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THICK AS THIEVES? BIG PHARMA WIELDS ITS POWER WITH THE HELP OF GOVERNMENT REGULATION[†]

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INTRODUCTION

Americans are barraged by an endless flow of ads that claim to remedy medical maladies with prescribed drugs. The commercials depict productive and happy lives, with suggestive associations that human flourishing can be achieved via pharmaceutical intervention. The appeals are accompanied by an exhaustive inventory of potentially negative life-altering side effects. As ads end with this depiction of relational bliss through drug use, viewers hear a fast-paced listing of monotone non-segmented disclaimers, which can range from modest impacts (e.g., slight weight gain) to very serious implications (e.g., suicidal ideations). Research suggests that hearing about the risks of use may increase consumers' trust in the advertising.¹ Sufferers may also conclude that stronger means better (i.e., helping them more effectively manage their condition).² Patients may prefer a name-brand drug because the medicine may have a higher perceived quality due to advertising and promotional activities.³ American consumers are enculturated to reinforce their desire for convenience and accessibility, while also wanting their pains to go away. Moreover, they

[†] Portions of this article originally appeared in: Leslie Sekerka, Debra Comer & Lauren Benishek, *The Inordinate Power of Big Pharma*, in *BUSINESS ETHICS: BEST PRACTICES FOR DESIGNING AND MANAGING ETHICAL ORGANIZATIONS* 355 (Denis Collins ed., 2018).

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¹ Amanda L. Connors, Comment, *Big Bad Pharma: An Ethical Analysis of Physician-Directed and Consumer-Directed Marketing Tactics*, 73.1 ALB. L. REV. 243 (2009).

² See also Joanne Kaufman, *Think You're Seeing More Drugs Ads on TV? You Are, and Here's Why*, N.Y. TIMES, Dec. 24, 2017, <https://www.nytimes.com/2017/12/24/business/media/prescription-drugs-advertising-tv.html>.

³ Kathleen Iacocca, James Sawhill & Yao Zhao, *Why Brand Drugs Priced Higher Than Generic Equivalents*, 9 INT'L J. PHARM. & HEALTHCARE MKTG. 3 (2015).

expect to view ads that compel them to want novel products or new applications. When it comes to health, consumers tend to mitigate the risk of taking drugs.⁴ Cognitive dissonance fuels a process of rationalizing side effects as part of the cost of wellbeing.⁵

Direct-to-consumer pharmaceutical advertising (DTCPA) refers to any promotional effort by a pharmaceutical company to present pharmaceutical drug information to the public in the lay media.⁶ Drug companies claim the ads are designed to educate patients, encourage doctor-patient dialogue, and move people to take more responsibility for their healthcare.⁷ Opponents suggest that this type of marketing tends to normalize obscure disorders, encourages people to believe they suffer from certain dysfunctions, and prompts framing uncommon diseases in a normal light.⁸ When pharmaceutical firms get U.S. Federal Drug Administration (FDA) approval for a new product, under the auspices of health communication, the government enables them to market the drug and create demand where none previously existed.

⁴ Ho-Young Ahn et al., Consumers' Optimism Bias and Responses to Risk Disclosures in Direct-to-Consumer (DTC) Prescription Drug Advertising: The Moderating Role of Subjective Health Literacy, 48 J. CONSUMER AFFAIRS 175 (2014).

⁵ Johanna Jarcho et al., The Neural Basis Rationalization: Cognitive Dissonance Reduction during Decision Making, SOCIAL COGNITIVE AND AFFECTIVE NEUROSCIENCE, no. 6.4, 2011, at 460-67.

⁶ Billion Dollar Pills, ECONOMIST (Jan. 25, 2007), <https://www.economist.com/node/8585891> (in America, direct-to-consumer drug advertising has increased from spending of \$1.1 billion in 1997 to \$4.5 billion in 2006); The Impact of Direct-to-Consumer Advertising, U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143562.htm> (last visited Mar. 20, 2018).

⁷ Editorial, Turn the Volume Down on Drug Ads, N.Y. TIMES (Nov. 27, 2015), <https://www.nytimes.com/2015/11/27/opinion/turn-the-volume-down-on-drug-ads.html>.

⁸ Michael Wilkes et al., Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications, 2000 HEALTH AFF. 19(2) at 110, 112.; Martin Hirsch (2008). Side effects of corporate greed: Pharmaceutical companies need a dose of corporate social responsibility. 9 MINN. J. L., SCI. & TECH. 607 (2008).

Table 1. Top U.S. Drug Advertisement Expenditures (2016)⁹

Drug/Maker	Advertisement (in USD millions)	Purpose
Humira/AbbVie	\$439	Anti-inflammatory
Lyrica/Pfizer	\$392	Nerve pain management
Eliquis/Bristol-Myers Squibb	\$296	Blood thinner
Xeljanz/Pfizer	\$258	Anti-inflammatory
Opdivo/Bristol-Myers Squibb	\$168	Cancer treatment
Chantix/Pfizer	\$151	Smoking cessation
Cialis/Lilly	\$150	Erectile dysfunction
Trulicity/Lilly	\$142	Increase glucose (diabetes)
Pevnar/Pfizer	\$142	Pneumonia vaccine

The pharmaceutical industry spends hundreds of millions of dollars annually to market its products. Direct-to-consumer prescription ads are the second-fastest growing ad category, competing with other top marketers stemming from automotive, fast food, insurance, and cable/wireless providers.^{10,11} Ad spending for television by pharmaceutical companies has more than doubled in the last four years, representing a 65% increase in this genre since 2012. It is currently the seventh largest ad category in the U.S.,

⁹ Jon Swallen, Drug Advertising Booms to \$6.4 Billion, KANTAR (May 8, 2017, 4:00 PM), <http://us.kantar.com/business/health/2017/drug-advertising-booms/>.

¹⁰ Rachel Kornfield et al., Trends in Exposure to Televised Prescription Drug Advertising, 2003–2011, 48 AM. J. PREVENTIVE MEDICINE 5 (May 2015).

¹¹ Bruce Horovitz & Julie Appleby, Prescription drug costs are up; So are TV ads promoting them, USA TODAY (Mar. 16, 2017, 7:04 AM), <https://www.usatoday.com/story/money/2017/03/16/prescription-drug-costs-up-tv-ads/99203878/>.

investing \$6.4 billion in 2016.¹² Table 1 offers examples of top U.S. drug advertisement expenditures in 2016.¹³ Yet, greater ad spending does not necessarily correlate with product effectiveness. One of the most advertised drugs in 2016, Jublia (a toe fungus treatment),¹⁴ costs about \$600 a bottle but is reported to work in fewer than 20% of users.¹⁵

In 2016, 80 prescription drug advertisements were televised every hour, totaling 1,920 drug ads directed at American viewers per day.¹⁶ Television networks—ABC, CBS, NBC—along with cable channels like CNN draw millions of dollars from pharmaceutical advertising, approximately 8% of their ad revenue.¹⁷ Given U.S. viewers watch about five hours of television *daily*,¹⁸ many citizens are likely to spend more time listening to pharmaceutical advertisements than talking with their physician (typically 15 minutes per visit, four times a year).^{19,20,21}

All this advertising can increase the cost of prescription drugs.²² Ironically, these ads actually serve as tax deductions for pharmaceutical firms.²³ Legislation to eliminate this deduction is currently being debated in the U.S. Congress but powerful lobby groups backed by the industry are challenging

¹² Jon Swallen, Drug Advertising Booms to \$6.4 Billion, KANTAR (May 8, 2017, 4:00 PM), <http://us.kantar.com/business/health/2017/drug-advertising-booms/>.

¹³ *Id.*

¹⁴ Aimee Picchi, Drug ads: \$5.2 billion annually—and rising, CBS NEWS: MONEYWATCH (Mar. 11, 2016, 3:25 PM), <https://www.cbsnews.com/news/drug-ads-5-2-billion-annually-and-rising/>.

¹⁵ Treating Toenail Fungus, CONSUMER REPORTS (Jan. 7, 2016), <https://www.consumerreports.org/health/treating-toenail-fungus/>.

¹⁶ Alix Spiegel, Selling Sickness: How Drug Ads Changed Healthcare, NPR (Oct. 13, 2009), <http://www.npr.org/templates/story/story.php?storyId=113675737>.

¹⁷ Horovitz, *supra* note 10.

¹⁸ John Koblin, How Much Do We Love TV? Let Us Count the Ways, N.Y. TIMES (June 30, 2016), <https://www.nytimes.com/2016/07/01/business/media/nielsen-survey-media-viewing.html>.

¹⁹ Carol Peckham, Medscape Physician Compensation Report 2016, MEDSCAPE (Apr. 1, 2016), http://www.medscape.com/features/slideshow/compensation/2016/public/overview?src=wnl_physrep_160401_mscpedit&uac=232148CZ&impID=1045700&faf=1#page=26.

²⁰ Tim Mackey & Bryan Liang, It's Time to Shine the Light on Direct-to-Consumer Advertising, 13 ANNALS FAMILY MEDICINE 82 (2015).

²¹ Niall McCarthy, Americans Visit Their Doctor 4 Times A Year. People In Japan Visit 13 Times A Year [infographic], FORBES (Sep. 4, 2014, 8:47 AM), <https://www.forbes.com/sites/niallmccarthy/2014/09/04/americans-visit-their-doctor-4-times-a-year-people-in-japan-visit-13-times-a-year-infographic/#35107e87e347/>.

²² Thomas Dibacco, Just say no to drug ads on TV, WASH. TIMES (Feb. 8, 2017), <https://www.washingtontimes.com/news/2017/feb/8/drug-ads-on-tv-should-be-banned/>.

²³ Insideradio, Tax bill targets big pharma advertising deductions. (March 13, 2018), http://www.insideradio.com/free/tax-bill-targets-big-pharma-advertising-deductions/article_5db46c5a-2685-11e8-bb4e-1ba75015db76.html.

these reforms with tenacious veracity.²⁴ To better understand the interconnections between the U.S. government and the pharmaceutical industry, it is important to explain the industry's historical context. From there, issues can be discussed and ideas for systemic change considered.

I. THE GENESIS OF BIG PHARMA

To understand what drives these ads, it is necessary to examine the trillion-dollar pharmaceutical industry known as Big Pharma. Big Pharma is the name ascribed to a consortium of the world's largest drug companies. The term is applied to the vast and influential pharmaceutical industry and its trade group in the U.S., known as the Pharmaceutical Research and Manufacturers of America (PhRMA). Given the astronomical amount of money made in the global prescription drug business, the industry has inordinate power and influence over consumers' lives. It is no surprise, then, that Big Pharma is the subject of heated debate amongst many stakeholder groups.²⁵

Drug companies like Merck, Eli Lilly, and Roche; and chemical firms like Bayer, ICI, Pfizer, and Sandoz, have been in business for more than 100 years, going back to a time when most medicines were sold without prescriptions and roughly half were provided by local druggists. The period between 1918 and 1939 was marked by the discovery and modest production of penicillin and insulin.²⁶ As demand for analgesics and antibiotics escalated during World War II, a government-supported international collaboration, including Merck, Pfizer, Squibb, and Lilly, sought to mass produce penicillin.²⁷ The unprecedented success of this effort signaled a new direction for drug development involving collaboration between companies and the government, forecasting the advent of the modern pharma industry.

The implementation of state healthcare systems in the post-war period created a more stable market for prescribing and reimbursement processes. For example, in 1957 the UK established a pricing scheme that enabled reasonable

²⁴ Beth Bulick, Tax bill may target pharma's DTC deduction, but ad industry's ready to defend it, FIERCEPHARMA (Dec. 11, 2017, 8:06 AM), <https://www.fiercepharma.com/marketing/tax-bill-may-look-to-deny-pharma-advertising-deduction-but-ad-association-ready-to-defend>.

²⁵ See generally MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT (Random House, reprt. ed. 2005).

²⁶ David Taylor, The Pharmaceutical Industry and the Future of Drug Development, 41 PHARMACEUTICALS IN THE ENVIRONMENT 1 (R. Hester & R. Harrison eds., 2015).

²⁷ Discovery and Development of Penicillin, AM. CHEMICAL SOC. INT'L HISTORIC CHEMICAL LANDMARKS, <https://www.acs.org/content/acs/en/education/whatischemistry/landmarks/flemingpenicillin.html> (last visited Apr. 13, 2018).

investment returns and incentivized commercial investment in the research and manufacture of new products.²⁸ In the ensuing years, consumers benefited from the introduction of over-the-counter products like acetaminophen and ibuprofen, complemented by completely new classes of pharmaceuticals such as oral contraceptives, betablockers, ACE inhibitors, benzodiazepines, and a range of cancer treatments.²⁹

Between 1980–2000, drug development was largely in the hands of multinationals, prompting the creation of “blockbuster drugs.” These chemical compounds were designed to become consumer staples as treatments for common, chronic ailments. For example, the ulcer medication Tagamet quickly reached \$1 billion in sales, followed by a succession of other blockbusters like Eli Lilly’s Prozac (the first serotonin reuptake inhibitor) and Astra’s Omeprazole (the first proton pump inhibitor). Pfizer’s cholesterol drug Lipitor became the best-selling drug of all time, with \$125 billion in sales over 15 years. Pharmaceuticals strategically promote products expected to become the most profitable. For example, in 2011 Boehringer Ingelheim spent \$464 million advertising its blood thinner Pradaxa. The investment appears to have paid off: the drug passed the \$1 billion sales mark the following year.

Today, prescription drugs are a massive market. Americans spent \$325 billion in 2015 (equating to 1.8% of GDP and 10% of total national health expenditures) on retail prescriptions alone (not including drugs administered directly by healthcare providers).³⁰ Critics are concerned that pharmaceutical firms are driven more by financial self-interest than by their espoused values to serve society. Given today’s legal environment, this industry is expected to reach \$5.7 trillion by 2026, representing a 5/5% growth rate per year (2017–2026).³¹ Pharmaceuticals have an especially robust duty to society because they have the power to contribute to or deny the ability to live a healthy life.

²⁸ Lesley Hannah & Jessica Phillips, *Is the Current UK System of Pharmaceutical Price Regulation Working?*, LEXOLOGY (Feb. 20, 2017), <https://www.lexology.com/library/detail.aspx?g=4f3f95a6-a667-4d6d-a113-09ec8a094cdd>.

²⁹ DAVID TAYLOR, *The Pharmaceutical Industry and the Future of Drug Development, in PHARMACEUTICALS IN THE ENVIRONMENT (VOL. 41)* (R. Hester & R. Harrison eds., 2015).

³⁰ Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, BROOKINGS (Apr. 26, 2017), <https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/>.

³¹ *National Health Expenditure Projections 2017–2026: Forecast Summary*, CTRS. FOR MEDICARE & MEDICAID SERVS. (2018), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ForecastSummary.pdf>.

II. DIRECT-TO-CONSUMER PHARMACEUTICAL ADS

Ventola's research provides historical context for DTCPA practices today.³² The Division of Drug Marketing, Advertising, and Communications (DDMAC) within the FDA is responsible for DTCPA's regulation.³³ The FDA was given authority to approve pharmaceutical products for marketing in the U.S., as a result of the Federal Food, Drug, and Cosmetic Act, passed in 1938.³⁴ In 1962, the FDA was afforded statutory authority to regulate prescription drug labeling and advertising. Most recently, in 1969, the FDA stipulated that pharmaceutical ads must (1) not be false or misleading, (2) fairly represent a drugs risks and benefits, (3) include facts that are "material" to the product's advertised uses, and (4) briefly summarize every risk described in the product's labeling.³⁵ During the 1980s, the political climate became more favorable to the pharmaceutical industry. Patients also became more active participants in their medical decision-making, interacting with their healthcare providers.

With television introducing DTCPAs, the FDA had to consider new questions about how consumer drug advertising should be regulated.³⁶ In 1983, the FDA imposed a voluntary moratorium, requesting that pharmaceutical firms sustain from DTCPA while the agency studied the issue.³⁷ In 1985, the FDA published a notice in the *Federal Register* claiming regulatory jurisdiction over DTCPA, affirming that the prior standards of "fair balance" and "brief summary", were sufficient to protect American consumers against deceptive or misleading claims.³⁸ Including additional information was deemed costly and time prohibitive by pharmaceutical firms. As a result, ads ultimately ended up being largely geared to encourage help-seeking, rather than making direct product claims. Providing medical information to patients via DTCPA's presumably empowers them to discuss these treatments with their providers.

³² C. Ventola, Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?, 36 PHARMACY & THERAPEUTICS 669 (Oct. 2011).

³³ *Id.*; see also Connors, *supra* at note 23.

³⁴ William Boden & George Diamond, DTCA for PTCA – Crossing the Line in Consumer Health Education?, 358 NEW ENG. J. MED. 2197 (May 2008).

³⁵ *Id.*

³⁶ See Jeremy Greene & David Herzberg, HIDDEN in PLAIN SIGHT Marketing Prescription Drugs to Consumers in the Twentieth Century, 100 AM. J. PUB. HEALTH 793 (May 2010).

³⁷ *Id.*

³⁸ *Id.*

Twelve years later, after a hearing in 1995, the FDA issued a draft guidance (with final regulations in 1999), explaining that advertisers had to include only “major risks” and provide an “adequate provision” that would direct viewers elsewhere to access complete “brief summary” information elsewhere (via a toll-free number, a healthcare provider, website, etc.).³⁹ In 1997, advertising of prescription drugs and medical devices was legalized. The FDA further relaxed the regulations in 2004, eliminating complete prescribing information in print product claim ads and allowing the inclusion of a simplified brief summary instead.⁴⁰ At this point, pharmaceutical companies only had to provide information on “major risks” and provide simplified language (i.e., easier for the average consumer to understand).⁴¹

The FDA continues to regulate DTCPA, but critics say that now rules are too relaxed and inadequately enforced.⁴² Scholars writing for the *New England Journal of Medicine* suggest that DTCPA increases pharmaceutical sales by wielding a double-edged sword. The ads can simultaneously avert underuse, but also contribute to potential overuse.⁴³ Serious concerns were expressed and DTCPAs received increased attention when some very heavily advertised drugs were suddenly removed from the market, after finding that they carried serious risks. In 2015, the American Medical Association (AMA) voted that the U.S. government should impose a ban on this practice. And yet, DTCPAs continue to appear with disturbing regularity. The U.S. and New Zealand remain the only two countries that permit these types of advertisements.⁴⁴ It is therefore no coincidence that citizens of only two countries take an average of more than two prescription medications regularly: the U.S. and New Zealand.⁴⁵

The USFDA, the agency responsible for pharmaceutical regulation, has done little to address the AMA’s concern that these ads prompt consumers to seek inappropriate drugs and to believe that there is a pill for every ill, even for

³⁹ Gregory Abel et al., Direct-to-Consumer Advertising in Oncology, 11 *ONCOLOGIST* 217 (2006).

⁴⁰ Amy Shaw, Direct-to-Consumer Advertising (DTC) of Pharmaceuticals, *PROQUEST* (Mar. 2008), citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.549.4384&rep=rep1&type=pdf.

⁴¹ C. Ventola, Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic?, 36 *PHARMACY & THERAPEUTICS* 669 (Oct. 2011).

⁴² See Connors, *supra* at note 25. See also Donahue JM, Cervasco M, Rosenthal MB. A decade of direct-to-consumer advertising of prescription drugs. *NEW ENG. J. MED.* 2007; 357(7):673–81.

⁴³ *Id.*

⁴⁴ Direct-to-consumer Advertising Under Fire, *WORLD HEALTH ORG.*, <http://www.who.int/bulletin/volumes/87/8/09-040809/en/> (last visited May 3, 2018).

⁴⁵ U.S. Health Care from a Global Perspective, *COMMONWEALTH FUND*, <http://www.commonwealthfund.org/publications/issue-briefs/2015/oct/us-health-care-from-a-global-perspective> (last visited Mar. 26, 2018).

conditions effectively treated through diet and exercise.⁴⁶ Marcia Angell, former editor-in-chief of *The New England Journal of Medicine* disputes pharmaceutical companies' arguments that they need to boost profits to fund their research. She explains how these ads are "designed to convince people that they need pills... that happen to be more expensive" (i.e., typically those just entering the market).⁴⁷ When consumers go to see their physician, their requests for specific medications they have seen advertised are likely to be honored. Doctors do not want to lose patients, and they need to move quickly. Given expectations to see greater numbers of patients, it may be easier and faster to write a prescription than to discuss alternatives. Consumers have also started to expect easy, passive medication-based solutions to health concerns, becoming less interested in discussing other options (e.g., diet, lifestyle changes) that may be less convenient, but better for their long-term health. Between 1999-2012 there were significant increases in adult prescription drugs: from 51% in 1999-2000 to 59% in 2011-2012. During the same time, the prevalence of polypharmacy (use of multiple drugs to treat a single ailment/condition) also increased from 8.2% to 15%.⁴⁸

One study showed that people who regard DTCPA positively or neutrally may be more vulnerable to ad messaging. Promotion-focused ads that highlight positive health outcomes are favorable to individualistic-oriented persons whereas prevention-focused ads that underscore negative health outcomes (of not taking a drug) are favored by interdependent-oriented persons.⁴⁹ When an ad's focus matches their personal orientation, viewers are more likely to conclude a causal connection between taking the pharmaceutical and achieving the desirable lifestyle depicted in the ad. Furthermore, another study noted that the motivation for taking a drug (i.e., to live a desirable lifestyle versus to avoid pain or negative outcomes) was predominant and repeatedly reinforced within ads while risk information was presented only once.⁵⁰ Doctors are also influenced, led to prescribe name brand drugs, which may not be better than generic alternatives.

⁴⁶ See Ventola, *supra* at note 29.

⁴⁷ Interview: Marcia Angell, GPB: FRONTLINE (June 19, 2003), <https://www.pbs.org/wgbh/pages/frontline/shows/other/interviews/angell.html>.

⁴⁸ Elizabeth Kantor et al., Trends in Prescription Drug Use among Adults in the United States from 1999–2012, 314 JAMA 1818 (2015).

⁴⁹ Nithima Sumpradit et al., "Give Me Happiness" or "Take Away My Pain": Explaining consumer responses to prescription drug advertising, 2 COGENT BUS. & MGMT. 1 (2015).

⁵⁰ N. Sumpradit et al., A Cross-Media Content Analysis of Motivational Themes In Direct-To-Consumer Prescription Drug Advertising, 26(1) CLINICAL THERAPEUTICS 135 (2004).

In probing the contours of this issue, we must consider whether consumers experience the benefits defendants claim that DTCPAs provide. If, for instance, a consumer suffers a psychiatric or neurological illness that can impair their decision making capacity, they may be at risk of undue influence from these ads.⁵¹ Yet, one study found that 18% of the 50 drugs advertised most assiduously in the U.S. were medications used to treat these kinds of disorders.⁵²

One physician described how helpful conversations between patient and doctor, which pharmaceutical ads supposedly prompt, are not helpful when they hijack precious time in an already brief encounter.⁵³ He explained that he wants to focus on what is most relevant and beneficial for his patients' health, adding: "If I have to spend my time fending off marketing for a condition you don't have or a drug that's of no possible benefit to you, our time hasn't been used productively."⁵⁴ The medical community has shared its belief that DTCPA creates an inappropriate demand for medications and/or a demand for inappropriate medications.⁵⁵

The Protecting Americans from Drug Marketing Act was introduced in 2009, a bill designed to encourage companies to focus on developing new medicines, instead of developing marketing schemes. Legislation, which would amend the Internal Revenue Code (removing the tax deduction), is part of a growing trend to minimize the pervasiveness of DTCPA. Policymakers have asked for a three-year moratorium on advertising newly approved prescription drugs to consumers. Again, the AMA called for a ban on this form of promotion, with support from a variety of stakeholder groups. But efforts to push for a ban have stalled, given free-speech arguments made by the powerful drug lobby and assertions that such ads provide valuable information to patients about treatment options. Now moving to explore other aspects of the relationship between Big Pharma and the U.S. government, we can see how transactional reciprocity appears to fuel how legislation is cultivated and imposed.

⁵¹ Matthew Hollon, Direct-to-consumer marketing of prescription drugs: a current perspective for neurologists and psychiatrists, 18 CNS DRUGS 69 (2004).

⁵² *Id.*

⁵³ John Schumann, Those TV Drug Ads Distract Us From The Medical Care We Need, NPR (Apr. 29, 2017, 5:00 AM), <https://www.npr.org/sections/health-shots/2017/04/29/525877472/those-tv-drug-ads-distract-us-from-the-medical-care-we-need>.

⁵⁴ *Id.*

⁵⁵ *Id.* at 1098 (quoting from Prescription Drug Advertising Direct to the Consumer, 88 PEDIATRICS 174, 175 (1991)).

III. GOVERNMENT REGULATION

Government regulation is designed to ensure that businesses serve the public good, not just a fiduciary duty to their shareholders. But it is debatable if, when, and how these regulatory efforts effectively serve the public. Looking back, the 1940s, known as the “antibiotic era,” prompted a robust period for the discovery and development of pharmaceutical products. This has since evolved into an expensive, time-consuming, cumbersome, and bureaucratic process.⁵⁶ With the Thalidomide scandal in 1961, the medical community was shocked to learn that a drug being given to pregnant women caused serious birth defects. This prompted activists and stakeholder groups to take action, demanding a regulatory response.⁵⁷ This particular event triggered a government reassessment of government controls. New regulations were imposed to require efficacy, purity, and safety—greatly increasing research and development (R&D) costs, particularly in the area of clinical testing. An unintended consequence was that these enhanced regulations were deemed as barriers to market entry, providing impetus to drive the pharmaceutical industry’s consolidation.⁵⁸

Today, the pharmaceutical industry contributes heavily to the FDA’s annual budget. Back in 1992, the Prescription Drug User Fee Act (PDUFA) passed, making it the law for pharmaceutical companies to pay the FDA to review their applications for drug approvals. In response to a lethargic and burdensome process, this law was supposed to enable the FDA to work more efficiently and effectively, having more resources to conduct rigorous and timely reviews. In return, pharmaceutical firms would be able to send their products through the regulatory pipeline faster, and patients would receive new and potentially life-saving drugs more quickly. While the intent seemed to serve the greater good, many argued that PDUFA put the FDA into the pockets of the drug industry.⁵⁹ Avalere Health explored and reported how much pharma companies have actually paid the FDA through PDUFA, adding up the wide variety of fees collected for different types of applications (e.g., for each

⁵⁶ S. Projan, *Why is Big Pharma Getting Out of Antibacterial Drug Discovery?*, 6(5) *CURRENT OPINION IN MICROBIOLOGY* 427 (2003).

⁵⁷ Annas, George J., and Sherman Elias. “Thalidomide and the Titanic: Reconstructing the Technology Tragedies of the Twentieth Century.” *Health Law and Ethics* 89 (1999): 98–101. Retrieved from: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1508516/>.

⁵⁸ Taylor, D. (2015). *The pharmaceutical industry and the future of drug development*. *Pharmaceuticals in the Environment*, 1-33. DOI: 10.1039/9781782622345-00001 eISBN:978-1-78262-234-5.

⁵⁹ Ramsey, L., & Friedman, L.F. (2016). *The government agency in charge of approving drugs gets a surprising amount of money from the companies that make them*. *Business Insider*, August, 17. Retrieved from: <http://www.businessinsider.com/fda-user-fees-from-pharmaceutical-companies-2016-8>.

prescription drug application with clinical data, the fee in 2016 was over \$2 million). This report found that since PDUFA was passed in 1992, pharma companies have contributed \$7.67 billion to the federal agency's coffers.⁶⁰ This creates a interconnectedness between the two entities: a marriage between Big Pharma and the government can potentially blur the intent of government regulation and the role that it plays in protecting citizens.

Although interest groups have emerged to represent the rights of companies and patients alike (e.g., pharmaceutical manufacturers, governmental regulatory authorities, patent officers, academic and clinical researchers, attorneys, and political action committees [PACs]). With huge profits and a thousand paid lobbyists, Big Pharma often gains leverage in how legislation is crafted and/or abandoned. From 1998 to 2014, Big Pharma spent nearly \$3 billion on lobbying, drowning out the voices of consumers and the interest groups that try to represent them.⁶¹ While some stakeholder-driven activist groups, like Patients for Affordable Drugs, work to represent the voice of constituents, a number of powerful groups that claim to represent patient advocacy are tainted by special interest biases. One study shows that nearly all patient advocacy groups are manipulated or captured by the drug industry; over 80% of these groups take money from Big Pharma.⁶²

The Project on Government Oversight (POGO) reports that at least 39 of 42 patient advocacy groups who participated in discussions with the FDA over agency review processes for prescription drugs received funding from pharmaceutical companies.⁶³ Additionally, at least 15 advocacy groups have representatives of drug or biotechnology companies on their governing boards. Congress recently passed the 21st Century Cures Act in 2016, authorizing \$6.3 billion⁶⁴ in federal funding and weakening the FDA's approval process.⁶⁵ Over

⁶⁰ Woollett, J.J. (2016). FDA has received \$7.67 billion from manufacturers to fund drug review. Retrieved from: <http://avalere.com/expertise/life-sciences/insights/fda-has-received-7.67-billion-from-manufactures-to-fund-drug-review>.

⁶¹ Senate Office of Public Records data (2017). Pharmaceuticals/Health Products. Industry Summary, 2017. Open Secrets. Center for Responsive Politics. Retrieved from <https://www.opensecrets.org/lobby/indusclient.php?id=h04>.

⁶² Thomas, K. (March 1, 2017). More than 80 Percent of Patient Groups Accept Drug Industry Funds, Study Shows. New York Times. Retrieved from: <https://www.nytimes.com/2017/03/01/health/patient-groups-drug-industry-money.html>.

⁶³ David Hilzenrath, In FDA Meetings, "Voice" of the Patient Often Funded by Drug Companies, POGO (Dec. 1, 2016), <http://www.pogo.org/our-work/reports/2016/in-fda-meetings-voice-of-the-patient-often-funded-by-drug-companies.html>.

⁶⁴ Jennifer Steinhauer & Sabrina Tavernise, \$6.3 Billion Measure Aims to Cure Ailing Health Care Policies, N.Y. TIMES (Nov. 28, 2016) <https://www.nytimes.com/2016/11/28/us/politics/congress-cures-cancer-moonshot-alzheimers.html>.

1,400 lobbyists worked on the bill, which served as a major financial boon to the drug and medical device industries. While patient advocacy groups were engaged, many were not independent. For example, the National Health Council, a group that calls itself The United Patient Voice, has advocated before the FDA for faster drug approvals. Members of its board of directors include leaders from two of the main trade groups for the drug industry—Pharmaceutical Research and Manufacturers of America (PhRMA), and Biotechnology Innovation Organization (BIO)—along with executives from drug companies Sanofi, Johnson & Johnson, and Alkermes. PhRMA gave the National Health Council \$1.2 million in 2014; in all, 77% of its funding came from the pharmaceutical and biotech industries, according to POGO.⁶⁵ The United Patient Voice Policy Action Team also has a PhMRA representative on it, along with an employee of Johnson & Johnson.⁶⁷

According to reports by nonprofit MapLight, drug companies poured more than \$70 million into fighting California’s Proposition 61, intended to limit the prices state agencies pay for prescription drugs.⁶⁸ The industry often backs legislators who favor their shareholder-driven approach. For example, Big PhRMA spent \$7 million in 2016 for their “Go Boldly” ad campaign, giving millions to politicians who were up for election in both parties in dozens of states.⁶⁹ The drug companies lavished more than \$2 million on scores of groups representing patients with various diseases—many of them dealing with high drug costs. The trade group PhRMA is also known for hiring former government employees, who are connected to those in political office.⁷⁰ Using these relationships to pursue industry goals, Big Pharma maintains a significant

⁶⁵ H.R.34–21st Century Cures Act14th Congress (2015–2016). Retrieved from: <https://www.congress.gov/bill/114th-congress/house-bill/34/>.

⁶⁶ New POGO Investigation: FDA and Patient Groups Addicted to Drug Industry, POGO (Dec. 1, 2016), <http://www.pogo.org/about/press-room/releases/2016/new-pogo-investigation-fda-and-patient-groups-addicted-to-drug-industry.html?print=t>.

⁶⁷ David Dayen, New Report Exposes “Patient Advocacy” Groups as a Big Pharma Scam, THE INTERCEPT (Dec. 1, 2016, 2:12 PM), <https://theintercept.com/2016/12/01/new-report-exposes-patient-advocacy-groups-as-a-big-pharma-scam/>.

⁶⁸ Seipel, J. (2016, August 11). Election 2016: Big Pharma’s \$70 million tops California campaign contributions. The Mercury News. Retrieved from: <http://www.mercurynews.com/2016/07/11/election-2016-big-pharmas-70-million-tops-california-campaign-contributions/>.

⁶⁹ Jay Hancock, In Election Year, Drug Industry Spent Big to Temper Talk about High Drug Prices, NPR (Dec. 18, 2017, 7:00 AM), <https://www.npr.org/sections/health-shots/2017/12/18/571206699/in-election-year-drug-industry-spent-big-to-temper-talk-about-high-drug-prices>.

⁷⁰ See, e.g., Hiring Former Federal Government Employees as Lobbyists, CAPLIN & DRYSDALE (June 11, 2009), <http://www.capdale.com/Closing-the-Revolving-Door-Post-Employment-Lobbying-Restrictions-Following-HLOGA-and-Obamas-Executive-Order-on-Ethics-06-10-2009>; Jay Hancock & Shefali Luthra, States take on drug prices; Big Pharma takes on states, NBC NEWS (Jan. 30, 2018, 6:33), <https://www.nbcnews.com/health/health-care/states-take-drug-prices-big-pharma-takes-states-n842886>.

advantage that can be used to override stakeholder interests. Such integrated forms of control contribute to the high cost and limited availability of certain drugs. U.S. citizens pay more than those of any other country for their pharmaceuticals.⁷¹ U.S. prices for major brand-name drugs spiked 127% between 2008-2014.⁷² This is in comparison with an 11% rise in a shopping cart of common household goods (according to Express Scripts, the largest U.S. manager of drug plans).⁷³ Big Pharma often points to extensive development costs to justifying its pricing strategies. However, this explanation merits additional consideration.

Aiming to improve American-owned businesses in global markets, Congress enacted a series of laws designed to speed up tax-supported research on new products. One of these laws, the Bayh-Dole Act of 1980,⁷⁴ enabled universities and small businesses to patent and/or license any discoveries from their tax-funded medical research sponsored by the National Institutes of Health (NIH). Prior to this law, taxpayer-financed discoveries belonged to the public domain (i.e., new drugs were available to any company that wanted them). As the result of this legislation, universities that carried out NIH-sponsored work could charge royalties, providing income for non-profit institutions. Legislation was also passed that allowed the NIH to enter into deals with drug companies, transferring NIH discoveries directly to industry.

This wave of legislation provided a huge boost to the nascent biotechnology industry, thereby paving the way for a tremendous buildup of Big Pharma. Small biotech operations, many of them founded by university researchers, proliferated. Much of the burden for the initial phases of drug development shifted from Big Pharma to smaller firms. The smaller firms worked to secure deals with Big Pharma, who would then take over the marketing of these discoveries and some level of ownership.⁷⁵ When a patent held by a university or a small biotech company is licensed to a pharmaceutical, Big Pharma reaps huge rewards. Laws have evolved so that drug companies can lean upon other firms to perform a great deal of their R&D. This has enabled them to shift some of the creation and testing of new

⁷¹ Ben Hirschler, Exclusive - Transatlantic Divide: How U.S. Pays Three Times More For Drugs, REUTERS (OCT. 12, 2015, 10:30 AM), <https://www.reuters.com/article/us-pharmaceuticals-usa-comparison/exclusive-transatlantic-divide-how-u-s-pays-three-times-more-for-drugs-idUSKCN0S61KU20151012>.

⁷² Ben Hirschler, How the U.S. Pays 3 Times More for Drugs, SCI. AM., <https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/> (last accessed May 3, 2018).

⁷³ *Id.*

⁷⁴ P.L. 96-517, H.R.6933, 96th Cong. (1979-1980)

⁷⁵ Jennifer Alsiver, *Big Pharma Innovation in Small Places*, (May 13, 2016), <http://fortune.com/2016/05/13/big-pharma-biotech-startups/>.

drugs onto external operations.⁷⁶ Drug companies license a third of their brands from universities or small biotech operations, reflecting the irony that very small ventures drive a large part of Big Pharma's innovation.⁷⁷ According to HBM Partners, a healthcare investing firm, a vast majority of drugs originate in smaller operations—64% of them in 2015.⁷⁸

Costs of bringing a drug to market are uncertain, vague, and often unverifiable. Gaining market approval for the development of a new medicine is an arduous process, easily taking over a decade. Some estimates suggest that bringing a drug to market costs in the neighborhood of \$2.6 billion, according to a study by the Tufts Center for the Study of Drug Development.⁷⁹ To encourage drug development in the U.S., regulatory laws permit pharmaceutical firms to set their own pricing and provide protections that are tantamount to limiting free-market competition.⁸⁰ Other countries set a limit on what firms can charge based on the benefit of each drug. In theory, it seems prudent to ensure that pharmaceuticals can recoup some of their losses, so they will continue to invest in risk-intensive choices that benefit those in need. Drugs with very small markets present particularly high investment risks. Some drugs do not make it to market. Once a drug is approved, determining a reasonable profit remains controversial.

Part of the problem is the number of stakeholders in the system, including insurers, pharmacy benefit managers, pharmacies, and wholesalers, all of whom net profit from the sale of prescription drugs. While manufacturers bear the burden of drug production expenses they also keep the majority of the profit. To illustrate, of every \$100 spent on prescription drugs by consumers (i.e., patients), \$58 is received by the manufacturer, of which \$17 is spent on drug production, \$15 is kept as profit, and \$26 is utilized for other expenditures, such as marketing and R&D.⁸¹ Total net profit on a \$100 expenditure is \$23, of which \$15 goes to manufacturers, \$3 to insurers, \$3 to

⁷⁶ Jerry Avorn, *Powerful Medicines: The Benefits, Risks, and Costs of Prescription Drugs* (2005).

⁷⁷ Jennier Alsiver, *Big Pharma Innovation in Small Places*, *Fortune.com* (May 13, 2016), <http://fortune.com/2016/05/13/big-pharma-biotech-startups/>.

⁷⁸ *Id.*

⁷⁹ Sandra Peters, *Cost to Develop and Win Marketing Approval for a New Drug is \$2.6 Billion*, TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT (Nov. 22, 2014), <https://www.americanentrepreneurship.com/press-releases/cost-to-develop-and-win-marketing-approval-for-a-new-drug-is-26-billion.html>.

⁸⁰ U.S. Health Policy Gateway, *Pharmaceutical regulation*, (Apr. 14, 2018), <http://ushealthpolicygateway.com/vii-key-policy-issues-regulation-and-reform/1-health-care-regulation/pharmaceutical-regulation/>.

⁸¹ Neeraj Sood Et Al., *The Flow of Money Through The Pharmaceutical Distribution System*, USC SCHAEFFER CENTER (June 13, 2017), http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf.

pharmacies, and \$2 to pharmacy benefit managers.⁸² While these figures vary, depending on whether the purchased drugs are generic or branded, only 17% of the cost is estimated to fund drug development, while 23% of the total purchase price is absorbed by stakeholders as profit.⁸³

The unintended consequence of the money flow throughout the distribution system and supply chain is that pharmaceutical firms can corner the market on a particular drug and then drive up the price. It is arguable that the prices drug companies charge could be cut dramatically without threatening future investments in R&D or eroding future profits. Research and development is a relatively small part of Big Pharma's budget, especially in comparison to the amount spent on sales and marketing. For every dollar spent on R&D, nineteen dollars go to marketing.⁸⁴ Said differently, 9 out of 10 of the biggest pharmaceutical companies actually spend more on advertising than on R&D, according to *The Washington Post*.⁸⁵ Sixteen drugs accounted for more than \$100 million each in spending last year, with the most advertised drug being arthritis treatment Humira, at \$357 million, according to the health news site Stat.⁸⁶ The average stock return over the last decade for the 10 biggest pharmaceutical companies based on 2015 sales is 88%.⁸⁷ This statistic is skewed, impacted by the unseemly returns of over 480% during the period for Gilead.⁸⁸

Given its mega-profits, Big Pharma has become known for its ability to wield political and social influence over its stakeholders, including the federal government and its agencies, healthcare systems, insurance firms, medical practitioners and administrators, hospitals, and consumers. Big Pharma has become one of the most profitable industries in the U.S., with 25-30% net margin profits (2016), rivaled largely by accounting, legal, and investment

⁸² *Id.*

⁸³ See also Derek Lowe, How Much Do Drug Companies Spend on R&D, Anyway?, SCIENCE TRANSLATION MEDICINE (May 20, 2013), http://blogs.sciencemag.org/pipeline/archives/2013/05/20/how_much_do_drug_companies_spend_on_rd_anyway.

⁸⁴ Donald W. Light, Pharmaceutical Research and Development: What do we Get For All That Money?, BRITISH JOURNAL OF MEDICINE 322-45 (Aug. 7, 2012).

⁸⁵ Ana Swanson, Big Pharmaceutical Companies are Spending Far More on Marketing than Research, THE WASHINGTON POST, (Feb. 11, 2015), https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.ebb47e8f5c88.

⁸⁶ Rebecca Robbins, Drug Makers Now Spend \$5 billion a Year on Advertising. Here's what that Buys, Stat News, (Mar. 9, 2016), <https://www.statnews.com/2016/03/09/drug-industry-advertising/>.

⁸⁷ Keith Speights, 12 Big Pharma Stats that will Blow you Away, The Motely Fool, (Jul. 31, 2016), <https://www.fool.com/investing/2016/07/31/12-big-pharma-stats-that-will-blow-you-away.aspx>.

⁸⁸ *Id.*

services, along with leasing operations and dentists (in 2017).⁸⁹ The industry has so much power that it has actually shaped how Western medicine and its citizens think about their health and well-being. Pharmaceutical companies strategically produce what increases earnings for their shareholders. But when the zeal for profit becomes an overriding goal, the interests of non-shareholder stakeholders are ignored, as depicted in this 2015 email from Martin Shkreli, former CEO of Turing Pharmaceuticals, maker of Daraprim:

\$1bn here we come. I think it will be huge. We raised the price from \$1,700 per bottle to \$75,000. So 5,000 paying bottles at the new price is \$375,000,000 . . . almost all of it is profit and I think we will get 3 years of that or more. Should be a very handsome investment for all of us. Let's all cross our fingers that the estimates are accurate.⁹⁰

Reports about how Turing acquired the full rights to a 60-year-old generic drug and then promptly raised its price 5000% outline how Shkreli's bold projections complemented his strategy.⁹¹ The drug treats toxoplasmosis, a parasitic infection that is particularly perilous for HIV/AIDS patients. Turing's documents were made public when participants on the House Government Reform and Oversight Committee investigated citizen outrage. Their inquiry confirmed the stark and grotesque reality: Turing had raised the price of Daraprim exorbitantly because it could do so—legally. In addition to windfall profits, the company reaped stakeholder backlash that forced Shkreli out. Amidst protests and investigations, fraud charges were brought against Shkreli and he was sentenced to a 7-year prison sentence in 2018.⁹² His expulsion, however, provided no relief to patients in desperate need of the drug.

Unfortunately, such unseemly pricing strategies are not confined to one rouse greedy executive or a few unethical firms. Pricing decisions are

⁸⁹ Mary Ellen Biery, *These Are The 10 Most Profitable Industries in 2017*, FORBES (Aug. 6, 2017), <https://www.forbes.com/sites/sageworks/2017/08/06/these-are-the-10-most-profitable-industries/#632c67c715f0>.

⁹⁰ Barbara Kollmeyer, '\$1bn here we come.'—Martin Shkreli Told Turing Board as Daraprim Buy Got Closer, MarketWatch (Feb. 3, 2016), <http://www.marketwatch.com/story/1bn-here-we-come-martin-shkreli-told-turing-board-as-daraprim-buy-got-closer-2016-02-03>.

⁹¹ Robert McClean, *Martin Shkreli on Drug Price Hike: '\$1 Billion Here We Come'*, CNN Money (Feb. 3, 2016), <http://money.cnn.com/2016/02/03/news/shkreli-turing-daraprim-price-house-hearing/>; *see also* Andrew Pollack & Mathew Goldstein, *Martin Shkreli All But Gloated Over Huge Drug Price Increases, Memos Show*, N.Y. Times, (Feb. 2, 2016), <https://www.nytimes.com/2016/02/03/business/drug-makers-calculated-price-increases-with-profit-in-mind-memos-show.html>.

⁹² Renae Merle, *Martin Shkreli Sentenced to Seven Years in Prison for Defrauding Investors*, THE WASHINGTON POST, (Mar. 9, 2018), https://www.washingtonpost.com/news/business/wp/2018/03/09/martin-shkreli-to-be-sentenced-friday-faces-more-than-decade-in-prison/?utm_term=.20f4f410477f&wpisrc=al_news__alert-economy—alert-national&wpmk=1.

commonly based on the desire to maximize profits. For example, in early 2015 Valeant Pharmaceuticals purchased two heart medications. Taking sole ownership, the company subsequently hiked prices by 525% and 212%, respectively.⁹³

In just one year, Valeant garnered \$351 million in profits from these two products.⁹⁴ But this success was short lived. After the U.S. Attorney's offices subpoenaed the company, its stock price plunged. In another case, Mylan, maker of the EpiPen emergency remedy for anaphylaxis, paid nearly half a billion dollars to settle a Justice Department complaint for misclassifying the drug under Medicaid, while separately facing other legal

complaints for overcharging consumers.⁹⁵

Industry professionals argue, however, that the market for medicines is unique. Both Turing and Valeant trade in medicines for uncommon illnesses, so-called orphan drugs (i.e., a small user base for medicines that treat rare diseases/disorders). Because so few patients need these drugs, there is little incentive for others to produce them and little or no competition. Leveraging this power, one Turing PowerPoint presentation strategically underscored the firm's desire to control the market:

- Drugs are typically nondiscretionary and consumers are relatively price-insensitive.
- Typically, there is an inverse correlation between prevalence of a disease and the annual cost of treatment.
- Exclusivity (closed distribution) creates a barrier and pricing power.⁹⁶

Turing's internal strategy emphasized hiding costs from patients and avoiding fights with HIV/AIDS advocates and hospitals. But the firms that make headlines are not the only ones raising their prices; prescription

⁹³ Pharma and Arbitrary Drug Prices, Actuarial Outpost (Sept. 20, 2015, 7:07 PM), http://www.actuarialoutpost.com/actuarial_discussion_forum/archive/index.php/t-299668.html.

⁹⁴ Ankur Banerjee & Rod Nickel, Drugmaker Valeant raises profit forecast; shares spike, REUTERS (May 9, 2017), <https://www.reuters.com/article/us-valeant-pharm-in-results/drugmaker-valeant-raises-profit-forecast-shares-spike-idUSKBN18517P?feedType=RSS&feedName=businessNews>.

⁹⁵ Jackie Wattles, EpiPen maker Mylan agrees to \$465 million settlement, CNN: MONEY (Oct. 7, 2016), <http://money.cnn.com/2016/10/07/news/companies/epipen-mylan-465-million-fine/>.

⁹⁶ Jeffrey Young & Shane Ferro, Pharma bro emails reveal just how greedy drug companies can be, THE HUFFINGTON POST (Dec. 19, 2016), http://www.huffingtonpost.com/entry/martin-shkreli-pharma-bro-drug-prices_us_56b0fac5e4b0655877f75453.

medication prices have been rising faster than inflation for years.⁹⁷ Even the prices of generic drugs, which are supposed to provide consumers with less expensive options, have climbed: 30% profit in 2017 (i.e., generic drugs are now being priced to benefit shareholders over stakeholders).⁹⁸ Big Pharma maintains that their motives are to produce additional income to advance the science of treatment, funding not only R&D but also patient access programs that dispense free or low-cost medicines to the uninsured and reduced co-payments for certain populations. Valeant instituted patient access programs after receiving complaints about its prices. Although a few consumers benefit from these programs, the vast majority are hit hard by the high price of medication.

Big Pharma has been involved in numerous billion-dollar lawsuits (see Table 2). In recent years, pharmaceutical companies have agreed to pay over \$13 billion to resolve U.S. Department of Justice allegations of fraudulent marketing practices, including the promotion of medicines for uses that were not approved by the FDA.⁹⁹ Cases typically involve misbranding and off-label marketing, giving kickbacks to physicians for prescribing and/or recommending drugs, and strategically aligning with generic companies as a means to keep the overall cost of drugs higher than their justified benefits.¹⁰⁰ Increases in the size and number of these cases contributes to the concern that the government itself has been complicit in the illicit behavior.¹⁰¹

⁹⁷ Alison Kodjak, Should the U.S. government buy a drug company to save money?, NPR: HEALTH NEWS (Mar. 17, 2017), <http://www.npr.org/sections/health-shots/2017/03/17/520430944/should-the-u-s-government-buy-a-drug-company-to-save-money>.

⁹⁸ Emma Court, Why did these generic drugs' prices jump as much as 85%?, MARKETWATCH (June 29, 2017), <https://www.marketwatch.com/story/on-the-very-day-of-a-senate-hearing-on-drug-costs-the-prices-of-these-common-generics-were-raised-as-much-as-85-2017-06-21>.

⁹⁹ *Id.*

¹⁰⁰ See Press Release, Department of Justice, Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations>.

¹⁰¹ Paul J. Zwier, & Reuben Guttman, A failure of remedies: The case of Big Pharma (An Essay), 3 EMORY CORP GOVERNANCE ACCOUNTABILITY REV 41 (2016).

Table 2. Major Settlements between Big Pharma and the U.S. Department of Justice (2009-13)¹⁰²

Company Name	Drug Names	Settlement	Date
GlaxoSmithKline	Paxil, Wellbutrin	\$3 billion	2012
Pfizer	Bextra	\$2.3 billion	2009
Johnson & Johnson	Risperdal, Invega, Natrecor	\$2.2 billion	2013
Abbott Laboratories	Depakote	\$1.5 billion	2012
Eli Lilly	Zyprexa	\$1.4 billion	2009
Amgen	Aranesp	\$762 million	2012
Sanofi-Aventis	Hyalgan	\$109 million	2012

Pharmaceutical companies are undeterred by fines, legal fees, and settlement payouts, which they seem to view as costs of doing business. The reality is that consumers ultimately pay for government programs through their tax dollars. Cost increases also contribute to higher insurance premiums, higher deductibles, and decreased coverage. The U.S. is the only major market where pharmaceutical pricing remains unregulated. Mahmud Hassan, director of Rutgers Business School's pharmaceutical management program, says that stakeholders in the U.S.—patients, health insurers, and the government—pay more for their prescribed medicines than those in countries with national health programs, and sometimes double.¹⁰³

¹⁰² Lena Groeger, Big Pharma's big fines, PROPUBLICA (Feb. 24, 2014), <http://projects.propublica.org/graphics/bigpharma>.

¹⁰³ Jeffrey Young & Shane Ferro, Pharma bro emails reveal just how greedy drug companies can be, THE HUFFINGTON POST (Dec. 19, 2016); *see also*, Stephen Feller, Americans pay more than double what other nations pay for drugs, UPI (Aug. 23, 2016), http://www.upi.com/Health_News/2016/08/23/Americans-pay-more-than-double-what-other-nations-pay-for-drugs/8501471964588/.

IV. THE MEDICAL COMMUNITY

Doctors, scientists, research organizations, medical journals, teaching hospitals, and university medical schools all accept money from the pharmaceutical industry. Medical researchers sometimes coauthor articles in concert with Big Pharma or receive funds for ghostwriting information that reflects certain results that may ultimately be published in medical journals. Research conducted by scientists associated with pharmaceutical firms has been used to promote (directly or indirectly) many drugs—including antidepressants Paxil and Zoloft, anti-epilepsy drug Neurontin, painkiller Vioxx, and recalled weight loss drug Fen-Phen. It is common practice for a pharmaceutical firm to pay a medical reviewer to write a comprehensive assessment of a new drug for a medical journal. Accounts of slanted research have appeared in medical journals, despite claims by authors of their unbiased scientific evaluation, separate from any financial ties to the industry. For example, the disclosure that in 1967 the sugar industry paid Harvard scientists to obscure a link between sugar and heart disease.¹⁰⁴ An unintended consequence of this misleading information has been decades of research examining the effects of saturated fat—rather than sugar.¹⁰⁵ Researchers say that this thwarted a more thorough investigation, which has likely contributed to an increase in the rate of heart disease in the U.S.¹⁰⁶

A former editor of the *British Medical Journal* describes how the pharmaceutical industry can cleverly use medical journals to their own advantage.¹⁰⁷ Most, including the *Journal of the American Medical Association*, benefit from advertising dollars from Big Pharma. Drug companies also sponsor clinical trials that researchers are paid to administer. Academics and scientists conduct the research, collecting data and preparing and analyzing the findings. Nevertheless, sponsors often keep the data, prepare additional analyses, and report what supports their own agenda. Drug

¹⁰⁴ Cristin E. Kearns, et al., Sugar Industry Influence on The Scientific Agenda of The National Institute of Dental Research's 1971 National Caries Program: A Historical Analysis of Internal Documents, PLOS MED. 12(3): e1001798 (2015).

¹⁰⁵ Anahad O'Connor, How the sugar industry shifted the blame to fat, N.Y. TIMES (Sep. 12, 2016), http://www.nytimes.com/2016/09/13/well/eat/how-the-sugar-industry-shifted-blame-to-fat.html?_r=0.

¹⁰⁶ American Heart Association, Added sugars add to your risk of dying from heart disease, AMERICAN HEART ASSOCIATION: HEALTHY LIVING (Sep. 16, 2016), http://www.heart.org/HEARTORG/HealthyLiving/HealthyEating/Nutrition/Added-Sugars-Add-to-Your-Risk-of-Dying-from-Heart-Disease_UCM_460319_Article.jsp#.V-6cISWQLX4.

¹⁰⁷ Rosa Ahn, et al., Financial ties of principal investigators and randomized controlled trial outcomes: Cross sectional study, THE BRITISH MEDICAL JOURNAL 356 i6770 (2017).

companies may stage-manage drug trials, revealing the outcomes that put their products in the best light.

Doctors in the U.S. are typically required to take accredited continuing medical education (CME) coursework. The pharmaceutical industry provides a substantial proportion of the annual costs of CME, using this platform as a means to market their products.¹⁰⁸ Drug company representatives are key players within the U.S. healthcare delivery system, educating doctors so they can prescribe drugs appropriately. At the same time, pharmaceutical firms train their representatives to push the newest (often the most expensive) products.¹⁰⁹ As previously described, academic centers can receive royalties from Big Pharma on any drug or technology they help to create and patent, often underwritten with government funds. Columbia University, for example, received nearly \$790 million from licensing agreements with biotech and pharmaceutical companies during the 17-year life of its medical school's patent on a method for synthesizing certain biological products.¹¹⁰

In the U.S., there is one pharmaceutical sales representative for every 2.5 office-based physicians.¹¹¹ In recent years, however, some facilities have imposed a closed-door policy, reducing this practice (by some accounts to 1:5).¹¹² In some cases, physicians may welcome salespeople because they provide free samples, which they can then use for their patients. Big Pharma claims that this practice improves patient care, fosters appropriate medication use, and helps millions of financially struggling patients. But scholars have countered that “sampling” is not effective in improving drug access for the indigent, does not promote rational drug use, and raises the cost of care.¹¹³

¹⁰⁸ JEROME P. KASSIRER, M.D., *ON THE TAKE: HOW MEDICINE'S COMPLICITY WITH BIG BUSINESS CAN ENDANGER YOUR HEALTH* (Oxford University Press, 2005); *see also* Amanda L. Connors, *Big bad pharma: An ethical analysis of physician-directed and consumer-directed marketing tactics*, 73 *ALB. L. REV.* 243 (2009).

¹⁰⁹ MARCIA ANGELL, *THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT* (2004).

¹¹⁰ Alessandra Colaianni & Robert Cook-Deegan, *Columbia University's Axcel Patents: Technology transfer and implications for the Bayh-Dole Act*, *THE MILBANK QUARTERLY* 87(3), 683–715 (2009).

¹¹¹ Adriane Fugh-Berman & Shahram Ahari, *Following the script: How drug reps make friends and influence doctors*, *PLOS MED* (2007), <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0040150>.

¹¹² Tracy Stanton, *In a bad-news first for pharma reps, more than half of doctors now restrict access*, *FIERCEPHARMA*, (Sep. 3, 2015), <http://www.fiercepharma.com/sales-and-marketing/a-bad-news-first-for-pharma-reps-more-than-half-of-doctors-now-restrict-access>.

¹¹³ Susan Chimonas & Jerome Kassirer, *No more free drug samples?*, *PLOS MED*, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2669216/>.

Also troubling is that healthcare professionals are continuously encouraged to resolve patients' concerns by prescribing medications. Given the pressure to see more patients in less time, the system pushes physicians to provide quick prescription-driven remedies. As a result of DTCAs, consumers' can be psychologically manipulated and there is a greater likelihood for doctors to inappropriately prescribe certain drugs.¹¹⁴ Pharmaceutical companies also sponsor symposia and medical conventions, offering medical practitioners opportunities to extend their education. These events often include free travel and other benefits, making it difficult to be anything but favorably inclined towards the sponsoring firms that help subsidize them. In medical schools, preceptors, teachers, department chairs, and deans may sit on drug companies' boards of directors. Money from Big Pharma also supports educational programming within many medical schools and teaching hospitals. Company reps can gain access to doctors in these settings and promote their wares.¹¹⁵ This serves to reinforce a drug-intensive style of practice.

V. MOVING FORWARD

It has been a decade since Hirsch called for pharmaceutical firms to adopt a system of corporate social responsibility.¹¹⁶ He urged leaders to recognize and protect stakeholders, prompting a shift from the bottom line model to one that inculcates ethics and human rights. But years later, Big Pharma is still largely driven by providing fiduciary gains to shareholders and corporate executives. Its profound focus on self-interest places in question how much of what it does actually benefits society. Over the past several decades, the pharmaceutical industry has generally become a marketing machine to sell drugs that generate the ultimate highest profit potential. As Big Pharma wields its power within the U.S. Congress, FDA, academic medical centers, and within the medical profession itself, patients are likely to find themselves confused, frustrated about options, and without recourse.

More recently, consumers are now experiencing huge pricing variations for the exact same drugs. A study in April of 2018 by *Consumer Reports* suggests that pharmacies are now imposing their own price increases, without notice to consumers. In comparing what it would cost (retail cash prices for a one-month

¹¹⁴ Elizabeth C. Melby, The Psychological Manipulation of the Consumer-Patient Population Through Direct-to-Consumer Prescription Drug Advertising, 5 SCHOLAR 325 (2002).

¹¹⁵ MARCIA ANGELL, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT (2004).

¹¹⁶ Hirsch, M. L. (2008). Side effects of corporate greed: Pharmaceutical companies need a dose of corporate social responsibility. *Minn. J.L. Sci. & Tech.*, 9, 607.

supply of five commonly prescribed drugs, the range in prices was stunning. All five drugs were only \$66 when purchased at the online pharmacy HealthWarehouse.com, \$105 when purchased at Costco. The two highest-priced national retailers—CVS and Rite Aid—had prices closer to \$900 for the very same drugs.¹¹⁷ What adds to the distressing nature of this practice is that when a consumer uses their insurance, they may now be told that certain drugs are no longer covered by their insurance, and shocked to see what used to be \$10 is now much more (in this case \$60) (first author personal experience at CVS, April 1, 2018). In fact, taking this exact same prescription to another drugstore that day (in this case, Walgreen's), produced an approved co-pay amount of \$10 (i.e., the insurance did cover it). This lack of transparency includes bizarre rationales by drugstores, based on whether or not they received a coupon for the drug, from the manufacturer. At this point, consumers literally have to shop around to find where their co-pays will be honored and to find the best prices for their prescriptions. This may include resorting to crossing borders, literally or via the Internet to procure cheaper medicine. In largess, it is typically considered to be illegal for citizens to import prescription drugs into the U.S. And the Food and Drug Administration says:

Medicine bought from foreign sources, such as from Internet sellers, from businesses that offer to buy foreign medicine for you, or during trips outside the United States, may not be safe or effective. These medicines are illegal and may present health risks, and FDA cannot ensure the safety, efficacy and quality of medicine from these sources. FDA cannot help consumers who have problems with medicine obtained from outside U.S. regulation and oversight.¹¹⁸

As consumers continue to navigate this opaque and continuously changing market, the cost and complexities of drug discovery continue to increase. This is causing Big Pharma to shift from the development of medicine that targets short-course therapies for acute diseases to the long-term treatment of chronic conditions. And, despite a growing clinical need, there is a disturbing lack of investment in producing novel antibacterial agents. Drug options for treatment of infections have become increasingly limited, as antimicrobial resistance becomes increasingly robust. Generic antibiotics are in short supply, and the development of new antibiotics has been severely curtailed. Only four large

¹¹⁷ Lisa L. Gill, Shop Around for Lower Drug Price, Consumer Report (Apr. 5, 2018), <https://www.consumerreports.org/drug-prices/shop-around-for-better-drug-prices/>.

¹¹⁸ Dan Mangan, Patients Cross Borders for Online Deals on Medications, CNBC (May 23, 2014, 11:54 AM), <https://www.cnbc.com/2014/05/23/patients-cross-borders-for-online-deals-on-medications.html>.

pharmaceutical companies with antibiotic research programs remained in existence in 2002. As reported by Pew Research in 2016:

New discoveries dropped precipitously from the 1980s onward. As a result, the development of antibiotics has declined, with new FDA approvals for these drugs falling from 29 during the 1980s to nine in the first decade of the 2000s. All antibiotics approved for use in patients today are derived from a limited number of types, or classes, of antibiotics that were discovered by the mid-1980s. This is even more concerning than the decline of drug approvals because resistance to one antibiotic often leads to resistance to multiple antibiotics within the same class. Faced with poor discovery prospects and diminishing returns on investment, major drug companies have cut back or pulled out of antibiotic research altogether. This has left much of the remaining discovery work to small, “pre-revenue” companies with no products on the market and limited budgets and R&D capacity. Most industry antibiotic development programs are primarily focused on modifying existing classes of drugs discovered decades ago to circumvent bacterial resistance and better target difficult-to-treat infections. Though essential, such incremental advances are not likely to meet the looming public health challenge of antibiotic resistance in the long term.¹¹⁹

Pharmaceutical companies face a paradox wherein federal agencies call for antibiotic development even as other federal agencies enact policies limiting the appeal of that very development.¹²⁰

Critics from the medical stakeholder community claim there is insufficient science guiding pharmaceutical business decisions and that financial incentives go in the wrong direction. Big Pharma wants consumers to take a pill every day for the rest of their lives. Therefore, they invest in new forms of birth control, cholesterol blockers, and antidepressants that dominate the market. Meanwhile, vaccines have become scarce. Big Pharma and its university partners have been charged with paying little attention to salient issues of public health, and focusing instead on products expected to maximize profits. Critics underscore how Big Pharma has grossly subordinated patient needs in

¹¹⁹ Susan K. Urahn et al., A Scientific Roadmap for Antibiotic Discovery: A Sustained and Robust Pipeline of New Antibacterial Drugs and Therapies is Critical to Preserve Public Health, The Pew Charitable Trusts (May, 2016), <http://www.pewtrusts.org/~media/assets/2016/05/ascientificroadmapforantibioticdiscovery.pdf>.

¹²⁰ Richard J. Fair et al., Antibiotics and Bacterial Resistance in the 21st Century, *Perspectives in Medicinal Chemistry*, 6, 25 (2014).

favor of its own investment returns.¹²¹ Allen Frances, Chair of the DSM-IV Task Force, warns that the gradual mislabeling of everyday problems as illness has toxic implications for individuals and society: stigmatizing people, introducing them to potentially harmful medications, misallocating medical resources, and draining the budgets of families and the nation. Wellness has been shifted away from our own naturally resilient and self-healing capacity, into the hands of Big Pharma, who reap multi-billion-dollar profits at citizens' expense.¹²²

Big Pharma presents a disturbing ironic reality: the industry offers life-saving health benefits, and yet remains one of the least trusted. The reality is that “some of the largest drug companies in the world—the one’s that we rely on for life saving treatments—are convicted criminals.”¹²³ Are regulators enablers? Or, perhaps worse still, are they complicit in questionable or ethically unsound activities as a result of being driven by self-serving motives? Working to untie and address this Gordian knot of interrelated profiteering and motivated special interests will require increased stakeholder engagement and government activism. U.S. Senator Bernie Sanders (I-VT) asserts that “people must be prepared to stand up to powerful special interests like the pharmaceutical industry and like Wall Street.”¹²⁴ Before taking office, President Donald Trump said the pharmaceutical industry was “getting away with murder,” and vowed to do something about it.¹²⁵ The reality to date, however, is that Big Pharma has the power to continue to dictate the pricing of drugs in the U.S., where our legal platform continues to offer incentives for firms to extract exorbitant prices. Traditional common law remedies have not resulted in deterrence.¹²⁶

¹²¹ Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What to do About It*, (2014).

¹²² Allen Frances, *Saving Normal: An Insider’s Revolt against Out-of-control Psychiatric Diagnosis, DSM-5, Big Pharma and the Medicalization of Ordinary Life*, *Psychotherapy in Australia*, 19(3), 14 (2013).

¹²³ Reuben A. Guttman, *A Practitioner’s View of Institutional Corruption Through the Lens of the Health Care System: An Essay*, 5 *EMORY CORP. GOVERNANCE AND ACCOUNTABILITY REV.* 4 (2018), available at http://law.emory.edu/ecgar/_documents/volumes/5/1/guttman.pdf.

¹²⁴ Deirdre Fulton, *Sanders Tackles Drug Pricing (Again), This Time with Help from Big-Pharma Dems, Common Dreams* (Feb. 28, 2017), <https://www.commondreams.org/news/2017/02/28/sanders-tackles-drug-pricing-again-time-help-big-pharma-dems> (last visited Apr. 23, 2018).

¹²⁵ Caroline Humer et al., *Trump Says Pharma ‘Getting Away with Murder,’ Stocks Slide*, *Reuters* (Jan. 11, 2017, 12:07 PM), <http://www.reuters.com/article/us-usa-trump-drugpricing-idUSKBN14V24J>.

¹²⁶ Paul J. Zwier et al., *A Failure of Remedies: The Case of Big Pharma (An Essay)*, 3 *EMORY CORP. GOVERNANCE AND ACCOUNTABILITY REV.* 2, available at <http://law.emory.edu/ecgar/content/volume-3/issue-2/essays/failure-remedies-case-big-pharma.html>.

Despite public knowledge of Big Pharma's self-serving practices, pharmaceutical companies claim that their mission is to benefit people. Reformers call for restructuring the industry itself, so that it remains grounded in science but is genuinely motivated to provide safe and effective drugs for the public. Accomplishing this aim will require protracted and sustained citizen and stakeholder engagement, demonstrated via a determined commitment to prompt reflection, informed dialogue, and bipartisan reform. To create systemic change, fresh ideas need to be explored. One plan for tackling the expensive limited access to drugs has emerged from the medical community. The idea is for the U.S. federal government to buy pharmaceutical firms outright, rather than buying the drugs themselves.¹²⁷

For example, according to the Center for Disease Control and Prevention, Hepatitis C kills more Americans than any other infectious disease and often leads to a need for liver transplants.¹²⁸ Gilead Sciences Inc. makes Sovaldi and Harvoni, the two drugs that can swiftly cure this disease, but sells them at prices so high that few can afford them (a 12-week course is \$84,000).¹²⁹ States restrict their use, telling patients they are not sick enough to justify the cost. The drugs consistently eradicate the virus, which has infected an estimated 2.7 to 3.3 million people in America.¹³⁰ Buying the company instead of the drugs would cut the cost of treatment by almost two-thirds. The government could then sell the firm itself, but sustain the drug rights. Doing so would cut the cost of treatment, stop the disease from spreading, and reduce the number of liver transplants needed.

The idea of having the government purchase corporate shares at full price on the open market may seem far-fetched. But it represents the kind of transformational thinking that might help to promote deep change. Experts say that if the federal government treated illnesses as public health issues, rather than as Medicaid budget problems, innovative ideas like this one would be

¹²⁷ Alison Kodjak, Should the U.S. Government Buy a Drug Company to Save Money?, Health News from NPR (Mar. 17, 2017 at 3:49 PM), available at <http://www.npr.org/sections/health-shots/2017/03/17/520430944/should-the-u-s-government-buy-a-drug-company-to-save-money>.

¹²⁸ Centers for Disease Control and Prevention, Hepatitis C Kills More Americans than Any Other Infectious Disease, CDC Newsroom (May 4, 2016), available at <https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html>.

¹²⁹ Andrew Pollack, Harvoni, a Hepatitis C drug from Gilead, wins F.D.A. approval, New York Times (Oct. 10, 2014), <https://www.nytimes.com/2014/10/11/business/harvoni-a-hepatitis-c-drug-from-gilead-wins-fda-approval.html>.

¹³⁰ Alison Kodjak, Should the U.S. Government Buy a Drug Company to Save Money?, Health News from NPR (Mar. 17, 2017, 3:49 PM), <http://www.npr.org/sections/health-shots/2017/03/17/520430944/should-the-u-s-government-buy-a-drug-company-to-save-money>.

more likely to emerge.¹³¹ They argue that the government needs to focus explicitly on curing and saving patients, and to move away from reinforcing practices such as prescription-based care and drug dependency, which benefit the industry but harm citizens. Manufacturers and suppliers need to co-create stakeholder codes of conduct that reduce or eliminate DTCPA and reflect increasing efforts to support and enhance public awareness of disease prevention and management. Executives leading Big Pharma firms must be held accountable; liable for the misconduct they participate in, enable, or turn a blind eye toward. Prosecutors need to be able to exact penalties that are potent enough to affect corporate behavior, such as fines that involve garnishing 15% of a firm's annual profits and executive compensation and benefits. Some suggest that Big Pharma be regulated like public utilities.¹³² If the government regulated drug pricing, as it does for electricity, it would likely prompt competition between companies and drive prices lower, benefiting all, including government programs.

The convergence of IT and healthcare is another path that might prompt a shift in the Big Pharma model. Big data, apps, and mobile health are starting to transform healthcare and diagnostics in a significant way, with Apple and Google acting as steadfast disruptive catalysts. Medicines paired with companion diagnostics may be an increasingly leveraged strategy to gain market access. At present, AstraZeneca, Roche, Novartis and Sanofi are progressing as much as 60–80% of their clinical portfolios with companion diagnostics.¹³³ In the era of personalized and precision medicines, this strategy will likely translate into medicines accompanied with apps or wearable devices that help patients monitor key parameters and manage their diseases. How big pharma adapts to this 'beyond-the-pill' model will be an interesting development during the next decade.¹³⁴

In broader terms, academic institutions need to educate the next generation of business leaders to view social responsibility and governance as key components in the calculation of value and profit. It is not enough to increase the value of corporate stock in the short term. Firms must incorporate a stakeholder perspective, accompanied by a longer-term profit horizon. Perhaps

¹³¹ Diane Calmus, *The Long-term Care Financing Crisis*, The Heritage Foundation (Feb. 6, 2013), <http://www.heritage.org/health-care-reform/report/the-long-term-care-financing-crisis>.

¹³² Rosa Ahn et al., *Financial Ties of Principal Investigators and Randomized Controlled Trial Outcomes: Cross Sectional Study*, *BRITISH MEDICAL J.* 356 (Jan. 17, 2017).

¹³³ Ajay Gautam et al., *The Changing Model of Big Pharma: Impact of Key Trends*, 21 *DRUG DISCOVERY TODAY*, 379-384 (Mar. 2016).

¹³⁴ *Id.*

policymakers can leverage insights from business protocols like “B Corp,” where certification requires the ability of a firm to meet rigorous stances of social and environmental performance, accountability, and transparency.¹³⁵

Big Pharma, affecting the health and welfare of every citizen, is at the intersection of business and society. Policy and lawmakers who are free from the influence of lobbying forces must help corral Big Pharma, toward redirecting a reasonable portion of their profits to benefit consumers. This is both possible and feasible via legislation that imposes stricter regulations on DTCPA and limits drug patent extensions, as well as the reevaluation of the learned intermediary doctrine by the judicial system.¹³⁶ How this industry moves forward presents one of the biggest ethical challenges of the 21st century, seeking a balance between capitalism and the corporation’s duty to its share- and stakeholder constituents.

¹³⁵ Certified B Corporation, What Is a B Corp?, <https://www.bcorporation.net/what-are-b-corps> (last visited Apr. 23, 2018).

¹³⁶ Elizabeth C. Melby, Comment: The Psychological Manipulation of the Consumer-patient Population through Direct-to-consumer Prescription Drug Advertising, 5 SCHOLAR 325, 353 (2003).