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Leveraging Pharma to Lower Premiums: Medical Loss Ratio Regulation in the Pharmaceutical Industry

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Leveraging Pharma to Lower Premiums: Medical Loss Ratio Regulation in the Pharmaceutical Industry

Many recognize escalating drug prices as a significant dilemma related to America's rising healthcare costs. Yet few can agree on what to do about them. Unaffordable drug prices are a result of many complex forces. One theory to address this problem is to reduce all government intervention and let normal market forces act as they usually do to bring the goods' prices down to consumer-friendly ranges. However, the prescription drug market is not, and perhaps never can be, a normal market. Reasons for this include (1) a lack of price transparency, (2) information and control asymmetries between patients and physicians, (3) third-party payors, (4) demand that remains constant irrespective of any exorbitant price increases (i.e., market inelasticity), and (5) patent-ensured monopolies. These factors disrupt the normal market forces that usually maintain prices at levels amenable to the general public (i.e., price equilibrium). Left unchecked, Big Pharma increase their prices partly to pay for elevated marketing and other expenses and partly to recoup greater earnings. Consequently, they rake in substantial profits – at an average greater than any other industry. Thus, rising drug prices burden not only those who need them but also those who are expected to help pay for them.

To right this abnormal market, this Note suggests an alternative theory: that Congress should apply a medical loss ratio framework to the pharmaceutical drug industry, similar to the ratio framework applied to reform the health insurance industry. This framework seeks to balance corporate profits with consumer benefits by separating profits and "other" less value-adding expenses from those that add greater value to the consumer (i.e., "medical loss"). In the health insurance industry's 80:20 ratio framework, if the less value-adding expenses (e.g., profits, sales and marketing) cross the ratio threshold (20%), then the companies must reimburse the excess back to the consumer. This measure has eased some insurance premium increases. Similar reform is needed in the pharmaceutical industry, as currently the industry averages 21% profit – significantly above that of other industries – while also spending around 23% on sales and marketing and around 30% on manufacturing.

Therefore, the average medical loss ratio is roughly 30:70 (30% on medical loss and 70% on less value-adding areas). Imposing a stricter ratio threshold, such as 40:60, would provide some much-needed incentives for drug companies to reduce their lesser-value-adding expenses and, as a result, reduce drug prices. If Big Pharma failed to meet the 40% threshold, then the excess would be returned to the consumer. Imposing a medical loss ratio regulation in the pharmaceutical industry is a promising solution to one of our nation's greatest healthcare cost concerns.

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I. INTRODUCTION

Healthcare spending in America is growing at an alarming rate. In 2015 healthcare spending totaled \$3.2 trillion, or \$9990 per person.¹ This spending is projected to grow at an average of 5.8% between 2015 and 2025 – approximately 1.3% faster than the GDP.² With healthcare costs rising every year, controlling this growth has

1. *National Health Expenditures 2016 Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/NationalHealthExpendData/Downloads/highlights.pdf> (last visited Nov. 7, 2017).

2. Sean P. Keehan et al., *National Expenditure Projections, 2015–2025: Economy, Prices, and Aging Expected to Shape Spending and Enrollment*, 35 HEALTH AFF. 1522, 1522–31 (2016).

become a national priority.³ One area with noticeably rising costs is the pharmaceutical industry. Americans spent \$323 billion (roughly 10% of total healthcare expenditures) on prescription medications in 2016—and that is after rebates and discounts.⁴ For those under age sixty-five, drug prices are expected to jump 11.6% in 2017.⁵ As a comparison, wages are expected to rise only 2.5% in 2017.⁶ Perhaps unsurprisingly, when comparing industries' net profits and percent growth, biotech companies consistently rank higher than almost any other industry.⁷ It is these sky-high corporate profits that account for a remarkable portion of rising medication prices.⁸ While some individuals have recently proposed ways to rein in drug prices—such as foreign importation—more overarching reform is needed.⁹ To counter the pharmaceutical industry's abnormal market forces and to control unsustainable costs, Congress should enact a pharmaceutical Medical Loss Ratio (MLR)

3. Zeke Emanuel et al., *State Options to Control Health Care Costs and Improve Quality*, HEALTH AFF. (Apr. 28, 2016), <http://healthaffairs.org/blog/2016/04/28/state-options-to-control-health-care-costs-and-improve-quality/>; Steven M. Lieberman & Paul B. Ginsburg, *Would Price Transparency for Generic Drugs Lower Costs for Payers and Patients?*, BROOKINGS INST. (2017), https://www.brookings.edu/wp-content/uploads/2017/06/es_20170613_genericdrugpricing.pdf (outlining that every one percent in an average generic prescription reimbursement would cut \$1 billion from the nation's healthcare spending).

4. *U.S. Prescription Drug Spending as High as \$610 Billion by 2021: Report*, CNBC: HEALTH CARE (May 4, 2017, 6:12 AM), <https://www.cnbc.com/2017/05/04/us-prescription-drug-spending-as-high-as-610-billion-by-2021-report.html> ("U.S. spending on prescription medicines in 2016 increased by 5.8 percent over 2015 levels to \$450 billion based on list prices, and by 4.8 percent to \$323 billion when adjusted for discounts and rebates.").

5. For older Americans, price hikes will be a little lower at 9.9%. Aimee Picchi, *Prognosis for Rx in 2017: More Painful Drug-Price Hikes*, CBS NEWS: MONEYWATCH (Dec. 30, 2016, 12:32 PM), <https://www.cbsnews.com/news/drug-prices-to-rise-12-percent-in-2017/>.

6. *Id.*

7. Keith Speights, *12 Big Pharma Stats That Will Blow You Away*, MOTLEY FOOL (July 31, 2016, 2:04 PM), <https://www.fool.com/investing/2016/07/31/12-big-pharma-stats-that-will-blow-you-away.aspx>; see also Sean Williams, *7 Facts You Probably Don't Know About Big Pharma*, MOTLEY FOOL (July 19, 2015, 9:06 AM), <https://www.fool.com/investing/value/2015/07/19/7-facts-you-probably-dont-know-about-big-pharma.aspx> (explaining the finances of pharmaceutical companies).

8. Melody Petersen, *How 4 Drug Companies Rapidly Raised Prices on Life-Saving Drugs*, L.A. TIMES (Dec. 21, 2016, 3:35 PM), <http://www.latimes.com/business/la-fi-senate-drug-price-study-20161221-story.html> ("The companies raised prices—not to fund research to discover new drugs—but to boost profits for executives and investors.").

9. Rachel Bluth, *Should the U.S. Make It Easier to Import Prescription Drugs?*, PBS (Mar. 22, 2017, 10:33 AM), <https://www.pbs.org/newshour/health/u-s-make-easier-import-prescription-drugs>.

regulation, similar to that imposed by the Affordable Care Act (ACA) for health insurance companies.

A. MLR Regulation Corrects Market Failure in the Insurance Industry

Imposing an MLR regulation would assist in managing the market failures in the pharmaceutical industry, as it has for the health insurance industry. Market failure occurs when, for a variety of reasons, a market fails to function like a normal free market by not allocating resources efficiently or achieving price equilibrium.¹⁰ One type of market failure is inequality, in which transactions concentrate rewards in the hands of a few.¹¹ In the health insurance industry, inequality is exemplified when the free market economy fails to provide reasonable safeguards to prevent insurers from raising premiums – well beyond what a consumer would willingly spend – simply in order to concentrate wealth for the insurance executives.¹² Given the non-transparent and third-party payor natures of health insurance, normal market forces are often inadequate to achieve price equilibrium in this industry. The ACA’s insurance MLR regulation attempts to normalize resource allocation in this market by putting guidelines around how much revenue may be kept as profit or used for other administrative expenses.¹³

In general, an MLR distinguishes the dollars spent on “other” expenses, such as administrative expenses and profits, from “medical loss.”¹⁴ “Medical loss” is defined as care-related and improvement expenditures like treatment, providers’ salaries, and

10. *Types of Market Failure*, ECON. ONLINE, http://www.economicsonline.co.uk/Market_failures/Types_of_market_failure.html (last visited Dec. 27, 2017).

11. *Id.*

12. See Wendell Potter, *Why Big Insurance Adores the American Health Care Act*, MOYERS & CO. (Mar. 23, 2017), <http://billmoyers.com/story/why-big-insurance-adores-the-american-health-care-act/>; see also *Fighting Unreasonable Health Insurance Premium Increases*, CTR. FOR MEDICARE & MEDICAID SERV., <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ratereview05192011a.html> (last updated Nov. 16, 2011) (laying out the unexplained rapidly rising health insurance premiums and other health insurance trends pre-ACA that supported the need for the insurance MLR regulation).

13. See generally 45 C.F.R. § 158 (2017).

14. *Medical Loss Ratio*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/medical-loss-ratio-MLR/> (last visited Feb. 22, 2017).

research and development (R&D) costs.¹⁵ “Other” expenses include those providing relatively less value directly to the consumer, such as overhead, marketing, C-suite salaries, and profits.¹⁶ The ACA’s MLR regulation requires health insurance companies that keep more than 15% of their income from large employer plans for these “other” expenses (or 20% from small employer and individual plans) to rebate the excess back to the consumer.¹⁷ The regulation establishes an 85:15 or 80:20 ratio: Insurers must spend 85% or 80% of their revenues directly on “medical loss.” In doing so, the MLR regulation ensures that health insurers provide a reasonable amount of value to the consumer, in effect moderating their premium hikes.¹⁸ Consequently, the MLR regulation incentivizes insurers to invest in value-promoting care and improvements, while refining efficiencies in less value-adding areas — particularly by reducing administrative waste and outlandish profits. In an industry where normal free market forces are inadequate, the ACA’s MLR regulation has successfully pared down insurers’ “other” costs, including profits.¹⁹

B. MLR Regulation Returns Billions to Consumers

Since the enactment of the health insurance MLR regulation, health insurance companies have returned billions of dollars that were previously kept for profits and other administrative costs in

15. *Medical Loss Ratio*, *supra* note 14; Louise Norris, *Billions in ACA Rebates Show 80/20 Rule’s Impact*, HEALTHINSURANCE.ORG (Jan. 18, 2018), <https://www.healthinsurance.org/affordable-care-act/medical-loss-ratio-returns-nearly-2b-to-consumers/>; *Rate Review & the 80/20 Rule*, HEALTHCARE.GOV, <https://www.healthcare.gov/health-care-law-protections/rate-review/> (last visited Feb. 22, 2017).

16. *Medical Loss Ratio*, *supra* note 14.

17. *Id.*; Norris, *supra* note 15; *Rate Review & the 80/20 Rule*, *supra* note 15. By law, insurance companies cannot base the price of health premiums on health, medical history, or gender. They can only account for five things when setting premium prices: age, location, tobacco use, individual versus family enrollment, or plan category. *How Insurance Companies Set Health Premiums*, HEALTHCARE.GOV, <https://www.healthcare.gov/how-plans-set-your-premiums/> (last visited Nov. 7, 2017).

18. U.S. GOV’T ACCOUNTABILITY OFF., GAO-14-580, PRIVATE HEALTH INSURANCE: EARLY EFFECTS OF MEDICAL LOSS RATIO REQUIREMENTS AND REBATES ON INSURERS AND ENROLLEES 1 (2014) [hereinafter PRIVATE HEALTH INSURANCE].

19. *See* Norris, *supra* note 15.

the form of rebates for employers and consumers.²⁰ For example, seventy-five percent of the money returned was originally used to pay brokers and agents, but since brokers' and agents' pay fell on the "other" side of the MLR ratio, insurers had to rebate the excess funds so as to meet the ratio threshold.²¹ Insurers are further adjusting payments to agents and brokers, some reporting the MLR regulation thresholds as the primary motivator.²² Most remarkably, insurers' underwriting gain (i.e., profits) diminished markedly from \$8.8 to \$3.7 billion, from 2012 to 2014.²³ Specifically, insurers returned \$1.1 billion in rebates to consumers in 2012, \$504 million in 2013, down to \$333 million in 2014, up to \$469 million in 2015, and \$397 million in 2016.²⁴ The ACA's MLR regulation did its job. Insurers are right-sizing their premiums and rebating billions of dollars back to employers and individuals.²⁵ While tightening their belts and squeezing out less value-adding costs, these companies still recoup healthy profits.

Importantly, the MLR ratio is not arbitrary or impractical. Before the ACA's MLR regulation was enacted, most insurers (77% of insurers in the large employer market and 70% in the small market)

20. Specifically, insurers returned \$1.1 billion in rebates in 2012, \$504 million for 2013, down to \$333 million in 2014, up to \$469 million in 2015, and \$397 million in 2016. Norris, *supra* note 15.

21. PRIVATE HEALTH INSURANCE, *supra* note 18, at 18.

22. Furthermore, administrative costs for the 2014 individual market decreased despite an increase in premium revenue. This indicates insurers are expanding coverage to more individuals while maintaining efficient administrative expenses. *See id.* at 21; *see also* Mark A. Hall & Michael J. McCue, *Realizing Health Reform's Potential: How Has the Affordable Care Act Affected Health Insurers' Financial Performance?*, COMMONWEALTH FUND (July 2016), http://www.commonwealthfund.org/~media/files/publications/issue-brief/2016/jul/1886_hall_insurers_financial_performance_aca_rb_revised_07_26_2016.pdf.

23. Hall, *supra* note 22, at 4-5. To note, in 2017 insurers reported markedly increased underwriting gain and net income all while remaining within the ratio requirements. This merits further investigation, including into the effects of the recent repeal of the health insurer tax. Perhaps the influx of subsidy money means the resulting ratio of "other" should be smaller. *See* Bob Herman, *Blue Cross Blue Shield Insurers Are Still Doing Well*, AXIOS (Nov. 7, 2017), <https://www.axios.com/the-blue-cross-blue-shield-insurers-are-still-doing-well-2507217868.html>. One possible explanation is diversification of portfolios. For example, UnitedHealth Group has cut back their participation in the "money-losing" individual market from thirty-four states to three and diversified into various other profitable areas, such as data management, outpatient clinics, and surgical services. Jeff Sommer, *Gripes About Obamacare Aside, Health Insurers Are in a Profit Spiral*, N.Y. TIMES (Mar. 18, 2017), <https://www.nytimes.com/2017/03/18/business/health-insurers-profit.html>.

24. Norris, *supra* note 15.

25. *Id.*

already met these standards.²⁶ Furthermore, the legislation permits the Secretary of Health and Human Services “to adjust the MLR standard for the individual market in a State if requiring issuers to meet that standard may destabilize the individual market.”²⁷ The ratio’s purpose is not to impinge on financial viability; instead, it is to provide a check on insurer’s expenses when the free market alone has failed to do so. Ultimately, the MLR regulation acts as a value guardrail. While market instability and an influx of costs have pushed health insurance premiums upward, the MLR regulation has provided a much-needed check on profits and other expenses to ensure a certain level of consumer value. Otherwise, this value would be sacrificed for profits and shareholder dividends in this abnormal market.

C. Extend the MLR Regulation to the Pharmaceutical Industry

This Note proposes applying a similar MLR regulation to the pharmaceutical industry, another industry characterized by market failure. Similar to its effect on the health insurance industry, this ratio regulation would provide a much-needed check on excessive profits in the pharmaceutical industry. It would also ensure a certain level of value for consumers. Instead of impinging on financial viability, it would simply erect guardrails to stabilize this abnormal pharmaceutical market. Doing so could also incentivize drug companies to right-size their drug prices. Although the MLR ratio varies considerably by company, the ratio for the pharmaceutical industry, and specifically for Big Pharma, currently hovers somewhere around 30% “medical loss” and 70% “other” expenses.²⁸ Specifically, the pharmaceutical industry on average spends 70% of revenue on its “other” expenses: 23% of its revenues on marketing, 30% on manufacturing, and 21% on profits.²⁹ The “medical loss”

26. Still, less than half of the individual market insurers (43%) met the standard. *Explaining Health Care Reform: Medical Loss Ratio (MLR)*, KAISER FAMILY FOUND. (Feb. 29, 2012), <http://kff.org/health-reform/fact-sheet/explaining-health-care-reform-medical-loss-ratio-mlr/>.

27. 45 C.F.R. § 158.101 (2017).

28. See *infra* notes 29 and 30.

29. In 2013, the profit margin for pharmaceutical companies ranged from 10% to 42%, with an average of 18%. Pfizer was at the top of the profit list, and four other companies (Hoffman-La Roche, AbbVie, GlaxoSmithKline, and Eli Lilly) had profit margins of more than 20%. Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS

makes up about 30%, including 17% on R&D.³⁰ Due to differences between the two industries, this proposal acknowledges that the insurance industry's 80:20 ratio may not be practical here.³¹ Therefore, this proposal recommends a ratio of 40:60 for the pharmaceutical industry and, if necessary, a profit cap around 12% (down from the current 21%).³²

Part II discusses how the healthcare market's abnormal nature results in market failure in the pharmaceutical market. Part III enumerates the resultant disproportionate profit garnering in the pharmaceutical industry. Part IV proposes the application of an MLR regulation to the pharmaceutical industry to right this market, laying out ratio details, the incentives that result from assigning various expense categories to different sides of the ratio, and other related reasoning. Furthermore, it argues that applying the MLR regulation to the pharmaceutical industry provides a promising,

(Nov. 6, 2014), <http://www.bbc.com/news/business-28212223>. "[Twenty-one percent] is the 2015 profit margin that *Forbes* estimated for the healthcare technology industry, making it by far the most profitable industry of all, with major and generic pharmaceutical companies leading the way. The company really setting the pace is Gilead Sciences (NASDAQ:GILD), which has a profit margin of nearly 53% over the last 12 months." Speights, *supra* note 7. As a point of reference, the profit margin of pharmaceutical companies was essentially the same as that of banks (19%), but the banks' range of profit was lower, from 5% to 29%. SUZANNE M. KIRCHHOFF, CONG. RESEARCH SERV., R42735, MEDICAL LOSS RATIO REQUIREMENTS UNDER THE PATIENT PROTECTION AND AFFORDABLE CARE ACT (ACA): ISSUES FOR CONGRESS (2014); Prabir Basu et al., *Analysis of Manufacturing Costs in Pharmaceutical Companies*, 3 J. OF PHARMACEUTICAL INNOVATION 30, 30 (2008) ("In the pharmaceutical industry, costs attributed to manufacturing are a major part of a company's total expenses."), available at https://www.researchgate.net/publication/225466494_Analysis_of_Manufacturing_Costs_in_Pharmaceutical_Companies (accessed Mar. 13, 2018). "Manufacturing costs are a substantial part of their total cost structure. According to some estimates, these costs can be as high as 27-30% of sales for manufacturers of brand-name pharmaceuticals, more than double the share of costs for research and Development." *Id.*; Catherine D. Deangelis, *Big Pharma Profits and the Public Loses*, 94 MILBANK Q. 30, 30-33 (2016); ROCHE GROUP, FINANCE REPORT 2015, at 4 (2016), <http://www.roche.com/dam/jcr:74af99eb-b51a-4f13-88b2-aacaf9f53c0c/en/fb15e.pdf> (Pfizer, Hoffmann-La Roche, AbbVie, GlaxoSmithKline, and Eli Lilly).

30. See also Ben Adams, *The Top 10 Pharma R&D Budgets in 2016*, FIERCEBIOTECH (Apr. 26, 2017), <http://www.fiercebitech.com/special-report/top-10-pharma-r-d-budgets-2016> ("On average last year, the top 10 Big Pharmas spent just over 17% of their top line on research, with GlaxoSmithKline spending the second least in percentage terms at 12.9%, and the least in absolute numbers at £3.62 billion (\$4.49 billion).").

31. See *supra* note 15.

32. See Deangelis, *supra* note 29, at 30; Anderson, *supra* note 32.

collaborative solution to one of the nation's most pressing health-care cost conundrums. Part V concludes.

II. ABNORMAL MARKET FORCES IN THE HEALTHCARE INDUSTRY RESULT IN MARKET FAILURE

Normal market forces usually curb a good's price to a market equilibrium—a price amenable to both buyer and seller.³³ However, the unique arrangements in the American healthcare industry effectuate a market that lacks these steadying forces.³⁴ Normal market forces include buyers who are reasonably well informed, make purchases independent of third-party payors (e.g., insurance companies), and have multiple choices among suppliers.³⁵ These and other forces combine with basic supply and demand principles to create price equilibrium.³⁶ Admittedly, there are areas in healthcare that could be categorized as “normal” markets where healthcare is clearly a “product” for sale, such as elective eye surgeries, Fitbits, and over-the-counter Tylenol. But the market for prescription medication is anything but normal. In large part, this is due to the fact that it lacks many of these normal factors—quality and price transparency, independent buyers using their own money, and multiple options of goods from which to choose.³⁷ Without the normal “free market” forces, the laws of

33. Robert J. Graham, *How to Determine Price: Find Economic Equilibrium Between Supply and Demand*, DUMMIES, <http://www.dummies.com/education/economics/how-to-determine-price-find-economic-equilibrium-between-supply-and-demand> (last visited Jan. 24, 2018); Fiona M. Scott Morton, *The Problems of Price Controls*, 24 REGULATION 50, 50 (2001) (“The determining of market prices through the dynamic interaction of supply and demand is the basic building block of economics. . . . This dynamic interaction produces an equilibrium market price; when buyers and sellers transact freely, the price that results causes the quantity demanded by consumers to exactly equal the supply produced by sellers.”).

34. See Chris Ladd, *There Is Never a ‘Free Market’ in Health Care*, FORBES (Mar. 7, 2017, 10:00 AM), <https://www.forbes.com/sites/chrisladd/2017/03/07/there-is-never-a-free-market-in-health-care/#2427c6b71147>.

35. Alain C. Enthoven, *Market Forces and Efficient Health Care Systems*, 23 HEALTH AFF. 25, 25 (2004).

36. *Id.*

37. Shelby Livingston, *Is the Price Right? Solving Healthcare’s Transparency Problem*, MOD. HEALTHCARE, <http://www.modernhealthcare.com/reports/achieving-transparency-in-healthcare/#/> (“[T]he industry undoubtedly remains one of the nation’s most opaque. The scarcity of price and quality information is often blamed for the high cost of care.”) (last visited Dec. 20, 2017).

supply and demand do not balance each other in a way that leads to affordable pricing.

*A. Lack of Transparency in the Pharmaceutical Industry
Contributes to Market Failure*

In a normal market, consumers are well informed about their needs and choices.³⁸ For example, individuals know their shoe size and preferred shoe styles, and they can research the prices and quality of various shoes online or in stores.³⁹ This information empowers them to decide which shoes meet their needs, weigh the price and quality options, and make reasoned decisions regarding which shoes to buy. However, in the pharmaceutical industry similar transparency is much more difficult due to information and control asymmetries between patient and provider, a lack of transparent pricing, and healthcare's highly inelastic market.

1. Information and control asymmetries between physicians and patients hamper consumer power

Prescription drug consumers consistently lack information that is normally available to consumers in other markets. This partly stems from power and information asymmetries between prescribers and their patients.⁴⁰ Unlike shoe purchasers, ordinary prescription drug consumers do not have the necessary training to identify their health needs or the remedying medications.⁴¹ Rather,

38. See Enthoven, *supra* note 35, at 25.

39. *Perfect Competition*, ECONOMICS ONLINE, http://www.economicsonline.co.uk/Business_economics/Perfect_competition.html (last visited Feb. 12, 2018); see also *Consumer Protection*, ENCYCLOPEDIA.COM, <http://www.encyclopedia.com/social-sciences-and-law/law/law/consumer-product-safety-act> (last visited Feb. 12, 2018) (discussing what information consumers should reasonably be able to expect).

40. "The information asymmetry experienced by consumers, providers, and payers shield these critical stakeholders from the information they need to make decisions about what works best for them." INST. OF MEDICINE, *THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES* 335 (Pierre L. Yong, Robert S. Saunders & LeighAnne Olson eds., 2010), <https://www.ncbi.nlm.nih.gov/books/NBK53921/>. "As a rule the doctor has relevant information that the patient lacks." Stephen Shmanske, *Information Asymmetries in Health Services: The Market Can Cope*, 1 INDEP. REV. 191, 197 (1996).

41. Ariel Katz, *Pharmaceutical Lemons: Innovation and Regulation in the Drug Industry*, 14 MICH. TELECOMM. & TECH. L. REV. 1, 14 (2007).

Even more difficult for most consumers is knowing and evaluating the expected long-term effects of the drug, the possible complications, or the reactions

drug consumers are usually unaware of either the existence of or the differences between prescription drugs like Prilosec and Protonix, or Perjeta and Pegintron. And drugs are arguably more complex than shoes and other commodities and require a certain level of training to know which is appropriate for which medical need. In fact, the reasons patients even go to doctors in the first place include their extensive medical expertise and prescription pads, both of which patients lack.⁴² They turn to the experts whose years of training enable them to identify health needs, weigh options, and then sign that pad—because without a prescriber’s signature, patients cannot obtain prescription medication, even if the information about the medical need or the prescribed medication were more transparent.⁴³ The same is not true for shoes or houses. Not even car or computer repairs require a graduate-level licensed provider. In fact, with only a little training, consumers can buy and change their own engine oil or tires. But with prescription drugs the capacity to understand sufficiently the medical nuances and to consider the choices, as well as the power to access the prescription medication, lies with prescribers.⁴⁴ Sometimes only the

with other substances. Moreover, even if they were affluent enough to do so, because combining different drugs may be ineffective, or even lethal, consumers cannot simply try every drug and every cure until they find the one that works. They need to know before they commit to a specific drug that it is likely to work.

Id. (internal citations omitted).

42. See Shmanske, *supra* note 40, at 191 (“[O]ne type of asymmetric information occurs because the doctor typically has knowledge the patient does not—that’s why the patient sees the doctor in the first place.”).

43. “A drug intended for human use . . . shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug . . .” 21 U.S.C. § 353(b)(1)(B) (2012) (“The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale.”).

44. Katz *supra*, note 41.

Perhaps more importantly, however dramatic the effect of a drug on one person may be, since the effect of drugs may vary from person to person, meaningful information on drugs’ quality can be obtained only by looking at large samples and carefully applying statistical methods. Not only is this type of epidemiological research beyond the reach of consumers, it is also beyond the reach of most practicing physicians. Therefore, if sellers (drug companies) have better information about the efficacy and safety of their products, severe asymmetry of information about the quality of drugs (their efficacy and safety) may occur.

Id. at 14 (internal citations omitted).

drug companies themselves have the information.⁴⁵ Overall, the information and power imbalances in the prescription drug industry place incredible power into the hands of healthcare providers, beyond the reach of the average drug consumer.⁴⁶ As such, the consumer loses much of the ability to directly choose cheaper products and thus coax prices down to reasonable levels. Furthermore, the cost of meeting with a provider for the prescription further adds to the rising cost of drug distribution and other healthcare costs.

Some argue that these asymmetries are inconsequential since other markets with both information and power asymmetries, such as car repairs and housing markets, have coped and achieved some level of market equilibrium.⁴⁷ However, both cars and houses are some of our most expensive commodities, in part due to the potential for danger and resultant care we take to ensure our safety. Furthermore, the potential inconvenience or additional cost resulting from a mistake in car repairs or a housing purchase is very different than the potential bodily harm or even death resulting from misguided medication prescription. Certainly, harm done to a car or house can be costly. But it is much less personal.

Moreover, with individual differences in symptoms and anatomy, it is even harder for prescribers to know at the outset of a

45. The pharmaceutical companies have done the extensive chemical and epidemiological research on their products and are then responsible to disseminate that information out to prescribers. *Id.* "Therefore, if sellers (drug companies) have better information about the efficacy and safety of their products, severe asymmetry of information about the quality of drugs (their efficacy and safety) may occur." *Id.* at 14 n.65.

46. Charles Ornstein, Ryann Grochowski Jones & Mike Tigas, *Drug-Company Payments Mirror Doctors' Brand-Name Prescribing*, NPR (Mar. 17, 2016, 5:00 AM), <http://www.npr.org/sections/health-shots/2016/03/17/470679452/drug-company-payments-mirror-doctors-brand-name-prescribing> ("A ProPublica analysis has found that doctors who receive payments from the medical industry do indeed prescribe drugs differently on average than their colleagues who don't."); Shmanske, *supra* note 40, at 198 ("[P]atients still have no guarantee that competent, licensed doctors will not use their informational advantage for personal gain.").

47. See Shmanske, *supra* note 40, at 197.

The information asymmetry in the doctor-patient relationship is simply another case of scarcity with which the market can cope. . . . Getting a second opinion in health-care markets is comparable with comparison shopping in other markets, yet no one claims that markets fail because prudent buyers of clothing expend time, effort, and resources shopping or because would-be homebuyers order termite inspections.

Id.

medical encounter which medication is appropriate and how much of it to prescribe.⁴⁸ When someone walks into a hospital, the provider cannot run a manufacturer-guided diagnostic or look up the make and model to find the appropriate repair part like a car mechanic can when changing engine oil or spark plugs. Finding the right antibiotic, chemotherapy treatment, or more notably, the right psychiatric medication, often requires time and periods of trial and error, even for extensively trained physicians. This uncertainty characterizes the healthcare market more so than other markets.⁴⁹ This is why it is called a medical “practice.” Putting these decisions into the hands of untrained buyers is almost unconscionable—similar to handing car keys to a six-year-old. Consenting to the information asymmetry is essentially an imperative to engage in this market. Yet, at the same time, this asymmetry weakens buyer power, and thus the forces to lower prices are insufficient to achieve true price equilibrium.

2. Transparent drug pricing is often impractical, and the resultant lack of price information further limits buyer power

Buyer power is also limited due to costs that are often opaque—even less transparent than the need for or the fit of a specific medication.⁵⁰ Unlike shoes, prescription drugs are not price tagged, nor do hospitals list drug prices on a sign above the welcome desk like oil changes at a car repair shop.⁵¹ Prescribers don’t hand over a priced menu during their hospital rounds when they ask, “Do you prefer Zofran or Phenergan? Percocet or Norco?” In fact, doctors, on average, discuss drug costs with only 2.6 out of 10 patients.⁵² At

48. Anna D. Sinaiko & Meredith B. Rosenthal, *Increased Price Transparency in Health Care – Challenges and Potential Effects*, 364 NEW ENG. J. MED. 891, 891–93 (2011).

49. See Paul K.J. Han, William M.P. Klein & Neeraj K. Arora, *Varieties of Uncertainty in Health Care: A Conceptual Taxonomy*, 31 MED. DECISION MAKING 828, 828–38 (2011).

50. Livingston, *supra* note 37 (“[T]he industry undoubtedly remains one of the nation’s most opaque. The scarcity of price and quality information is often blamed for the high cost of care.”) (last visited Dec. 20, 2017).

51. Cf. *Featured Auto Services*, WALMART, <https://www.walmart.com/cp/auto-services/1087266> (last visited Dec. 27, 2017).

52. *Doctors and Rx Prices: Ending the Silence*, CONSUMER REP. (June 21, 2016), <https://www.consumerreports.org/drugs/doctors-and-rx-prices-ending-the-silence/> (“[Six] percent of people currently taking a prescription drug found out about the cost of their new medication during a doctor’s visit, when the prescription was being written.”).

times, this is because even the physicians are unaware of drug costs, further limiting patients' access to price information.⁵³ Once the medication is prescribed, nurses administering the ordered medication to the patients usually do not discuss the cost.⁵⁴ Not only are they similarly unaware of the price, but some would even consider that type of discussion unethical.⁵⁵

Drug prices are complicated. While consumers are usually aware of their drug copay, the ultimate drug price is often obscured by insurance rebates or discounts mandated to government payors (e.g., Medicaid).⁵⁶ This leads to elevated, ever-fluctuating list prices that determine the consumers' portion to be paid.⁵⁷ Complex "drug formularies" from the insurance companies further complicate drug prices because consumers will pay vastly different amounts depending on the drug status (e.g., cheaper "preferred drugs" or generics, or expensive specialty and brand drugs).⁵⁸ Even calling to get a price estimate can be a fruitless endeavor. "It depends on your insurance," is a far-too-common response. Overall, drug prices are

53. See Livingston, *supra* note 37 ("[C]linicians often don't know the price tag of the medical services they provide.").

54. See Lieberman & Ginsburg, *supra* note 3, at 1 ("The U.S. system for selling prescription medicines involves multiple parties, differs markedly for generic and brand drugs, has complex, nontransparent financial arrangements, and limits available information in asymmetric ways that disadvantage third-party payers and patients.").

55. In my experience, nurses make efforts to save patients money in simple ways. But when a patient is seriously ill the priority becomes the patient's care and comfort. Price discussions become superfluous and insensitive.

56. "[T]he complex charges for prescription drugs often range from co-payments of \$15-\$100 for 'preferred' drugs to 45% or more of the cost of specialty or non-preferred drugs." Grace-Marie Turner, *Price Transparency Is Critical to Drug Pricing Solutions*, FORBES (July 11, 2017, 4:59 PM), <https://www.forbes.com/sites/gracemarieturner/2017/07/11/price-transparency-is-critical-to-drug-pricing-solutions/#1193fda5204a>. "A huge system of drug rebates and discounts happens behind the scenes in the pharmaceutical supply chain, further distorting the market and confusing consumers about the actual price of a drug. Only a trickle of these discounts and rebates actually reaches the consumer." *Id.*

57. "Even though rebates paid by biopharmaceutical companies can substantially reduce the prices insurers and pharmacy benefit managers (PBMs) pay for brand medicines, insurers use list prices—rather than discounted prices—to determine how much to charge patients when they pay their share, further increasing what consumers pay." *Id.*

58. Insurance companies generally create complex "drug formularies" in which their insured patients pay less for "preferred" drugs, especially generics, but can pay much more for expensive brand and specialty drugs. Laurie Toich, *Drug Rebates: Do Patients Really Benefit?*, AM. J. PHARMACY BENEFITS (Apr. 26, 2017), <http://www.ajpb.com/news/drug-rebates-do-patients-really-benefit>; see also Turner, *supra* note 56.

much less transparent than the prices of other products.⁵⁹ Many suppliers refuse even to disclose how they set prices.⁶⁰ And even when price transparency is not an issue, there is little patients can do to shop around for the best price if they are locked in to an insurance plan with a set drug copay. A copay that is always a set amount irrespective of the drug prescribed further removes the consumer from the cost information and reduces buyer power.

Furthermore, the urgent nature of healthcare itself differentiates it from other industries. Few persons would stop emergency medical services in an ambulance or in the intensive care unit to price-compare drugs or obtain approval from the consumer. Nor does it do much good to explain to a patient undergoing surgery the price of all the medicines the hospital has contracted to use for anesthesia and preventive antibiotics. It is also unreasonable to explain to sick, hospitalized patients (or their families) all of the drugs that are being used in the patient's care. These examples demonstrate that pushing for drug price transparency to reduce the cost of these particularly expensive areas in healthcare is impractical. Since consumers' access to this information—and thus their ability to compare quality and price—is severely limited, or even at times impossible, buyer power rests mainly outside their control. Instead, the buyer power lies dominantly in the hands of providers and insurers.⁶¹

Admittedly, prescribers and patients have some increasing access to the price of medications, as well as increased incentive to pay attention.⁶² A price comparison may be accessible to patients

59. See Livingston, *supra* note 37 (“For the most part, consumers remain in the dark about what they will be asked to pay after visiting a primary-care doctor or undergoing an inpatient procedure. In that way, healthcare is unlike every other aspect of the consumer experience in America. It would be unimaginable to leave a broken-down car with a mechanic before getting a cost estimate, for example. But in healthcare, ‘everyone’s flying blind.’”).

60. *Id.*

61. *Id.*

62. See, e.g., Patrick McGreevy, *More Transparency Proposed for Prescription Drug Price Increases Under Bill Passed by California Senate*, L.A. TIMES (May 30, 2017, 4:33 PM), <http://www.latimes.com/politics/essential/la-pol-ca-essential-politics-updates-more-sunlight-proposed-for-prescription-1496186778-htmstory.html> (“Alarmed by skyrocketing prices for some prescription drugs, the California Senate on Tuesday approved a measure aimed at increasing pressure to hold down costs to consumers by requiring more public reporting of price hikes.”); see also Livingston, *supra* note 37 (“[M]any other healthcare organizations,

via a call to a local pharmacy or by visiting certain websites.⁶³ The majority of health plans (self-insured employers in particular) offer cost-estimating tools for healthcare prices.⁶⁴ And some insurance companies list drug prices per drug tier.⁶⁵ Yet sources indicate few patients (three percent) actually compare costs of care among providers—often because they are unaware of the above-mentioned tools.⁶⁶ And frequently drug copays are set by the insurer or depend on the pharmacy, so price comparison at the time of prescribing would be practically useless.

3. Healthcare is a highly inelastic market

Most importantly, unlike a physical body, commodities like shoes and cars can be replaced. In commodities markets, the repair, maintenance, or inspection costs are all controlled by normal market forces, regardless of the information and power imbalances inherent in the service. When shoes wear out, the consumer throws them away and buys a new pair at a normal market rate. If the repair costs for a damaged car outweigh replacement costs, the car is “totaled.” The consumer compares the price and quality of new models and uses what equity is left on the “totaled” car to purchase a new one—again at a normal market rate.

Healthcare offers consumers no such alternatives. There is no market-controlled replacement model available if cancer metastasizes throughout a body or when heart-failure-induced fluid build-up makes it difficult to breathe. Grandma isn’t “totaled” when her urinary tract infections become resistant to normal antibiotics, nor is mom when her cancer pain becomes unbearable. It is hard to cut off funds for chronic pain or a failing body because, unlike a car,

from providers to insurers, are working to increase price transparency for the services they provide, to varying degrees of success.”).

63. See, e.g., PHARMACYCHECKER.COM, <https://www.pharmacychecker.com> (last visited Jan. 19, 2017); SCRIPTSAVE WELLRX, <https://www.wellrx.com/prescriptions> (last visited Jan. 19, 2017).

64. See Livingston, *supra* note 37 (“Nearly all major health plans offer a cost-estimator tool or contract with a third-party vendor to provide one so that commercially insured patients can search for a common clinical service and obtain a cost estimate.”).

65. *How Do Drug Tiers Work?*, BLUE CROSS BLUE SHIELD BLUE CARE NETWORK OF MICHIGAN, <http://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html> (last updated Oct. 2, 2017).

66. See Livingston, *supra* note 37.

mom is irreplaceable. There is no “going market rate” for the price of a loved one. Consumers cannot refuse to participate in this market, so the medical bills pile up. In other words, this market is highly inelastic; no matter how high prices rise, the demand for life-saving drugs stays constant. As such, the costs of life-saving or quality-of-life-enhancing prescription drugs from profit-maximizing companies know few market bounds. To illustrate, the biggest cash cow for the pharmaceutical industry is oncology (worth \$78.9 billion).⁶⁷ Pharmacyclics’ cancer drug Ibrutinib alone raked in revenue over *67 times* the R&D investment.⁶⁸ Clearly, consumers’ usual qualms over paying astronomical prices were absent for this product. Either they didn’t care what it cost, or they didn’t know – probably both. In general, when cancer, or any other debilitating mental or physical illness, rears its ugly head buyers have priorities other than deal-shopping. In a way, it is a collective sense of humanity – an unwillingness to begrudge the funds needed in order to save a life or prolong suffering – that throws normal market forces out the window. The normal market is not designed for life-or-death situations. Drugs are.

Combined together, the information imbalance between patient and prescriber, opaque pricing information, and the strong sense of empathy intrinsic to human nature all render the prescription drug market uniquely inelastic. Consequently, with so much power outside consumer control, this market’s asymmetries of information and control cripple the patient-buyer’s typical ability to compare options, match them to their needs, and pick those options that are simultaneously effective and affordable.⁶⁹

67. Bryan Mc Govern, *Why Consider Investing in Pharmaceutical Stocks?*, INVESTING NEWS (Jan. 1, 2018), <https://investingnews.com/daily/life-science-investing/pharmaceutical-investing/investing-in-pharmaceutical-stocks/> (“The 2015 report from Statista also reveals some of the biggest cash cows for the sector, with oncology pharma taking the lead on an indicated value in sales of \$78.9 billion.”).

68. Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval*, 177 J. AM. MED. ASS’N INTERNAL MED. 1569, 1572 (2017).

69. Ironically, even if we did have price transparency, it is not guaranteed to lower costs. One Harvard Medical School study actually concluded that offering price estimators did not necessarily lower costs; it often raised them, as people equated higher cost with higher quality. See Livingston, *supra* note 37 (“[A] 2016 Harvard Medical School study . . . found that offering employees a price-estimator tool (in the study’s case, the Truven calculator) did not lower healthcare spending. In fact, employees who used the tool ended up

B. Third-Party Payors Further Frustrate Aspects of a Normal Market

The third-party payor role of health insurance is unlike other types of insurance and further complicates this market. Consumers in most commodity markets control their money when they transfer it directly to sellers in exchange for goods.⁷⁰ For example, when one buys groceries or a cell phone, the known amount of cash transfers directly to the seller at the time the customer acquires the goods. Even when the immediate exchange between buyer and seller is obscured by an independent middleman, such as a credit card company, the customer is usually aware of and responsible for the whole price of the purchased item. Yet the middleman role played by health insurers obscures the amount paid and insulates the consumer from the loss.

A middleman is one who facilitates transactions between a buyer and seller for a fee, often resulting in price increases.⁷¹ Insurers are a specific type of middleman. Unlike retailers or other types of middlemen, insurers collect scheduled payments, or premiums, from customers in exchange for a guarantee of some compensation in the event of an expensive loss – such as an earthquake or hospital visit.⁷² In the event of such a loss, the customer pays a portion as a deductible or out-of-pocket maximum, while the insurer pays the rest.⁷³ In essence, insurance transfers risk “from an individual to a company,” pooling it with other individuals so as to mitigate the losses felt by any one individual.⁷⁴ Health insurers thus use pooled resources to insulate the financial losses of

spending more than those who didn't. The researchers suggested consumers could spend more if they equate high cost with high quality.”). The Livingston article also quotes Alan Sager, a Boston University professor of health law, policy, and management, offering his opinion: “Asking patients to become informed about price and quality, and make decisions about diagnosis and treatment in light of information about price and quality, I think that's largely a waste of time; and worse, it imposes radically unfair burdens on many patients.” *Id.*

70. *See Consumer Spending*, INVESTOPEDIA, <https://www.investopedia.com/terms/c/consumer-spending.asp> (last visited Feb. 12, 2018).

71. *Middleman*, INVESTOPEDIA, <http://www.investopedia.com/terms/m/middleman.asp> (last visited Jan. 15, 2018).

72. CATHY PARETO, *Introduction to Insurance*, INVESTOPEDIA (2010), <http://elibrary.vssdcollege.ac.in/web/data/books-com-sc/bcom-3/Introduction%20To%20insurance.pdf>.

73. *Id.*

74. *Glossary of Insurance Terms*, NAT'L ASS'N OF INS. COMMISSIONERS, http://www.naic.org/consumer_glossary.htm (last visited Jan. 15, 2018).

prescription drug (and other) costs felt by any one consumer. By its very design, health insurance is meant to limit a consumer's exposure to healthcare costs. For some types of insurance (e.g., fire or earthquake insurance) this design may not pose a substantial cost burden. However, because health insurance is used much more frequently than other types of insurance, costs escalate with corresponding frequency.

1. The frequent need for health insurance burdens consumers more so than other insurance types

Health insurance plays a much larger role in a person's habitual finances than other insurance types. For commodities like cars and houses, an insurer's role is largely limited to rarer catastrophic situations like a car crash or fire.⁷⁵ Yet health insurance pays for much more than just catastrophes. While brake repairs or oil changes are not covered by car insurance, preventive health screenings and other checkups are often covered by health insurance. While car insurance does not pay for the gas needed to run the engine, health insurance often covers drugs that must be taken on a daily basis. While many may not need these daily medications when they are young and healthy, few escape the infirmities of old age. Additionally, one may have ailing dependents requiring significant resources. Eventually, everyone needs health insurance. In other words, unlike other insurance types, health insurance is constantly necessary to help defray healthcare costs for a significant number of people.

This unusually large role played by insurers in the pharmaceutical industry reduces consumers' access to information and, therefore, their ability to price discriminate between products. Specifically, predetermined provider networks frustrate the impact that price comparisons and second opinions have on promoting competitive pricing the way they do in other markets.⁷⁶ Usually

75. *Mandated Car Insurance vs. Mandated Health Insurance: What's the Difference?*, UNITED POLICYHOLDERS, <http://www.uphelp.org/news/mandated-car-insurance-vs-mandated-health-insurance-what%E2%80%99s-difference/2012-10-31> (last visited Jan. 15, 2018) ("While health insurance covers preventive measures, including checkups and screenings, as well as catastrophic events, such as cancer treatments, heart surgery or intensive care, auto insurance doesn't cover preventive measures such as oil changes and brake checks.").

76. *Preferred Provider Organization (PPO)*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/preferred-provider-organization-PPO/> (last visited Jan. 15, 2018).

insurance companies charge the same copay at any pharmacy in their preferred network; seeing different providers within the network doesn't change that. And leaving the insurer's preferred network means paying more, which further limits patients' choices. This is vastly different than other types of insurance; for example, car insurers don't stipulate which mechanics to see or at what dealer to shop. And changing health insurance companies in order to find a cheaper provider usually isn't an option because health insurers are either chosen by an employer or changed once a year on the Affordable Care Act's individual marketplace. Thus, insurers play a more continuous and invasive role in healthcare than in other markets – a role that proportionately limits drug consumers' buyer power.

Over the years, the health insurer's role has continued to expand as the pharmaceutical cost burden has shifted from individuals to third-party payors. Between 1960 and 1988, direct out-of-pocket expenditures fell 28%, while public financing increased 17.6% and private financing increased 10%.⁷⁷ Even now, third parties continue to shield costs. In 2015, 49% of Americans' health insurance was provided through an employer.⁷⁸ In addition, almost 85% of those enrolled in the ACA exchanges received healthcare subsidies from the government.⁷⁹ In reality, only about ten cents on every healthcare dollar are contributed directly from the patient.⁸⁰ The remaining cost is negotiated by insurers and the government.⁸¹

One ironic result of this cost shielding is that the insured end up paying more than they otherwise would, since normal pressures

77. Patricia M. Danzon, *Health Care Industry*, CONCISE ENCYCLOPEDIA OF ECONS. (1993), <http://www.econlib.org/library/Enc1/HealthCareIndustry.html>.

78. *Health Insurance Coverage of the Total Population*, KAISER FAM. FOUND., <https://www.kff.org/other/state-indicator/total-population/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D> (last visited Jan. 15, 2018) (webpage allows the user to examine the health care coverage of the population using a variety of filters).

79. See Louise Norris, *Will You Receive an Obamacare Premium Subsidy?*, HEALTHINSURANCE.ORG (Jan. 1, 2017), <https://www.healthinsurance.org/affordable-care-act/will-you-receive-an-obamacare-premium-subsidy/>.

80. John Graham, Opinion, *Surprise Medical Bills: A Growing Problem Requiring Price Transparency*, FORBES (Dec. 1, 2016, 10:14 AM), <https://www.forbes.com/sites/theapothecary/2016/12/01/surprise-medical-bills-a-growing-problem-requiring-price-transparency/#389daf3b7d27>.

81. *Id.*

to prevent costs from rising do not exist. In the first two years of the ACA's enactment, out-of-pocket spending plunged 21.4% for the poorest Americans.⁸² Yet, for the average American household, premiums rose 12%, which computes to an even larger dollar amount.⁸³ Healthcare costs that were avoided by some were compensated for by others. In essence, because health consumers have historically been shielded from the true cost of healthcare, without adequate government or normal market forces to rein in expenses, healthcare costs have risen stiflingly high. For many, the ACA has started to reverse the cost shielding trend by passing on these inflated costs as higher premiums and deductibles. Yet for the poorest, the cost shielding trend continues, and when consumers are so heavily insulated from the price, price becomes a non-issue — partly because it can't be an issue. Insurers and other third parties are necessary to aggregate the funds needed to cover elevated drug prices and thus mitigate the financial loss felt by consumers. The minimum-wage earner and the chronically sick could never afford the prices necessary to recoup the millions or billions of dollars required for a drug's development, prescribers' salaries, or other costs.⁸⁴ Free market advocates insist that eliminating the insurer would bring costs down. But again, this is not a normal market. Those most in need of the expensive care provided in this market (such as nursing homes, intensive care units, and cancer drugs) are often the least able to work to pay for it. Consequently, third parties must continue to shield consumers from some expensive prescription drug costs.

82. Dan Mangan, *Out-Of-Pocket Health Spending Dropped by Nearly 12 Percent – But Premiums Rose After Obamacare Rolled Out*, CNBC: HEALTH CARE (Jan 22, 2018, 2:31 PM), <https://www.cnbc.com/2018/01/22/out-of-pocket-health-spending-dropped-after-obamacare-rolled-out.html>.

83. *Id.*

84. *Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion*, TUFTS CTR. FOR STUDY DRUG DEV. (Nov. 18, 2014), <https://www.outsourcing-pharma.com/Article/2016/03/14/Tufts-examines-2.87bn-drug-development-cost> (“Developing a new prescription medicine that gains marketing approval, a process often lasting longer than a decade, is estimated to cost \$2,558 million . . .”).

2. Third-party payor costs contribute to elevated drug prices

Coordination among the various players in the healthcare industry carries additional hidden costs.⁸⁵ The overhead required for the negotiating middlemen (e.g., insurance company employees and executives, pharmacy benefit managers, pharmacists, drug reps) continues to drive up prices.⁸⁶ One notable example is pharmacy benefit managers (PBMs), on whom health plans depend for negotiating reimbursement terms with retail pharmacies.⁸⁷ These negotiations derive revenues from a combination of fees from the drug companies, as well as shared savings from the maintenance of pharmacy networks.⁸⁸

Ultimately, this unusually significant and disconnected third-party payor system both isolates consumers from financial loss and escalates costs in the pharmaceutical industry—indeed, in the whole healthcare system.⁸⁹ With removed consumers and profit-maximizing middlemen, drug prices can rise unfettered.⁹⁰

85. See Danzon, *supra* note 77.

86. See Jayne O'Donnell, *Do Drug Benefit Managers Reduce Health Costs?*, USA TODAY (Mar. 3, 2014, 2:30 PM), <https://www.usatoday.com/story/money/personalfinance/2014/03/03/pharmacy-benefit-managers-healthcare-costs-savings/5495317/> (“As more people become insured under the Affordable Care Act, PBMs will become both more profitable and powerful, which could thwart efforts to keep drug costs down, some critics say. Express Scripts, for example, is ranked 24th on the *Fortune* 500, thanks in part to its \$29 billion deal to buy Medco last year. Last month, the company said it expects to have 10% to 20% growth in earnings per share for the next several years, thanks to ‘health care trends, industry positioning and the overall environment.’”); Rob Sawicki, *How Insurance Companies Drive Up the Cost of Life-Saving Drugs for Patients*, HUFFINGTON POST (Dec. 4, 2015, 12:37 PM), http://www.huffingtonpost.com/rob-sawicki/how-insurance-companies-d_b_8710216.html; Turner, *supra* note 56 (“Caterpillar moved away from its PBM, suspecting that a quarter of the manufacturer’s \$150 million annual drug bill was being wasted.”).

87. See Lieberman & Ginsburg, *supra* note 3, at 1 (“Health plans rely heavily on contracted pharmacy benefit managers (PBMs) to negotiate reimbursement terms on their behalf with retail pharmacies. However, PBMs also operate mail-order pharmacies, giving them knowledge of actual generic drug costs. . . . This disincentive to keep generic drug reimbursement low for their health plan client poses an apparent conflict of interest for PBMs and increases health plan spending to the extent that a lack of information about actual generic drug costs leads to excessive reimbursement.”).

88. *Pharmacy Benefit Managers*, HEALTH AFFAIRS 1, 2 (2017), https://www.healthaffairs.org/doi/10.1377/hpb20171409.000178/full/healthpolicybrief_178.pdf.

89. See Lieberman & Ginsburg, *supra* note 3, at 1; see also Danzon, *supra* note 77.

90. See Paul Fronstin & Jack VanDerhei, *Savings Medicare Beneficiaries Need for Health Expenses: Some Couples Could Need as Much as \$350,000*, 38 EMP. BENEFIT RES. INST. NOTES 1, 7 (2017), https://www.ebri.org/pdf/notespdf/EBRI_Notes_Hlth-Svgs.v38no1_31Jan17.pdf; see also Norris, *supra* note 79.

C. Monopolistic Features Increase Drug Prices

Normal markets provide consumers with options.⁹¹ A market composed of multiple players prevents one seller from elevating a product's prices out of control, since buyers can buy the lower-priced option.⁹² Alternatively, a monopolized market lacks the rivalry between players that manages price and quality.⁹³ This dearth of competition concentrates selling power in the hands of a single player.⁹⁴ That player then has total control to raise prices.⁹⁵ In most markets, antitrust laws, such as the Federal Trade Commission Act, prevent monopolies and promote cost-curbing conditions.⁹⁶

However, the American pharmaceutical industry actually facilitates monopolies.⁹⁷ In some cases, medication and treatment options are limited because science hasn't advanced and few cures exist.⁹⁸ However, in many cases patents restrict choices by blocking innovation of new or improved products.⁹⁹ As defined by statute, a patent is "the right to exclude others from making, using, offering for sale, or selling . . . or importing the invention."¹⁰⁰ While patents

91. See Enthoven, *supra* note 35, at 25–27.

92. *Perfect Competition*, *supra* note 39.

93. *Monopoly*, INVESTOPEDIA, <http://www.investopedia.com/terms/m/monopoly.asp> (last visited Jan. 15, 2018).

A monopoly is characterized by the absence of competition, which can lead to high costs for consumers, inferior products and services, and corrupt behavior. A company that dominates a business sector or industry can use that dominance to its advantage, and at the expense of others. It can create artificial scarcities, fix prices, and otherwise circumvent natural laws of supply and demand. It can impede new entrants into the field, discriminate, and inhibit experimentation or new product development, while the public—robbed of the recourse of using a competitor—is at its mercy. A monopolized market often becomes an unequal, and even inefficient, one.

Id.

94. *Id.*

95. *Id.*

96. *The Antitrust Laws*, FED. TRADE COMMISSION, <https://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/antitrust-laws> (last visited Dec. 28, 2017).

97. See Aaron S. Kesselheim, Jerry Avorn & Ameet Sarpatwari, *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J. AM. MED. ASS'N 858, 859 (2016).

98. *8 Diseases for Which We Still Haven't Found a Cure*, EMGN.COM, <http://emgn.com/entertainment/8-diseases-still-havent-found-cure/> (last visited Dec. 28, 2017).

99. "[T]he current system is not working well . . . the most notable current feature of pharmaceutical innovation is the huge 'drought' in the development of new products." Michele Boldrin & David K. Levine, *The Case Against Patents*, 27 J. ECON. PERSP. 3, 13 (2013).

100. 35 U.S.C. § 154(a)(1) (2012).

help drug makers recoup R&D costs, they also restrict the choices available to consumers.¹⁰¹ These market exclusivity rights bypass normal market safeguards and create an ideal environment for single-product domination.¹⁰² As to be expected, this monopolization pushes up prices. In fact, the 2013 per capita spending for drugs in America was \$858—over twice the \$400 average of nineteen other industrialized nations (many with government-mandated drug price controls).¹⁰³ Further exacerbating rising prices is the requirement imposed on the majority of U.S. government drug payment plans (e.g., Medicare Part D) to cover nearly all drug products.¹⁰⁴ Under this requirement, drug companies can charge whatever they like, and insurers must pay for products if prescribed. Admittedly, prior authorizations and other tools do serve as a check on prices.¹⁰⁵ Yet as a whole, these pharmaceutical monopolies are a substantial factor in unrestricted prescription drug prices. It is true that patents provide the incentives for drug companies to take on the lengthy and risky process of developing new drugs. Thus, the solution may not be to get rid of the patent system. Instead, there may be a way to alter the market structure as a whole to allow for both patents and some restraint on drug prices.

*D. Without Normal Market Forces, Basic Supply and Demand
Fail to Establish Price Equilibrium*

The tension between supply and demand normally keeps a good's price within a manageable range.¹⁰⁶ Yet as explained in subsections A through C, this is not a normal market. The demand is almost constant for healthcare services, especially for long-term conditions, and thus buyer power is significantly weaker than in

101. See Kesselheim et al., *supra* note 97.

102. *See id.*

103. *Id.*

104. *See id.*

105. "Prior authorization is a requirement from your insurance company to your physician. The physician has to get specific medications (or operations) approved by the insurance company before the insurance company will provide full (or any) coverage for them." *Prior Authorization for Prescription Drugs: All You Need to Know*, HEALTH MARKETS (Mar. 17, 2016), <https://www.healthmarkets.com/resources/health-insurance/prior-authorization-for-prescription-drugs/>.

106. Adam Hayes, *Economics Basics: Supply and Demand*, INVESTOPEDIA, <http://www.investopedia.com/university/economics/economics3.asp> (last visited Dec. 28, 2017).

other normal markets. Without the buyer power to counteract the massive patent-enhanced seller power, a balanced price equilibrium is near impossible.

1. In general, supply and demand in normal markets result in all-around satisfactory prices

As demand rises, sellers can raise the price of a good without fear of alienating buyers.¹⁰⁷ For example, if a substantial number of buyers desire a Tesla sports car, producers can raise prices and still sell plenty of cars.¹⁰⁸ But when a good's price rises higher than the buyer's ability or desire to pay, demand drops.¹⁰⁹ For example, some demand for the Tesla is lost because of its exorbitant price. On the other hand, when demand decreases too low – like for a United Airlines flight after a scandal – so does the price.¹¹⁰ In order to maximize profits, sellers will attempt to produce and advertise more of the higher-priced merchandise (e.g., a Tesla car or the latest edition iPhone) over a cheaper model because the return on investment is much higher.¹¹¹ Together, supply and demand balance each other to reach a price equilibrium – an attractive price for both buyers and sellers.¹¹²

107. See *Pricing Products*, LUMEN LEARNING, <https://www.boundless.com/business/textbooks/boundless-business-textbook/product-and-pricing-strategies-15/pricing-products-96/impacts-of-supply-and-demand-on-pricing-449-1939/> (last visited Dec. 28, 2017) (“If demand increases and supply is unchanged, then it leads to a higher equilibrium price and higher quantity. If demand decreases and supply is unchanged, then it leads to a lower equilibrium price and lower quantity.”).

108. See Zachary Shahan, *Tesla's 2016 Deliveries = 76,230+ Vehicles, Production = 83,922 Vehicles*, CLEAN TECHNICA (Jan. 3, 2017), <https://cleantechnica.com/2017/01/03/teslas-2016-deliveries-production/>.

109. See Irena Asmundson, *Supply and Demand: Why Markets Tick*, INT'L MONETARY FUND, <http://www.imf.org/external/pubs/ft/fandd/basics/supdem.htm> (last updated July 29, 2017).

110. *Law of Supply and Demand*, INVESTOPEDIA, <http://www.investopedia.com/terms/l/law-of-supply-demand.asp> (last visited Dec. 28, 2017); see also Marquita Harris, *United Is Offering "Apology Fares" That Include Cheap Flights to Europe*, REFINERY29 (Apr. 26, 2017, 6:00 PM), <http://www.refinery29.com/2017/04/151846/united-airlines-apology-fares-cheap-flights> (“Prices have dropped significantly in less than two weeks. Those hefty discounts include: ‘round-trip flights to Trinidad and Tobago for as little as \$274 (typically \$550); flights to Paris for \$433 (typically \$800); and round-trip fares to Mexico City for less than \$200 (typically \$500),’ as noted by the site.”).

111. See Asmundson, *supra* note 109 (“The higher the price, the more suppliers are likely to produce.”).

112. Graham *supra*, note 33.

Yet without normal market forces, the pharmaceutical industry cannot establish this price equilibrium. Without the usual access to prices or the needed expertise to understand their needs and options, uninformed consumers cannot make informed choices between products. Nor are they always aware of increasing drug prices, especially when third-party payors veil the costs.¹¹³ Likewise, when a rare, life-changing drug has a monopoly on the market, the (inelastic) demand for this drug remains elevated—like that of the latest iPhone—but without any incentive to reduce and normalize the price for those waiting for the price reduction. In fact, per the principles of supply and demand, drug companies will spend billions of dollars on aggressive marketing strategies to promote more of their high-margin prescription drugs (like the Teslas and iPhones) and thus achieve higher profits.¹¹⁴ With profits feeding marketing expenses and further profits, and buyer power severely diminished, price equilibrium is nearly impossible to achieve.

2. Long-term conditions ensure demand, further distorting price equilibrium

Long-term conditions further weaken buyer power.¹¹⁵ Those with chronic health conditions, such as diabetes, congestive heart failure, and Parkinson's disease, depend on medications to manage symptoms.¹¹⁶ Additionally, one in twenty-five adults is living with

113. See Ginger Skinner, *To Get the Lowest Drug Prices It Pays to Shop Around*, CONSUMER REP. (Dec. 14, 2017), <https://www.consumerreports.org/drug-prices/why-drug-costs-keep-rising-what-you-can-do-about-it/>.

114. See Peterson, *supra* note 8 (“The companies raised prices—not to fund research to discover new drugs—but to boost profits for executives and investors.”).

115. David Ferguson, *Most Healthcare Providers Unprepared for Longitudinal Care*, FIERCEHEALTHCARE (Dec. 2, 2015, 11:01 AM), <http://www.fiercehealthcare.com/healthcare/most-healthcare-providers-unprepared-for-longitudinal-care>.

116. See, e.g., *Diabetes: Symptoms and Causes*, MAYO CLINIC (July 31, 2014), <http://www.mayoclinic.org/diseases-conditions/diabetes/basics/complications/con-20033091>; *Understand Heart Failure*, AM. HEART ASS'N, http://www.heart.org/HEARTORG/Conditions/HeartFailure/Heart-Failure_UCM_002019_SubHomePage.jsp (last visited Dec. 30, 2017) (“Although it can be difficult to live with a chronic condition like heart failure, you can learn to manage the symptoms and live a full and enjoyable life.”); *Understanding Parkinson's*, PARKINSON'S FOUND., http://www.pdf.org/about_pd (last visited Dec. 30, 2017). Wellbutrin (an antipsychotic) and diltiazem (for heart rhythm problems) must be taken daily—sometimes up to four times a day. *Diltiazem (Oral Route)*, MAYO CLINIC, <http://www.mayoclinic.org/drugs-supplements/diltiazem-oral-route/proper-use/DRG-20071775> (“For oral dosage form (tablets): Adults—At first, 30 milligrams (mg) four times a day before

a debilitating mental illness—including bipolar disorder and long-term recurring major depression.¹¹⁷ In fact, one in six Americans takes psychiatric medication, and eight out of ten of those report long-term use.¹¹⁸ While much controversy surrounds the use of psychotropic medications, they can often both improve symptoms and increase the effectiveness of other treatments, like psychotherapy.¹¹⁹ Overall, this guaranteed demand removes these consumers' ability to choose to forego the drug product, tipping the

meals and at bedtime. Your doctor may increase your dose if needed.”); *Medications for Arrhythmia*, AM. HEART ASS'N, http://www.heart.org/HEARTORG/Conditions/Arrhythmia/PreventionTreatmentofArrhythmia/Medications-for-Arrhythmia_UCM_301990_Article.jsp#.WdlBMbpFzIU; Lisa Rapaport, *Many Patients Skip Prescribed Drugs After a Heart Attack*, REUTERS (June 3, 2015), <https://www.reuters.com/article/us-heart-medication/many-patients-skip-prescribed-drugs-after-a-heartattackidUSKBN0OJ2M720150603>; *Wellbutrin SR*, RXLIST, <http://www.rxlist.com/wellbutrin-sr-drug.htm> (“The usual adult target dose for WELLBUTRIN SR is 300 mg per day, given as 150 mg twice daily.”); Lisa Rapaport, *Many Patients Skip Prescribed Drugs After MI*, REUTERS (June 2, 2015), <https://uk.reuters.com/article/us-heart-medication/many-patients-skip-prescribed-drugs-after-mi-idUKKBN0OJ2KU20150602>.

117. E.g., Shaunak A. Ajinkya, Pradeep R. Jadhav & Shruti Rajamani, *Which Is A More Debilitating Disorder Schizophrenia or Dysthymia? – A Comparative Study*, 9 J. CLINICAL & DIAGNOSTIC RES. 1, 1 (2015) (“Schizophrenia and Dysthymia are debilitating disorders that affect general health and functioning.”); *Living with a Mental Health Condition*, NAT'L ALLIANCE ON MENTAL ILLNESS, <https://www.nami.org/Find-Support/Living-with-a-Mental-Health-Condition> (last visited Dec. 30, 2017) (“[A]cross the population, 1 in every 25 adults is living with a serious mental health condition such as schizophrenia, bipolar disorder or long-term recurring major depression.”); *'Monkey Mind': When Debilitating Anxiety Takes Over*, NPR (July 3, 2012, 1:30 PM), <http://www.npr.org/2012/07/03/156200170/monkey-mind-when-debilitating-anxiety-takes-over> (“For some, anxiety can be much more than just sweaty palms and quivering hands. It can be a debilitating condition with severe physical and mental effects.”).

118. Thomas J. Moore & Donald R. Mattison, *Adult Utilization of Psychiatric Drugs and Differences by Sex, Age, and Race*, 177 J. AM. MED. ASS'N INTERNAL MED. 274, 274 (2017) (“[An estimated] 11.5% of adults reported taking prescription medication for ‘problems with emotions, nerves, or mental health’ in 2011.”); Sara G. Miller, *1 in 6 Americans Takes a Psychiatric Drug*, SCI. AM. (Dec. 13, 2016), <https://www.scientificamerican.com/article/1-in-6-americans-takes-a-psychiatric-drug/> (“[M]ore than eight in 10 adults who were taking psychiatric drugs reported long-term use . . .”).

119. Laura Weiss Roberts & Shaili Jain, *Ethical Issues in Pharmacology*, PSYCHIATRIC TIMES (May 7, 2011), <http://www.psychiatristimes.com/articles/ethical-issues-psycho-pharmacology> (“There are also concerns about the widespread application (some would say overprescription) of psychotropics—a controversy that is further fueled by the fact that nonpsychiatric providers are the source of most psychotropic prescriptions in the United States.”); see also *Mental Illness: Diagnosis & Treatment*, MAYO CLINIC, <http://www.mayo-clinic.org/diseases-conditions/mental-illness/basics/treatment/con-20033813> (last visited Dec. 30, 2017) (“Although psychiatric medications don’t cure mental illness, they can often significantly improve symptoms. Psychiatric medications can also help make other treatments, such as psychotherapy, more effective.”).

power heavily in favor of the drug producer.¹²⁰ For some, medication and other mental health services mean the difference between holding down a steady job or complete dependence on disability programs.¹²¹ Interestingly, providing access to psychotropic medication saves the U.S. healthcare system around \$25 billion annually in reduced admissions to mental institutions.¹²² The inverse has also been demonstrated. “[S]tudies have shown that when patients’ access to psychotropic drugs is arbitrarily restricted by insurers, patients use hospital care at a cost to those insurers that greatly exceeds the drug cost savings they foolishly attained.”¹²³ This is because regular adherence to costly medications is critical to a stable health condition and, thus, to being a productive member of society.¹²⁴ Unlike in normal markets for Teslas or iPhones, the poor cannot always wait for the rich to buy enough of the prescription medication so that prices deflate enough. Deciding to forego the latest iPhone or Tesla does not carry the same consequences as foregoing psychiatric or heart medication. Producers of drugs for chronic health conditions are practically guaranteed a constant, long-term demand of a mostly inelastic market. In fact, eighty-six percent of all healthcare

120. See Rapaport, *supra* note 116 (“Ultimately, regardless of the reason, patient non-adherence to medications after a heart attack has been associated with poor outcomes—these can include repeat hospitalization, progression of their underlying disease, or even reduced survival,” said Mathews, a researcher at Duke University Medical Center in Durham, North Carolina.”).

121. Robert E. Drake, Jonathan S. Skinner, Gary R. Bond & Howard H. Goldman, *Social Security and Mental Illness: Reducing Disability with Supported Employment*, 28 HEALTH AFF. 761, 761 (2009) (suggesting that providing supported employment along with “mental health care would improve financial security” of people with serious mental illnesses and “could even save the government money”).

122. J.D. Kleinke, *The Price of Progress: Prescription Drugs in the Health Care Market*, 20 HEALTH AFF. 43, 47 (2001) (“According to a study by Lichtenberg, ‘Drug treatments have saved the cost of keeping about 400,000 patients in mental institutions about \$25 billion annually.’”).

123. *Id.*

124. See, e.g., Kimberly Holland & Valencia Higuera, *The Dangers of Abruptly Stopping Antidepressants*, HEALTHLINE (Apr. 3, 2017), <https://www.healthline.com/health/depression/dangers-of-stopping-antidepressants> (“Quitting without consulting your doctor can be life-threatening.”); see also Rapaport, *supra* note 116 (“Ultimately, regardless of the reason, patient non-adherence to medications after a heart attack has been associated with poor outcomes—these can include repeat hospitalization, progression of their underlying disease, or even reduced survival,” said Mathews, a researcher at Duke University Medical Center in Durham, North Carolina.”).

spending is for patients with one or more chronic conditions.¹²⁵ In this way, the pharmaceutical industry is unlike any other, not subject to normal market forces and consumer pressures. In other words, prices cannot reach equilibrium because buyers cannot refuse to buy, leaving sellers with little reason to cut prices.

E. Summary: The Pharmaceutical Industry Cannot Be a Normal Market

Consumers are relatively powerless to rein in drug companies' prices. Near-constant demand and little buyer power tips the balance of power heavily in the hands of the drug companies. Without typical market forces to provide balance, the industry cannot achieve price equilibrium. Around the world, governments usually step in to help manage prices from getting out of control.¹²⁶ Yet American lawmakers have imposed relatively few price constraints on prescription drugs.¹²⁷ Instead, Americans have chosen to depend on normal market forces and public opinion in order to curb these prices, with only minimal impact.¹²⁸ Again, without aspects of normal markets like quality and price transparency, independent buyers dealing directly with sellers, and monopolistic safeguards in the prescription drug market, basic supply and demand principles operate such that drug producers are free to set exorbitant prices.¹²⁹ Only as more consumers feel the painful monetary losses through insurance premium hikes will this "price gouging" garner enough public attention to effectuate lower prices.¹³⁰

125. DEP'T OF HEALTH & HUM. SERVICES, AGENCY FOR HEALTHCARE RES. & QUALITY, AHRQ PUB. NO. 14-0038, MULTIPLE CHRONIC CONDITIONS CHARTBOOK 7 (2014), <https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf> ("[Eighty-six percent] of healthcare spending is for patients with one or more chronic conditions.").

126. See Asmundson, *supra* note 109 ("As a result, governments usually regulate such monopolies to ensure that they do not abuse their market power by setting prices too high.").

127. Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), <https://hbr.org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive>.

128. Jay Hancock, *Everyone Wants to Reduce Drug Prices. So Why Can't We Do It?*, N.Y. TIMES (Sept. 23, 2017), <https://www.nytimes.com/2017/09/23/sunday-review/prescription-drugs-prices.html>.

129. See Kesselheim et al., *supra* note 97.

130. *Is There a Cure for High Drug Prices?*, CONSUMER REP., <https://www.consumerreports.org/drugs/cure-for-high-drug-prices> (last updated July 29, 2016).

With the healthcare industry hanging in the balance, this unrestrained market has ceded significant price control to profit-amplifying corporations in the pharmaceutical industry.¹³¹ One physician remarked that the prices of cancer drugs have soared so high “that we are getting into areas that are almost unimaginable economically.”¹³² In the insurance industry, the ACA has begun to bring insurers’ margins to a reasonable level by enforcing the health insurance MLR regulation – with undeniable success at reducing waste.¹³³ Yet the pharmaceutical industry has thus far eluded any such value mandate, despite similarities in market abnormalities and even starker shareholder manipulation than the insurance industry.¹³⁴ Consequently, the abnormal market conditions, combined with a lack of moderating regulations, have led to pronounced profit-taking in the pharmaceutical industry.

III. PRONOUNCED PROFIT-TAKING EXISTS IN THE PHARMACEUTICAL INDUSTRY

Without normalizing market forces at play, pharmaceutical companies are left unchecked to reap skyrocketing profits. As they recoup their profits, these companies simultaneously neglect development of some less profitable, albeit much-needed, drugs.

A. *The Pharmaceutical Industry Reaps Mammoth Profits*

The priority of for-profit corporations is to maximize the return on shareholders’ investments. The landmark case of *Dodge v. Ford Motor Co.* noted explicitly that a business’s primary purpose is to amplify the “profit of the stockholders.”¹³⁵ Although more observation than a binding rule, this “shareholder primacy norm” theory both captures and strengthens the widespread approach of

131. See Fox, *supra* note 127.

132. Gina Kolata, *What Does It Cost to Create a Cancer Drug? Less Than You’d Think*, N.Y. TIMES (Sept. 11, 2017), <https://www.nytimes.com/2017/09/11/health/cancer-drug-costs.html>.

133. See PRIVATE HEALTH INSURANCE, *supra* note 18.

134. See, e.g., Andrew Pollack, *Martin Shkreli Resigns from Turing Pharmaceuticals*, N.Y. TIMES (Dec. 18, 2015), <https://www.nytimes.com/2015/12/19/business/martin-shkreli-resigns-turing-drug-company.html>.

135. *Dodge v. Ford Motor Co.*, 170 N.W. 668, 684 (Mich. 1919); Marshall M. Magaro, Note, *Two Birds, One Stone: Achieving Corporate Social Responsibility Through the Shareholder-Primacy Norm*, 85 IND. L.J. 1149, 1153 (2010) (discussing shareholder wealth maximization).

pharmaceutical companies. Unlike other developed countries, the United States grants drug companies free rein to charge “whatever they want.”¹³⁶ Medicare isn’t even allowed to negotiate drug prices.¹³⁷ So, unhindered by normal market forces, the pharmaceutical industry has magnified this *Dodge* charge to amplify stockholder profit.

The major drug companies’ profits are substantial. Generally included in the term “Big Pharma” are fifteen pharmaceutical giants, notably Johnson & Johnson (\$276 billion market value), Novartis (\$273 billion), and Roche (\$248 billion).¹³⁸ They enjoy significant yearly shareholder yields and profit margins.¹³⁹ While the S&P 500 companies realize a median of 2% shareholder yields (or payouts to stockholders), those of Big Pharma are well above that; Pfizer’s shareholder yields, for example, were over 6% in 2015.¹⁴⁰ As for average profit margins, the pharmaceutical industry was at the top of a 2013 *Forbes* study, right next to the banking industry, at a 19% profit margin.¹⁴¹ Five of the Big Pharma companies made profit margins of 20% or higher.¹⁴² In comparison, the industries with the next-highest average profit margins were the media, 12%; oil and

136. Deangelis, *supra* note 29, at 30–31 (“What has accounted for the pharmaceutical companies’ very large profit margins? For one thing, the United States, unlike other developed countries, allows pharmaceutical companies to charge whatever they want as long as they do not collude with one another in setting the prices. In other words, these companies can charge whatever the market will bear. For example, Solvadi, Gilead’s hepatitis C drug, costs \$1,000 for each pill, which amounted to sales of \$3.5 billion between April and June of 2015.”).

137. *Id.* at 31 (“Making matters worse, the US Congress, influenced by pharmaceutical lobbyists, has not allowed Medicare to negotiate drug prices, as do most health care systems, HMOs, and some insurance companies. In those countries that negotiate the prices of their national insurance plans with Big Pharma, most drugs sell for much less. Obviously, lobbyists for the pharmaceutical industry in the United States have been very successful.”).

138. Compare Williams, *supra* note 7 (identifying market values of pharmaceutical companies), with Dan Caplinger, *How Much Is the Coca-Cola Company Worth?*, MOTLEY FOOL (Sept. 6, 2016, 12:16 PM), <https://www.fool.com/investing/2016/09/06/how-much-is-the-coca-cola-company-worth.aspx> (identifying Coca-Cola’s net worth at \$188–213 billion).

139. See generally Jeremy Jones, *Calculating Shareholder Yield*, YOUNG RES. & PUB., INC. (Apr. 27, 2017), <https://www.youngresearch.com/authors/jeremyjones/calculating-shareholder-yield> (showing that shareholder yields are returned capital divided by market capitalization).

140. Williams, *supra* note 7.

141. *Id.*

142. See Anderson, *supra* note 32 (identifying the companies as Pfizer, Hoffmann-La Roche, AbbVie, GlaxoSmithKline, and Eli Lilly).

gas, 8%; and car manufacturers, 6%.¹⁴³ Big Pharma's profits are almost twice those of the next-highest industry. This trend doesn't seem to be changing any time soon, considering that another Forbes study in 2015 found the average profit margin of healthcare technology companies was now 21%.¹⁴⁴ The 2015 profit margins for Johnson & Johnson were 22%; Roche, 20%; and Novartis, 36% (when comparing profits over sales).¹⁴⁵ But the company Forbes found to be setting the pace was Gilead Sciences, with a profit margin nearly 53% over a one-year period.¹⁴⁶ With margins sometimes three-fold those of other profitable industries, it's no wonder these companies attract investors.¹⁴⁷

Maintaining these returns necessitates consistently elevating pharmaceutical prices. Despite the recent upsurge in the proportion of cheaper generic versions used to fill prescriptions (82% in 2016, compared to 66% in 2010), brand versions have maintained their roughly 78% market share of overall profits.¹⁴⁸ To maintain those profits, the drug companies implemented 17% *annual price hikes*, at a time when general inflation averaged 1.62%.¹⁴⁹ In recent years, the news has exposed instances of price gouging and opportunistic profit-taking. For example, Europe and Canada sold the generic drug deflazacort, a steroid used to treat children with Duchenne

143. *See id.*

144. *See supra* note 7.

145. JOHNSON & JOHNSON CO., ANNUAL REPORT (FORM 10-K) (Jan. 3, 2016); NOVARTIS, NOVARTIS ANNUAL REPORT 2015 (2015), <https://www.novartis.com/sites/www.novartis.com/files/novartis-annual-report-2015-en.pdf> (last visited Jan. 25, 2018); ROCHE GROUP, FINANCE REPORT 2015 (2015), <http://www.roche.com/dam/jcr:74af99eb-b51a-4f13-88b2-aacaf9f53c0c/en/fb15e.pdf>.

146. *See supra* note 7.

147. Hugh Dive, *Investing in Biotech and Pharma*, AURORA FUNDS MGMT., <http://www.aurorafunds.com.au/investing-in-biotech-and-pharma> (last visited Apr. 7, 2018) ("Biotechnology and pharmaceuticals are probably the most seductive and exciting sectors of the market to invest in. Not only can investors have the warm and fuzzy feeling that they are helping humanity (an emotion not readily generated by buying shares in Westpac or BHP), but when drugs or devices are developed and successfully adopted, it can be very profitable.").

148. BLUE CROSS BLUE SHIELD ASS'N, HEALTH OF AMERICA REPORT, RISING COSTS FOR PATENTED DRUGS DRIVE GROWTH OF PHARMACEUTICAL SPENDING IN THE U.S. (May 3, 2017), https://www.bcbs.com/sites/default/files/file-attachments/health-of-america-report/BCBS.HealthOfAmericaReport.RisingCostsPatentedDrugs_1.pdf.

149. *Id.*; *see also* *Historical Inflation Rates 1914-2018*, US INFLATION CALCULATOR, <http://www.usinflationcalculator.com/inflation/historical-inflation-rates> (last visited Apr. 7, 2018).

muscular dystrophy, at a price between \$1000 to \$2000 per year.¹⁵⁰ Yet the U.S. Food and Drug Administration (FDA) has approved Marathon Pharmaceuticals to sell the same drug in the United States for \$89,000 (a 6000% price increase) under the brand name Emflaza.¹⁵¹ Other notable examples include Turing Pharmaceuticals' Daraprim (\$750 per pill, as increased from \$13.50), and AMAG Pharmaceuticals' Makena (\$1500 per pill, while a different but similar drug was sold for \$20).¹⁵² Although Turing Pharmaceuticals' former CEO Martin Shkreli was recently convicted for fraud, the conviction was for securities and conspiracy but had nothing to do with Daraprim price hikes.¹⁵³ Altogether, there seem to be few checks on these price hikes – especially when there are such profits to be made!

B. Big Pharma's Expenses Spur Their Profits

The cost of moving a drug to the profit-making stage is significant. It takes ten to fifteen years to research and develop one drug¹⁵⁴ at an average cost between \$648 million to \$2.65 billion.¹⁵⁵ Many drugs fail at various steps along the way, resulting in millions of dollars of lost funds.¹⁵⁶ Estimates suggest only one out of every 5000 to 10,000 drugs makes it to clinical trials.¹⁵⁷ From there, only three out of ten are profitable, and only one of these three becomes a blockbuster drug grossing at least \$1 billion per year.¹⁵⁸ Patents compensate for these risks and protect a company from competition, maximizing a drug's return. Yet over the last few

150. Matthew Herper, *Why Did That Drug Price Increase 6,000%? It's the Law*, FORBES (Feb. 10, 2017, 1:52 PM), <https://www.forbes.com/sites/matthewherper/2017/02/10/a-6000-price-hike-should-give-drug-companies-a-disgusting-sense-of-deja-vu/#348085ca71f5>.

151. *Id.*

152. *See id.*; *see also* Pollack, *supra* note 134.

153. Aaron Smith, *Martin Shkreli Sentenced to 7 Years in Prison for Fraud*, CNN MONEY (Mar. 9, 2018, 5:25 PM), <http://money.cnn.com/2018/03/09/news/martin-shkreli-sentencing/index.html>.

154. Paula Tironi, *Pharmaceutical Pricing: A Review of Proposals to Improve Access and Affordability of Prescription Drugs*, 19 ANNALS HEALTH L. 311, 324 (2010).

155. *See Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion*, *supra* note 84 ("Developing a new prescription medicine that gains marketing approval, a process often lasting longer than a decade, is estimated to cost \$2,558 million.").

156. *See* Tironi, *supra* note 154.

157. *Id.*

158. Anderson, *supra* note 32.

years, several prominent patents have expired, allowing increased competition and falling profits.¹⁵⁹ These patent expiries will cost the industry an unprecedented \$240 billion in the decade between 2010 and 2020.¹⁶⁰

To offset costs and maximize profits, the pharmaceutical industry promotes sales by spending a staggering amount of money on advertising. Nine Big Pharma companies spend substantially more on sales and marketing than on R&D (Johnson & Johnson, Novartis, Pfizer, Sanofi, Merck, GlaxoSmithKline, AstraZeneca, Eli Lilly, and AbbVie).¹⁶¹ While most other industries spend an average of 10% of revenue on marketing, these Big Pharma companies averaged over twice that with 23% in 2013.¹⁶² While different business models call for varying proportions of marketing expenditures, only the consumer packaged goods industry approaches this proportion.¹⁶³ Spending a quarter of some of the most substantial profits in the world on marketing is significant. By comparison, Big Pharma R&D expenditures averaged only 16% of revenue.¹⁶⁴ To note, Johnson & Johnson spent over twice as much on marketing (\$17.5 billion) as R&D (\$8.2 billion).¹⁶⁵ It is true that it

159. *See id.*

160. Richard Anderson, *Pharmaceuticals Industry Facing Fundamental Change*, BBC News (Nov. 7, 2014), <http://www.bbc.com/news/business-29659537>.

161. *Id.*; see also Elizabeth Whitman, *How the US Subsidizes Cheap Drugs for Europe*, INT'L BUS. TIMES (Sept. 24, 2015, 1:52 PM), <http://www.ibtimes.com/how-us-subsidizes-cheap-drugs-europe-2112662> (referencing Makovsky Instagram tweet indicating pharmaceutical companies spend more on marketing than research).

162. *See* Anderson, *supra* note 32 (featuring data from which to calculate marketing budget as a percent of revenue: Johnson & Johnson 25%, Novartis 25%, Pfizer 22%, Roche 18%, Sanofi 20%, Merck 22%, GSK 24%, AstraZeneca 28%, Eli Lilly 25%, AbbVie 23%); Sarah Brady, *What Percent of Revenue Do Publicly Traded Companies Spend on Marketing and Sales?*, VITAL, <https://vtldesign.com/digital-marketing/content-marketing-strategy/percent-of-revenue-spent-on-marketing-sales/> (last visited Apr. 7, 2018); Christine Moorman, *Who Has the Biggest Marketing Budgets?*, FORBES (Mar. 5, 2014, 11:41 AM), <https://www.forbes.com/sites/christinemoorman/2014/03/05/who-has-the-biggest-marketing-budgets/#18a8dc6a24> ("To put these figures in perspective, The CMO Survey reports that marketing budgets represent approximately 10.9% of overall firm budgets.").

163. *Marketing Budgets Vary by Industry*, WALL STREET J.: DELOITTE, <http://deloitte.wsj.com/cmo/2017/01/24/who-has-the-biggest-marketing-budgets>.

164. *See* Anderson, *supra* note 32 (featuring data from which to calculate R&D budget as a percent of revenue: Johnson & Johnson 12%, Novartis 17%, Pfizer 13%, Roche 18%, Sanofi 14%, Merck 17%, GSK 13%, AstraZeneca 17%, Eli Lilly 24%, AbbVie 15%).

165. *Id.*; see also Kim T. Gordon, *Defining Sales and Marketing*, ENTREPRENEUR, <https://www.entrepreneur.com/article/46086> (last visited Apr. 7, 2018) (indicating sales and marketing expenses can include networking activities and advertisements).

markets and sells more than just pharmaceuticals (medical devices, household supplies, etc.). But considering that pharmaceutical-specific advertising has grown more than any other advertising category in the last four years, it is reasonable to assume Johnson & Johnson has similarly focused its advertising expenses on its pharmaceuticals.¹⁶⁶ Last year the pharmaceutical industry spent \$6 billion in advertisements alone, mostly via television.¹⁶⁷

This advertising may be not only exorbitant but also wasteful. Notably, the United States and New Zealand are the only two countries in the world to permit this type of product claims advertising.¹⁶⁸ In 2015 the American Medical Association (AMA) called for an outright ban of this direct-to-consumer advertising.¹⁶⁹ The organization argued that it “inflates demand” because inquisitive patients, armed with a brand name and a sunny testimonial, arrive at their prescriber appointments asking why they can’t have access to these brand drugs.¹⁷⁰ Yet, per the AMA, this deceptive consumer-targeted advertising cannot correct the information asymmetries inherent in the physician-patient relationship. As discussed in section II.A.1, patients still lack the extensive medical training that guides physicians’ prescription decisions. A quick television advertisement with “glossed-over” side effects cannot effectively educate patients enough about price, quality, or alternative options to make them truly informed consumers.¹⁷¹ Yet those prescribers who do have the requisite education often feel pressured to prescribe the higher-priced drugs to please these patients, irrespective of true need.¹⁷² Thus, they prescribe more of these medications than is necessary. By providing just enough information to slightly offset

166. Bruce Horovitz & Julie Appleby, *Prescription Drug Costs Are on the Rise; So Are the TV Ads Promoting Them*, KAISER HEALTH NEWS (Mar. 20, 2017), <http://khn.org/news/prescription-drug-costs-are-on-the-rise-so-are-the-tv-ads-promoting-them>; INT’L TRADE ADMIN., 2016 TOP MARKETS REPORT: MEDICAL DEVICES 2 (2016), http://www.trade.gov/topmarkets/pdf/Medical_Devices_Executive_Summary.pdf (“The major U.S. medical device companies include . . . Johnson & Johnson.”).

167. Horovitz & Appleby, *supra* note 166.

168. C. Lee Ventola, *Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?*, 36 PHARMACY & THERAPEUTICS 669, 669 (2011).

169. Horovitz & Appleby, *supra* note 166.

170. *Id.*

171. *Id.*

172. *Id.*

these information asymmetries, the advertising confuses the prescriber's role in the patient-consumer's decision. In the end, there is little evidence to show that direct-to-consumer marketing provides any real benefit to the patient.¹⁷³

In all fairness, the required R&D expenditures are substantial in this industry and provide many jobs that help the economy. However, it is clear that Big Pharma's investing in advertising and promotion of the most expensive brand name drugs ultimately drives up pharmaceutical sales and, thus, profits for the stockholders.¹⁷⁴ And there may not be as many benefits to this advertising as the drug industry would like to claim.

C. High Prices and Low Returns Lead to Inaccessibility Problems

The skewed drug market often renders much-needed drugs inaccessible. A 2010 article reports that twenty-nine percent of adults reported neglecting to fill a prescription in the last two years due to its impractical price.¹⁷⁵ Twenty-three percent reported cutting pills in half or skipping doses so their medications would last longer.¹⁷⁶ This type of behavior increased the rate of hospitalizations and ER visits.¹⁷⁷ The prohibitive prices frustrate the most cost-efficient care and result in wasted resources and unsafe physical conditions.

At the same time, development of much-needed drugs is ignored. Drug companies lack the incentives to spend resources developing products that, while unprofitable, would treat neglected conditions (Chagas disease, filarial disease, leishmaniasis, etc.)—

173. See S. Gilbody, P. Wilson & I. Watt, *Benefits and Harms of Direct-to-Consumer Advertising: A Systematic Review*, 14 *QUALITY & SAFETY HEALTH CARE* 246, 246 (2005) ("Direct to consumer advertising is associated with increased prescription of advertised products and there is substantial impact on patients' request for specific drugs and physicians' confidence in prescribing. No additional benefits in terms of health outcomes were demonstrated.").

174. *Id.*

175. Tironi, *supra* note 154, at 317; see also Turner, *supra* note 56 (Kaiser Family Foundation reports this number at 8% from 2004 to 2014); see also Cynthia Cox & Bradley Sawyer, *How Does Cost Affect Access to Care?*, PETERSON-KAISER HEALTH SYS. TRACKER (Jan. 17, 2018), <https://www.healthsystemtracker.org/chart-collection/cost-affect-access-care> (reporting that in 2016 nineteen percent of adults in worse health decided to delay or forego filling prescription drugs).

176. Tironi, *supra* note 154, at 317.

177. See *id.* at 322.

both in the developing world and in the United States.¹⁷⁸ The development of cures for any one of these diseases would not provide the “blockbuster” dividend payouts that have become the specialty of this industry.¹⁷⁹ And public pressure to address these health conditions is, alone, insufficient to override the entrenched profit-maximizing mindset.¹⁸⁰ Consequently, drug companies have few incentives to dedicate the funds needed for this R&D, leaving these drugs undeveloped and the related health conditions untreated.¹⁸¹

In summary, without the normal, steady free-market forces in place, the mandate to maximize wealth leads to unfettered price increases and mammoth profit-taking. While R&D expenses are admittedly substantial, they do not justify the excessive profits taken or marketing expenditures spent by drug companies.¹⁸² Ultimately, desperately needed drugs become impossibly expensive or otherwise inaccessible. Some form of regulation is needed to manage the out-of-control gains and drug inaccessibility.

IV. PROPOSAL: APPLY A MODIFIED MLR REGULATION TO THE PHARMACEUTICAL INDUSTRY

To help right this abnormal market and curb unnecessary price increases, the government should enact a value-focused pharmaceutical MLR regulation—patterned after the health insurance MLR regulation. As explained in Part I, this regulation requires insurers to rebate funds if they spend less than the designated amount on value-enhancing activities, such as medical care.

If this regulation were to be applied to the pharmaceutical industry, many of the same effects that have already been observed in the insurance industry would also be observed here. First, it would help right the abnormal market. Admittedly, this regulation alone would not fix the information and control asymmetries in this market, nor render transparent pricing more practical in every situation. Neither would it turn the highly inelastic market more elastic (by more closely linking demand to price). However, it

178. See Anderson, *supra* note 160. See generally DRUGS FOR NEGLECTED DISEASES INITIATIVE, <https://www.dndi.org/> (last visited Apr. 7, 2018).

179. See Anderson, *supra* note 29.

180. See *id.*

181. See *id.*

182. See Kolata, *supra* note 132.

would likely improve transparency by compelling disclosure of the aggregate amount spent in certain cost categories to demonstrate compliance with the imposed ratio. And even if transparency is not improved, this regulation would fill the role usually played by price transparency in normal markets by providing a counterweight to the drug companies' selling power by limiting their potential profits and, thus, their prices. Even if elasticity – the link between price and demand – is not improved, prices would be constrained by this normalizing force (instead of rising unrestrainedly). Big Pharma would no longer charge “whatever they want.” If Big Pharma did not reduce prices themselves to keep their profits below the threshold, they would be compelled to rebate the excess.

Second, this regulation would also address some of the challenges posed by the third-party insurer. Even though consumers would still be shielded from the true costs of healthcare, the regulation would put some limitation on sellers from implementing unchecked price hikes simply to maximize their own profits. In this way, insurance companies could still play a continuous role in mitigating the financial losses felt by any one individual, including those least able to pay, while also reducing the tension between supplier and buyer power so that it would not be as skewed toward suppliers.

Third, this regulation could relieve some of the monopolistic features of this industry. Patents could still provide some insurance against the financial risk of research and development, but the financial returns from the patents would have some type of a check. Prices and profits could even normalize. Furthermore, this regulation might accomplish the goals of proposed government price negotiations by, again, restraining seller power and checking prices. The overall effect would be to improve the balance between supplier and buyer power, thereby establishing price equilibrium. While this market may never achieve normalcy, this measure could correct it substantially.

Similar to the health insurance industry, MLR regulation would provide some check on unlimited, exorbitant profits – currently an impossible feat considering the heavy-handed seller power. Eventually, Big Pharma might stop placing so much emphasis on unneeded expenditures, like wasteful advertising, since it wouldn't

be allowed to keep more than a certain percentage of the returns. Also, similar to the health insurance industry, this regulation would incentivize players to invest in value-promoting research and development, and other improvements; it would also refine efficiencies in less value-adding areas, like pharmacy benefit manager costs and profits. And finally, like in the insurance industry, MLR regulation has the potential to cut billions of dollars in American healthcare costs, potentially even shifting some of the cost burden away from American taxpayers.

The adopted pharmaceutical ratio could mirror the health insurance's 80:20 ratio (80% medical loss and 20% other). But as discussed above, expenditure ratios within the pharmaceutical industry are dissimilar to any other industry (17% R&D, 23% sales and marketing (S&M), 30% manufacturing, and 21% profits).¹⁸³ Expecting a blanket 80:20 ratio in the drug industry therefore seems unreasonable, if not drastic. Again, the purpose of the MLR regulation is not to impinge on financial viability but to impose guardrails around expenditures to ensure a certain level of value for the consumer. Erecting these guardrails requires designating each cost category as either value-contributing or lesser-value-contributing; analogizable to separating out the fat (or "other") from the meat (or medical loss). Under the ACA's regulation, the insurance company's value-contributing expenditures—denoted as medical loss—include medical claims, quality improvement activities, taxes, and licensing fees.¹⁸⁴ Profits, administrative fees, marketing, agent commissions, and community benefit expenditures constitute the lesser-value-contributing, or "other," category.¹⁸⁵

183. See Deangelis, *supra* note 29, at 30 ("In 2013 the profit margin for pharmaceutical companies ranged from 10% to 42%, with an average of 18%. Pfizer was at the top of the profit list, and 4 other companies (Hoffman-La Roche, AbbVie, GlaxoSmithKline, and Eli Lilly) had profit margins of more than 20%. As a point of reference, the profit margin of pharmaceutical companies was essentially the same as that of banks, but the banks' range of profit was lower, from 5% to 29%."); Adams, *supra* note 30 ("On average last year, the top 10 Big Pharmas spent just over 17% of their top line on research, with GlaxoSmithKline spending the second least in percentage terms at 12.9%, and the least in absolute numbers at £3.62 billion (\$4.49 billion)."); Williams, *supra* note 7 (explaining pharmaceutical companies had average profit margins of 19%).

184. See *Explaining Health Care Reform: Medical Loss Ratio (MLR)*, *supra* note 26.

185. See PRIVATE HEALTH INSURANCE, *supra* note 18, at 4-5; *Medical Loss Ratio*, HEALTHCARE.GOV, <https://www.healthcare.gov/glossary/medical-loss-ratio-MLR/> (last visited Apr. 7, 2018).

In order to implement a similar regulation in the pharmaceutical industry, this industry's major cost categories should be evaluated for their value contribution, the inherent incentives already at play, and the effect of this regulation on these incentives. The rest of Part IV will examine each of the pharmaceutical companies' major cost categories for current incentives to limit or increase expenditures. Each section will conclude with a recommendation regarding which side of the ratio (medical loss or "other") to assign each cost category. Ultimately, this Note recommends a 40:60 ratio for the pharmaceutical industry.

A. Profits Are "Other"

The pharmaceutical industry's substantial profits can comfortably be assigned to the "other" category.¹⁸⁶ Importantly, this does not mean that drug companies should be bereft of profits. Profits and incentives play an important role in the economy. The MLR regulation simply puts guidelines around expenses to avoid unfair extremes in profits and other administrative costs while requiring value for consumers' ever-increasing healthcare dollars.¹⁸⁷ Value returned to the consumer is the ultimate line between medical loss and other expenses.¹⁸⁸ Corporate profits provide relatively less, if any, value to the consumer; consequently, they fall on the "other" side of the MLR ratio.

B. Manufacturing and Distribution Are "Other"

Manufacturing and distribution costs, at times between 27% to 30% of Big Pharma's revenue, make up the bulk of the value, or "medical loss," that is provided to drug consumers.¹⁸⁹ The drugs that are manufactured and distributed to consumers save lives, ease suffering, and improve health. Considering that this constitutes the

186. See *supra* Part III.

187. "The 80/20 rule is ensuring that insurance companies provide consumers value for their premium dollars." *The 80/20 Rule: Providing Value and Rebates to Millions of Customers*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://www.cms.gov/CCIIO/Resources/Forms-Reports-and-Other-Resources/mlr-rebates06212012a.html> (last visited Apr. 7, 2018).

188. See *id.*

189. KIRCHHOFF, *supra* note 29; Basu et al., *supra* note 29, at 30 ("In the pharmaceutical industry, costs attributed to manufacturing are a major part of a company's total expenses.").

major value that Big Pharma provides, it might naturally fall on the “medical loss” side of the ratio, similar to the insurance companies’ medical claims expense category. But this comparison is mostly surface-level. Health insurance companies are mainly responsible for the financial coverage of medical expenses—essentially a transfer of funds.¹⁹⁰ But they are not involved in the actual delivery of the medical care. In contrast, pharmaceutical companies are responsible for the payment *and* the actual manufacturing and distribution of the drugs themselves. Considering that there are significantly more steps along the pharmaceutical supply chain than for the payout of medical claims, and that drug companies control more aspects of these expenses than do insurance companies, these costs are more susceptible to potential abuse.¹⁹¹ And because the “medical loss” side determines the amount of profits a Big Pharma company could keep, assigning manufacturing and distribution expenses to the “medical loss” side would incentivize Big Pharma to inflate each step they controlled so as to be able to keep additional profits.

In order to determine whether pharmaceutical manufacturing and distribution costs should be considered “medical loss” or “other,” this subsection will analyze (1) the significant control that the drug industry has over this cost category, (2) the potential for abuse of this power and the result of misaligning the incentives by assigning manufacturing costs to the “medical loss” side of the MLR ratio, and (3) possible solutions to correct this misalignment. Analyzing these factors highlights the differences between the insurance industry’s medical claims payouts and Big Pharma’s manufacturing and distribution costs. The differences in control and thus the potential for abuse of this cost category indicate that manufacturing and distribution expenses should not be grouped on the medical loss side of the ratio, since this could inflate that side of the ratio and by extension inflate the “other” side of the ratio, including profits. The analysis will conclude that this industry’s

190. *What Is Health Insurance?*, MED. NEWS TODAY, <https://www.medicalnewstoday.com/info/health-insurance> (last updated Jan. 5, 2016).

191. Allen Jacques, *2017 Trends & Transformations in the Pharma Supply Chain*, PHARMACEUTICAL PROCESSING (Dec. 29, 2016, 8:30 AM), <https://www.pharmpro.com/article/2016/12/2017-trends-transformations-pharma-supply-chain> (“The pharmaceutical supply chain is one of the most complex supply chains in the world.”).

manufacturing and distribution costs should be categorized as “other” to maintain the incentive to not inflate these costs in order to keep more profits, but instead, run these processes efficiently.

1. Big Pharma exercises significant control over manufacturing and distribution costs

Supply chains in the pharmaceutical industry are some of the most complex in the world.¹⁹² For instance, drug production can start overseas with ingredients arriving from various locations.¹⁹³ For drugs entering the United States, the facilities and procedures must meet the strict standards of both U.S. and international regulators.¹⁹⁴ In addition to regulatory complexity, the physical process of getting drugs to consumers is itself no small feat. Once a drug is manufactured, it is transported to numerous countries; stored in warehouses; processed by distributors; and delivered to retailers, hospitals, pharmacies, clinics, and so on until it eventually arrives in the hands of the consumer.¹⁹⁵ These supply chains are further complicated by sophisticated international contracts, intricate distribution channels, business-to-business price negotiations, importation tariffs, labor regulations, equipment maintenance, pharmacy benefit managers, etc.¹⁹⁶ There are many ways that Big Pharma could manipulate their expenses so as to inflate their costs and thus inflate the profit side of the ratio.

Although, emphasizing the pharmaceutical industry’s logistical challenges is not meant to oversimplify the insurance industry.

192. *Id.*

193. See Basu et al., *supra* note 29, at 30-31.

194. Mike Benson, *Pharmaceutical Industry Regulations*, MKT. REALIST (Jan. 22, 2015, 11:06 AM), <http://marketrealist.com/2015/01/pharmaceutical-industry-regulations>.

195. *Id.*; see also THE HENRY J. KAISER FAM. FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN (2005), http://avalere.com/research/docs/Follow_the_Pill.pdf.

196. IMS INST. FOR HEALTHCARE INFORMATICS, UNDERSTANDING THE PHARMACEUTICAL VALUE CHAIN (2014), <https://www.scribd.com/document/271050319/Understanding-Pharmaceutical-Value-Chain-pdf>; Elaine M. Whittington, *Types of Contracts*, INST. FOR SUPPLY MGMT. (1994), <https://www.instituteforsupplymanagement.org/pubs/Proceedings/conf/proceedingsdetail.cfm?ItemNumber=5238&SSO=1>; see *Drafting Commercial Contracts for the Pharmaceutical Industry*, FALCONBURY, <https://falconbury.co.uk/product/details/234/drafting-commercial-contracts-for-the-pharmaceutical-industry> (last visited Apr. 7, 2018) (“In such a highly regulated industry, understanding the key challenges of negotiation and drafting an effective and watertight contract on an international level is a complex topic.”).

Insurers' hospital reimbursements are based predominantly on per diem amounts or fee-for-service schedules, which must be negotiated annually between each hospital and insurer with their individual bargaining powers.¹⁹⁷ Furthermore, insurance actuaries must navigate market regulation and draw on historical experience when developing rates.¹⁹⁸ Insurance is complex to be sure.

However, the ability to inflate this expense category is different in the pharmaceutical industry. While an insurer may dictate which hospital or doctor is available to its enrollees, the insurer is not on the hospitals' administration team negotiating supply contracts, running the nursing units, or managing doctors. Insurers are a step removed from the management decision process.¹⁹⁹ Drug companies, however, exert significantly more control over their major expenses. They directly oversee most of their products—from negotiating research and development contracts, to running manufacturing plants.²⁰⁰ Phrases like “integrate out global operations” or “reduce manufacturing costs” make good business sense to the pharmaceutical industry but sound out of place when applied to the insurance industry's control over hospitals or pharmacies.²⁰¹ Insurance companies do not develop restructuring plans for clinics or merge unprofitable hospitals. The differences in each industry's ability to control the largest portion of its costs has critical ramifications—and deserves thoughtful consideration. Ultimately, this area is much more susceptible to abuse than the regulated insurance claims payouts.

197. Uwe E. Reinhardt, *How Do Hospitals Get Paid? A Primer*, N.Y. TIMES (Jan. 23, 2009, 6:40 AM), <https://economix.blogs.nytimes.com/2009/01/23/how-do-hospitals-get-paid-a-primer>.

198. Kurt Wrobel, Opinion, *On Individual Health Insurance Reform, Actuarial Details Matter*, FORBES (Jan. 24, 2017, 12:19 PM), <https://www.forbes.com/sites/realspin/2017/01/24/on-individual-health-insurance-reform-actuarial-details-matter/#1945846e62b1>.

199. Sandhya Somashekhar & Ariana Eunjung Cha, *Insurers Restricting Choice of Doctors and Hospitals to Keep Costs Down*, WASH. POST (Nov. 20, 2013), http://wapo.st/17rq8bF?tid=ss_mail&utm_term=.8d7e47dbc3a7 (“[I]nsurers are restricting their choice of doctors and hospitals in order to keep costs low, and . . . many of the plans exclude top-rated hospitals. . . . In most cases, the decision was about the cost of care.”).

200. *Merck Closing 8 Plants, 8 Research Sites*, CBS NEWS (July 8, 2010, 9:10 AM), <https://www.cbsnews.com/news/merck-closing-8-plants-8-research-sites>.

201. *Id.*

2. *Manufacturing and distribution costs are susceptible to abuse by Big Pharma, and thus, these costs would benefit from being grouped in the “other” category*

Because Big Pharma controls so much of the manufacturing and distribution expenses, there is much more room for abuse. As such, this cost category should be on the same side of the ratio as the profits (the “other” side). This way, these expenses would cut into the profit allowance, as they do now. If these expenses were on the “other” side, the incentive would continue to be to run an efficient supply chain, thus minimizing expenditures instead of building them up.²⁰² Currently, companies cut manufacturing expenditures because it saves them money.²⁰³ Profit maximization—and few other strong forces—usually impose maximum limits on labor costs, ingredients, or other manufacturing expenses.²⁰⁴ Therefore, it is possible that assigning this category to the medical loss side of the ratio would eliminate the only incentive to run an efficient supply chain.

Assigning manufacturing and distribution expenses to the medical loss side will, in fact, weaken or remove the companies’ incentive to minimize these expenses. Again, the MLR regulation would require a company to limit its profits and “other” expenses to a certain ratio based on the “medical loss.” If the “other” expenses, including profits, exceeded an amount that was proportionate to the “medical loss” or value provided to the consumer, then the company would be required to refund the excess back to the consumer. Therefore, a Big Pharma CEO seeking to increase her allowable profits could simply increase her medical loss side, such as workers’ salaries or the amount of ingredients purchased. That way, as the value (“medical loss”) side of the ratio grows, so does the lesser-value (“other”) side, including profits. And considering

202. Tuan Nguyen, *6 Ways to Get Smart and Cut Manufacturing Costs*, MANUFACTURING TRANSFORMATION (Jan. 21, 2014), <http://www.aprison.com/blog/2014/01/6-ways-to-get-smart-and-cut-manufacturing-costs> (suggesting that manufacturing intelligence solutions “can help executives better manage their manufacturing assets in a way that meets customer demand and might actually also help a company to save some money”).

203. See *Merck Closing 8 Plants, 8 Research Sites*, *supra* note 200 (“Those cuts are intended to save the Whitehouse Station, N.J., company about \$3.5 billion a year starting in 2012. Merck said Thursday the restructuring plans announced so far will bring savings of about \$2.7 billion to \$3.1 billion in 2012, most of its target.”).

204. See Nguyen, *supra* note 202.

all the control that drug companies have over distribution, and all the middlemen and contracts in this supply chain, there is ample opportunity to drive manufacturing and distribution costs up – an opportunity largely unavailable to health insurers whose medical claims payouts are heavily regulated. This heavy claim regulation limits what hospitals and doctors can collect and, therefore, limits the medical claims paid out by insurance companies, which therefore limits the insurance companies' eligible profits. However, there is little regulation to limit what drug companies can pay out for the ingredients or labor required to manufacture and distribute medication. And if drug companies voluntarily shrink their manufacturing and distribution costs, they also shrink their allowable profits. Thus, by assigning this cost category to the "medical loss" side, pharmaceutical companies would lose the incentive to run factories and supply chains efficiently.

The reality of this problem is readily illustrated by analogy to the current U.S. healthcare spending crisis, which was caused in large part by the way hospitals were historically paid: the cost-plus payment model.²⁰⁵ The cost-plus payment structure reimbursed hospitals for the *cost* of care they provided *plus* a certain percentage on top.²⁰⁶ As a result, by 1980 hospitals had lost the incentive to minimize costs.²⁰⁷ Hospital management groups, looking to earn bigger profits, manipulated reimbursements by simply inflating their expenditures.²⁰⁸ Drug companies could easily make parallel moves if such a system were adopted. For instance, if manufacturing and distribution costs are counted as medical loss, then wasting batches of medications and charging excessive fees by

205. Elizabeth Teisberg, Michael E. Porter & Gregory B. Brown, *Making Competition Work in Healthcare*, HARV. BUS. REV. (July–Aug. 1994), <https://hbr.org/1994/07/making-competition-in-health-care-work> ("Beginning in the post-World War II period, hospitals were reimbursed on a cost-plus basis, which in turn produced rapidly escalating hospital costs.").

206. RICHARD E. McDERMOTT & KEVIN D. STOCKS, *CODE BLUE 61* (3d ed. 2002) ("Before 1984, most insurance plans paid hospitals their billed charges less a nominal discount. Medicare and many Medicaid plans paid cost-plus. Hospitals were reimbursed actual costs, plus a markup for profit.").

207. LINDA GORMAN, *THE HISTORY OF HEALTH CARE COSTS AND HEALTH INSURANCE 9* (2006), <https://www.westandfirm.org/docs/Gorman-01.pdf> ("The three reimbursement methods used by the [Blue Cross Organizations] did not create normal business incentives. They assumed that all hospital costs should be paid whether or not they were generated by an inefficient organization. For the nonprofit [Blue Cross Organizations], a reduction in costs reduced the amount of revenue collected.").

208. *See id.*

pharmacy benefit management companies could become real investment strategies for the pharmaceutical industry – especially if such budget increases could justify expansion of the marketing budget to sell more drugs and make more profits.

However, the analogy to the cost-plus payment model is imperfect, and any problems created by categorizing manufacturing and distribution costs as medical loss may be offset by potential benefits. Indeed, creating incentives to inflate costs might result in pharmaceutical cost-increasing measures that are actually pro-competitive. Hypothetically, drug production could immigrate to more expensive areas like the United States, resulting in job creation and economic stimulation. If this MLR regulation ends up mirroring the cost-plus payment model by placing this cost category on the “medical loss” side and thus flipping the current incentive to cut costs and maximize profits, it would drive up manufacturing costs – in effect robbing the consumer of the very value the MLR regulation tries to ensure.

One of the biggest differences between enacting an MLR regulation and the cost-plus payment model is that, unlike the blank check of “plus” returns that the government promised hospitals, pharmaceutical companies would not be guaranteed a “plus” or margin. In other words, they would not get a guaranteed check for every expense; rather, this MLR regulation proposal guarantees only that drug companies could keep a limited amount of their profits that they have garnered themselves, in proportion with their medical loss expenses. Consequently, pharmaceutical companies would still have to organize their expenses to remain financially solvent. Similarly, health insurers under the MLR regulation have not received a blank check for all their expenses. Like the health insurers who fled the “money-losing” individual marketplace for more profitable services, Big Pharma would likely shed any money-draining manufacturing and distribution processes in favor of the ones that can turn a profit.²⁰⁹ They would never choose to spend so much in manufacturing and distribution that they would lose money overall. But at the same time, these companies could still spend a little extra on one supply contract, pay their distributors a little more in one area, and everything

209. See Sommer, *supra* note 23.

would add up to increase their expenses (and thus their allowable profits) without draining their coffers. Again, drug companies exert much more control over this expense category, and there is ample room to drive up costs enough to balloon their profits right where they want them.

In sum, the decision of which side to assign manufacturing and distribution costs comes down to how much power drug companies have over their costs and reimbursement rates and, therefore, the potential for abuse. The drug companies' control over costs deserves additional study. Although, given reported 17% annual price hikes, it seems drug companies exert at least some significant control over their reimbursements. But outside forces also play a role in influencing rates. Exactly what the balance is between all these forces remains to be determined, but it is clear that Big Pharma has significant control over this cost category, and any new incentives should limit the probable abuse. Regardless, categorizing manufacturing and distribution expenses as "medical loss" does nothing to reduce the country's overall healthcare costs—a main goal of this proposal.

3. Alternative options to align incentives

If manufacturing and distribution costs are categorized as medical loss, other regulatory measures could help to keep drug prices within a manageable range. That is, some value-enhancing measures could limit the drug companies' ability to increase manufacturing costs for the sole purpose of growing the medical loss side of the equation and, by extension, profit eligibility. Clearly, infusing price transparency and other free market forces into this industry to manage drug prices should be a priority. But for the reasons enumerated above, this is not always possible.²¹⁰ Incentivizing reduction of manufacturing and distributions costs would help correct the market where price transparency and other normal market forces could not be achieved.

210. *See supra* Section II.A.2.

Price regulation is one proven method of controlling costs.²¹¹ This type of regulation could prevent the unnecessary ratcheting up of manufacturing and supply-chain costs. Moreover, if an MLR regulation were enacted, it is likely that companies would be less inclined to fight against such price controls since profits would be more constricted regardless. Price controls or other guidelines surrounding production expenses could allow manufacturing and distribution costs to stay on the medical loss side of the ratio while still ensuring value. And evidence suggests that a reduction in production costs will increase expenses in R&D—a potential double win.²¹²

There are, however, potential issues with adopting traditional price controls. These include (1) pushing prices so far below natural levels that talent and investor capital leave the market, (2) the inability of fixed prices to respond to changes in markets or costs, (3) the risk that lengthy political discussions or formulas adjusted per the bias of an agency would cause implementation delays of the set prices, (4) possible excess supply or demand that the market itself cannot correct, and (5) perverse incentives such as quality reduction by those looking to cut costs.²¹³ Given these issues, traditional price controls are probably not the answer to preventing abuse in the manufacturing cost category.

Alternative options could counteract some of these cost-raising incentives. One option is to borrow again from the ACA's MLR regulation and mandate public reporting of cost hikes of ten percent or more in this category.²¹⁴ Setting a cap for these hikes is

211. France has seen the growth in its medication costs slow (2.1% in 2008, 2% in 2009, 1.1% in 2010) due to reduced reimbursements and regulated price reductions. Annie Fenina et al., *Les Comptes Nationaux de la Santé en 2010*, ÉTUDES ET RESULTATS, Sept. 2011, at 1, <http://drees.social-sante.gouv.fr/IMG/pdf/er773-2.pdf>.

212. See Basu et al., *supra* note 29.

213. Fiona M. Scott Morton, *The Problems of Price Controls*, 24 REGULATION 50, 50-51 (2001).

214. See PRIVATE HEALTH INSURANCE, *supra* note 18 (indicating an insurance carrier must publicly explain premium rate increases at rates of 10% or more through rate review); *Fighting Unreasonable Health Insurance Premium Increases*, CTRS. FOR MEDICAID & MEDICARE SERVS., <https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/ratereview05192011a.html> (last visited Apr. 7, 2018) (“Under the final regulation: Starting September 1, 2011, insurers seeking rate increases of 10 percent or more for non-grandfathered plans in the individual and small group markets are required to publicly disclose the proposed increases

another option. Alternatively, government oversight could be increased to ensure fair valuation. Capping aggregated reimbursements (think capitated payments) would mean that intentional waste (e.g., batches of faulty medicine, unnecessary contract raises) would still cut into a pharmaceutical company's profits and hopefully minimize this unwanted behavior. It is also possible that competing players could provide the needed competition to keep pharmaceutical manufacturers running lean, such as Intermountain Healthcare's upcoming nonprofit generic drug company.²¹⁵ Yet it is unlikely that even this type of competition would help reduce prices of patented, brand-name drugs.²¹⁶

Moving manufacturing and distribution expenses to the "other" side of the MLR ratio might be the best way to incentivize reducing waste. If manufacturing were to be lumped with "other" expenses, then those costs would cut into profits—and Big Pharma's incentives would be aligned with reducing waste—just like they do currently. Big Pharma CEOs would squeeze everything on that side of the ratio to expand the profits section as much as possible. It would encourage efficiency in manufacturing, as do current market forces. This would also eliminate much of the arbitrariness associated with traditional price controls while still restricting prices to accentuate value. Instead of depending on price regulation based on lagging or even random data, prices could fluctuate naturally with expenses and innovation while still leaving a reasonable profit margin. Logically, the "other" section should be expanded to include manufacturing expenses.

4. Manufacturing and distribution expenses should be classified as "other"

Manufacturing and distribution expenses should be on the "other" side of the Medical Loss Ratio. Admittedly, this category

and the justification for them. Such increases will be reviewed by either State or Federal experts to determine whether they are unreasonable.").

215. Reed Abelson & Katie Thomas, *Fed Up with Drug Companies, Hospitals Decide to Start Their Own*, N.Y. TIMES (Jan. 18, 2018), <https://www.nytimes.com/2018/01/18/health/drug-prices-hospitals.html>.

216. Beth Jones Sanborn, *Intermountain-Led Generic Drug Venture Faces Big Hurdles, Could Forge New Regulatory and Political Ground*, HEALTHCARE FINANCE (Mar. 15, 2018), <http://www.healthcarefinancenews.com/news/intermountain-led-generic-drug-venture-faces-big-hurdles-could-forge-new-regulatory-and>.

provides value to the consumer in that this category actually produces and delivers the life-changing or life-enhancing drugs to the consumer. And the costs are substantial—like insurance payouts. But assigning manufacturing and distribution expenses to the “other” side would be the best insurance against abuse and provide the most value to the consumer. Furthermore, like the health insurance industry, Big Pharma does not have a guaranteed “cost-plus” profit in proportion to manufacturing expenditures. The reimbursements would not be automatic the way they were for hospitals under the cost-plus payment model. As a final note, when calculating the rebates, it will be important to exclude any manufacturing expenses from Big Pharma’s non-pharmaceutical areas (household goods, information management arms, etc.) from the manufacturing and distribution directly related to drugs. In conclusion, the manufacturing and distribution category is valuable medical loss. Yet, given the incentives that would result if this were assigned to the “medical loss” side of the ratio, more value is preserved if this category is assigned to the “other” side of the ratio. Further inquiry and careful analysis in this area are strongly urged.

C. Lawsuits Are “Medical Loss”

Under the insurance MLR regulation, the medical loss side is adjusted by certain funds set aside as reserves.²¹⁷ One allotment of reserve money is specifically for potential future lawsuits.²¹⁸ These funds are counted as part of the medical loss, per the National Association of Insurance Commissioners’ (NAIC) and Department of Health and Human Services’ (HHS) recommendations.²¹⁹ Although this “value” designation could incentivize Big Pharma to open themselves up for lawsuits, lawsuit reserves should be allocated to the medical loss side, given the realities of this industry and pending different recommendations from HHS.

217. See KIRCHHOFF, *supra* note 29.

218. See *id.*

219. See *id.*

D. Research and Development Is “Medical Loss”

Drug companies’ constant refrain is, essentially, “only an attractive return on investment will entice the capital necessary to fund world-changing breakthroughs.”²²⁰ Indeed, capital is funneled into the drug industry, at least in part, because of the substantial financial returns.²²¹ And to be sure, pharmaceutical breakthroughs are medical loss. Developments in this area mean people live longer and healthier lives, sometimes with fewer medical costs.²²² In fact, the resulting discoveries from all that American capital differentiate this country’s drug innovation from that of others.²²³ American pharmaceutical innovation is second to none. If R&D were further incentivized under an MLR regulation, Big Pharma might even turn additional attention to unprofitable, but badly needed, neglected drugs. Thus, promoting the value inherent in this category is vital.

Yet theoretically, there is still room for abuse. Drug companies could certainly throw money into research for the sake of increasing this side of the ratio without any real advancements. Currently, annual projected Big Pharma R&D returns on investment are down

220. See Lydia Ramsey, *Pharma Companies’ No. 1 Justification for High Drug Prices Is Bogus*, BUS. INSIDER (Dec. 9, 2015, 12:53 PM), <http://www.businessinsider.com/research-and-development-costs-might-not-factor-into-drug-pricing-2015-12> (“Pharmaceutical companies often cite the cost of researching and developing new compounds as the reason for their high drug prices.”); Williams, *supra* note 7.

221. See Williams, *supra* note 7.

222. *The Value of Medical Innovation: An Overview*, HEALTHCARE INST. N.J. (last updated Aug. 29, 2017), <http://hinj.org/value-of-medical-innovation> (“Globally, between 1960 and 1997, new therapies accounted for 45 percent of the increase in life expectancy in 30 developing and high-income countries. . . . New therapies have contributed to a nearly 22 percent decline in cancer deaths since the 1990s. U.S. cancer survivorship alone has more than tripled since 1970, with nearly 14.5 million cancer survivors alive in the country last year. . . . The HIV/AIDS death rate has dropped nearly 85 percent since the introduction of highly active antiretroviral treatment (HAART) in 1995.”).

223. Elizabeth Whitman, *How the U.S. Subsidizes Cheap Drugs for Europe*, INT’L BUS. TIMES (Sept. 24, 2015, 1:52 PM), <http://www.ibtimes.com/how-us-subsidizes-cheap-drugs-europe-2112662> (“The U.S. accounted for 46 percent of global life sciences research and development—the vast majority of which is in biopharmaceuticals—according to the December 2013 issue of R&D Magazine. ‘The U.S. is the global leader in biomedical innovation,’ Mark Grayson, a spokesman for PhRMA, a pharmaceutical industry trade group that represents many of the world’s biggest drug companies, said in an email.”).

to 3.2%.²²⁴ An MLR regulation might, in practice, encourage waste in research funds. Big Pharma could find a myriad of ways to prop up these expenses. For example, more drugs might begin to perform overlapping functions without real differentiated value from each other—with their development costs all ascribed to “R&D.” Production costs might shift even more to the expensive American labor force.²²⁵ Big Pharma could push for greater FDA scrutiny to rack up costs in this category. And drug companies could purposefully keep drugs in the development stage longer. For these reasons R&D, like manufacturing costs, might belong on the “other” side.

However, R&D ultimately belongs with the medical loss. Again, unlike in the cost-plus payment model, there would be a check on these expenditures—the need to maintain a profit. Not all research leads to substantial discoveries, so there is no guaranteed return in this investment area. Furthermore, a drug cannot begin to return a profit until it has passed the FDA gate.²²⁶ Thus, drug companies would still push for minimal, not more, costly FDA intervention. Stockholder considerations, pressure for substantial breakthroughs, and public perception would all encourage efficient R&D. And importantly, this might incentivize development of neglected drugs that otherwise would not return a profit. With the value and controls inherent in this category, R&D should ultimately stay on the medical loss side.

224. *A New Future for R&D? Measuring the Return from Pharmaceutical Innovation 2017*, DELOITTE, <https://www2.deloitte.com/uk/en/pages/life-sciences-and-healthcare/articles/measuring-return-from-pharmaceutical-innovation.html> (last visited Apr. 7, 2018).

225. Vanessa Fuhrmans & Scott Hensley, *Drug Makers Are More Vocal Against Europe's Price Controls*, WALL STREET J. (Dec. 13, 2001), <https://www.wsj.com/articles/SB1008191144635615520>.

226. *See Development & Approval Process (Drugs)*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/drugs/developmentapprovalprocess/> (last updated Jan. 16, 2018) (“American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world. The main consumer watchdog in this system is FDA’s Center for Drug Evaluation and Research (CDER). The center’s best-known job is to evaluate new drugs before they can be sold. CDER’s evaluation not only prevents quackery, but also provides doctors and patients the information they need to use medicines wisely. The center ensures that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks.”).

E. Taxes, Fees, and Depreciation Are “Medical Loss”

In insurance MLR regulation, taxes, as well as regulatory or licensing fees, are considered medical loss.²²⁷ However, federal income taxes on investment income and capital gains (profit from a sale or investment) are not.²²⁸ Here, taxes and fees are similarly set by outside forces, such as government regulations.²²⁹ As a result, penalizing companies for paying these costs does not make sense. Furthermore, it is unlikely that Big Pharma will advocate for an increased tax rate. The incentives are already sufficient to keep these costs low; no artificial incentives are required. Depreciation of property and other assets can be calculated using various methods.²³⁰ Some uniform way of measuring this should be established to prevent one drug company from obtaining an unfair advantage over the others. These categories can all be grouped similarly to their counterparts in the insurance industry on the medical loss side.

F. Marketing Is “Other”

This subsection argues that although advertising drug information does result in valuable informed consumerism, assigning marketing to the medical loss side of the MLR ratio creates perverse incentives for drug companies. In general, the staggering financial returns from marketing investment are too high for drug companies not to want to flood this category with cash. The incentives would be especially counterproductive because the greater their profit allowance grows, the more they would spend on advertising. Instead, marketing should be categorized as “other,” thereby incentivizing drug companies to minimize marketing expenses.

227. See *Explaining Health Care Reform: Medical Loss Ratio (MLR)*, *supra* note 26.

228. See *id.*

229. *Topic Number: 409 – Capital Gains and Losses*, IRS, <https://www.irs.gov/taxtopics/tc409> (last updated Mar. 13, 2018).

230. Ben McClure, *An Introduction to Depreciation*, INVESTOPEDIA, <https://www.investopedia.com/articles/fundamental/04/090804.asp> (last visited Apr. 7, 2018).

1. Promoting awareness of medications is valuable

Valid arguments suggest that marketing should be categorized as medical loss. In an era of increased transparency, consumers want to be empowered and educated about drugs.²³¹ They want to sit down with their physicians and have informed conversations.²³² But if physicians are unaware of a particular drug, they will not prescribe it and patients cannot gain access to it. Thus, promoting awareness of beneficial treatments through marketing is valuable.²³³ Furthermore, there is merit to the drug makers' claim that unless they see attractive profits, investments in R&D will drop. And the best way to turn a profit is to advertise the product.²³⁴

Moreover, informal controls play a minimal role in reducing marketing expenses, supporting the position that they should be considered medical loss. Consumers along both party lines advocate for reductions in drug prices, while the media publicizes the excesses.²³⁵ Additionally, the pot of revenue is somewhat finite, and marketing funds have to come from somewhere. Furthermore, if the MLR regulation is enacted and profits are limited to a reasonable rate, there may not be the same pressure to engage in profit-

231. NAT'L CTR. FOR BIOTECHNOLOGY INFO., *THE HEALTHCARE IMPERATIVE: LOWERING COSTS AND IMPROVING OUTCOMES: WORKSHOP SERIES SUMMARY* (2010), <https://www.ncbi.nlm.nih.gov/books/NBK53921>.

232. See Horovitz & Appleby, *supra* note 166 ("Reis said her mother did take the Lyrica 'and it's helped.' That's a good thing, says the brand guru who takes pride in looking out for her mom. 'The ad spurred the conversation.'").

233. Russell Huebsch, *What Are the Benefits of Direct-to-Consumer Advertising?*, HEARST NEWSPAPERS, <http://smallbusiness.chron.com/benefits-direct-to-consumer-advertising-3587.html> (last visited Apr. 7, 2018) ("The 2004 study showed that DTCA ads were especially helpful in getting low-income families to seek medical care. Low-income individuals and families are typically the hardest demographic to reach for any public awareness campaign.").

234. Robert Pear, *Marketing Tied to Increase in Prescription Drug Sales*, N.Y. TIMES (Sept. 20, 2000), <https://www.nytimes.com/2000/09/20/us/marketing-tied-to-increase-in-prescription-drug-sales.html> ("Sales of these drugs contributed powerfully to the steep increase in prescription drug spending in 1999.").

235. Mary Ellen McIntire, *Republicans Eye Boosting Competition to Help Trump Lower Drug Prices*, MORNING CONSULT (Dec. 9, 2016), <https://morningconsult.com/2016/12/09/republicans-eye-boosting-competition-help-trump-lower-drug-prices> ("President-elect Donald Trump says he wants to lower drug prices, an idea that's been pushed primarily by Democrats but has support from some key GOP senators."); Petersen, *supra* note 8 ("The companies raised prices—not to fund research to discover new drugs—but to boost profits for executives and investors."); Ransdell Pierson & Bill Berkrot, *Democrats Take Aim at Drug Prices, Prompting Sharp Drops in Biotech Stocks*, REUTERS (Sept. 28, 2015, 6:30 PM), <http://www.reuters.com/article/us-valeant-pharms-congress/democrats-take-aim-at-drug-prices-prompting-sharp-drops-in-biotech-stocks-idUSKCN0RS28N20150929>.

maximizing marketing. Enacting the MLR regulation could naturally reduce these expenses. However, despite these potential benefits, other concerns suggest marketing should be assigned to the “other” side.

2. Marketing should be classified as “other” to align incentives

Linking increased marketing expenses to increased profits by putting marketing on the medical loss side of the ratio would only exacerbate current problems. A Big Pharma CEO faced with managing huge profit cuts would start looking at her levers. The last thing she would do is pull the lever that shrinks the “other” side of the ratio – her allowed profits – any more than she absolutely must. If her marketing expenditures are considered medical loss, then she would be prone to ratchet them up. Unlike the individual marketplace, advertising is not “money losing.” The return on advertising investment is substantial. If these expenditures started producing profits that exceeded the imposed ratio threshold, the CEO would find a legitimate channel for those extra funds. Most likely she would move them into R&D. But it is highly improbable that she would voluntarily reduce any medical-loss-qualifying expenditures because that would cut her overall allowable profit amount – which she’s already losing. Instead, she would likely continue to channel funds into potentially wasteful marketing expenses that would continue to dwarf the R&D expenditures, effectively robbing value from consumers. The effects would be almost identical to the effects of the cost-plus payment model: The more the CEO spends on marketing, the more profits she is guaranteed. Overall, drug prices would not drop as desired if marketing expenses were considered to be medical loss.

Instead, categorizing marketing costs as “other” would incentivize minimizing advertising expenditures while still spending enough to attract a profit. This Note does not propose slashing marketing to cram it with profits into a twenty percent limit. However, categorizing marketing as “other” effectively incentivizes waste reduction in this area. It could significantly reduce direct-to-consumer advertising without outright banning it. This type of advertising could drop to a reasonable level, which would result in less pressure on physicians from advertisement-prepped patients to prescribe unnecessary treatment. Since there is such an influ-

ential return on marketing investment, the only genuine outside force on marketing expenditures is its detraction from profits.²³⁶ Removing this link would seriously frustrate the effort to reduce unnecessary marketing and its associated waste. It is therefore imperative that these expenditures be condensed. Marketing belongs on the “other” side of the MLR ratio.

G. Community Benefit Expenditures Are “Medical Loss”

In some ways, public health education campaigns and other community benefit expenditures are like marketing. They increase awareness of a product and promote sales.²³⁷ Consequently, some might argue that such expenditures are no better than advertising; they are just pharmaceutical propaganda for drugs. However, the material can provide substantial value to the public—similar to the value noted above in the marketing section (IV.F).²³⁸ Given the material’s similar nature to advertising, it would make sense to combine this with marketing. But as long as community benefit expenditures are defined narrowly as educational initiatives—as they are in the health insurance ratio regulation—and exclude purely promotional initiatives, this can be medical loss.

H. Salaries and Agent Commissions Are “Other”

The purpose of a for-profit business is to make a profit.²³⁹ Larger profits thus equate to more success. Competitive salespersons’ and agents’ salaries, along with attractive commissions, are critical to effectively managing resources and creating this profit.²⁴⁰ In

236. See Pear, *supra* note 234.

237. See *Public Health Campaigns that Change Minds*, MILKEN INST. SCH. PUB. HEALTH (Nov. 8, 2016), <https://publichealthonline.gwu.edu/blog/health-communication-campaigns/> (“How do you motivate an individual to quit smoking? Persuade a community to vaccinate their children? Incentivize a whole nation to eat better? These types of questions are at the heart of every health communication campaign, which aim to change how people think about their health and simultaneously provide them with the resources and incentives to improve it.”).

238. See *id.*

239. See *Dodge v. Ford Motor Co.*, 70 N.W. 668, 684 (Mich. 1919) (discussing the shareholder primacy norm).

240. DAVID A. BJORK, HEALTHCARE EXECUTIVE COMPENSATION: A GUIDE FOR LEADERS AND TRUSTEES 3 (2012) (“Hospitals may be tax-exempt charities serving the public good, but they are still big, complicated businesses with narrow profit margins, and they need talented executives to keep them strong. Tax exemption and public funding for Medicare and Medicaid have no bearing on what it costs to recruit and retain executives.”).

general, salary incentives produce results. Thus, both outside and inside forces urge maximizing this category. Ultimately, salaries, including those of pharmacy benefit managers, should be expansive enough to attract talent but contained enough to encourage efficiency (while avoiding extreme profit-taking). Salaries should fall on the “other” side.

I. Administrative Expenses Are “Other”

The administrative expenses category contemplates office expenses such as rent, utilities, supplies, and administrative personnel. These expenses provide relatively little value to the drug consumer. Therefore, encouraging efficiency, quality, and thrift is important here. In order to minimize waste in this area, administrative costs should be categorized as “other” and left out of the medical loss category.

J. Exceptions to Consider

There are exceptions to the 80:20 rule in the health insurance industry for a reason.²⁴¹ Similarly, some pharmaceutical companies do not follow the standard Big Pharma model. Some companies lack the funds or infrastructure for major R&D.²⁴² Others require only a modest marketing budget. Exceptions should be made per the various business models. There should be room for some reasonable flexibility.

K. Ratio Should Be 40:60

Imposing an overall MLR ratio, like the 80:20 ratio in the insurance industry, could reduce drug prices while reserving to pharmaceutical companies control over pricing and budget details. With a similar overall ratio, these companies would have the flexibility to choose to spend more on advertising and keep less for

241. See *Explaining Health Care Reform: Medical Loss Ratio (MLR)*, *supra* note 26. For other insurance designs, the ratio is flexible so as to facilitate financial viability. *See id.* For example, Special Circumstances Adjustments apply to newer plans, min-med plans, and expatriate plans to address individual insurance situations. Low-enrollment insurers are similarly held to different ratios to adjust for less predictability in claims expenses. Alternatively, if employers wish to self-insure and avoid paying the “non-value” margins to an insurance company, they are not subject to the MLR regulation requirement. *See id.*

242. *See id.*

profits, or vice versa. However, as described above, pharmaceutical companies have greater power to increase the costs of production. Thus, a mixed ratio might better achieve the main goal of targeting value. A specific profit percentage cap, such as 12% (the next highest industry's average profits), combined with an overall medical loss ratio like 70:30, could provide a helpful general framework, leaving Big Pharma flexibility over the details.

Again, Big Pharma currently averages 21% in profits.²⁴³ A 12% profit margin seems reasonable and competitive. After adding sales and marketing (currently 23%; ideally, it should match other industries' 10% average), manufacturing and distribution costs (30%), as well as administrative costs, salaries and commissions, etc., the "other" portion of the ratio could approach 60%, which would leave 40% for medical loss. Similar to what has happened to the insurance industry, Big Pharma has the potential to rebate billions of dollars back to Americans, easing the increases in prescription prices.²⁴⁴ Players in the pharmaceutical industry might even tighten their belts and squeeze out costs that don't add value to consumers—all while making a reasonable margin of profit—just like insurers. Admittedly, this ratio would benefit from a more detailed economic analysis that could arrive at a more calculated ratio, adjustable as the market fluctuates.

V. CONCLUSION: REDUCED TAXPAYER BURDEN, INCREASED AFFORDABILITY

Where should the refunds go when pharmaceutical profits exceed the 12% cap, or if the "other" category oversteps 60%? The health insurance industry rebates their excess to individuals and corporations.²⁴⁵ Yet for pharmaceutical companies without easily accessible means to rebate consumers, issuing rebates to individuals and corporations likely would be too complicated and burdensome. However, there is another potential way to channel these funds to lower insurance premiums (which is perhaps a more

243. See Williams, *supra* note 7.

244. See PRIVATE HEALTH INSURANCE, *supra* note 18.

245. See *The 80/20 Rule: Providing Value and Rebates to Millions of Customers*, *supra* note 187 ("The 80/20 rule is ensuring that insurance companies provide consumers value for their premium dollars.").

widespread pain point worth addressing). At first, the government could collect and distribute this money to reimburse the still-unfunded ACA risk corridors that were intended to be operational in the initial years of the ACA's implementation.²⁴⁶ This would relieve taxpayers of their \$8 billion debt still owed to insurance companies.²⁴⁷ After that bill is paid, the funds could then be distributed evenly to insurers on an ongoing basis in a way that extends the ACA's reinsurance payments and spreads out savings to the consumers.²⁴⁸ Since insurance companies have their own value-driving MLR, premium price growth could slow and—dare we hope—slightly reverse. This type of regulation could defray individual and family healthcare expenditures, increasing affordability for all. If this result is unpalatable then these funds could be channeled toward other worthwhile endeavors—such as funding nursing or doctor scholarships or helping provide insurance for those with disabilities.

This proposal might have other advantages as well. Big Pharma might move drug production jobs to the United States in an attempt to lever up production costs and thus their profit eligibility. Drug companies might finally shift the R&D cost burden from the United States by lowering prices in America while keeping prices abroad fixed.²⁴⁹ Some may argue that markets eventually find ways around

246. See Livingston, *supra* note 37.

247. See *id.*

248. See Cynthia Cox, Ashley Semanskee, Gary Claxton & Larry Levitt, *Explaining Health Care Reform: Risk Adjustment, Reinsurance, and Risk Corridors*, HENRY J. KAISER FAM. FOUND. 6 (2016), <http://www.kff.org/health-reform/issue-brief/explaining-health-care-reform-risk-adjustment-reinsurance-and-risk-corridors> (“Reinsurance differs from risk adjustment in that reinsurance is meant to stabilize premiums by reducing the incentive for insurers to charge higher premiums due to concerns about higher-risk people enrolling early in the program, whereas risk adjustment is meant to stabilize premiums by mitigating the effects of risk selection across plans. Thus, reinsurance payments are only made to individual market plans that are subject to new market rules (e.g., guaranteed issue), whereas risk adjustment payments are made to both individual and small group plans. Additionally, reinsurance payments are based on actual costs, whereas risk adjustment payments are based on expected costs. As reinsurance is based on actual rather than predicted costs, reinsurance payments will also account for low-risk individuals who may have unexpectedly high costs (such as costs incurred due to an accident or sudden onset of an illness). . . . [R]einsurance payments represent a net flow of dollars into the individual market, in effect subsidizing premiums in that market.”).

249. See Mc Govern, *supra* note 67 (“[T]he European Federation of Pharmaceutical Industries and Associations released a report on the pharmaceutical industry. In this report,

this type of price regulation with reduced efficiencies and quality.²⁵⁰ But perhaps reduced efficiency is precisely what we want—at least in the realm of stockholder return-on-investment efficiency. While neglected drug R&D provides relatively little financial reward to an investor, if drug companies were somehow incentivized to raise their R&D expenditures, then perhaps much-needed (albeit unprofitable) drugs might become more available to non-financial stakeholders such as patients and their families. Ironically, this type of inefficiency could result in value for patients, who are the ones really in need. And any measures drug companies might take to reduce quality can be managed by the FDA.²⁵¹

In conclusion, an MLR regulation could provide much-needed value to the pharmaceutical industry in ways that the current market structure fails to do. Ultimately, however, more thorough analysis is needed to identify the optimal ratio and category classification for each expense category. But in the current push to expedite healthcare affordability and access, a pharmaceutical MLR regulation could provide the much-needed guardrail to facilitate maximum value for American healthcare consumers.

*Cami R. Schiel**

it was revealed Europe accounted for 22.2 percent of all pharmaceutical sales of 2015, while the US took 48.7 percent of the margin.”).

250. See Morton, *supra* note 33 (“[P]rice controls, in combination with government requisitioning and corruption, created chaos in the French economy. Merchants responded by reducing the quality of their goods and the black market blossomed, Bourne noted. ‘It was the honest merchant who became the victim of the law.’”).

251. See *Development & Approval Process (Drugs)*, *supra* note 226 (“American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world. The main consumer watchdog in this system is FDA’s Center for Drug Evaluation and Research (CDER). The center’s best-known job is to evaluate new drugs before they can be sold. CDER’s evaluation not only prevents quackery, but also provides doctors and patients the information they need to use medicines wisely. The center ensures that drugs, both brand-name and generic, work correctly and that their health benefits outweigh their known risks.”).

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