www.forbes.com/sites/johannabennett/2018/01/22/celgene-buys-juno-therapeutics-a-risky-9b-bet/?sh=6363d8a817c7>

<sup>23</sup> Pharmaceutical mergers and megamergers stifle innovation, STAT, Retrieved at: <https://www.statnews.com/2019/07/10/pharmaceutical-mergers-stifle-innovation/>

<sup>24</sup> AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results, AbbVie, Retrieved at: <https://news.abbvie.com/news/abbvie-reports-full-year-and-fourth-quarter-2018-financial-results.htm>

<sup>25</sup> HUMIRA MANUFACTURER’S EFFORTS TO BLOCK GENERIC OPTIONS CHALLENGED IN COURT, US PIRG, Retrieved at: <https://uspirg.org/news/usp/humira-manufacturer%E2%80%99s-efforts-block-generic-options-challenged-court>

<sup>26</sup> A Decade of Biopharma M&A and Outlook for 2020, Pharma Intelligence, Retrieved at: <https://pharmaintelligence.informa.com/-/media/informa-shop-window/pharma/2020/files/whitepapers/ma-whitepaper.pdf>



2019,<sup>27</sup> likely propelled forward by the passage of tax reform in 2017.<sup>28</sup> An analysis from consulting firm McKinsey found that, in the first half of 2018, there were 212 deals in the pharmaceutical sector, up from 151 deals in the same period the year prior.<sup>29</sup>

## Innovation is Disappearing

Mergers and acquisitions are just the tip of the iceberg of pharmaceutical companies' anticompetitive, profit-driven behaviors. Pharmaceutical companies often claim that lowering the prices of prescription drugs in the United States would devastate innovation.<sup>30</sup> Yet, **as prices have skyrocketed over the last few decades, these same companies' investments in research and development have failed to match this same pace.**<sup>31</sup> Instead they've dedicated more and more of their funds to enrich shareholders or to purchase other companies to eliminate competition.<sup>32</sup>

In 2018, the year that Donald Trump's tax giveaway to the wealthy went into effect, 12 of the biggest pharmaceutical companies spent more money on stock buybacks than on research and development.<sup>33</sup> This didn't just begin in 2018, though the tax law exacerbated the issue. **From 2008-2018, big pharmaceutical companies spent more on stock buybacks and dividends than they did on research and development.**<sup>34</sup>

As their focus has shifted to shareholders and stock prices, **innovative drug development has fallen.** According to research from Harvard Medical School, the development of transformative drugs, defined as those that are "both innovative and have groundbreaking effects on patient care" are diminishing.<sup>35</sup> Of 26 transformative drugs and drug classes approved between 1984 and 2009, only four were approved after 2000. **The discovery of new molecular entities or novel drugs in the last decade (2000-2010) were in line with or slightly above those rates observed in the 1980s, despite technological improvements that should have catapulted new cures forward.**<sup>36</sup> Many of the drugs studied were based on substantial research and

**"In 2018, the year that Donald Trump's tax giveaway to the wealthy went into effect, 12 of the biggest pharmaceutical companies spent more money on stock buybacks than on research and development."**

<sup>27</sup> Ibid.

<sup>28</sup> What's behind the pharmaceutical sector's M&A push, McKinsey & Company, Retrieved at: <https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/whats-behind-the-pharmaceutical-sectors-m-and-a-push>

<sup>29</sup> Ibid.

<sup>30</sup> Pharma Companies Argue That Lower Drug Prices Would Mean Fewer Breakthrough Drugs. Is That True?, Kellogg Insight, Kellogg School of Management, Retrieved at: <https://insight.kellogg.northwestern.edu/article/pharma-companies-argue-lower-drug-prices-fewer-breakthrough-drugs>

<sup>31</sup> R&D Costs for Pharmaceutical Companies Do Not Explain Elevated US Drug Prices, Health Affairs, Retrieved at: <https://www.healthaffairs.org/doi/10.1377/hblog20170307.059036/full/>

<sup>32</sup> Financialization of the U.S. Pharmaceutical Industry, Institute for New Economic Thinking, Retrieved at: [https://www.ineteconomics.org/uploads/papers/Lazonick\\_financialization.pdf](https://www.ineteconomics.org/uploads/papers/Lazonick_financialization.pdf)

<sup>33</sup> Pharmaceutical companies spending on R&D and buybacks, Axios, Retrieved at: <https://www.axios.com/big-pharma-stock-buybacks-research-123f10f1-79d0-44be-a515-a6603fbcf9a.html>

<sup>34</sup> US Pharma's Financialized Business Model, Institute for New Economic Thinking, Retrieved at: <https://www.ineteconomics.org/research/research-papers/us-pharmas-financialized-business-model>

<sup>35</sup> The Roles of Academia, Rare Disease, And Repurposing In the Development of the Most Transformative Drugs. Health Affairs, Retrieved at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1038>

<sup>36</sup> Ibid.

development work conducted by scientists at academic medical centers, supported by taxpayer dollars.

**At the same time, the number of infection outbreaks and unique diseases rose.**<sup>37</sup> In a functioning market, supply and demand would be more closely aligned. As new diseases requiring new cures emerged, new drugs should have increased at a similar pace. In reality, new threats, such as antibiotic resistant superbugs, aren't inspiring new cures.<sup>38</sup> This is due largely in part to one simple factor: **antibiotics don't make money.** The financial incentives, no matter the threat to our country's health, simply aren't there.<sup>39</sup>

**Instead of taking risks to find new, critically needed drugs, large pharmaceutical companies are just repackaging the same products over and over:** In 2018, only 1 in 3 new brand-name drugs that drug companies launched were "first in class" drugs.<sup>40</sup> Many "new" products were in fact small changes for existing products that were created to extend patent monopolies.<sup>41</sup> In fact, **between 2005 and 2015, approximately 75% of new drug patents were for those already being sold on the market.**<sup>42</sup> Of the roughly 100 highest selling drugs, nearly 80% sought and received an additional patent to extend their monopoly period at least once; nearly 50% extended it more than once.<sup>43</sup>

**"In a functioning market, supply and demand would be more closely aligned. As new diseases requiring new cures emerged, new drugs should have increased at a similar pace."**

Some of this may be an unintended consequence of the *Orphan Drug Act*, which provided financial incentives and avenues for the pursuit of "orphan drugs" or those innovative biologics or drugs that will treat a rare condition or disease (less than 200,000 people).<sup>44</sup> Since the legislation was signed into law in 1983, more than 200 companies have brought almost 450 "orphan drugs" to market.<sup>45</sup> Unfortunately, many drug companies have found ways to abuse this law, manipulating it to create monopolies on drugs that serve a larger swath of the population and charging astronomical prices.<sup>46</sup> A Kaiser Health News study found that "More than 70 [orphan drugs] were drugs first approved by the Food and Drug Administration for mass market use... More than 80 other orphans won FDA approval for more than one rare disease, and in some cases, multiple rare diseases. For each additional approval, the drugmaker qualified for a fresh batch of incentives."<sup>47</sup> One Johns

<sup>37</sup> Infection outbreaks, unique diseases rising since 1980, Brown University, Retrieved at: <https://news.brown.edu/articles/2014/10/diseases>

<sup>38</sup> If Scientists Don't Develop New Antibiotics Soon, 'We'll All Be in a Lot of Trouble,' Pew Trust, Retrieved at: <https://www.pewtrusts.org/en/research-and-analysis/articles/2020/11/20/if-scientists-dont-develop-new-antibiotics-soon-well-all-be-in-a-lot-of-trouble>

<sup>39</sup> Big pharma failing to invest in new antibiotics, says WHO, The Guardian, Retrieved at: <https://www.theguardian.com/business/2020/jan/17/big-pharma-failing-to-invest-in-new-antibiotics-says-who>

<sup>40</sup> Center for Drug Evaluation and Research: ADVANCING HEALTH THROUGH INNOVATION 2018 NEW DRUG THERAPY APPROVALS, United States Food and Drug Administration, Retrieved at: <https://www.fda.gov/media/120357/download>

<sup>41</sup> Ibid.

<sup>42</sup> May your drug price be evergreen, Journal of Law and the Biosciences, Retrieved at: <https://academic.oup.com/jlb/article/5/3/590/5232981>

<sup>43</sup> Ibid.

<sup>44</sup> What is the Purpose of the Orphan Drug Act?, PLOS Medicine, Retrieved at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5207521/>

<sup>45</sup> Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies, Retrieved at: <https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/>

<sup>46</sup> Drugs For Rare Diseases Have Become Uncommonly Rich Monopolies, NPR, Retrieved at: <https://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies>

<sup>47</sup> Drugmakers Manipulate Orphan Drug Rules to Create Prized Monopolies, Retrieved at: <https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/>

Hopkins researcher described this as “salami slicing”: large pharmaceutical companies identify small patient populations to gain additional approvals, thus reaping financial incentives and securing market exclusivity for a longer period of time.<sup>48</sup> **Instead of focusing on the next big innovation in the industry, channeling their efforts into research, they concentrate on gaming the system.**

Recently, Gilead Sciences, the makers of remdesivir, an antiviral drug that has been considered as a possible COVID-19 treatment, submitted an application for approval of remdesivir as an orphan drug for COVID-19.<sup>49</sup> Gilead sought this application in early March, when there were still few cases of COVID-19 in the U.S.<sup>50</sup> After backlash that this was an “unconscionable abuse” of the program, Gilead withdrew its application.<sup>51</sup> Criticisms focused on the reality, clear even in the earlier days of the pandemic, that there would ultimately be far more than 200,000 cases of COVID-19.

## Who’s Really Responsible for New Drugs?

As the focus of Big Pharma has shifted away from competing with other companies and towards Wall Street, innovation has dropped off. In reality, **most basic research is funded by or conducted through the National Institutes of Health,<sup>52</sup> other government sources, and venture capitalists.**<sup>53</sup> This drives innovation in small labs firms, which are often spun off of taxpayer-funded academic research.<sup>54</sup> These small labs are then purchased by giant firms after they’ve assumed the risk needed to develop a blockbuster drug, as exhibited in the Celgene-Juno acquisition, and as will be discussed later with Amgen-Immunex.

Research from McKinsey found that the share of revenues coming from innovations “sourced outside of Big Pharma” rose from 25 percent in 2001 to 50 percent in 2016.<sup>55</sup> For example, Forest Laboratories, which has since been acquired by AbbVie, acquired Clinical Data in 2011, two weeks after it had received approval from the Food and Drug Administration for a novel antidepressant, Viibryd.<sup>56</sup> Roche, another pharmaceutical giant, acquired Promedior, a research focused company, who had conducted research needed for the development of a drug for idiopathic pulmonary fibrosis.<sup>57</sup> **Bristol-Myers Squibb’s acquisition strategy has been described as “a string of pearls,” in which it targets “a large number of external assets with high scientific promise.”**<sup>58</sup>

**“The share of revenues coming from innovations ‘sourced outside of Big Pharma’ rose from 25 percent in 2001 to 50 percent in 2016.”**

<sup>48</sup> Ibid.

<sup>49</sup> Gilead Sciences Statement on Request to Rescind Remdesivir Orphan Drug Designation, Gilead, Retrieved at: <https://www.gilead.com/-/media/gilead-corporate/files/pdfs/company-statements/remdesivir-orphan-drug-designation.pdf>

<sup>50</sup> Ibid.

<sup>51</sup> Letter to Gilead Chairman and Chief Executive Officer, Daniel O’Day, Public Citizen, Retrieved at: <https://www.citizen.org/wp-content/uploads/Letter-from-50-groups-to-Gilead-renoounce-remdesivir-orphan-drug-claim.pdf>

<sup>52</sup> Contributions of NIH funding to new drug approvals 2010-2016, Proceedings of the National Academy of Sciences, Retrieved at: <https://www.pnas.org/content/115/10/2329.short>

<sup>53</sup> The Roles of Academia, Rare Disease, And Repurposing In the Development of the Most Transformative Drugs. Health Affairs, Retrieved at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1038>

<sup>54</sup> Pharma 101, Public Citizen, Retrieved at: <https://www.citizen.org/article/pharma-101-a-primer/>

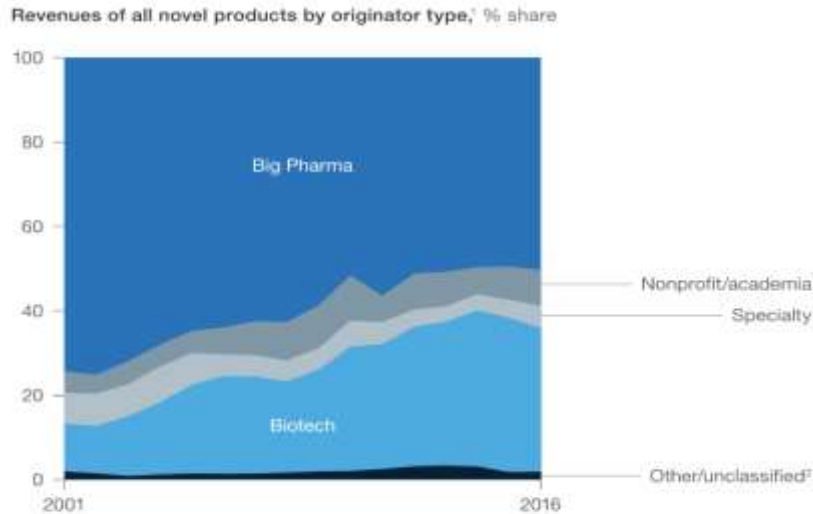
<sup>55</sup> What’s behind the pharmaceutical sector’s M&A push, McKinsey & Company, Retrieved at: <https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/whats-behind-the-pharmaceutical-sectors-m-and-a-push>

<sup>56</sup> A Decade of Biopharma M&A and Outlook for 2020, Pharma Intelligence, Retrieved at: <https://pharmaintelligence.informa.com/-/media/informa-shop-window/pharma/2020/files/whitepapers/ma-whitepaper.pdf>

<sup>57</sup> Ibid.

<sup>58</sup> Ibid.





<sup>59</sup>New-molecular-entity (NME) compounds launched in a given year cumulated across half of the remaining exclusivity period (7–8 years), \$ billion (3-year walking average). Includes all innovative compounds classified as NME or biologics license application, excluding generics, biosimilars, and new-drug-application products.  
<sup>60</sup>Includes chemicals, consumer, generic, and unclassified companies.

(Source: McKinsey & Company, Evaluate Pharma, Pharma Projects Database)<sup>59</sup>

**Big pharmaceutical companies are not responsible for most major breakthroughs in new drugs.** The previously mentioned Harvard Medical School analysis found that the most “common pattern of interaction” between pharmaceutical companies and academic medical centers in the discovery of transformative drugs are academic medical centers investing in “basic research about disease mechanisms and the demonstration of the proof of concept for a given molecule,” at which point, industry collaborators (small firms) develop the product for clinical testing.<sup>60</sup> The researchers found that “companies clearly play a major role in funding and conducting the clinical trials necessary to gain FDA approval. However, **the fraction of pharmaceutical sales revenue devoted to total R&D is generally under 20 percent...** the share spent on the basic research that often generates truly innovative new compounds is estimated to be far smaller.”<sup>61</sup>

**“In 2018, small firms discovered 64% of drugs launched, up from 31% in 2009.”**

Many of the companies who take this initial stage research and guide it through further research and clinical trials aren’t the major players in the pharmaceutical space. They are small biotechnology firms who cultivate creativity and foster innovative thinking. In 2018, small firms discovered 64% of drugs launched, up from 31% in 2009.<sup>62</sup>

**Unfortunately for American patients, as soon as these companies are acquired, the innovation stops. The culture of creativity is killed. New pipeline drugs, as mentioned, are**

**forgotten. The small firm’s vision is lost, and the big firm’s profits become priority.** This happens across the industry, and the story of Amgen and Immunex provides a perfect study.

<sup>59</sup> What’s behind the pharmaceutical sector’s M&A push, McKinsey & Company, Retrieved at: <https://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/whats-behind-the-pharmaceutical-sectors-m-and-a-push>

<sup>60</sup> The Roles of Academia, Rare Disease, And Repurposing In the Development of the Most Transformative Drugs. Health Affairs, Retrieved at: <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2014.1038>

<sup>61</sup> Ibid.

<sup>62</sup> Small Pharma Driving Big Pharma Innovation, PharmaVOICE, Retrieved at: <https://www.pharmavoices.com/article/2020-01-pharma-innovation/>

## “We’ve Lost Our Soul”: The Story of Amgen and Immunex

**The Development of Enbrel** In 2002, Amgen, one of these pharmaceutical giants, acquired Immunex, a small biotech firm focused on therapies for immune diseases.<sup>63</sup> In exclusive conversations with former Immunex, and later Amgen, employees, my staff found that they all painted a similar picture: after the acquisition, the innovative, creative culture the company had worked so diligently to foster was destroyed. Piece by piece, it was broken down, until, as one employee put it, “we’ve lost our soul.”

Amgen, at the time the largest biotech company in the world, announced that it would acquire Immunex in December 2001. The acquisition was completed in July 2002. **Amgen initiated the acquisition because of a potential breakthrough drug that Immunex controlled: etanercept (Enbrel), which treats rheumatoid arthritis and other chronic immune-mediated diseases.**<sup>64</sup> These disorders result from the body mistakenly attacking its own cells. Enbrel helps block this by interfering with, or inhibiting, tumor necrosis factor (TNF), a signaling cell involved in the inflammation rheumatoid arthritis causes.<sup>65</sup>

In 1992, Marc Feldmann and Ravinder Maini demonstrated that TNF inhibiting therapy had tremendous potential to combat autoimmune disease like rheumatoid arthritis.<sup>66</sup> This breakthrough science, which initially endured some skepticism,<sup>67</sup> drew the attention of biotech companies: Roche and Genentech began research (first separately, then together after a merger) into one form of TNF receptor,<sup>68</sup> while Immunex began research into another.<sup>69</sup> Roche/Genentech began clinical trials in the US for rheumatoid arthritis, working with the lab of Michael Weinblatt at Brigham and Women’s Hospital in Boston.<sup>70</sup> Roche and Genentech were six months ahead of Immunex in their US clinical trials and had positive results in Europe, but the US trials were ultimately unsuccessful.<sup>71</sup>

At first, Immunex had previously experimented with anti-TNF treatments for patients with bacterial sepsis<sup>72</sup> but this indication, or use, for the drug ultimately failed, destabilizing the small company’s financial prospects in the process.<sup>73</sup> Immunex switched its clinical testing from developing a sepsis therapy to studying the effects in rheumatoid arthritis.<sup>74</sup> Immunex

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<sup>63</sup> Amgen Completes Acquisition Of IMMUNEX, Amgen, Retrieved at: <https://investors.amgen.com/news-releases/news-release-details/amgen-completes-acquisition-immunex>

<sup>64</sup> Etanercept (Enbrel®) Drug Information Sheet, Johns Hopkins, Retrieved at: <https://www.hopkinsarthritis.org/patient-corner/drug-information/etanercept-enbrel/>

<sup>65</sup> Ibid.

<sup>66</sup> Anti-TNF Therapy, from Rationale to Standard of Care: What Lessons Has It Taught Us?, Journal of Immunology, Retrieved at: <https://www.jimmunol.org/content/jimmunol/185/2/791.full.pdf>

<sup>67</sup> A Conversation with Marc Feldmann, Journal of Clinical Investigation, Retrieved at: <https://www.jci.org/articles/view/71860>

<sup>68</sup> Roche and Genentech cloned and sought to bring to market the p55 soluble TNF receptor (lenercept).

<sup>69</sup> Immunex focused on developing the p75 TNF receptor (etanercept).

<sup>70</sup> Our office spoke with Dr. Michael Weinblatt who confirmed the details of his work on the development of Enbrel and of the other details provided here about the discovery process.

<sup>71</sup> Treatments no longer in development for rheumatoid arthritis, BMJ Journals Retrieved at:

[https://ard.bmj.com/content/61/suppl\\_2/ii43#ref-27](https://ard.bmj.com/content/61/suppl_2/ii43#ref-27) and An Assessment of the Effect of Anti-Drug Antibody Formation on the Pharmacokinetics and Pharmacodynamics of sTNF55-IgG (Ro 45-2081-Lenercept [LEN]) (S.C.) IN PATIENTS WITH RHEUMATOID ARTHRITIS (RA), Ovid, Retrieved at: <https://insights.ovid.com/arthritis-rheumatism/arhe/1998/09/001/assessment-effect-anti-drug-antibody-formation/158/0000889>

<sup>72</sup> “Sepsis is a potentially life-threatening condition caused by the body’s response to an infection. The body normally releases chemicals into the bloodstream to fight an infection. Sepsis occurs when the body’s response to these chemicals is out of balance, triggering changes that can damage multiple organ systems.” Mayo Clinic, Retrieved at: <https://www.mayoclinic.org/diseases-conditions/sepsis/symptoms-causes/svc-20351214#:~:text=Sepsis%20is%20a%20potentially%20life,can%20damage%20multiple%20organ%20systems.>

<sup>73</sup> Information confirmed through conversations with Dr. Michael Weinblatt, rheumatologist at Brigham and Women’s Hospital, Mike Widmer, former Vice President and Director of Biological Sciences, and other former Immunex researchers.

<sup>74</sup> Information confirmed through conversations with Dr. Michael Weinblatt, rheumatologist at Brigham and Women’s Hospital, Mike Widmer, former Vice President and Director of Biological Sciences, and other former Immunex researchers.

researchers Craig Smith, Ray Goodwin, and Patricia Beckmann were crucial in developing p75 TNF receptor technology for commercial use.<sup>75</sup>

Immunex worked with the lab of researcher Brian Seed at Massachusetts General Hospital to develop a fusion for the receptor. Seed's previous work had focused on creating this kind of fusion technology for treatments intended to combat HIV. Seed leveraged insights he learned from making IgG fusion proteins for HIV to help in making Enbrel.<sup>76</sup> Although Seed was the first to make the Ig fusion technology, the patent for some of the technology was held by Genentech/Roche.<sup>77</sup> Enbrel received FDA approval for treatment for rheumatoid arthritis on November 2, 1998.<sup>78</sup> **Once Enbrel was in clinical use, it attained multibillion-per-year blockbuster sales.** Immunex, and later Amgen, owed both Seed/Massachusetts General Hospital and Genentech/Roche considerable royalties from the drug's sales.<sup>79,80</sup>

**The Amgen-Immunex Acquisition** In early October, in a Committee on Oversight and Reform hearing, **Congresswoman Porter questioned the current CEO of Amgen, Robert Bradway.<sup>81</sup> Bradway downplayed the role of Immunex and Brian Seed in the development of Enbrel, prompting a former Immunex, and later Amgen, Principal Scientist to contact our office.** Laurent Galibert, the scientist, wanted to provide clarification on Bradway's testimony and the transformation Galibert watched the company undergo after the acquisition.

**"In exclusive conversations with former Immunex, and later Amgen, employees, my staff found that they all painted a similar picture: after the acquisition, the innovative, creative culture the company had worked so diligently to foster was destroyed."**

Through conversations with Galibert and multiple other former employees of Immunex/Amgen, our office pieced together a story of a small biotech company in which **scientific discovery and innovation were devastated during an acquisition.** Galibert characterized the acquisition, and many others like it, with a simple metaphor: you buy a hen house, burn the hen house, kill the chickens inside, and sell their eggs.

<sup>75</sup> A Zigzagging Path Points Straight to Success, ScienceMag, Retrieved at: <https://www.sciencemag.org/careers/2011/03/zigzagging-path-points-straight-success> and Summary for Patent: RE36755, Retrieved at: <https://www.drugpatentwatch.com/p/biologics/patent/RE36755>

<sup>76</sup> Seed's "...work on immunoglobulin fusion proteins led to the identification of several co-receptors and ligands and laid the basis for the development of several therapeutic fusion proteins that conceptually underlies much of the current biologics effort in the pharmaceutical industry. It was this work that led to the creation of etanercept (Enbrel)..." Who We Are, Translational Medical Group, Retrieved at: <https://tmgmgh.harvard.edu/about/who-we-are>

<sup>77</sup> "In 1998, Roche and Immunex entered into a cross-license agreement, in which Roche non-exclusively licensed Immunex under the applications which subsequently became the patents-in-suit and Immunex granted Roche the option to license its own patents and applications ("the 1998 Agreement"). JTX-13... Under the terms of the 1998 Agreement, Immunex paid royalties to Roche equivalent to 2% of Enbrel sales." Immunex Corporation, Amgen Manufacturing, Limited, and Hoffmann-La Roche Inc., v. Sandoz Inc., Sandoz International GMBH and Sandoz GMBH, Retrieved at: <https://www.bigmoleculerwatch.com/wp-content/uploads/sites/2/2018/10/Sandoz-Corrected-Findings-of-Fact-Conclusions-of-Law.pdf>

<sup>78</sup> Scientists who pioneered arthritis drug quit Amgen, Seattle Times, Retrieved at: <https://archive.seattletimes.com/archive/?date=20030814&slug=amgen14>

<sup>79</sup> Lucrative Licensing Deals With Drug, Biotech Firms Are Raising Ethics Issues For Hospitals, Sherman, Silverstein, Kohl, Rose & Podolsky, P.A., Retrieved at: <https://www.sskrplaw.com/lucrative-licensing-deals-with-drug-biotech-firms-are-raising-et.html>

<sup>80</sup> Boston hospital rakes in \$284M on drug rights, Fierce Healthcare, Retrieved at: <https://www.fiercehealthcare.com/healthcare/boston-hospital-rakes-284m-drug-rights>

<sup>81</sup> Rep. Katie Porter, Twitter, Retrieved at: <https://twitter.com/RepKatiePorter/status/1311723496947494918>

**“Galibert characterized the acquisition, and many others like it, with a simple metaphor: you buy a hen house, burn the hen house, kill the chickens inside, and sell their eggs.”**

Galibert, a Principal Scientist at Immunex, stayed on with the company through the acquisition. **He described the shift in the focus as a move from “research and development” to “search and development.” Rather than conducting research, Amgen wanted to instead search for new products to acquire.** Immunex had been a leader in immunotherapy, but much of the research they had in very early stages was quite risky, and, at the time, immunotherapy was a less well-respected field. Galibert discussed this: “Immunex was full of amazing visionary scientists and the team they had was scientifically speaking could have eloped in terms of creativity... It’s a rare event that’s happening once in a decade... we had anticipated immunotherapy when everyone else thought it was a dream. It took everyone else 11 years to realize that we were right.”

To avoid this risk, Amgen killed nearly all programs involving early immunotherapy research. Those few projects that were maintained were later successful, and Galibert believes it is likely others could have been fruitful had Amgen not feared their cost and risk. **Galibert explained that not only did Amgen “sterilize the creativity and imagination of researchers” but they also “prevented the development of drugs that should have reached the patient much earlier.”** Galibert explained, “Everybody makes mistakes. Abandoning immunotherapy when Immunex was holding a dominant position was one. What I find regrettable in this is not so much that a mistake was made but that it was made because of arrogance and a certain form of self-serving mentality.”

Stewart Lyman, the company’s former Director of Extramural Research, echoed these sentiments. He had worked for Immunex for fourteen years as Senior Staff Scientist in the Molecular Biology Department before being promoted to a management position. He stayed with Amgen before leaving the company to work as a consultant. When he was a scientist at Immunex, his team collaborated with other companies and researchers, advancing cures faster and avoiding unnecessary pitfalls. Rather than working on research others had already found wouldn’t lead anywhere, they took advantage of the expertise of scientists across the globe. They used this information to prioritize their research, save money, and better direct efforts. **When Immunex was acquired, many of their ongoing collaborations were quickly snuffed out, ending an effort that had helped to save lives and money.**

Immunex’s Director of Human Resources, Beth Fortmueller (later Amgen Human Resources Site Head for Amgen Washington), shared with our office a cultural document that Immunex put together in advance of the merger in hopes of preserving the company’s focus on innovation. “What’s Made Us, Immunex: A Story of Transformation & Evolution” was published in February 2002. The former Scientific Director at Amgen who worked for Immunex as well prior to the acquisition,<sup>82</sup> explained to our staff: going into the acquisition, “there was a lot of angst, because Immunex was an innovative company with a strong history of science. We were worried that it would be shut down or worried that we wouldn’t be able to keep the same focus on science.” They created this document in hopes that they could preserve it, but unfortunately, they failed.

<sup>82</sup> Individual requested that their name not be publicly disclosed in this report.



Beth Fortmueller left Amgen two years after the acquisition. By the time she left, all of the Discovery Research leadership that had come with her had already left Amgen.<sup>83</sup> She explained that, “for her personally, **it felt like death by a thousand cuts.**” There was a lot of rhetoric about taking the best from each company, but in reality, it became rapidly clear that it wasn’t a merger, but truly an acquisition.

Amgen’s CEO at the time, Kevin Sharer<sup>84</sup> held a meeting at Seattle Symphony Hall near the end of the acquisition. The event was supposed to be an opportunity for Immunex employees to meet Sharer and get an understanding for his leadership and the future of the company. As employees continued to ask questions, he became visibly more frustrated. The atmosphere became agitated, as Immunex employees felt their questions weren’t being addressed. **Sharer finally answered one question with a statement that definitively set the tone for the rest of the acquisition: “Listen, we won, you lost. Get over it.”** Immunex employees started booing, and Fortmueller remembered reflecting, “you just made my job so much harder.”

This attitude was clear in further decisions that Amgen made about Immunex programs that they cut, in addition to those pipeline research projects that Amgen killed. Charles Maliszewski had helped lead **a postdoctoral fellowship program at Immunex, training the fellows who produced interesting research and ideas for the company. Immunex leadership felt it was important to develop this talent not just for their company but for the world. It was among the most productive programs they had in terms of discovery,** allowing unfettered, new ideas to develop in the company. Maliszewski described losing this program as “one of the most disappointing aspects of the merger.” That some of their greatest research came from these fellows was not surprising to Maliszewski, who explained that the reporting matrix at Immunex was not top down, but in fact very flat. **Ideas from the most junior individuals, even those without an advanced degree, could percolate to the top level of the company, creating amazing benefits and fostering a great culture.** Former employee Claudi Wyszynski explained further in the culture document, “This is the first company that I’ve worked for where I feel that I can develop in areas that are not currently within my job title scope. I feel management wants my input; I’m treated professionally and respected.”<sup>85</sup>

**“People were ‘afraid’ of Roger Perlmutter, Amgen’s Executive Vice President and Head of R&D. People never questioned him, the way they would have done at Immunex. When ideas were squashed, no one spoke up.”**

Everyone we spoke with felt that **this culture completely disappeared after the acquisition.** They described infighting at Amgen, as people were “constantly trying to climb over each other for the attention of higher ups.” Maliszewski told us people were “afraid” of Roger Perlmutter, Amgen’s Executive Vice President and Head of R&D.<sup>86</sup> People never questioned him, the way they would have done at Immunex. **When ideas were squashed, no one spoke up.** Maliszewski felt his excitement for work waning, but stayed on in a futile hope of continuing the culture of Immunex. He had worked for Immunex for 17 years, but only spent 2 years at

<sup>83</sup> The Process Science research department leadership stayed on. Fortmueller indicated that this department was better led, and more respected, at Amgen.

<sup>84</sup> Sharer has since left the company and now works at Merck.

<sup>85</sup> What’s Made Us: Immunex, A story of Transformation and Evolution, February 2002.

<sup>86</sup> Roger Perlmutter, Merck, Retrieved at: <https://www.merck.com/leadership/roger-m-perlmutter-m-d-ph-d/>



Amgen. He was making far more money than he had at Immunex but it wasn't enough to keep him from leaving, nor was a special option program he was offered. This was an incentive program that "you were supposed to keep secret." You received a letter that you knew only a few others had received. It provided a 5-year stock option in the company as an incentive to stay with Amgen. Maliszewski turned the offer down and left 6 months later. He explained: **"working for a pharmaceutical company like Amgen felt like selling my soul. The research focus was not particularly creative research, whereas the biotech companies were like academic labs, doing discovery or taking on the followup work of initial discovery."**

Enbrel wasn't the only drug that Amgen was after: Dr. Lyman explained that one of the few pipeline projects that Amgen didn't kill was a drug which they later marketed as Prolia, a treatment for bone density and osteoporosis.<sup>87</sup> Amgen had been working on a similar treatment at the same time as Immunex, and the companies had competing patents and other intellectual property protections. Galibert confirmed this, having written one of the patents for Prolia.<sup>88</sup> In the end, Amgen didn't develop the molecule that the company had originally been working on, but they instead developed an antibody that was also controlled by the intellectual property Immunex held.<sup>89</sup> Through the acquisition of Immunex, they had also gained ownership of this intellectual property.

## The Path Forward

Our country today faces an unprecedented health crisis. While this pandemic has shocked the world in a way few expected, we all know it won't be the last. New threats, like superbugs, remain on the horizon, while old foes, such as Alzheimer's and ALS, still have few or no treatment options. **Policies to propel new cures forward, to return the pharmaceutical industry to its initial mission, are desperately needed. Together, we must chart a new path forward, fostering policies that can help save lives.**

Many experts see large pharma companies' efforts to "satisfy investors' desire for growth" as the primary cause for the post M&A innovation drop, as "from a financial perspective, funders of pharmaceutical businesses do not generally have the 12 to 20 year perspective that is required to translate bioscience ideas into products."<sup>90</sup> Companies should not tie bonuses to financial metrics but instead link bonuses to either 1) measures of health outcomes such as reduced mortality, or 2) revenue reinvested for research and development of new drugs. **If companies will not take these actions on their own, legislators should consider tying requirements for this to merger conditions, patent exclusivity, or some other mechanism.**

**"Companies should not tie bonuses to financial metrics but instead link bonuses to either 1) measures of health outcomes such as reduced mortality, or 2) revenue reinvested for research and development of new drugs."**

<sup>87</sup> Prolia, RX List, retrieved at: <https://www.rxlist.com/prolia-drug.htm>

<sup>88</sup> Immunex researchers held the patent that protected the idea of interfering with RANKL (the target that led to the invention of Prolia): Method of inhibiting osteoclast activity, Retrieved at: <https://patents.google.com/patent/US7790684B2/en>

<sup>89</sup> Ibid.

<sup>90</sup> Vertical disintegration: a strategy for pharmaceutical businesses in 2009?, Nat Rev Drug Discov, Retrieved at: <https://pubmed.ncbi.nlm.nih.gov/19483701/>

Beyond this, **the Federal Trade Commission (FTC) must evaluate and push back against pharmaceutical companies' various anti-competitive behaviors.** FTC Commissioner Rohit Chopra wrote in his Dissenting Statement in the Bristol-Myers Squibb/Celgene merger: “When enforcers conduct wide-ranging, intensive inquiries that do not uncover unlawful conduct, then, of course they cannot take action. However, when they wear blindfolds or cling to the status quo, they cannot assume that the public is protected.”<sup>91</sup> **It's time for the FTC to take its blindfold off and make some critically needed changes.** This must include three parts:

1. **REVIEW PAST CASES:** The FTC needs to stop health care industry mergers, taking time to **review past mergers to see if promises in merger agreements were met and/or if anticompetitive behavior grew or changed after the merger.** After looking back at past mergers, the FTC must first decide if these agreements have been upheld, and if not, whether or not these companies should be broken up.
2. **ESTABLISH NEW STANDARDS:** The FTC must then reevaluate the standards they are using for health care mergers in light of information gathered from this review. Moving forward, **the FTC should incorporate into merger review anticompetitive conduct as part of the assessment as part of whether or not the merger should be considered anticompetitive behavior.** This can include, but should not be limited to, litigation on pay-for-delay schemes, abuse of the *Orphan Drug Act*, or other patent abuses, such as patent thickets and evergreening. The FTC should also “require divestiture of products, including candidates in early-stage clinical trials, in overlapping markets.”<sup>92</sup>
3. **EXPAND SCOPE:** While larger mergers, like Bristol-Myers Squibb/Celgene, reach the level of the DOJ or FTC's analysis, many small acquisitions do not. **Currently, most M&A deals are considered de facto legal and some individual or organization must contest them in order to stop the merger or acquisition. This means most M&A deals move forward with little scrutiny, but legislation can and should be passed to alter this presumption for health care companies and health-related industries.** Under such legislation, any health care entity, including pharmaceutical companies, pharmaceutical benefit managers, hospitals, and others, would be required to apply for and obtain permission from the FTC before moving forward. In this application, they would be required to prove that the merger or acquisition is more likely than not to result in improved health care quality and cost for consumers. Impacted parties, including patients and health care workers, must have an opportunity to submit perspectives that will be considered by the FTC during the scrutiny process.

As a minimum, alternative approach, one could pursue something similar to the process established in Washington State. **Now, in Washington, there is a requirement that a hospital must notify the State Attorney General of any acquisitions.**<sup>93</sup> **A similar requirement for disclosure and notification could at least ensure that government watchdogs have access to the information needed to evaluate smaller mergers.** This would prevent firms from further “manipulating the size of horizontal acquisitions to reduce the likelihood of antitrust scrutiny.”<sup>94</sup>

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<sup>91</sup> Dissenting Statement of Commissioner Rohit Chopra: In the Matter of Bristol-Myers Squibb/Celgene, Commission File No. 1910061.

<sup>92</sup> By Any Means Necessary: How Allergan Gamed the System to Raise Drug Prices and Flood the Country with Pills, Public Citizen, Retrieved at: <https://www.citizen.org/article/by-any-means-necessary/>

<sup>93</sup> Washington State to Implement Mandatory Healthcare M&A Reporting, McGuire Woods, Retrieved at: <https://www.mcguirewoods.com/client-resources/Alerts/2019/8/washington-state-implement-mandatory-healthcare-m-a-reporting#:~:text=Washington's%20new%20law%20%E2%80%94%20which%20will%20notice%20to%20the%20Washington%20AG.>

<sup>94</sup> Confronting Rising Market Power, Economics for Inclusive Prosperity, Retrieved at: <https://econfp.org/policy-brief/confronting-rising-market-power/>

As part of this, the FTC must consider appropriate penalties for offenders, whether that be breaking companies up, revoking patents, preventing patent exclusivity in the future, issuing compulsory licenses, and/or imposing personal liability for management.<sup>95</sup>

Congress must also take action. Fiona Scott Morton, Professor of Economics at Yale University's School of Management, has proposed that **Congress could authorize the FTC and other relevant antitrust authorities "to analyze and comment publicly on the effects on competition of significant proposed agency regulations."**<sup>96</sup> These analyses would help regulators understand when a proposed regulation may have an anticompetitive effect that could increase drug prices or reduce competition.

Finally, **Congress must pass legislation that creates barriers to skyrocketing costs.** This is, above all else, the most important factor in decreasing costs. This begins with drug price negotiation legislation such as the *Elijah E. Cummings Lower Drug Costs Now Act*, but must continue, extending to a larger class of drugs and covering all payers and the uninsured.<sup>97</sup> I am proud that this legislation included my legislation, the *Freedom from Price Gouging Act*, which would require drug manufacturers to pay the government back when they increase their prices of drugs beyond the price of inflation.<sup>98</sup>

Beyond just negotiating a better deal for American consumers, we must pass legislation to prevent anti-competitive abuses of the drug patenting system, including:

- the *Preserve Access to Affordable Generics and Biosimilars Act*, which would prevent pay-for-delay tactics, in which drug companies pay-off competitors to keep lower-cost products off the market;<sup>99</sup>
- the *Affordable Prescriptions for Patients Through Promoting Competition Act*, which would stop "product-hopping," the practice by which drug corporations make superficial tweaks to pre-existing products to undermine competitors;<sup>100</sup> and
- the *Stop STALLING Act* to stop abuses of the regulatory process, which include drug companies filing sham petitions to delay approval of competitors.<sup>101</sup>

**It's time we reevaluate the standards for approving these mergers. It's time we pass legislation to lower drug prices. And it's time we rethink the structure of leadership at big pharmaceutical companies. Together, these strategies can help us bring more innovative, and critically needed, cures and treatments to market.**

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<sup>95</sup> By Any Means Necessary: How Allergan Gamed the System to Raise Drug Prices and Flood the Country with Pills, Public Citizen, Retrieved at: <https://www.citizen.org/article/by-any-means-necessary/>

<sup>96</sup> Economics for Inclusive Prosperity, as cited.

<sup>97</sup> H.R. 3, Elijah E. Cummings, Lower Drug Costs Now Act, Library of Congress, Retrieved at: <https://www.congress.gov/bill/116th-congress/house-bill/3?q=%7B%22search%22%3A%5B%22h.r.+3%22%5D%7D&s=2&r=1>

<sup>98</sup> Rep. Porter Introduces Legislation to Crack Down on Pharmaceutical Price Spikes, Rep. Katie Porter, Retrieved at: <https://porter.house.gov/news/documentsingle.aspx?DocumentID=71>

<sup>99</sup> H.R. 2375, Preserve Access to Affordable Generics and Biosimilars Act, Library of Congress, Retrieved at: <https://www.congress.gov/bill/116th-congress/house-bill/2375?q=%7B%22search%22%3A%5B%22h.r.+2375%22%5D%7D&s=3&r=1>

<sup>100</sup> H.R. 5133, the Affordable Prescriptions for Patients Through Promoting Competition Act, Library of Congress, Retrieved at: <https://www.congress.gov/bill/116th-congress/house-bill/5133?q=%7B%22search%22%3A%5B%22h.r.+5133%22%5D%7D&s=4&r=1>

<sup>101</sup> H.R. 2374, the Stop STALLING Act, Library of Congress, Retrieved at: <https://www.congress.gov/bill/116th-congress/house-bill/2374/cosponsors?q=%7B%22search%22%3A%5B%22h.r.+2374%22%5D%7D&s=6&r=1&overview=closed&searchResultViewType=expanded>