DePaul University
University Libraries

DePaul Journal of Health Care Law

Volume 23
Issue 2 *2022*

Article 2

June 2022

Manipulating the Prescription Drug Market: Spiking Prices, Inducing Demand, and Costs to the Public

Katherine Drabiak, J.D.
University of South Florida College of Public Health, kdrabiak@usf.edu

Manipulating the Prescription Drug Market: Spiking Prices, Inducing Demand, and Costs to the Public

AUTHOR:

Katherine Drabiak, JD
Associate Professor
College of Public Health
University of South Florida HEALTH
kdrabiak@usf.edu

ABSTRACT:

In 2016, Mylan made headlines when it spiked the price of its EpiPen AutoInjector by 400%, raising the price from an average of $57 to $500. Critics called the price hike "outrageous, "brutal" and "corrupt." Public outcries fueled a demand for a Congressional investigation, and Mylan negotiated a settlement with the United States Department of Justice over alleged violations of the False Claims Act. Although competition self-corrected and similar products entered the marketplace, this case – and other similar cases involving generic drugs and insulin – highlighted the skyrocketing costs of prescription drugs in the United States. In 2019, United States outpatient spending on prescription drugs totaled $369.7 billion. Despite massive expenditures, the United States ranks below comparable countries on health outcomes. This article traces the reasons for high medication prices; describes two key lawsuits alleging patterns of anticompetitive pricing, collusion, and fraud; and analyzes how corporate practices contribute to unnecessary and harmful healthcare costs through the pharmacological imperative. Industry practices described in this article reflect a pattern of organizational business ethics that contravenes market guardrails through both alleged and admitted dishonesty and illegal conduct. This article proposes solutions that will improve patient health, reduce healthcare costs, and uphold market fairness by reforming the expectations of corporate conduct.

INTRODUCTION

In 2016, Mylan made headlines when it spiked the price of its EpiPen AutoInjector by 400%, raising the price from an average of $57 to $500.[1] Patients with severe anaphylactic reactions to allergens such as insect stings or bites, foods, or drugs expressed worry about how they could afford their lifesaving medication.

[2] According to the American College of Allergy, Asthma, and Immunology, food allergies constitute the leading cause of severe allergic reactions that occur outside the hospital system.[3] People with severe or anaphylactic allergies may experience symptoms such as shortness of breath, repetitive coughing, weak pulse, generalized hives, tightness in the throat, trouble breathing or swallowing, or cardiac arrest.[4] In severe cases, without immediate intervention, the anaphylactic reaction can be deadly.[5] With one click, an autoinjector delivers rapid acting epinephrine subcutaneously to quell patient symptoms until the patient can access emergency medical care.[6]

At the time, one other similar product existed in the market, called Adrenaclick from Amdreda Pharmaceuticals.[7] Despite a significantly less expensive price tag, Adrenaclick had undergone several product modifications, transferred ownership between different companies, and switched product names.[8] This resulted in uncertainty among physicians and pharmacists about product existence, availability, and distribution.[9] As a result, despite two similar products in the market, EpiPen dominated market share, accounting for 95% of filled prescriptions for patients using an epinephrine autoinjector.[10]

---

[1] Emily Willingham, *Why Did Mylan Hike EpiPens Price 400%? Because They Could*, FORBES (Aug. 21, 2016), https://www.forbes.com/sites/emilywillingham/2016/08/21/why-did-mylan-hike-epipen-prices-400-because-they-could/?sh=686e7335280c.

[2] FDA, LABEL FOR EPIPEN, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/019430s053lbl.pdf (last visited Feb. 16. 2022) [hereinafter LABEL FOR EPIPEN].

[3] *Epinephrine Autoinjector*, AM. COLL. OF ALLERGY, ASTHMA, AND IMMUNOLOGY, https://acaai.org/allergies/allergy-treatment/epinephrine-auto-injector (last updated Feb. 1, 2018).

[4] *Anaphylaxis*, AM. COLL. OF ALLERGY, ASTHMA, AND IMMUNOLOGY, https://acaai.org/allergies/anaphylaxis (last updated Jan. 29, 2018).

[5] *Id.*

[6] LABEL FOR EPIPEN, *supra* note 2.

[7] Dean Celia, *Untangling the Mylan EpiPen Controversy*, POPULATION HEALTH LEARNING NETWORK: FIRST REPORT MANAGED CARE (Oct. 2016), https://www.managedhealthcareconnect.com/article/untangling-mylan-epipen-controversy; Katie Thomas, *Why the Lone EpiPen Competitor Hasn't Taken Off*, N.Y. TIMES (Nov. 2, 2016), https://www.nytimes.com/2016/11/02/business/also-ran-to-epipen-reaches-for-a-closing-window-of-opportunity.html.

[8] Thomas, *supra* note 7.

[9] *Id.*

[10] *Id.*; *see also* Pauline Bartolone, *EpiPen's Dominance Driven by Competitors' Stumbles and Tragic Deaths*, NAT'L PUB. RADIO (Sept. 7, 2016, 12:52 PM), https://www.npr.org/sections/health-shots/2016/09/07/492964464/epipen-s-dominance-driven-by-competitors-stumbles-and-tragic-deaths; Sy Mukherjee, *Mylan's EpiPen is Bleeding Market Share to Its Rivals*, FORTUNE (Mar. 6, 2017, 12:29 PM), https://fortune.com/2017/03/06/mylan-epipen-competitors-surge/.

Critics called the price hike "outrageous," "brutal," and "corrupt."[11] Public outcries[12] demanded a Congressional investigation.[13] The United States Department of Justice (DOJ) alleged that Mylan violated the False Claims Act by charging brand name prices while misclassifying EpiPen as a generic drug to avoid paying rebates owed primarily to Medicaid.[14] Approximately one year later, Mylan reached a $465 million settlement with the DOJ to resolve allegations under the False Claims Act, without reaching a determination of liability.[15]

Although competition self-corrected and similar products entered the marketplace,[16] this case – and similar other cases – highlighted the significant costs of prescription drugs in the United States. In 2020, United States outpatient spending on prescription drugs totaled $348.4 billion.[17] Despite massive expenditures, the United States ranks below comparable countries on health outcomes such as hospital admissions for chronic disease, medical error, and premature death rate.[18] Our healthcare system addresses acute emergencies, such as responding to allergic anaphylactic shock, the steady war against diseases such as diabetes, and slowly burning epidemics such as the opioid crisis. Catastrophic price increases in individual drug pricing and overall costs to the healthcare system point to more significant issues: determining who can access medically necessary prescription drugs; whether manufacturer conduct in the marketplace driving price increases arises to legal wrongdoing; and examining the presumption that specific medications constitute an optimal medically necessary intervention.

Corporate actions designed to increase prices and induce demand for prescription medications to reflect neutral market practices. However, ongoing litigation suggests manufacturers crossed a boundary by integrating strategic anticompetitive practices designed to artificially and unduly influence both price and demand. Industry practices reflect a pattern of organizational business ethics that contravened market guardrails through both alleged and admitted collusion, fraud, dishonesty, and illegal conduct in the pricing and promotion of prescription drugs.

---

[11] Celia, *supra* note 7; *but see* Uwe Reinhardt, *Mylan's CEO a Villain? Depends on Your Preferred Brand of Capitalism*, HEALTH AFFAIRS FOREFRONT (Sept. 6, 2016), https://www.healthaffairs.org/do/10.1377/forefront.20160906.056352/full/ (discussing profit maximization as a form of capitalism presuming "open and free competition without deception or fraud.").

[12] *Mylan CEO on EpiPen Drug Price Controversy: "I get the Outrage",* CBS NEWS (Jan. 27, 2017, 6:54 AM), https://www.cbsnews.com/news/epipen-price-hike-controversy-mylan-ceo-heather-bresch-speaks-out/.

[13] Julia Thibault, *America's Oldest Drug Cartel: Civil RICO Action In Re Insulin Pricing Litigation and the Case for Overruling the Indirect Purchaser Rule*, 46 AM. J. L. & MED. 470, 482 (2020).

[14] Press Release, U.S. Dep't of Justice, Mylan Agrees to Pay $465 Million to Resolve False Claims Act Liability for Underpaying EpiPen Rebates, (Aug. 17, 2017), https://www.justice.gov/opa/pr/mylan-agrees-pay-465-million-resolve-false-claims-act-liability-underpaying-epipen-rebates.

[15] *Id.*

[16] Bartolone, *supra* note 10; Thomas, *supra* note 7; *see also* Arlene Weintraub, *EpiPen Alternatives Snatch up Market Share as Mylan's Allergy Shot Falters: Report*, FIERCE PHARMA (Mar. 7, 2017, 9:01 AM), https://www.fiercepharma.com/pharma/epipen-alternatives-snatch-up-market-share-as-mylan-s-allergy-shot-falters-report; Caroline Chen, *EpiPen Competitor Will Re-Launch After Being Pulled off Market*, CHI. TRIBUNE (Oct. 26, 2016), https://www.chicagotribune.com/business/ct-epipen-competitor-auviq-relaunch-20161026-story.html.

[17] *National Health Expenditure Fact Sheet*, CTRS. FOR MEDICARE AND MEDICAID SERVS., https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet (last updated Dec. 15, 2021).

[18] Nisha Kurani & Emma Wager, *How Does the Quality of the U.S. Health System Compare to Other Countries?*, PETERSON-KFF HEALTH SYSTEM TRACKER (Sept. 30, 2021), https://www.healthsystemtracker.org/chart-collection/quality-u-s-healthcare-system-compare-countries/#item-start.

Section I will explore the context and reason for skyrocketing prices and the corresponding impact of high prescription prices on patient health. In Section II, this article will examine barriers to medication access in two examples: generic drugs, where many competitors exist, and insulin, where few competitors exist. This section will provide an overview of two separate actions, *In Re Generic Pharmaceuticals Pricing Litigation* and *In Re Insulin Pricing Litigation*, which alleged a variety of claims arising from purported anticompetitive pricing strategies, collusion, and fraud under the Sherman Act and the Racketeer Influenced Corrupt Organizations Act. In Section III, this article will explore the forces driving high expenditures on prescription drugs in the United States and analyze the industry's promotion techniques. Section III will describe the intersection of inefficient, harmful healthcare spending and corporate strategies to expand market demand by distorting research, promulgating misleading claims, and engaging in fraudulent marketing practices. Finally, Section IV will offer insights on potential solutions to reform expectations for corporate conduct in a manner that will promote patient health, reduce healthcare costs, and permit an honest market to flourish.

I. HIGH COST AND HIGH SPENDING ON PHARMACEUTICAL DRUGS IN THE UNITED STATES

This section will provide an overview of the reasons behind spending and cost of prescription drug medications in the United States. While patent law is designed to reward manufacturers for novel therapies and improvements to medications, research suggests that not all price increases reflect innovation. Instead, the drug pricing system entails a complex and opaque network that has created difficulty for patients to understand the true price of medications. Both market competition and patients can suffer when anticompetitive practices pervade the drug distribution chain.

A. Patient Spending on Pharmaceutical Medications

In 2020, United States outpatient spending on prescription drugs totaled $348.4 billion,[19] and the United States spends 54-209% more than other high income countries per capita on pharmaceutical drugs.[20] Data from the Kaiser Family Foundation demonstrates that the United States spends more than twice the amount on healthcare than comparable countries, and yet has worse health outcomes.[21] In addition to ranking low compared to similar nations for hospital admissions for chronic disease, medical error, and premature death rate, the United States ranks last in health care access and quality, indicating higher rates of amenable mortality than peer countries.[22] Mortality amenable to healthcare refers to rates of death that health policy scholars consider preventable by timely and effective care.[23] This includes a broad range of health conditions, including cardiovascular disease, diabetes, and cancer that health providers could

[19] *National Health Expenditure Fact Sheet*, *supra* note 17.
[20] Nathan E. Wineinger et al., *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, JAMA NETWORK OPEN, May 31, 2019, at 1, 2.
[21] Nisha Kurani & Cynthia Cox, *What Drives Health Spending in the U.S. Compared to Other Countries*, PETERSON-KFF HEALTH SYSTEM TRACKER (Sept. 25, 2020), https://www.healthsystemtracker.org/brief/what-drives-health-spending-in-the-u-s-compared-to-other-countries/.
[22] Kurani & Wager, *supra* note 18.
[23] *Id.*

assist with prevention or treatment.[24] Notably, high prescription medication costs constitute only a portion of overall spending; the main driver for high healthcare costs originates from inpatient and outpatient care. [25]

In the past decade, the prices for prescription drugs have increased dramatically, far above the rise of inflation as measured by the Consumer Price Index.[26] A study in the *Journal of the American Medical Association* found that from 2008 to 2015, the prices for the most commonly used prescription drugs increased by 164%.[27] Physician Dr. Eric Yang and colleagues analyzed 14.4 million pharmacy claims for 1.8 million patients across the United States, finding that list prices more than doubled over the past seven years.[28] Similarly, biostatistics researcher Nathan Wineinger and colleagues analyzed pricing and payment data for the top forty-nine selling prescription medications. For the thirty-six drugs that have been available since 2012, more than 44% of these medications doubled in price over a five-year period.[29]

1. Manufacturers' Reasons Behind Price Setting

a. Research and Development

Manufacturers assert several reasons for rising costs, such as investment in research and the development of novel therapies.[30] According to some estimates, bringing a new drug to market is incredibly expensive, amounting to $2.6 billion for research, development, and the cost of late stage clinical trials.[31] However, physician and health policy scholar Dr. Aaron Kesselheim and colleagues note that a significant amount of research occurs in academic institutions, which receives funding from public sources such as the National Institutes of Health.[32] According to one analysis into the origin of twenty-six pharmaceutical products, about half of the products originated from publicly funded research.[33] In addition to public funding, venture capital companies may also sponsor product research and development.[34] Kesselheim and colleagues estimate that the portion of revenue that pharmaceutical companies invest in research and development ranges from 10-20%.[35] Rather than research and development, some figures suggest industry directs its budget toward marketing and promotion practices designed to increase product visibility, uptake, and use.[36]

b. Reward for Novel Iterations

While manufacturers may justify high costs for new products, many critics question high prices for drugs or

---

[24] GBD 2016 Healthcare Access and Quality Collaborators, *Measuring Performance on the Healthcare Access and Quality Index for 195 Countries and Territories and Selected Subnational Locations: A Systematic Analysis from the Global Burden of Disease Study 2016*, 391 LANCET 2236, 2238 (2018).
[25] Kurani & Cox, *supra* note 21.
[26] Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the Unites States: Origins and Prospects for Reform*, 316 JAMA 858, 860 (2016).
[27] *Id.*
[28] Eric Yang et al., *Changes in Drugs List Prices and Amounts Paid by Patients and Insurers*, JAMA NETWORK OPEN, Dec. 9, 2020, at 1, 4.
[29] Wineinger et al., *supra* note 20, at 1.
[30] Yang et al., *supra* note 28, at 2.
[31] Kesselheim et al., *supra* note 26, at 863.
[32] *Id.*
[33] *Id.*
[34] *Id.*
[35] *Id.*
[36] Lisa M. Schwartz & Steve Woloshin, *Medical Marketing in the United States, 1997-2016*, 321 JAMA 80, 81 (2019).

biologics that have existed in the market for many years. Insulin, for example, was discovered back in 1921 by a team led by Frederick Banting and Charles Best at the University of Toronto.[37] Though Banting and Best applied for a patent, they sold it to the university for $1, stating plainly their goal of ensuring the availability and accessibility of their discovery to the public.[38] Banting and Best teamed with Eli Lilly, which applied for United States patents on manufacturing improvements, and began licensing the rights to manufacture insulin to other companies.[39]

Despite patient access for almost 100 years, an article in the *New England Journal of Medicine* noted that insulin does not constitute a singular entity, but rather a family of related products.[40] Since its initial introduction, manufacturers transformed the type of insulin – from isolating animal insulin and attempting to reduce impurities, to using recombinant DNA to create human insulin, to creating analog insulin.[41] Each subsequent iteration constitutes an incremental improvement, representing greater safety, offering more flexibility in dosing, or increased convenience.[42] Manufacturers protect these iterations through the filing of additional patents, thereby continuously extending the length of patents covering a specific product.[43] Manufacturers assert these aggregate discoveries fulfill the purpose of patent law and optimize benefits to patients by maximizing innovation.

Opponents of this practice, however, refer to this process as patent evergreening; asserting that such slight modifications represent merely trivial advancements.[44] Additionally, Wineinger and colleagues note that drug pricing increases do not always correspond to time in the market.[45] That is, drugs on the market for several years also demonstrated significant price jumps, which Wineinger and colleagues assert undermines manufacturers' argument that high prices reflect manufacturer's motivation to recoup investment in initial drug development.[46] In the case of insulin, for example, the price of insulin increased 300% from 2002 to 2013, which suggests external pricing strategies are not tied to innovation and development costs.[47]

c. Higher Prices, But Higher Rebates

Manufacturers assert that higher list prices may correspond to higher rebates and discounts to patients.[48] When media reports surfaced about Mylan's EpiPen price spikes, CEO Heather Bresch highlighted Mylan's introduction of the MyEpiPen Savings Card, a patient assistance program, and the EpiPen for Schools, a program that provides free EpiPens to United States schools.[49] Manufacturers may offer rebates to Pharmacy Benefit Managers (PBMs), who negotiate in the distribution chain with insurers and pharmacies, ideally passing along a lower price or medication co-pay. Despite the rebates, some health policy scholars, such as Neeraj

[37] Jeremy A. Greene & Kevin R. Riggs, *Why Is There No Generic Insulin? Historical Origins of a Modern Problem*, 372 NEW ENG. J. MED. 1171, 1171 (2015); Thibault, *supra* note 13, at 472.
[38] *Id.*
[39] *Id.*
[40] Greene & Riggs, *supra* note 37, at 1173.
[41] *Id.* at 1172.
[42] *Id.*
[43] *Id. at 1173*.
[44] Roger Collier, *Drug Patents: The Evergreening Problem*, 185 CANADIAN MED. ASS'N J. E385, E385 (2013).
[45] Wineinger et al., *supra* note 20, at 7.
[46] *Id.*
[47] Kesselheim et al., *supra* note 26.
[48] Yang et al., *supra* note 28, at 2.
[49] Willingham, *supra* note 1.

Sood, assert rebates may not offer true benefits to patients.[50] Higher rebates function to pass revenue to PBMs, who retain a portion from each transaction rather than reflecting true cost savings.[51] Additionally, rebates generally do not apply to generic drugs, which account for 89-90% of dispensed prescription drugs.[52]

2. Reasons for Higher Net Prices to Patients

a. Opaque and Complex Payment Systems

Health policy scholars describe the pharmaceutical pricing system as opaque and complex based on confidential interactions and multiple players in the distribution chain.[53] Pharmaceutical manufacturers set one price referred to as the benchmark price, or price to consumer, and the sticker price, or the price that manufacturers offer to bulk distributors. Within this transaction, middlemen in the distribution chain such as wholesalers and distributors, PBMs health plans, and pharmacies negotiate price discounts. Ideally, the middlemen negotiate discounts and pass savings to the patient purchasing the medication. Manufacturers may negotiate with PBMs and middlemen to provide higher rebates to the PBM in exchange for favorable placement on the pharmacy formulary. However, these negotiations are confidential, the actual price is classified as a trade secret, and product specific rebates similarly constitute proprietary information.[54] From 2012 to 2016 one estimate showed that rebates to PBMs and pharmacies increased from $40B to over $100B.[55] Rather than negotiating on behalf of patients and receiving fair compensation for such service, some scholars assert PBMs are acting to maximize their own profit at the expense of patients.[56] Sood and colleagues demonstrated a correlation between rising prescription drug prices and rebates to PBMs.[57] Part of the rising prices borne by patients can be attributed to a larger share of the transaction that PBMs receive.

In October 2020, the Centers for Medicare and Medicaid published the Transparency in Coverage Final Rule to address drug pricing, health care service costs, and billing confusion.[58] The rule set forth requirements for group health plans and health insurance companies to disclose cost-sharing information upon request, which would include cost comparisons, the negotiated rate and historical net price for prescription drugs, and provide information to increase price

---

[50] NEERAJ SOOD ET AL., USC SCHAEFFER CTR. FOR HEALTH POLICY AND ECON., THE ASSOCIATION BETWEEN DRUG REBATES AND LIST PRICES 1 (2020); *see also* Tami Luhby, *Just Who Gets Those Big Drug Rebates?*, CNN (May 7, 2018, 7:58 AM), https://money.cnn.com/2018/05/07/news/economy/drug-prices-rebates/index.html.

[51] *Id.*

[52] Kesselheim et al., *supra* note 26.

[53] S. Vincent Rajkumar, *The High Cost of Insulin in the United States: An Urgent Call to Action*, 95 MAYO CLINIC PROCEEDINGS 22, 24 (2020); Jing Luo & Walid F. Gellad, *Origins of the Crisis in Insulin Affordability and Practical Advice for Clinicians on Using Human Insulin*, CURRENT DIABETES REPORTS, Jan. 2020, at 1, 2; Wineinger et al., *supra* note 20.

[54] *See* Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61, 78-84, 90-110, 122-4 (2020).

[55] Lydia Ramsey Pflanzer, *The Makers of Insulin are Being Accused of Price-Fixing in a Class Action Lawsuit*, BUSINESS INSIDER (Jan. 30, 2017, 2:58 PM), https://www.businessinsider.com/sanofi-novo-nordisk-lilly-named-in-class-action-insulin-lawsuit-2017-1.

[56] Kwanghyuk Yoo, *Pharmacy Benefit Managers and Generic Pharmaceuticals Pricing Conspiracy: Unveiling Lock-In Mechanisms, Structural Shortcomings and Antitrust Evidence*, 64 S.D. L. REV. 43, 76 (2019).

[57] SOOD ET AL., *supra* note 50, at 3.

[58] Transparency in Coverage, 85 Fed. Reg. 72,158 (Jan. 11, 2021) (to be codified at 26 C.F.R. pt. 54); Centers for Medicare and Medicaid Services, E**rror! Hyperlink reference not valid.**Transparency in Coverage Final Rule Fact Sheet (Oct. 29, 2020), https://www.cms.gov/newsroom/fact-sheets/transparency-coverage-final-rule-fact-sheet-cms-9915-f.

conscious decision-making.[59] Despite increasing pricing awareness, the rule does not require plans to disclose rebates and other discounts they negotiate with manufacturers and PBMs.[60]

b. Cost Sharing Practices and Changes to Insurance

In addition to rising costs for certain medications, both insurance premiums and out-of-pocket spending in the form of deductibles, copayments and coinsurance have increased.[61] Adjusting for inflation, from 2010 to 2016, patients paid 53% more for prescription drugs.[62] In addition to higher medication prices, consumers paid higher deductibles, higher copays, or encountered insurance coverage changes using separate prescription plans.[63] Over the last ten years, average enrollee out-of-pocket spending grew 58%, more than double the increase in wages during the same period.[64]

c. Use of Generics or Biosimilars

Ideally, one method of curbing high prescription costs would be the option for consumers to purchase generic or biosimilars.[65] In 1984, Congress passed the Hatch-Waxman Act with the dual purpose of fostering innovation while facilitating manufacturers' ability to introduce more cost efficient options with generic drugs.[66] In 1960, fewer than one in ten medications dispensed at pharmacies was a generic medication, but today pharmacies fill 80%-90% of prescriptions with a generic.[67] Using generic or biosimilar medications, in theory, can significantly reduce costs saving the healthcare system billions of dollars per year.[68]

In the case of insulin, few competitors existed in the market until recently, and Novo Nordisk, Sanofi, and Lilly controlled 99% of the global insulin market.[69] Several manufacturers introduced biosimilar formulations as an alternative to high prices. However, physicians have noted barriers to patient use, such as physician reluctance to prescribe biosimilar formulations or physicians prescribing the newer and more expensive formulations of insulin, such as prescribing analog insulin versus human insulin, which is less costly.[70] Pharmacies and PBMs may decline to add biosimilars as a preferred product on the formulary, or pharmacy substitution laws may require pharmacists to fill the prescription as the physician ordered without substituting a generic or biosimilar.[71] Thus, despite availability, the lower cost medication may not reach the consumer.

d. Lack of Competition

---

[59] *Id.*

[60] Harris Meyer, *Surprise Federal Drug Rule Directs Insurers to Reveal What They Pay for Prescription Drugs*, KAISER HEALTH NEWS (Nov. 19, 2020), https://khn.org/news/article/surprise-federal-drug-rule-directs-insurers-to-reveal-what-they-pay-for-prescription-drugs/.

[61] Yang et al., *supra* note 28, at 7; Matthew Rae et al., *Tracking the Rise in Premium Contributions and Cost-Sharing for Families with Large Employer Coverage*, PETERSON-KFF HEALTH SYSTEM TRACKER (Aug. 14, 2019), https://www.healthsystemtracker.org/brief/tracking-the-rise-in-premium-contributions-and-cost-sharing-for-families-with-large-employer-coverage/.

[62] Yang et al., *supra* note 28.

[63] Luo & Gellad, *supra* note 53, at 6.

[64] Rae et al., *supra* note 61.

[65] Rajkumar, *supra* note 53, at 23.

[66] *See* Colleen Kelly, *The Balance Between Innovation and Competition: The Hatch-Waxman Act, the 2003 Amendments, and Beyond*, 66 FOOD & DRUG L.J. 417, 420-21 (2011).

[67] Greene & Riggs, *supra* note 37, at 1174.

[68] *Id.*

[69] Fiona Conner et al., *Unaffordability of Insulin: Patients Pay the Price*, 7 LANCET 748, 748 (2019).

[70] Kasia Lipska et al., *Use and Out-of-Pocket Insulin for Type 2 Diabetes Mellitus from 2000 Through 2010*, 311 JAMA 2331, 2332 (2014).

[71] Rajkumar, *supra* note 53, at 25, at 24; Luo & Gellad, *supra* note 53, at 4.

In other instances, despite the option for generic or biosimilar medications, the cost of the generic option is similarly high. According to Kesselheim and colleagues, although the price of many generic drugs has remained stable, from 2008 to 2015, the cost of 400 generic drugs increased by more than 1000%.[72] Thus, the issue of rapidly high prices occurs in both the branded and generic/biosimilar markets. Health policy experts assert that high prices do not merely reflect pricing decisions to recoup research costs, reward novel developments, or ordinary business strategy. Rather, several scholars assert that manufacturers engaged in anticompetitive conduct and collusion artificially and substantially inflate prices in perfect lockstep.[73]

B. Impact of Drug Pricing on Patient Health

The high cost of prescription medication exerts a direct impact on patient health. If patients have difficulty paying for prescription medications, they may forgo, skip or ration medication. According to one survey obtained in 2015, about one-quarter of patients reported that they declined to fill their prescription based on the drug cost.[74] For patients that require daily maintenance medication, such as patients with Type 1 diabetes, skipping or rationing medication can lead to serious health consequences, long-term complications, and in the most severe cases, even death.[75] In 2019, *Lancet* reported that 26% of patients rationed insulin due to cost.[76] Price spikes not only affect patients financially, but can significantly impact patient health and well-being.

II. BARRIERS TO MEDICATION ACCESS: LITIGATION ALLEGING ANTI-COMPETITIVE STRATEGIES

Significant price increases occurred in two separate examples: for generic drugs where many competitors exist, and for insulin, where few competitors exist. First, this section will provide an overview of *In Re Generic Pharmaceuticals Pricing Litigation,* which alleged manufacturers engaged in anticompetitive pricing strategies to allocate market share and fix prices in violation of the Sherman Act and state consumer protection laws. Second, this section will describe *In Re Insulin Pricing Litigation*, which alleged that insulin manufacturers engaged in anticompetitive pricing strategies and misrepresented the pricing and rebate system in violation of the Racketeer Influenced Corrupt Organizations Act and state consumer protection laws. This section provides an overview of the claims, the status of the case, and an analysis for how these cases may impact the industry.

A. Allegations of Antitrust Violations and *In Re Generic Pharmaceutical Pricing Litigation*

In Re Generic Pharmaceutical Pricing Litigation provides one example alleging that actions of multiple pharmaceutical manufacturers relating to price spikes for generic prescription drugs not only adversely affected consumer ability to pay and access medication, but rose to legal violations of both the Sherman Act and state antitrust laws.

---

[72] Kesselheim et al., *supra* note 26.
[73] *See* Luo & Gellad, *supra* note 53; Rajkumar, *supra* note 53; Thibault, *supra* note 13, at 478.
[74] Kesselheim et al., *supra* note 26, at 864.
[75] Rajkumar, *supra* note 53, at 26; *Diabetes*, MAYO CLINIC, https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 (last visited Feb. 28, 2022) (describing complications of diabetes).
[76] Conner et al., *supra* note 69.

1. Background on the Sherman Act and Antitrust Law

In 1890, Congress passed the Sherman Act, designed to promote free and unfettered competition.[77] The Sherman Act prohibits any contract or conspiracy in restraint of trade, and any "monopolization, attempted monopolization, or conspiracy" that amounts to an "unreasonable" restraint of trade.[78] Unlawful actions under the Sherman Act include "plain arrangements" to "fix prices, divide markets, or rig bids."[79] These three actions constitute *per se* legal violations.[80] The Federal Trade Commission (FTC) describes price fixing as an agreement among competitors to raise, lower, or stabilize prices without legitimate justification.[81] Bid rigging refers to advance agreements to determine business contracts rather than competing for contracts in the market.[82] Finally, FTC defines customer allocation as plain agreements not to compete among businesses or specific agreements about market shares.[83] Enforcement includes civil liability or criminal penalties.[84] Antitrust laws are designed to promote vigorous competition while providing consumers the benefits of lower prices, higher quality products, and consumer choice among products.[85] State laws also contain similar provisions that prohibit restraint of trade and unfair competition.[86]

2. *In Re Generic Pharmaceutical Pricing Litigation*

a. Background of the Case

In December of 2016, forty-seven states (now fifty states and one United States territory) filed a lawsuit against twenty pharmaceutical manufacturer Defendants, alleging a conspiracy to artificially inflate and manipulate prices, reduce competition, and unreasonably restrain trade for generic drugs sold across the United States.[87] While the original complaint focused on only a few products and a handful of Defendants, over the past several years, the Attorney General of Connecticut amended the complaint, which represents Multidistrict Litigation across states, to include more than 200 generic products, dozens of manufacturers, and individually named Defendants who served in pivotal executive sales and marketing roles.[88]

The complaint alleges that Defendants engaged in two interrelated practices. First, it asserts that Defendants established and maintained artificial allocation of product market share. Second, it alleges that Defendants communicated and adhered to specific pricing strategies amounting to

---

[77] Sherman Antitrust Act of 1890, 15 U.S.C § 1; *The Antitrust Laws*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws (last visited Feb. 28, 2022).
[78] Sherman Antitrust Act of 1890, 15 U.S.C § 1; *The Antitrust Laws*, *supra* note 77.
[79] *The Antitrust Laws*, *supra* note 77.
[80] *Id.*
[81] *Price Fixing*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/price-fixing (last visited Feb. 28, 2022).
[82] *Bid Rigging*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/bid-rigging (last visited Feb. 28, 2022).
[83] *Market Division or Customer Allocation*, FED. TRADE COMM'N, https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/dealings-competitors/market-division-or (last visited Feb. 28, 2022).
[84] *Id.*
[85] *The Antitrust Laws*, *supra* note 77.
[86] *Id.*; *see also* Complaint at 480-541, Connecticut v. Sandoz, Inc., No. 3:20-cv-00802 (D. Conn. June 10, 2020) [hereinafter Complaint].
[87] Press Release, Conn. Attorney Gen. Office, Court Unseals States' Latest Generic Drug Complaint, Including Excerpts from "Diary of Collusion" Meticulously Documenting Widespread Price-Fixing (Jan. 28. 2021), https://portal.ct.gov/AG/Press-Releases/2021-Press-Releases/Court-Unseals-Latest-Generic-Drug-Complaint; Yoo, *supra* note 56, at 45-46 (describing allegations set forth in Plaintiffs' Complaint in *In Re Generic Drug Litigation)*.
[88] Complaint, *supra* note 86.

price fixing.[89] Allegations set forth in the complaint build upon information obtained from confidential witnesses involved in the alleged conduct and discovery of thousands of documents, such as internal emails, memoranda, text messages, and 11 million telephone call records.[90]

b. Case Overview

The Connecticut Attorney General asserts that Defendants communicated to establish rules of engagement for participating in the market, which included a formula to determine a set allocation of market share.[91] In competitive markets, market share would ordinarily be determined by winning or maintaining customers' business. Market share may vary widely, undergo modifications when new entrants appear in the market, and may differ based on manufacturer price. Defendant Taro, a leading manufacturer of topic dermatological products, created a graphic representation and chart, which provides specific market share percent based on a number of competitors and time in the market, awarding greater market share to the earlier market entrants.[92] Plaintiffs allege Taro and other Defendants relied on this chart for determining percent of market share when entering a new market, such as when Taro became the third entrant into the Lidocaine market.[93] Both internal communications and communications between manufacturers refer to this practice as "playing nice in the sandbox," which refers to agreeing to a set market share and then acting to avoid increasing market share above the arrangement.[94]

Additionally, Plaintiffs allege that ceding market share and holding consistent allocations permits manufacturers to charge supra-competitive prices.[95] In internal emails between employees at Defendant Fougera, one executive explained the process of voluntarily yielding the market to hold prices high.[96] In 2010, Fourgera operated exclusively, providing Imiquimod, a topical anti-tumor medication. When an additional manufacturer Perrigo entered the market, one executive at Fourgera explained the process in an internal company email, stating: "Perrigo is satisfied with the 35-40% market share" because if "the market settles out at the current prices, we are in a much better position than a higher share at a lower price."[97] Internal emails further explained that Perrigo should be satisfied with this share because "any further attempts to gain share would result in driving prices down."[98]

Once each manufacturer agreed to a specific market share, the complaint alleged that Defendants communicated price planned price increases to artificially inflate prices offered by each Defendant under common agreement. In one example, Perrigo, Fougera and Teva each manufactured Betamethasone Dipropionate, a topic steroid cream for skin conditions such as

---

[89] *Id.* at 36-38 (discussing market share and ceding market share for new entrant); *Id.* at 48 (discussing the two-part strategy of allocating a fair share then increasing prices; at 48-50 discussing strategy to hold back when a competitor increases price); *Id.* at 80-82 (discussing phone conversations between Defendants Perrigo and Fougera about price and subsequent price increases of Betamethasone Dipropionate).
[90] *Id.* at 7.
[91] *Id.* at 36.
[92] *Id.*
[93] *Id.* at 37 (In an internal launch summary for Lidocaine, Taro was the third entrant, and was "preceded by Sandoz (~55% share) and Hi-Tech (~45% share)." The internal launch communication stated "Taro had targeted 20-25% share and had achieved 26.3% share…which it stated was "consistent with a traditional 3 player market"").
[94] *Id.* at 33, 39-40, 86, 91-92.
[95] *Id.* at 38, 91-92.
[96] *Id.* at 63.
[97] *Id.*
[98] *Id.*

eczema.[99] When Teva exited the market, a senior executive at Fougera emailed an employee at Perrigo, communicating: "Current WAC [wholesale acquisition cost] is $6.50, that will need to go up significantly. Thinking $40 or so."[100] Phone records prosecutors pulled during discovery demonstrate a series of multiple phone calls following the email between key executives at Perrigo and Fougera the same day as the email.[101] About two weeks later, Perrigo increased the wholesale acquisition cost of Betamethasone Dipropionate by 504%, raising the price to $37.50.[102] Three days after Perrigo's price increase, Fougera held an internal meeting to discuss price increases.[103] That same day, discovery phone call logs show multiple calls between key executives at Fougera and Perrigo.[104] Five days after Fougera's pricing meeting, it similarly raised the price of Betamethasone Dipropionate to $39.99.[105]

The complaint describes multiple examples alleging Defendants colluded to agree upon market share, acted to avoid increasing market share above specified percent values, and conspired to raise prices in lockstep with other manufacturers in the market. Plaintiffs assert joint and several liability against Defendants in violation of the Sherman Antitrust Act, alleging a horizontal conspiracy to allocate markets and fix prices.[106] Additionally, Plaintiffs allege respective state law violations corresponding to state specific protections governing trade practices and prohibiting anticompetitive conduct amounting to antitrust violations.[107]

Plaintiffs request an injunction against further actions constituting anticompetitive conduct or unfair and deceptive acts, disgorgement of ill-gotten gains, damages, and civil penalties.[108]

Defendants adopted multiple strategies through the course of litigation, first filing a motion to dismiss based on lack of evidence of actual agreement and asserting lack of direct facts to unlawful agreement of parallel conduct.[109]

The court granted a partial motion to dismiss against specific Defendants but denied motions to dismiss against most Defendants, permitting the action to proceed.[110] At the time of this writing, the litigation is still pending.

c. Analysis

Consolidating and coordinating similar factual and legal allegations through the process of Multidistrict Litigation (MDL) facilitates consistency and efficiency. MDL reduces the potential for duplication during discovery, inconsistency in pretrial rulings (such as the scope of discovery or permitting certain witnesses), and uniformity in outcomes. Hundreds of pages of Plaintiffs' complaint describe common actions, phrasing, and conduct from multiple different manufacturers relating to different products allegedly aimed at achieving two main goals: to establish and preserve agreed-upon market share and to artificially set higher prices. The

[99] *Id.* at 80
[100] *Id.*
[101] *Id.* at 80-81.
[102] *Id.*
[103] *Id.* at 81.
[104] *Id.*
[105] *Id.* at 82.
[106] *Id.* at 430-78.
[107] *See id.* at 480-541.
[108] *Id.* at 542.
[109] *See In Re: Generic Pharmaceuticals Pricing Antitrust Litigation*, 338 F.Supp.3d 404, 441-46 (E.D. Pa. 2018) (discussing timing of conduct as sequential business decisions rather than parallel conduct).
[110] *Id.* at 454.

factfinder will determine whether the pattern of repeated actions constitutes credible and sufficient evidence to support the alleged civil violations.

Litigation involving allegations of anticompetitive actions by manufacturers confers benefits to patients, the healthcare system, and the market. First, it provides transparency and insight as to how manufacturers interact together by investigating allegations of collusive and anticompetitive conduct.[111] This may reveal secret pricing information, agreements to divide markets, and information on the role of multiple market players such as manufacturers, PBMs, pharmacies, and consumers.[112] Second, uncovering this information provides the critical function of accountability for allocating responsibility, reducing blame-shifting, and identifying the source of skyrocketing prices.[113] Finally, enforcing legal compliance or determining penalties can restore competitive conduct and correct market failures, producing lower prices and greater availability of prescription drug choices.[114] Addressing allegations of deception or improper anticompetitive conduct will permit free and open competition, which will positively impact future accessibility and cost of medications.[115]

3. Related Criminal Antitrust Violations Against Generic Pharmaceutical Manufacturers

The civil enforcement litigation led by Connecticut parallels a criminal investigation by the Department of Justice (DOJ) into antitrust violations. According to the DOJ, it uncovered price-fixing, bid-rigging, and customer-allocation schemes by multiple generic pharmaceutical manufacturers.[116] Based on evidence uncovered during this investigation, the DOJ criminally charged seven manufacturers.[117] At the time of this writing, five manufacturers entered into deferred prosecution agreements, in which Defendants collectively agreed to pay over $426 million in criminal penalties for collusion that affected over $1 billion of generic drug sales.[118]

Deferred prosecution agreements entail an agreement between the prosecutor and manufacturer that provides a mechanism to resolve the criminal charges.[119] The prosecutor files

---

[111] Michael Sinha et al., *Antitrust, Market Exclusivity, and Transparency in the Pharmaceutical Industry*, 319 JAMA 2271, 2272 (2018).

[112] *See generally* Yoo, *supra* note 56, at 47 (discussing the role of PBMs as intermediaries in the pharmaceutical supply chain); Yoo, *supra* note 56, at 49-50 (asserting horizontal collusion between manufacturers, PBMs and insurance companies).

[113] Sinha, *supra* note 111 (discussing the problem of blame shifting among market players).

[114] *Id.*; *see also* Yoo, *supra* note 56, at 58-60 (discussing how collusion and conspiracy between PMBs, manufacturers, and pharmacies result in market failures and high prices to the consumer).

[115] Reinhardt, *supra* note 11 (describing the markets of capitalism can maximize profits with free and open competition presuming the absence of fraud and deception).

[116] U.S. DEP'T OF JUSTICE, ANTITRUST DIV., ANTITRUST DIVISION SPRING UPDATE 2021 (2021), https://www.justice.gov/atr/division-operations/division-update-spring-2021/generic-drugs-investigation-targets-anticompetitive-schemes [hereinafter SPRING UPDATE].

[117] *Id.*

[118] *Id.*

[119] *See* Eugene McCarthy, *A Call to Prosecute Drug Company Fraud as Organized Crime*, 69 SYRACUSE L. REV. 439, 458-59 (2019) (asserting non prosecution agreements and deferred prosecution agreements constitute an insufficient corporate deterrent to criminal acts); *see generally* Cindy R. Alexander & Mark A. Cohen, *The Evolution of Corporate Criminal Settlements: An Empirical Perspective on Non-Prosecution, Deferred Prosecution and Plea Agreements*, 52 AM. CRIM. L. REV. 537 (2015) (describing non prosecution agreements and deferred prosecution agreements as a means to address corporate crime); Sara Sun Beale, *The Development and Evolution of the U.S. Law of Corporate Criminal Liability and the Yates Memo*, 46 STETSON L. REV. 41 (2016) (describing the purpose of non-prosecution agreements and deferred prosecution agreements as a mechanism to monitor, incentivize changes to corporate conduct, and enforce legal compliance).

criminal charges and requires the manufacturer to enter into an agreement that may entail paying a corporate fine and instituting internal reform.[120] If the manufacturer complies with the agreement, at the end of a specified time period, the prosecutor will dismiss the charges.[121] The nature of the agreement and amount of the fine varies based on manufacturer and details of conduct.[122]

In addition to charges against manufacturers, the DOJ criminally charged four executives relating to violations of antitrust law.[123] Three of the four executives pled guilty, and the remaining Defendants await trial.[124] The DOJ stated: "American consumers have the right to generic drugs sold at prices set by competition, not collusion," and it intends to hold both manufacturers and individuals accountable for conduct that violates federal antitrust law.[125]

B. Racketeer Influenced and Corrupt Organizations Act and *In Re Insulin Pricing Litigation*

In Re Insulin Pricing Litigation provides another example alleging that the actions of three pharmaceutical manufacturers not only adversely affected consumer ability to pay and access medication, but also rose to legal violations of both RICO and state consumer protection laws.

1. Background on Racketeer Influenced and Corrupt Organizations Act and state consumer protection laws

In 1970, Congress passed the Racketeer Influenced and Corrupt Organizations Act (RICO) which aimed to eliminate the infiltration of organized crime and racketeering into legitimate businesses operating in interstate commerce.[126] Congress initially enacted RICO as a measure to address evasion of criminal responsibility arising from both organized crime syndicates (such as the Mafia) as well as white-collar crime.[127] In 1967, the President's Task Force on Organized Crime compared the Mafia to a business corporation: a closely controlled hierarchy where the purpose of the organization focuses on a long-term business strategy to maintain order, abide by specific corporate rules, and maximize profits.[128]

RICO contains several components: it aims to (1) prohibit a person or corporation (2) from participating in an enterprise (3) by committing two or more related predicate offenses (4) that constitute a pattern of racketeering activity (5) affecting interstate commerce.[129] An enterprise includes " any individual, partnership, corporation, or association or other legal entity" working toward a common goal.[130] This could include multiple levels of employees

---

[120] McCarthy, *supra* note 119, at 450.
[121] *Id.*
[122] *See* Press Release, U.S. Dep't of Justice, Pharmaceutical Company Admits to Price Fixing in Violation of Antitrust Law, Resolves Related False Claims Act Violations (May 31, 2019), https://www.uspsoig.gov/sites/default/files/document-library-files/2019/DOJ%20News%205-31-19.pdf [hereinafter Heritage Pharmaceuticals Settlement]; *see also* Press Release, U.S. Dep't of Justice, Generic Pharmaceutical Company Admits to Fixing Price of Widely Used Cholesterol Medication (May 7, 2020), https://www.justice.gov/opa/pr/generic-pharmaceutical-company-admits-fixing-price-widely-used-cholesterol-medication [hereinafter Apotex Corp. Settlement].
[123] SPRING UPDATE, *supra* note 116.
[124] *Id.*
[125] *See* Heritage Pharmaceuticals Settlement, *supra* note 122; *see also* Apotex Corp. Settlement, *supra* note 122.
[126] Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C. §§ 1961-1968; *see also* U.S. DEP'T JUSTICE, JUSTICE MANUAL § 9-110.100 (2018), https://www.justice.gov/jm/jm-9-110000-organized-crime-and-racketeering.
[127] McCarthy, *supra* note 119, at 471.
[128] *Id.* at 472.
[129] Racketeer Influence and Corrupt Organizations Act, 18 U.S.C.§ 1962(c); *see also* McCarthy, *supra* note 119, at 462.
[130] 18 U.S.C. § 1961(4); McCarthy, *supra* note 119, at 464; Thibault, *supra* note 13, at 484.

within one organization but also include individuals outside the organization that work to further the organization's purpose. Applying this to the health field, legal scholars describe how this may include members of the board of directors, top executives, and pharmaceutical representatives in addition to related players, such as PBMs, pharmacies, or complicit physicians.[131] Predicate offenses include crimes such as mail fraud, wire fraud, or false claims.[132] This could include mailing or electronically communicating misleading material such as pricing information or brochures on product rebates; press releases describing drug benefits that excludes critical data; or publishing ghostwritten journal articles that omit important information about product risks or alternatives.[133] The law defines a pattern of racketeering activity as at least two acts of racketeering activity within ten years after the commission of the prior act.[134] Common aims refer to activities that demonstrate a way of conducting business or a specific pattern in how the enterprise operates.[135] This may include patterns of actions designed to increase prescribing a particular medication, expand the market by influencing physicians and public perception of safety and efficacy, raise the price of a product, or increase profit accomplished through predicate offenses. RICO provides for both criminal penalties and civil enforcement.[136]

States also contain consumer protection laws designed to prohibit deceptive or fraudulent conduct, such as concealing material information or suppressing material facts from consumers, or inducing consumers to purchase products based on such false misrepresentations.[137] These laws are designed to guard against unscrupulous business practices that cause confusion, misunderstanding, injury, or financial harm.[138] Each state's law varies; for example, some states require specific intent.[139] Notably, some states directly address price confusion or price

---

[131] *See* McCarthy, *supra* note 119, at 474-76 (discussing the application of RICO to corporate board of directors, executives, sales representatives, and physicians who knowingly engage in promoting pharmaceutical products based on fraudulent data); *see also* Thibault, *supra* note 13, at 484-86 (discussing the application of RICO to pharmaceutical manufacturers and limitations in the law); Deanna Minasi, *Confronting the Ghost: Legal Strategies to Oust Medical Ghostwriters*, 86 FORDHAM L. REV. 299, 317-22 (2017) (discussing the application of RICO to healthcare fraud and enforcing the statute against pharmaceutical manufacturers and physicians who engage in ghostwriting to promote fraudulent, incomplete, or misleading data on pharmaceutical drugs and biologics).

[132] 18 U.S.C. § 1341.

[133] Minasi, *supra* note 131, at 322 (describing an example of mail fraud as publishing ghostwritten articles in medical journals that are disseminated by mail); McCarthy, *supra* note 119, at 439-40, 452-54 (describing an online pharmaceutical press release to promote product benefits that contains false and misleading statements that may lead to inappropriate prescribing); *see also* Class Action Complaint at 63-64, 73-86, 87-100, Chaires et al v. Sanofi, U.S. et al, No. 1:17-cv-10158 (D. Mass. Jan. 30, 2017) (alleging Sanofi, Novo Nordisk and Lilly engaged in making false claims and fraud by raising prices of insulin and worked in conjunction with PBMs to provide to convince payors and plan sponsors to place their product as favorable on the formulary by convincing payers and sponsors that they were receiving a discount).

[134] 18 U.S.C. § 1961(5).

[135] *See* McCarthy, *supra* note 119, at 463.

[136] 18 U.S.C. §§ 1963-1964.

[137] *See* CAROLYN CARTER, NAT'L CONSUMER LAW CTR., CONSUMER PROTECTION IN THE STATES: A 50-STATE EVALUATION OF UNFAIR AND DECEPTIVE PRACTICES LAWS (2018), https://www.nclc.org/images/pdf/udap/udap-report.pdf; *see also* Class Action Complaint, *supra* note 133.

[138] *See* CARTER, *supra* note 137, at 1.

[139] *See* Carolyn Carter, *Consumer Protection in the States, a 50-State Evaluation of Unfair and Deceptive Practices Laws*, NATIONAL CONSUMER LAW CENTER, March 2018, at 28, https://www.nclc.org/images/pdf/udap/udap-report.pdf.

gouging.[140] Michigan, for example, prohibits charging consumers a price that is "grossly in excess" of the price at which similar products are sold.[141] Several states also prohibit falsely representing that purchasing a product confers a specific price advantage or a price reduction exists when it does not.[142] State consumer protection laws provide civil enforcement through fines and penalties, while some states provide a mechanism to seek punitive damages for violations that demonstrate wantonness,[143] malice,[144] or "despicable conduct with willful and disregard" for consumer harm.[145]

2. In Re Insulin Pricing Litigation

a. Background of the Case

In 2017, patients with diabetes who rely on insulin filed a class action complaint, *Chaires v. Sanofi*, subsequently consolidated with other similar suits under the class action lawsuit *In Re Insulin Pricing Litigation*, against Sanofi, Novo Nordisk, and Eli Lilly.[146] First, the complaint alleges that Defendants manipulated the spread of insulin prices. Despite the real price of insulin holding constant, Defendants raised the benchmark price that consumers pay in order to provide a larger cut to PBMs in exchange for favorable placement on pharmacy formulary.[147] Second, Plaintiffs alleged that the three Defendants conspired to commit pricing fraud by communicating pricing increases among manufacturers and raising prices in perfect lockstep.[148] Plaintiffs cited an opinion piece from the *New York Times* by physician Dr. Kasia Lipska that referred to the three Defendants as "the insulin racket."[149] Lipska's research demonstrated the following price increases for insulin from 2010 to 2015: Sanofi's price rose 168%, Novo Nordisk's price rose 169%, and Eli Lilly's price rose 325%.[150]

As a result of price increases, Plaintiffs assert they experienced difficulty paying for insulin, causing them financial harm, adverse health effects, and emotional worry.[151] Prohibitive pricing, according to Plaintiffs, led them to underdose their medication, skip refills, inject expired insulin, and avoid physician visits.[152] Despite variation among out-of-pocket prices based on insurance plan and coverage, one Plaintiff stated he paid $900 for a monthly supply.[153] *In Re Insulin Pricing Litigation* reveals the impact to patients from steep price increases of essential medication, alleging Defendant's conduct between manufacturers and interacting with PBMs arose to pricing fraud.[154]

---

[140] *See* MICH. COMP. LAWS § 445.903; IND. CODE § 24-5-0.5-3; MINN. STAT. § 325D.44; OHIO REV. CODE ANN. § 1341.01; UTAH CODE ANN. § 13-11-1.
[141] MICH. COMP. LAWS § 445.903.
[142] *See* MICH. COMP. LAWS § 445.903; IND. CODE § 24-5-0.5-3; MINN. STAT. § 325D.44; OHIO REV. CODE ANN. § 1341.01; UTAH CODE ANN. § 13-11-1.
[143] CONN. GEN. STAT. § 42-110g.
[144] DEL. CODE ANN. tit. 6 § 2513.
[145] MICH. COMP. LAWS § 445.903
[146] Class Action Complaint, *supra* note 133, at 1; *see also* Thibault, *supra* note 13, at 483-486.
[147] Class Action Complaint, *supra* note 133, at 27-29, 42, 48-49.
[148] *Id.* at 5-6, 39-41 (discussing raising prices in lockstep); *Id.* at 58 (alleging fraud).
[149] *Id.* at 2.
[150] *Id.*
[151] *Id.* at 51.
[152] *Id.*
[153] *Id.* at 1.
[154] *Id.* at 58.

b. Case Overview

Plaintiffs describe the complex pricing and distribution system that involves pharmaceutical companies, wholesalers, insurers, and PBMs.[155] PBMs create formularies of preferred drugs, and manufacturers may offer price discounts in exchange for an exclusive formulary position.[156] PBMs work with both pharmacies and insurers: pharmacies can fill the prescription with the preferred drug, and insurance companies may only reimburse the consumer for the drug with the preferred formulary position.[157] Plaintiffs assert that manufacturers leveraged this power with PBMs to "game the system."[158] Instead of PBMs negotiating better prices for consumers by choosing the lower-priced drug for a preferred position on the formulary, Plaintiffs assert manufacturers raised the benchmark price, the price to consumers, while holding the real drug price constant.[159] By increasing the spread between the real price and the benchmark price, Plaintiffs allege that Defendants offered greater rebates to PBMs to pocket in exchange for placing their drug on the preferred formulary.[160] Thus, Plaintiffs maintain that PBMs' claims to consumers advertising large rebates misrepresents the pricing scheme.[161]

The complaint asserts that each manufacturer not only raised prices but also did so in a coordinated and consistent manner.[162] Plaintiffs allege the prices are "so untethered from reality as to be fraudulent," and the increase in rebates to PBMs comes at the steep cost of consumer access.[163] Tables in the complaint illustrate both: an increase in price spread for each drug over time and an increase in benchmark price from each manufacturer following a similar model.[164] Plaintiffs assert not only did the spread increase over time for each drug but also that manufacturers each increased their price at around the same time.[165]

Plaintiffs allege each Defendant engaged in similar actions that violate RICO.[166] First, Plaintiffs allege that manufacturers created and maintained a pricing enterprise.[167] Inflating cost to consumers, the manufacturer granted PBMs substantial discounts in exchange for exclusive or favorable formulary placement.[168] PBMs participated and assisted the enterprise by convincing payers and insurance plan sponsors to select their product by misrepresenting that this selection provided a true discount.[169] Second, Plaintiffs allege predicate offenses, including mail fraud and wire fraud wherein PBMs distributed promotional materials containing false statements relating to insulin price and the existence, amount, and purpose of rebates.[170] Finally, Plaintiffs

[155] *Id.* at 19.
[156] *Id.*
[157] *Id.*
[158] *Id.* at 27.
[159] *Id.*
[160] *Id.* at 27-30.
[161] *Id.* at 29-30.
[162] *Id.* at 39-41.
[163] *Id.* at 44-48 (tables illustrating the spread in real versus benchmark price); *Id.* at 49 (alleging fraudulent pricing).
[164] *Id.*
[165] *Id.* at 44-48 (tables illustrating the spread in real versus benchmark price); *Id.* at 39-41 (increase in benchmark price across three Defendants).
[166] *Id.* at 59-71 (describing RICO as applied to Sanofi); *Id.* at 73-86 (describing RICO as applied to Novo Nordisk); *Id.* at 87-100 (describing RICO as applied to Eli Lilly).
[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] *Id.*

assert these actions constitute a coordinated plan and cohesive actions using a similar method of commission, which amounts to a pattern of racketeering activity affecting interstate commerce that caused financial and health harm to plaintiffs.[171]

In addition to RICO violations, Plaintiffs allege these actions violate various state consumer law protections.[172] Plaintiffs assert that inflating the benchmark price, concealing or omitting information about the price spread, and misrepresenting rebate information constitutes a misleading or deceptive practice.[173] The actual drug price constitutes material information for consumers during purchasing decisions.[174] Plaintiffs maintain that consumers relied on this misleading and confusing pricing information, suffering financial and other harm in connection to the sale.[175] The complaint incorporated specific provisions described *supra* that prohibit price gouging, excessive pricing, false representations that a product contains a pricing advantage when it does not, and claiming the appropriateness of punitive damages in applicable states.[176] Plaintiffs requested damages that reflect three times the overcharges, the amount to be determined at trial.[177]

In response, Defendants filed a motion to dismiss both the RICO and state law claims.[178] Defendants maintained that no pricing enterprise existed and asserted that Plaintiffs did not adequately plead mail and wire fraud.[179] Higher prices or price differences connected to different insurance plans and payment systems do not amount to fraud, according to Defendants.[180] Defendants also undermined causation arguments, asserting that even if Plaintiffs knew of pricing differences, this would not change the price of the medication and the amount Plaintiffs pay.[181] Finally, Defendants asserted that Plaintiffs lacked standing to bring a RICO claim because they are classified as indirect purchasers of insulin because multiple entities exist in the distribution chain standing between manufacturer and consumer.[182] Defendants also moved to dismiss the state law consumer protection claims under various theories, including that Plaintiffs failed to demonstrate unconscionable, unfair, or fraudulent conduct and that Plaintiffs did not demonstrate standing to bring suit in all states.[183]

The court partially granted the Defendants' motion by dismissing the RICO claims, finding that the Plaintiffs could not recover as indirect purchasers.[184] The court found that plaintiffs adequately pled elements of RICO demonstrating an enterprise, predicate offenses relating to misleading price information, a pattern of racketeering activity affecting interstate

---

[171] *Id.*
[172] *Id.* at 101-60.
[173] *Id.*
[174] *Id.*
[175] *Id.*
[176] *Id. at* 139-145 (state law provisions).
[177] *Id.* at 160.
[178] Stipulation and Order, *In Re* Insulin Pricing Litigation, No. 3:17-CV-0699-BRM-LHG (D.N.J. Sept. 6, 2018), ECF No. 201; Defendants' Notice of Motion to Dismiss the First Amended Class Action Complaint, *In Re* Insulin Pricing Litigation, No. 3:17-CV-0699-BRM-LHG (D.N.J. May 14, 2018), ECF No. 158 [hereinafter Motion to Dismiss].
[179] Motion to Dismiss, *supra* note 178, at 24-25.
[180] *Id.*
[181] *Id.* at 25.
[182] *Id.* at 24, 26-27.
[183] *See In Re* Insulin Pricing Litig., No. 3:17-cv-0699-BRM-LHG, 2019 WL 643709, at *16 (D.N.J. Feb. 15, 2019).
[184] *Id.* at *13; *see also* Thibault, *supra* note 13, at 485-486.

commerce, and financial harm.[185] However, based on the distribution, manufacturers sold to wholesalers or PBMs rather than directly to the consumer, receiving a pass-through of inflated prices.[186] The court applied controlling precedent from Third Circuit antitrust cases to RICO, holding that indirect purchasers do not have standing.[187] The court also dismissed several state law claims but permitted other state law claims to proceed.[188] At the time of this writing, multiple state law claims are still pending.

c. Analysis

Consolidating similar factual and legal claims through class action litigation permits plaintiffs a means to access justice, maintains judicial economy, and incentivizes reform of corporate behavior.[189] Individually, injuries may appear insignificant or minor, but in the aggregate, they demonstrate the substantial impact of the alleged harm to a specific population group.[190] Traditionally, class action claims permit litigants who would otherwise be unable to bring claims access to the judicial system.[191] Through discovery, plaintiffs may uncover similar methods of maximizing corporate interests using actions that circumvent or ignore laws governing corporate conduct. *In Re Insulin Pricing Litigation* brings transparency to practices involved in setting insulin prices and the causes of spiking out-of-pocket costs for consumers. Litigation will force manufacturers to account for price increases and whether these practices reflect legitimate economic strategy or whether the actions rise to the level of "price gouging" and misleading rebate information. The factfinder will determine whether this conduct falls under permissible corporate practices designed to raise prices or violates state consumer protection laws.

Despite the court's ruling that Plaintiffs did not have the standing to bring the RICO claims, several legal scholars suggest theories to overcome this barrier and use RICO as an enforcement mechanism in cases alleging corporate fraud.[192] Several exceptions exist to the indirect purchaser rule, and courts in a different jurisdiction permitted claims to proceed when the antitrust violator and the direct purchaser are co-conspirators or if there is "no realistic possibility" that direct purchasers would litigate.[193] Legal scholar Kwanghuk Yoo asserts that

---

[185] *Id.* at *6-7.
[186] *Id.* at *9.
[187] *Id.* at *9-12.
[188] The court dismissed several of Plaintiffs' state law claims based on lack of standing. *See id.* at *16-22; *see also In Re* Insulin Pricing Litig., No. 3:17-cv-0699-BRM-LHG, 2020 WL 831552 (D.N.J. Feb. 20, 2020) (opinion addressing state law claims).
[189] Janet Walker, *Who's Afraid of U.S. Style Class Actions?*, 18 SW. J. INT'L L. 509 510 (2012); *see also* Joshua D. Blank & Eric A. Zacks, *Dismissing the Class: A Practical Approach to the Class Action Restriction on the Legal Services Corporation*, 110 PENN. ST. L. REV., Summer 2005, at 9-10.
[190] *See generally* Katherine Drabiak, Roundup Litigation: *Using Discovery to Dissolve Doubt*, 31 GEO. ENVTL L. REV. 697, 723-24 (2019) (describing how discovery documents promote transparency to corporate practices and can reform corporate behavior to improve public health).
[191] Blank & Zacks, *supra* note 189, at 10-11.
[192] *See* Thibault, *supra* note 13, at 488-89; *see* McCarthy, *supra* note 119, at 475-477 (advocating the use of RICO for criminally prosecuting pharmaceutical fraud); *see generally* Yoo, *supra* note 56 (discussing the central role of PBMs in alleged price conspiracies; Sarah Kelley, *Chain, Chain, Chain-Chain Of (Pharma) Fools: Why Third Party Payors Maintain the Proximate Causal Chain Under RICO § 1964(C)*, 62 B.C. L. REV. E. SUPP. II.-44 (2021) (discussing the role of third party payors such as health insurance companies, health funds, or government programs in bringing claims for fraud against pharmaceutical medications that cause patients harm, such as increasing cancer risk); Minasi, *supra* note 131, at 312-22 (describing how the practice of scientific ghostwriting medical journal articles constitutes a RICO violation).
[193] *See* Illinois Brick Co. v. Illinois, 431 U.S. 720, 745 (1977); Thibault, *supra* note 13, at 488.

purchasers such as PBMs constitute not only key intermediaries in the supply chain but also additional co-conspirators.[194] If the direct purchasers such as PBMs and wholesalers would not litigate based on their financial stake in the operation, then in certain jurisdictions, plaintiffs may make an argument for an exception to the indirect purchaser rule.

III. TARGETED PRESCRIBING

In addition to high healthcare and spending costs from medication price increases, inefficient spending may arise from overprescribing and overutilization of medication. First, this section will address the problem of focusing on pharmacological interventions for treating chronic and preventable diseases. Second, this section will describe corporate strategies designed to increase prescribing to more patients through five specific patterns and practices.

A. Prescribing Trends and Reliance on Pharmacological Solutions

1. Treating Chronic Preventable Disease

Inefficient spending arises when the healthcare system focuses on pharmacological interventions for disease management without assessing whether the condition is acute, requires chronic reliance on medication, or if the condition is reversible or preventable.[195] To be sure, modern medical care excels when providing acute treatment, such as in the case of using an epinephrine autoinjector for anaphylaxis.[196] Effective acute care has also successfully decreased mortality and preventable death arising from complications during routine care, such as postpartum hemorrhage in childbirth.[197] Some chronic diseases require ongoing disease management and medications, like Type 1 diabetes and the use of insulin.[198]

However, these examples of acute care and necessary medication for disease management are eclipsed by the significant burdens and expenditures arising from preventable chronic disease.[199] Relying on the pharmacological imperative, prioritizing medications as the most important treatment method, and using available medications, may not only leave patients ill and unwell[200] but also incurs significant cost. Three examples of common chronic disease conditions, cardiovascular disease/stroke, diabetes, and cancer, account for significant mortality,

---

[194] Yoo, *supra* note 56, at 55.

[195] Farshad Fani Marvasti & Randall S. Stafford, *From Sick Care to Health Care - Reengineering Prevention into the U.S. System*, 367 NEW ENG. J. MED. 889, 889-91 (2012).

[196] *See Epinephrine Auto-injector, The first-line treatment for anaphylaxis is epinephrine (adrenaline)*, AM. COLL. OF ALLERGY, ASTHMA, & IMMUNOLOGY, https://acaai.org/allergies/management-treatment/epinephrine-auto-injector/ (last updated Feb. 1, 2018).

[197] This condition I experienced personally after the birth of my third child. Postpartum hemorrhage is a terrifying, but largely preventable and treatable condition with appropriate medical attention. *See* AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, ACOG COMMITTEE OPINION NO. 794: QUANTITATIVE BLOOD LOSS IN OBSTETRIC HEMORRHAGE, e154 (2019) [hereinafter ACOG COMMITTEE OPINION NO. 794].

[198] *What Is Type 1 Diabetes?*, CDC, https://www.cdc.gov/diabetes/basics/what-is-type-1-diabetes.html (last updated Mar. 11, 2022).

[199] *Health and Economic Costs of Chronic Disease*, CDC, https://www.cdc.gov/chronicdisease/about/costs/index.htm (last updated Mar. 29, 2022); Sandro Galea & Nason Maani, *The Cost of Preventable Disease in the USA*, 5 LANCET PUB. HEALTH e513, e513-e514 (2020); *see also* Susan Levine et al., *Health Care Industry Insights: Why the Use of Preventive Services Is Still Low*, 16 PREVENTING CHRONIC DISEASE (2019).

[200] ANDREW WEIL, MIND OVER MEDS: KNOW WHEN DRUGS ARE NECESSARY, WHEN ALTERNATIVES ARE BETTER, AND WHEN TO LET YOUR BODY HEAL ON ITS OWN 3-19 (2017).

and healthcare costs but are largely preventable.[201] Prevention may include individually modifiable risk factors[202] like optimizing nutrition, movement, sleep, or reducing tobacco and alcohol use, or it may include addressing risks arising from market products[203] and environmental risks, such as pesticides,[204] pollution,[205] or personal care products.[206]

According to the *New England Journal of Medicine*, cardiovascular disease, cancer, and diabetes cause 70% of United States deaths and account for nearly 75% of health care expenditures.[207] These expenses translate to billions of dollars.[208] For example, cardiovascular disease and stroke costs the healthcare system $214 billion per year.[209] Data from the Centers for Disease Control and Prevention (CDC) shows that 877,500 people die annually from cardiovascular disease and stroke, which accounts for one-third of all deaths in the United States[210] Eighty percent of cardiovascular disease and stroke, according to the CDC, are preventable.[211] Diabetes constitutes the most expensive chronic condition in the United States, accounting for one-quarter of all healthcare costs.[212] Diabetes affects a significant portion of the population: thirteen percent of adults have diabetes, and it accounted for 101,106 deaths in 2020.[213] Notably, only five to ten percent of people with diabetes have Type 1 diabetes.[214] The remaining patients have Type 2 diabetes, which is preventable with optimal nutrition and physical activity.[215] Data from the National Vital Statistics System showed 598,932 people in 2020 died from cancer.[216] According to the World Health Organization, thirty to fifty percent of cancer is also preventable through individual lifestyle modifications, such as nutrition,

---

[201] *Health and Economic Costs of Chronic Disease*, *supra* note 199; Galea & Maani, *supra* note 199; AM. PUB. HEALTH ASS'N, PUBLIC HEALTH AND CHRONIC DISEASE: COST SAVINGS AND RETURN ON INVESTMENT 1- 2, https://www.apha.org/~/media/files/pdf/factsheets/chronicdiseasefact_final.ashx (providing statistics for health care costs and lost productivity costs for specific types of chronic disease).

[202] *See* Preventing Chronic Diseases: A Vital Investment, WORLD HEALTH ORGANIZATION (2005), http://apps.who.int/iris/bitstream/handle/10665/43314/9241563001_eng.pdf?sequence=1.

[203] Nicholas Freudenberg & Sandro Galea, *The Impact of Corporate Practice on Health: Implications for Health Policy*, 29 J. PUB. HEALTH POL'Y 86, 87 (2008) (describing corporate practices as determinants of health).

[204] *See* Drabiak, *supra* note 190 (describing pesticide use and cancer risk).

[205] WORLD HEALTH ORG., NONCOMMUNICABLE DISEASES AND AIR POLLUTION i (2019), https://www.euro.who.int/__data/assets/pdf_file/0005/397787/Air-Pollution-and-NCDs.pdf.

[206] Katherine Drabiak, *Dying to Be Fresh and Clean? Toxicants in Personal Care Products, the Impact on Cancer Risk, and Epigenetic Damage*, 35 PACE ENVT'L L. REV. 75, 83 (2017) (describing personal care products and cancer risk).

[207] Marvasti & Stafford, *supra* note 195, at 889; *see also* Farida B. Ahmad & Robert N. Anderson, *The Leading Causes of Death in the US for 2020*, 325 JAMA 1829, 1830 (2021) (Table One illustrates causes of death in 2020. Heart disease (690,882), cancer (598, 932 people), and diabetes (101,106) account for far more deaths in total than other causes including even COVID-19 during 2020 (345,323).).

[208] *Health and Economic Costs of Chronic Disease*, *supra* note 199.

[209] *Id.*

[210] *Id*.

[211] *Preventing 1 Million Heart Attacks and Strokes,* CDC, https://www.cdc.gov/vitalsigns/million-hearts/index.html (last updated Sept. 6, 2018).

[212] *Health and Economic Costs of Chronic Disease*, *supra* note 199.

[213] CDC, NATIONAL DIABETES STATISTICS REPORT 2020 2 (2020), https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf; Ahmad & Anderson, *supra* note 207.

[214] CDC, *supra* note 212, at 1.

[215] *Prevent Type 2 Diabetes*, CDC, https://www.cdc.gov/diabetes/prevent-type-2/index.html (last updated Dec. 21, 2021).

[216] Ahmad & Anderson, *supra* note 207.

movement, and tobacco use.[217] A prevention model focused on forestalling the development of disease before symptoms or life-threatening events occur is the best solution to address current rates of disease, mortality, and healthcare costs.[218]

2. Overdiagnosis and Overtreatment

Despite the importance of prevention, these efforts must shield against overdiagnosis and overtreatment, which similarly not only increases healthcare costs but also can produce an iatrogenic risk of patient harm.[219] Overdiagnosis refers to labeling disease such as cancer, through screening that would not have caused the patient any symptoms or adverse effects and would not have been detected except through screening.[220] Overtreatment refers to when physicians intervene with treatment that exposes the patient to myriad side effects, adverse effects, and risks but is not medically necessary and holds no scientific benefit.[221] For example, physicians have described significant risks from overdiagnosis and overtreatment of cancer for both women (breast cancer) [222]and men (prostate cancer),[223] where treatment may include chemotherapy medication, hormone replacement therapy, surgery, or radiation. These interventions involve a variety of risks, such as neurological damage, increased risk for other cancers, infertility, and for males, impotence and incontinence.[224] Not every diagnosis requires treatment, and initiating treatment in some cases can expose patients to iatrogenic harm arising from the intervention, not the diagnosed disease.[225] In clinical care, more intervention and more treatment are not necessarily better but require a careful assessment of potential risks and benefits – not only at the individual clinical level but also at the level of clinical standards that reflect policy choices.

B. Industry Strategies to Promote Product Uptake

In some instances, pharmaceutical executives, clinicians, and interested stakeholders harness the pharmacological imperative to medicalize health conditions and promote drug uptake

---

[217] *Preventing Cancer*, WORLD HEALTH ORG., https://www.who.int/activities/preventing-cancer; *see also* Susan Gapstur et al., *A Blueprint for the Primary Prevention of Cancer: Targeting Established, Modifiable Risk Factors*, 68 CA: A CANCER JOURNAL FOR CLINICIANS 446, 447 (2018); Noelle LoConte et al., *Lifestyle Modifications and Policy Implications for Primary and Secondary Cancer Prevention: Diet, Exercise, Sun Safety, and Alcohol Reduction*, 38 AMERICAN SOCIETY OF CLINICAL ONCOLOGY EDUCATIONAL BOOK 88, 88-89 (2018).

[218] *Health and Economic Costs of Chronic Disease*, *supra* note 199; Karen Kmetik et al., *Pandemic Makes Chronic Disease Prevention a Priority* 2021, at 1, 1.

[219] H. GILBERT WELCH ET AL., OVERDIAGNOSED: MAKING PEOPLE SICK IN THE PURSUIT OF HEALTH (2011).

[220] Karsten Juhl Jørgensen, *Mammography Screening: Benefits, Harms, and Informed Choice*, 60 DANISH MED. J., 2013 at 1, 4 (discussing mammography screening advertisements as marketing for business rather than evidenced based practice); Katherine Drabiak, *The Impact Of A Developing Regulatory Framework Governing LDTs In Precision Oncology: Re-Envisioning The Clinical Risk Assessment Paradigm*, 13 J. HEALTH & BIOMEDICAL L. 1, 34-40 (2017) (discussing overdiagnosis and overtreatment relating to breast and ovarian cancer screening, risk assessment, and treatments).

[221] *See* Laura Esserman et al., *Overdiagnosis and Overtreatment in Cancer: An Opportunity for Improvement*, 310 JAMA 797 (2013); Jaiman Bhatt & Laurence Klotz, *Overtreatment in Cancer – Is It A Problem?*, 17 EXPERT OPINION ON PHARMACOTHERAPY, Jan. 20, 2016, at 1, 2.

[222] Jaiman Bhatt & Laurence Klotz, *supra* note 220, at 3.

[223] MARK SCHOLZ & RALPH BLUM, INVASION OF THE PROSTATE SNATCHERS: AN ESSENTIAL GUIDE TO MANAGING PROSTATE CANCER FOR PATIENTS AND THEIR FAMILIES (2010).

[224] *See* Drabiak, *supra* note 219, at 52-89 (describing risks related to the American Society of Clinical Oncology's recommendations for clinical risk reduction for breast and ovarian cancer for interventions including chemotherapy, surgeries, and additional medications such as hormone replacement); SCHOLZ & BLUM, *supra* note 222 (generally discussing risks from cancer versus risks from interventions that include male infertility, impotence, and incontinence).

[225] Isaac Kohane at al., *The Incidentalome: A Threat to Genomic Medicine*, 296 JAMA 212, 214 (2006).

through actions that follow similar patterns. These strategies encompass public relations techniques designed to influence public opinion of product necessity, desirability, safety, and effectiveness.[226]

1. Medicalize the Problem

First, stakeholders solidify or create the market by naming a problem through a medical lens. The industry rebrands shyness or discomfort with social situations as social anxiety disorder; sadness, stress, and dissatisfaction becomes depression; or low libido in females is instead hypoactive sexual desire disorder.[227] Critics of this practice refer to this process of medicalizing common issues and exaggerating their severity as "disease mongering."[228] These practices influence physician education and prescribing behavior,[229] which impacts clinical guidelines, how many patients take classes of medications, and the perception that medication constitutes an optimal strategy. In turn, prescription decisions influence individual health outcomes, costs to the system for medications, and burden society when medications induce harm.[230] In the example of labeling and medicating mental health conditions, several critics note that clinical trial data demonstrates marginal benefit for certain psychiatric medications but serious potential drawbacks such as flattened affect, apathy, personality changes, and increased risk of long-term chronic depression, dementia, suicide.[231] Certainly, naming a problem provides patients the benefit of therapeutic listening, but responding by medicalizing and medicating as a first-line response can impose costs on patient health and the healthcare system.

2. Portray Medicine as a Magic Bullet

Second, stakeholders convince patients and policymakers that this medication or intervention will effectively solve the problem. Peppering terms such as "promising," "highly effective," and "significant clinical benefit" in medical journals portrays pharmacological interventions as magic bullets. To promote product use, the industry may market a certain medication as better, safer, and more effective than a previous candidate. As a stark example in history, Bayer used this strategy when introducing Heroin as a replacement for morphine,

---

[226] NICHOLAS FREUDENBERG, LETHAL BUT LEGAL: CORPORATIONS, CONSUMPTION, AND PROTECTING PUBLIC HEALTH 90 (2014); Drabiak, *supra* note 190, at 703-05 (discussing public relations strategies to confuse the public and neutralize negative attention of product risks); Edward Bernays, *The Engineering of Consent*, 250 ANNALS AM. ACAD. POL. & SOC. SCI. 113, 113-20 (1947) (Bernays developed the concept of "engineering of consent," wherein stakeholders manipulate public opinion, deliberately plan, and exert influence on the public to achieve a specific outcome by using stories, mass movements, campaigns, and *creating* news. The public relations industry implemented many of Bernays' ideas into principles for marketing and advertising.)

[227] PETER BREGGIN, MEDICATION MADNESS: THE ROLE OF PSYCHIATRIC DRUGS IN CASES OF VIOLENCE, SUICIDE, AND CRIME (2009) (describing serious risks associated with psychiatric medication relating to public health and safety); ROBERT WHITAKER, ANATOMY OF AN EPIDEMIC: MAGIC BULLETS, PSYCHIATRIC DRUGS, AND THE ASTONISHING RISE OF MENTAL ILLNESS IN AMERICA (2010) (discussing medication trends, clinical trials and long term consequences of psychiatric medication); Antonie Meixel et al., *Hypoactive Sexual Desire Disorder: Inventing a Disease to Sell Low Libido*, 41 J. MED. ETHICS 859, 859 (2015).

[228] Freudenberg, *supra* note 225, at 59; McCarthy, *supra* note 119, at 447.

[229] Sunita Sah & Adriane-Fugh Berman, *Physicians Under the Influence: Social Psychology and Industry Marketing Strategies*, 41 J. L. MED. & ETHICS 665, 665-72 (2013).

[230] BREGGIN, *supra* note 226; WHITAKER, *supra* note 226.

[231] *Id.*; *see also* Robert Nikkel & Robert Whittaker, *Flooding the World with Psychiatric Drugs Could Boost the Burden of Mental Disorders*, STAT (Oct. 22, 2018), https://www.statnews.com/2018/10/22/flooding-world-psychiatric-drugs-boost-burden-mental-disorders/#:~:text=Today%20in%20the%20United%20States,drug%20on%20a%20daily%20basis (discussing long term chronic depression and global health burden).

asserting Heroin was a safer and less addictive alternative.[232] Similarly, stakeholders who work with patients with Opioid Use Disorder (OUD) assert that Medication Assisted Treatment (MAT) should be the first line of treatment given that replacement medications are safer, less addictive, and do not produce euphoria as compared to primary drugs of opioid abuse.[233] However, product data submitted to the FDA, classification by the Drug Enforcement Administration, and multiple scientific studies demonstrate the opposite.[234] MAT may produce euphoria, induce dependence, cause neurological damage and serious risks, and may not be effective at treating OUD for many patients.[235] In previous research, I've described this process as shifting iatrogenic opioid dependency from one drug to another, which poses challenges for individual recovery and wellness, public safety, and at significant financial cost.[236] This strategy of portraying medical interventions as a magic bullet is not limited to addiction medicine but crosses multiple medical specialties and conditions. For instance, promises relating to regenerative medicine for back pain or pushing risky experimental methods of treating infertility.[237]

3. Expand Disease Classifications

Third, stakeholders expand potential patient pools by increasing eligibility for particular drugs. The industry can achieve this metric through two main avenues: influencing clinical care guidelines to expand disease classifications and promoting to encourage off-label product uses.

In the first instance, clinicians and professional societies can lower or modify the benchmark of who constitutes a patient group. For the example of patients with Opioid Use Disorder, this involved sweeping in patients with a history of injection drug abuse and polysubstance abuse along with patients who developed opioid dependence from medically indicated physician opioid prescriptions, which classified all patients under one umbrella. MAT was then recommended as the standard of care for this varied patient pool.[238] As another example, cardiology guidelines that specify clinical metrics for determining whether a patient suffers from hypertension also follow the model of expanding the patient pool by changing the

---

[232] Jim Edwards, *Yes, Bayer Promoted Heroin for Children -- Here Are the Ads That Prove It*, BUSINESS INSIDER (Nov. 17, 2011), https://www.businessinsider.com/yes-bayer-promoted-heroin-for-children-here-are-the-ads-that-prove-it-2011-11.

[233] Katherine Drabiak, *Expanding Medication Assisted Treatment Is Not the Answer: Flaws in the Substance Abuse Treatment Paradigm*, 21 DEPAUL J. HEALTH CARE L. 1, 34, 43-45 (2019) (describing claims promoting MAT medications as better, safer, nonaddictive) (describing federal policy and clinical care guidelines promoting MAT as the standard of care and first line treatment for all patients with OUD).

[234] *Id.* at 49.

[235] *Id.* at 36-41 (describing FDA and DEA classifications); *Id.* at 45-53 (describing scientific and medical journal research on benefit metrics such as reduce opioid use and risks such as neurological damage).

[236] *Id*. at 4-11 (describing the intersection of drug abuse and crime such as larceny, motor vehicle accidents, violent crime, and child abuse/neglect); *Id*. at 61-65 (explaining the intersection of patients enrolled in MAT and crime, such as engaging in polysubstance abuse and causing motor vehicle accidents from impairment); *Economic Burden of Illness in Opioid Use Disorder (OUD) and Medication-Assisted Treatments*, AM. J. MANAGED CARE (Oct. 15, 2020), https://www.ajmc.com/view/economic-burden-of-illness-in-opioid-use-disorder-oud-and-medication-assisted-treatments.

[237] *See* Katherine Drabiak, *Challenging FDA's Authority to Regulate Autologous Adult Stem Cells for Therapeutic Use: Celltex, Substantial Risks, and the Implications of US v. Regenerative Sciences*, 23 HEALTH MATRIX 493, 519-522 (2013) (describing regenerative medicine's claims); Katherine Drabiak, *Emerging Governance of Mitochondrial Replacement Therapy: Assessing Coherence Between Scientific Evidence and Policy Outcomes*, 20 DEPAUL J. HEALTH CARE L. 1, 50-57 (2018) (discussing evidence behind promoting the experimental procedure Mitochondrial Replacement Therapy as a "treatment" for infertility).

[238] *See* Drabiak, *supra* note 232, at 35-45.

benchmark of what constitutes disease. In 2016, the United States Preventive Services Task Force recommended increased screening of all people over forty to determine the risk of cardiovascular disease and stated that the use of statins, a medication designed to lower the risk of heart disease and stroke, should be considered the primary method of prevention.[239] In 2017, the American College of Cardiology and the American Heart Association lowered the cut-off for blood pressure that clinicians would label as hypertension, widening the patient pool for patients eligible for statins.[240] This strategy effectively increased statin use, where one in four adults over forty now take statin medication.[241] While clinical guidelines focus on clinical benefit, statin use also corresponds to potentially serious risks, increased blood glucose/risk of diabetes, liver damage, and memory loss.[242]

4. Increase the Patient Pool through Off Label Marketing

The industry may also expand patient use of medication by promoting off-label use for new disease indication or promotion of a product to children.[243] Physicians may legally prescribe medications off-label based on clinical assessment and professional judgment. However, manufacturers that advertise a product for an off-label or unapproved use through false or misleading claims are guilty of drug misbranding under the federal Food, Drug, and Cosmetic Act.[244] In 2016, a settlement between Amarin and the FDA examined the boundaries of the misbranding prohibition and raised the question of what constitutes sufficient evidence to demonstrate what product claims are truthful and non-misleading.[245] Proponents of off-label use and product promotion assert this practice permits communication and flow of critical information to treating physicians, ensures physicians are informed of all options, and makes off-label treatments available to patients.[246] However, the pharmaceutical industry demonstrates a pattern of prohibited off-label promotion across patient populations for multiple drugs that

[239] U.S. Preventive Services Task Force, *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: US Preventive Services Task Force Recommendation Statement*, 316 JAMA 1997, 1998 (2016).
[240] Paul Whelton et al., *2017 ACC/AHA/AAPA/ABC/ACPM/AGS/APhA/ASH/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines*, 71 J. AM. COLL. CARDIOLOGY 1269 (2018); *Statin Side Effects: Weigh the Benefits and Risks*, MAYO CLINIC (Jan. 14, 2020), https://www.mayoclinic.org/diseases-conditions/high-blood-cholesterol/in-depth/statin-side-effects/art-20046013.
[241] Connie Newman et al., *Statin Safety and Associated Adverse Events: A Scientific Statement from the American Heart Association*, 39 ARTERIOSCLEROSIS, THROMBOSIS, AND VASCULAR BIOLOGY e38, e39 (2019) (stating one-fourth of adults over age 40 take statin medication).
[242] *See id.* at e60-e61; Patrick Clark, Office of Communications, *Cholesterol-Lowering Drugs Get Labeling Changes*, FDA (May 22, 2015), https://www.fda.gov/drugs/special-features/cholesterol-lowering-drugs-get-labeling-changes (listing side effects and risks of statins).
[243] *Understanding Unapproved Use of Approved Drugs "Off Label,"* FDA (Feb. 5, 2018), https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label.
[244] 21 U.S.C. § 352(a).
[245] Deborah Mazer & Gregory Curfman, *FDA Sanctions Off-Label Drug Promotion*, HEALTH AFFAIRS FOREFRONT (July 19, 2016), https://www.healthaffairs.org/do/10.1377/hblog20160719.055881/full.
[246] *Id.*

continues despite legal sanction.[247] In one instance, Pfizer settled criminal and civil claims relating to off-label marketing for *four* drugs at once, paying a massive $2.3 billion penalty.[248]

One particularly egregious example involved Johnson & Johnson's off-label promotion of Risperdal, an antipsychotic medication that is FDA approved for patients with schizophrenia.[249] The Pennsylvania Attorney General alleged Johnson & Johnson and its subsidiary Janssen violated the False Claims Act by promoting Risperdal for off-label uses that federal health care programs did not cover, made false and misleading statements about product safety and efficacy, and paid kickbacks to physicians to prescribe Risperdal.[250] Johnson & Johnson expressly promoted off-label, unapproved uses of Risperdal for three additional vulnerable populations: elderly people with dementia, people with developmental disabilities, and children.[251] Investigations uncovered corporate marketing plans to increase prescribing in each sector, with corresponding kickbacks for physicians who met prescribing metrics.[252] Johnson & Johnson marketed Risperdal to the geriatric population assuring physicians it had "proven efficacy" and "an excellent safety and tolerability profile" in geriatric patients for reducing agitation and behavior control.[253] The complaint alleged Johnson & Johnson similarly executed marketing strategies to children and people with developmental disabilities by portraying Risperdal as a safe and effective treatment for attention deficit hyperactivity disorder, oppositional defiant disorder, obsessive-compulsive disorder, and autism.[254] Despite FDA warnings to cease unapproved promotion, Johnson & Johnson continued its campaigns.[255] In 2013, Johnson & Johnson agreed to settle criminal and civil liability by paying $2.2 billion.[256] Off-label promotion not only incurs additional wasteful spending but exposes patients to potentially ineffective and risky medications. For Risperdal, these risks include stroke, diabetes, and endocrine changes.[257]

---

[247] Freudenberg, *supra* note 225, at 55-56 (providing a table of multiple and repeated allegations against pharmaceutical companies for off label promotion, fraud, kickbacks, failure to disclose safety data, and illegal marketing practices).

[248] Press Release, U.S. Dep.'t of Justice, Justice Department Announces Largest Health Care Fraud Settlement in Its History, Office of Public Affairs (Sept. 2, 2009), https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history.

[249] FDA, LABEL FOR RISPERDAL, https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020272s056,020588s044,021346s033,021444s03lbl.pdf (last visited Apr. 15, 2022) [hereinafter LABEL FOR RISPERDAL] (FDA approved Risperdal to treat irritability in children with autism in 2006; the claims described by the Department of Justice relate to off label promotion from 1999-2005, prior to FDA approval for other product indications.).

[250] Press Release, U.S. Dep.'t of Justice, Johnson & Johnson to Pay More Than $2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations; *see also* Centers For Medicare And Medicaid, Off Label Pharmaceutical Marketing: How to Recognize and Report It (Oct. 2015), https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/Downloads/off-label-marketing-factsheet.pdf (describing prohibited off label marketing, kickbacks, and harm to patients).

[251] U.S. Dep.'t of Justice, *supra* note 248.

[252] *Id.*

[253] *Id.*

[254] Centers For Medicare And Medicaid, *supra* note 248.

[255] U.S. Dep.'t of Justice, *supra* note 248.

[256] *Id.*

[257] *Id.*; *see also* LABEL FOR RISPERDAL, *supra* note 247.

5. Create Favorable Evidence that Demonstrates Product Benefit and Downplays Risk

To influence professional and public opinion, manufacturers implement several techniques to shape what scientific evidence reaches regulators and the public and, accordingly, how the public perceives the product. First, manufacturers conduct many clinical trials, but they may select only a few trials that demonstrate product benefit to submit during the approval process and for publication.[258] By omitting evidence of product ineffectiveness, discarding clinical trials that yield unfavorable results, and revealing product risks, manufacturers produce data designed to lead to preferential prescribing.[259] In some cases, data collection and reporting in publication goes beyond dismissing negative findings to engaging in data fabrication, resulting in publications based on fraudulent data. In the most extreme examples, manufacturers and paid researchers may engage in insidious conduct during clinical trials to influence trial data, such as fraudulently misreporting data, skewing perception toward product safety, or effectiveness. [260] In one example, in 2009, a prominent physician-researcher funded by Pfizer admitted to fabricating twenty-one journal articles relating to Pfizer drugs, including Celebrex and Lyrica.[261]

Another high-profile example of clinical trial data suppression involved GlaxoSmithKline and Paxil use for children. Back in 2004, New York Attorney General alleged GlaxoSmithKline engaged in "repeated and persistent fraud" linked to clinical trial data and Paxil promotion.[262] At the time, the Attorney General cited five studies investigating the use of Paxil in children, wherein two studies demonstrated the drug was more effective than a placebo for depression (one published), but three studies revealed a risk of suicide increased two-fold with Paxil use.[263]

Federal law that aims to provide an accurate record of clinical trials already exists. Title VIII of the Food and Drug Administration Amendments Act of 2007 requires study sponsors to register and disclose certain information related to clinical trials.[264] However, one report indicated that the industry reported only 17% of its trials, which suggests that compliance with clinical trial reporting requirements falls short.[265] Enforcing mandatory reporting as a prerequisite during the regulatory approval process and in publishing can increase data transparency.

In addition to downplaying or burying unfavorable data in trials, the industry may create more favorable evidence by funding additional trials and engaging in ghostwriting scientific

[258] Freudenberg, *supra* note 225, at 54-57 (describing selectively reporting clinical trial data, omitting key safety data, and illegal drug promotion); McCarthy, *supra* note 119, at 442-46 (describing fraud occurring in testing and drug marketing, clinical trial bias, and publication bias); Minasi, *supra* note 131, at 303-04 (describing selective publishing in clinical trials, distortion of drug benefit, and preferential prescribing).

[259] Freudenberg, *supra* note 225, at 54-57; McCarthy, *supra* note 119, at 442-46; Minasi, *supra* note 131, at 303-04; *see also* Erick Turner et al., *Selective Publication of Antidepressant Trials and Its Influence on Apparent Efficacy*, 358 NEW ENG. J. MED. 252, 252-59 (2008).

[260] McCarthy, *supra* note 119, at 445-47; Daniele Fanelli, *How Many Scientists Fabricate and Falsify Research? A Systematic Review and Meta-Analysis of Survey Data*, 4 PLOS ONE e5738, e5738 (2009).

[261] Gardiner Harris, *Doctor's Pain Studies Were Fabricated, Hospital Says*, N.Y. TIMES (Mar. 10, 2009), https://www.nytimes.com/2009/03/11/health/research/11pain.html.

[262] Minasi, *supra* note 131, at 304-05; Meredith Wadman, *Spitzer Sues Drug Giant for Deceiving Doctors*, 429 NATURE 589, 589 (2004); McCarthy, *supra* note 119, at 453-54.

[263] Minasi, *supra* note 131, at 304-05.

[264] *Id.* at 307.

[265] *Id.*

publications.[266] Ghostwriting involves industry publishing articles that are authored by the corporation or a scientific consulting firm but instead, identify the primary authors as respected professionals such as a physician or university researcher.[267] By design, the industry pre-authors the article, recruiting the professional to simply sign his name without meeting the formal criteria for authorship.[268] Ghostwriting "covertly shapes the literature in favor of commercial interests" by increasing the appearance of product benefit through the prestige of professionals without fully (or at all) acknowledging industry involvement.[269] One study published in *British Medical Journal* found that 21% of publications met the criteria for ghostwriting or honorary authorship.[270] Ghostwriting not only disregards the integrity of authorship but creates articles designed to tip the scales of evidence showing significant benefit and minimal risk, which influences physician prescribing. Withholding adverse data, reporting positive data, and ghostwriting favorable articles sharply and effectively distorts perception of the drug and increases the chance that physicians may prescribe an ineffective or harmful medication.

C. Business Patterns

Critics of industry practices assert each of these practices – disease mongering, promoting off-label uses, paying kickbacks tied to prescribing metrics, elevating benefits and downplaying risk, suppressing clinical trial data, and ghostwriting publications constitute widespread fraud and a pattern of conducting business.[271] Indeed, numerous cases involved manufacturers facing civil and or criminal allegations for multiple drugs at one time, where settlement claims or alternate prosecution agreements involved negotiation relating to several drugs.[272] In many cases, manufacturers settle claims with prosecutors through the process of either deferred prosecution agreements or non-prosecution agreements.[273] Manufacturers may agree to specific conditions set forth in a corporate integrity agreement, pay a fine, and avoid prosecution.[274] Despite the common use of deferred prosecution agreements and non-prosecution agreements, repeat conduct by the same manufacturers and across the industry suggests this litigation alternative constitutes an ineffective deterrent.[275]

IV. SOLUTIONS

The convergence of high medication prices, the burden of preventable chronic disease, and the push to increase pharmacological interventions raise a critical question: What is the role of

[266] *Id.* at 308-10; McCarthy, *supra* note 119, at 446; Freudenberg, *supra* note 224, at 209; Catherine DeAngelis & Phil Fontanarosa, *Impugning the Integrity of Medical Science: The Adverse Effects of Industry Influence*, 299 JAMA 1833, 1834 (2008).
[267] Minasi, *supra* note 131, at 308-10; McCarthy, *supra* note 119, at 446; Freudenberg, *supra* note 224, at 209; DeAngelis & Fontanarosa, *supra* note 264.
[268] Minasi, *supra* note 131, at 308-10; McCarthy, *supra* note 119, at 446; Freudenberg, *supra* note 224, at 209; DeAngelis & Fontanarosa, *supra* note 264; *see also* Joseph Wislar et al., *Honorary and Ghost Authorship in High Impact Biomedical Journals: A Cross Sectional Survey*, 343 BRIT. MED. J. 1, 1, 4 (2011).
[269] Minasi, *supra* note 131, at 309.
[270] Wislar et al., *supra* note 266, at 4.
[271] Minasi, *supra* note 131, at 312-13, 317-18; McCarthy, *supra* note 119, at 442-45, 454-58; Freudenberg, *supra* note 224, at 56-57.
[272] McCarthy, *supra* note 119, at 454-58.
[273] *Id.*; *see also* Beale, *supra* note 119, at 55; Alexander & Cohen, *supra* note 119, at 538.
[274] McCarthy, *supra* note 119, at 454-58; *see also* Beale, *supra* note 119, at 55; Alexander & Cohen, *supra* note 119, at 538.
[275] McCarthy, *supra* note 119, at 457-58; Beale, *supra* note 119, at 63; Alexander & Cohen, *supra* note 119, at 539.

the law in facilitating effective, fair, and transparent solutions? This section will describe potential answers to the problems of high medication costs and explain how strict enforcement and shifting organizational ethics can curb costs and consumer harm.

A. High Prices and Anticompetitive Market Actions

In response to price spikes, health policy experts suggest a variety of potential solutions to increase transparency behind the reasons for certain prices.[276]

Several strategies relate to changing the information landscape. Many health policy experts call for a general increase of transparency to information about how the reimbursement, rebate, and pricing system functions.[277] This includes increasing public knowledge about how PBMs function and whether they are passing on actual savings to patients.[278] Physicians can discuss the option of generic or biosimilars with patients, and pharmacists can explain pricing differences.[279] As an alternate option, the FDA could leverage its authority to "name and shame" specific pharmaceutical manufacturers, a strategy discussed by law professor Sharon Yakin. [280] This strategy entails publicly naming manufacturers that engage in legally improper conduct, such as if brand name manufacturers act to allegedly block competition from generic drug companies.[281] By design, naming and shaming attempts to leverage compliance by potential reputational damage but its effectiveness hinges upon whether the message reaches the correct audience.[282]

Next, health policy experts propose strategies to modify current laws already in place. These options include patent reform, limiting secondary patents for trivial modifications, or easing regulatory requirements for generic and biosimilar entry into the market.[283] Another option includes promoting the use of generic drugs and biologics over branded drugs. Some experts recommend modifying state laws governing pharmacy prescribing to mandatory generic substations or eliminating the requirement for patient consent when switching from a brand to generic medication.[284] Additionally, multiple state bills are currently pending that would address PBMs' role, such as designating PBMs as fiduciaries to modify their legal duties toward purchasers or capping the amount PBMs can obtain for their services.[285]

Finally, as a strategy to prevent monopoly power and dramatic price increases, some health policy experts suggest intervening in the market with price caps or setting negotiating prices.[286] Policymakers introduced federal proposals to Congress to cap prices, limit increases to fall within inflation, or enact other mechanisms of stringent pricing controls.[287] Despite the initial appeal of price caps, the heavy hand of government regulation would likely produce unintended

---

[276] *See* Sharon Yadin, *Shaming Big Pharma*, 36 YALE J. REG. BULL. 131 (2019); Kesselheim et al., *supra* note 26, at 864-67; Rajkumar, *supra* note 53, at 23; Wineinger et al., *supra* note 20, at 7.
[277] Wineinger et al., *supra* note 20, at 7.
[278] Rajkumar, *supra* note 53, at 25.
[279] *Id.* at 23.
[280] Yadin, *supra* note 274, at 131-32, 137-38.
[281] *Id.*
[282] *Id.* at 140.
[283] Kesselheim et al., *supra* note 26, at 864-67; Rajkumar, *supra* note 53, at 23, 25.
[284] Kesselheim et al., *supra* note 26, at 864-67; Rajkumar, *supra* note 53, at 23, 25.
[285] *2022 State Legislative Action to Lower Pharmaceutical Costs*, NAT'L ACAD. FOR STATE HEALTH POLICY, https://www.nashp.org/rx-legislative-tracker/ (last updated Apr. 15, 2022).
[286] Rajkumar, *supra* note 53, at 25; Kesselheim et al., *supra* note 26, at 865.
[287] Meredith Freed et al., *Moving the Needle on Prescription Drug Costs: Using the Innovation Center and Other Demonstration Authority*, KAISER FAMILY FOUNDATION (Mar. 25, 2021), https://www.kff.org/medicare/issue-brief/moving-the-needle-on-prescription-drug-costs-using-the-innovation-center-and-other-demonstration-authority/.

adverse consequences.[288] In the long term, this may restrain manufacturers from innovation because they would have less incentive to allocate research and development toward newer, better, and more effective medications.[289] Instead, manufacturers may have a perverse incentive to expand the market for existing products, such as rebranding existing drugs to additional ages and patient groups, a strategy which may increase profits but at the expense of patient health. Most importantly, artificial market intervention does not address the underlying corporate behavior and allegations of violating existing laws. The cases described here relating to pricing, competition, and marketing demonstrate that manufacturers would likely attempt to recoup lost profits through alternate channels, leaving the fundamental problems unaddressed.

The most effective strategy entails enforcing compliance with existing laws relating to the specific, alleged behavior: leveraging antitrust laws, state consumer protection laws, and RICO that are designed precisely to address anticompetitive conduct, collusion, rigging the market, price-fixing, and fraudulent behavior. Litigation provides significant benefits to public health by serving as a mechanism for corrective enforcement while providing transparency of inappropriate and illegal corporate practices, which should incentivize corporate behavior change.

B. Pharmacotherapy as a First Line Solution, Clinical Trials Misconduct, and Inappropriate Product Promotion

To address overreliance on pharmacotherapy, clinical trials misconduct, inappropriate promotion, and prescribing requires a variety of strategies.

First, our healthcare system could adopt incentives to prevent chronic diseases, such as healthcare systems that offer functional medicine programs and reimbursement for care models that offer patients avenues to address lifestyle and environmental risk factors.[290] This encompasses targeted prescribing, where clinicians assess whether the patient presents with the condition that requires acute or ongoing medication management or whether the clinician could offer the patient alternate disease management or prevention. Finally, optimal clinical care also means guarding against overdiagnosis and overtreatment in prevention efforts and accurately describing the risks and benefits of medications.

Federal law already exists to track clinical trials, which requires more stringent enforcement from the FDA. As a means to minimize bias in study design and reporting findings, some health policy experts recommend creating a barrier between corporate sponsors and the investigator conducting the research.[291] The investigator should independently conduct the study and report findings without the involvement of the sponsor to minimize the chance of selective reporting. In addition to enforcing reporting clinical trial results, health policy scholars recommend mandatory disclosure of trials during the authorship process.[292] To disincentivize ghostwriting, physicians Catherine DeAngelis and Phil Fontanarosa suggest that both journals and institutions enforce authorship policies that designate criteria for authorship and manuscript

---

[288] Michael Giberson, *The Problem with Price Gouging Laws*, 34 REGULATION 48, 50 (2011); Thomas Sowell, *Price Controls*, CAPITALISM MAGAZINE (Nov. 16, 2005), https://www.capitalismmagazine.com/2005/11/price-controls/.
[289] Sowell, *supra* note 286.
[290] *See What is Functional Medicine?*, CLEVELAND CLINIC, https://my.clevelandclinic.org/departments/functional-medicine/about (last visited Apr. 17, 2022); Tom Blue, *How to Package Functional Medicine for Widespread Adoption*, 18 INTEGRATIVE MED. 28, 29-31 (2019).
[291] DeAngelis & Fontanarosa, *supra* note 264, at 1835.
[292] Minasi, *supra* note 131, at 329.

contribution.[293] Some health law scholars suggest the level of publication fraud rises to meet the definition of prohibited conduct set forth in RICO and suggest levering RICO as a means to combat the problem of ghostwriting.[294]

Similarly, numerous laws already exist that prohibit inappropriate drug promotion by industry, such as the False Claims Act, prohibitions against misbranding drugs, and state consumer protections laws. These laws would also provide a mechanism for accountability for physicians that overprescribe without medical benefit, prescribe in harmful manners, or receive kickbacks tied to prescribing. Fully enforcing existing laws provides a strong remedy for accountability for both manufacturers and physicians.

C. Solutions for Reform

Despite these seemingly distinct areas that encompass healthcare costs, pricing strategies, and marketing practices, this article asserts that we must look at these three phenomena as an integrated and coherent issue. Skyrocketing prices and allegations of anticompetitive conduct, collusion, and fraud constitute one portion of the corporate aim to increase profits. As a second part of the puzzle, the industry prioritizes the pharmacological imperative, narrowly frames prevention, strategically structures and selects clinical trial data, creates favorable publications to tip the scales of evidence to demonstrate benefit, and engages in tactics to increase patient pool. The result is that medications may be prohibitively expensive for those in dire need, many patients may take a medicine they do not need or exposes themselves to harmful side effects, and both the patient and the healthcare system suffer.

The industry has no fault in the aim of maximizing profits. The purpose of business centers around bringing a useful and desirable product to the marketplace. To fuel innovation, we should not enact structures such as price caps nor encourage disdain for the general principle of maximizing profit. Patients may even be willing to pay a premium for what they view as a highly effective or desirable product, even if it carries significant risks. The fundamental error, however, occurs when the actors in the market presume profit maximization permits discarding guardrails of honesty, fair dealings, and legal compliance. The extensive allegations, ongoing litigation, and litany of repeated non-prosecution and deferred prosecution agreements strongly suggest corporate actions aim to maximize profits through patterns of conduct that rely upon blatant disregard for the law.

Civil enforcement actions such as those described *supra* and criminal investigations constitute necessary powerful strategies for reform. Yet, unethical conduct and lack of corporate integrity point to a problem more significant than simply reporting noncompliance and enforcing current laws.[295] To be sure, this constitutes a necessary and critical step. But this article recommends two additional considerations to reform corporate behavior.

First, although non-prosecution and deferred prosecution agreements seem ideal for conserving judicial efficiency, they appear ineffective as a deterrent. Fully litigating claims, including naming and shaming corporate practices and publicly posting key discovery documents demonstrating alleged legal violations, may incentivize corporate behavior change out of necessity to preserve goodwill.

Second, the industry could revise organizational corporate ethics aims. Psychologist Mihaly Csikszentmihalyi's work that specializes in maximizing human happiness and fulfillment is

[293] DeAngelis & Fontanarosa, *supra* note 264, at 1835.
[294] Minasi, *supra* note 131, at 317-22; *see generally* McCarthy, *supra* note 119.
[295] DeAngelis & Fontanarosa, *supra* note 264, at 1834.

particularly instructive here. Csikszentmihalyi describes reframing the mindset of how we define what constitutes "good business."[296] Rather than maximizing profit by relying on aggressively dishonest practices, corporate leadership can structure aims toward transactions that make a genuine contribution to human happiness and well-being.[297] Csikszentmihalyi posits that revising the "soul" of business to include characteristics of empathy, generosity, and responsibility will not only provide public benefit but also amounts to a sustainable corporate design. Consumers in the market will reward manufacturers for providing quality useful products through consistent purchasing, and trust in product claims, and this model will result in a consistently stable business.[298] Many physicians and patients still may elevate and even prefer pharmacological solutions and medical intervention, but these choices should be based on accurate and honest manufacturer information.

CONCLUSION

The price spikes for EpiPens, insulin, and generic drugs demonstrated the impact on patients when they are unable to access an expensive lifesaving or medically necessary medication. These cases revealed only the tip of the iceberg. Price increases across several sectors of medication illustrated not simply barriers to access from high cost but a web of factors driving a complex system to increase prices and induce demand. Corporate strategy to raise prices, maximize profits, and increase product uptake constitute expected business decisions to maintain a viable, thriving business. However, prohibitive pricing and high demand in the cases described here signal a more extensive problem beyond reasonable business strategies.

In Re Generic Pharmaceuticals Pricing Litigation and *In Re Insulin Pricing Litigation* alleged multiple manufacturers leveraged this system to their benefit by engaging in anticompetitive and illegal conduct to allocate market share, rig bids, and artificially raise inflate prices. Manufacturers may also engage in a set of techniques to promote product uptake of medications through distorting data, manipulating clinical trials, and engaging in intentional off-label promotion.

These strategies pervade corporate conduct across multiple sectors ranging from market behavior with other competitors, to setting prices, to promotion and product utilization. Extensive allegations across several manufacturers for multiple products combined with the history of repeated alternate prosecution agreements for similar violations suggest that these actions reflect a business model that tolerates or even accepts dishonesty and legal violations as the cost of doing business. To effectively reform skyrocketing medication costs, facilitate access to necessary medication, and ensure evidence-based treatment recommendations, this mindset must change. While manufacturers may exercise discretion in a variety of pricing, promotional, and development decisions, this conduct must be bound by legal and ethical parameters that disavow dishonesty, deception, and fraud. Sustainable change requires fundamentally re-envisioning the corporate mindset bound by ground rules that prioritize fairness, goodwill, and honest market competition.

[296] MIHALY CSIKSZENTMIHALYI, GOOD BUSINESS: LEADERSHIP, FLOW, AND THE MAKING OF MEANING (2004).
[297] *Id.* at 25.
[298] *Id.* at 145.