Robin Feldman
Arthur J. Goldberg Distinguished Professor of Law
Director, Center for Innovation

UC Hastings Law | 200 McAllister Street | San Francisco, CA 94102
phone 415 565 4661 | feldmanr@uchastings.edu
https://www.uchastings.edu/academics/centers/center-for-innovation/

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Carolyn B. Maloney
Chairwoman of the Committee on Oversight and Reform
U.S. House of Representatives
2308 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Maloney,

Thank you for the opportunity to offer perspectives from my research for the Committee's hearing on Unsustainable Drug Prices.[1] It is tremendously heartening to see bipartisan congressional focus on the issue of high drug prices, which are reducing patient access to affordable medicine, creating financial hardships for families, and burdening taxpayers.

The skyrocketing price of prescription medication is a widespread problem in the pharmaceutical industry. For example, my analysis of approximately one million Medicare patients between 2010 and 2017 found that—even after accounting for rebates—the average price of brand-name drugs increased by a shocking 313 percent.[2] Thus, it is not surprising that one in four Americans has difficulty affording medication, and three in ten say costs have prohibited them from taking their medications as prescribed.[3]

With out-of-pocket costs rising and patients dangerously rationing medication, these prices are causing real pain for American families. Diabetic patients, for example, paid nearly $6000 a year out-of-pocket for insulin in 2016. Patients with arthritis saw the price of Humira rise to $1552 a month in 2019.[4] As difficult as these burdens are for any patient, the burden of paying high prices lands particularly hard on lower-income groups, threatening access to life-saving treatments and creating further gaps in equity across society.

For more than a decade, the Center for Innovation (C4i) at the University of California Hastings has documented the tactics used by pharmaceutical companies to prolong their market share, reduce competition, and maintain monopoly pricing. From pay-for-delay[5] to citizen petitions[6] to product hopping[7] to other tactics, a wide range of troubling behaviors has become endemic to the pharmaceutical industry. Although the industry is complex and convoluted with significant distortions and inefficiencies,[8] we have documented four important sets of tactics used persistently by pharmaceutical companies.

Pay-for-delay tactics. Since the passage of the Hatch-Waxman Act in the early 1980s, the nation has pinned its hopes on the market-disciplining effects of generic drugs. Generics are expected to enter the market rapidly when a drug's patent protection expires, driving prices down to competitive levels.[9] Something, however, is seriously amiss. Although generics continue to enter the market in record numbers, drug prices, out-of-pocket costs, and real spending on drugs continue to soar unabated.

Part of the problem lies in collusive agreements between brand and generic companies, in which the brand provides some form of value to the generic in exchange for the generic remaining off the market for a period of time. In this manner, the brand company pays part of its monopoly rent to keep the generic on the sidelines. Prices stay high, and competition languishes.

When competitors shake hands and agree that the less-expensive medication should stay off the market, it is bad for consumers. Government simply shouldn't be encouraging such behavior.

In a landmark decision nearly a decade ago, the Supreme Court opened the door for antitrust suits against brand and generic pharmaceutical companies who engage in these collusive settlements. Since that time, however, the courts have stumbled in trying to address the problem, as pharmaceutical companies have tried to confuse the meaning of the words "pay," "for," and "delay."

In the meantime, pay-for-delay agreements continue to burden patients and taxpayers. In a study I released last week titled *The Price Tag of "Pay for Delay"*,[10] I examined the magnitude of that burden, finding that the cost to society is as high as ten times previous estimates. Specifically, in laying the groundwork for the lawsuit that would eventually lead to the *Actavis* decision, the Federal Trade Commission (FTC) in 2010 estimated that pay-for-delay agreements cost American consumers $3.5 billion annually.[11] This figure has been cited repeatedly by scholars and policymakers alike. Updating that work with the additional information now available, I found that the 2010 figure vastly understates the landscape.

In particular, our study applied six different methodologies to provide as fair and broad a view as possible. The range of methodologies show that at a minimum, the cost of pay-for-delay settlements on the U.S. population between 2006 and 2017 is $6.4 billion per year—almost double that of the 2010 FTC estimate. The methodology with the largest result suggests that the cost could be as high as $36 billion per year—ten times higher.

Congress carefully created two systems for the rapid entry of lower-priced drugs, the Hatch-Waxman system for non-biologic drugs and the Biologics Price Competition and Innovation Act (BPCIA) for biologics. Pay-for-delay agreements manipulate these legislative initiatives, blocking the intent of Congress.

Patent evergreening and product-hopping. The practice of patent evergreening, which can be defined as artificially extending the protection period for a drug, also contributes to the problem of high drug prices. Pharmaceutical companies have become adept at piling protections on, over and over again, extending their period of exclusivity and building a higher wall of protections that generics must climb.

This behavior has become business as usual in the pharmaceutical industry. For example, we analyzed all non-biologic drugs on the market between 2005 and 2015, combing through more than 160,000 data points to examine every instance in which a company added a new patent or exclusivity.[12] Our results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Rather than creating new medicines, pharmaceutical companies are largely recycling and repurposing old ones. Specifically, 78% of the drugs associated with new patents are not new drugs coming on the market; they are drugs we already have.[13] Once companies start down the road of extending protection, they show a tendency to return to the well, with the majority adding more than one extension and 50% becoming serial offenders.[14] The problem is growing across time. In many cases, companies obtain these protections by making minor modifications to existing drugs, and then moving the

market to the new drug, which is protected by shiny new patents or evergreening. Known as product-hopping, this behavior prevents generic substitution and keeps lower-priced medicines away from patients.

In my view, the question isn't whether drug modifications have value for society; the question is whether government should be intervening in the market to provide additional protection. When a company makes a secondary change to a drug, such as changing from a tablet to a capsule, the R&D cost is far less than for the initial discovery of the drug. A company should be able to earn its reward in the market for the modification. It is the substantial investment in the initial drug innovation for which the government should put its thumb on the scale and provide a significant period of monopoly power.

Rebates and formulary manipulation. Perverse incentives percolating throughout the prescription drug market also push players toward higher prices. At the center lies the highly secretive and concentrated Pharmacy Benefit Manager (PBM) industry middle players who negotiate between drug companies and health insurers by arranging for rebates and establishing coverage levels for patients. Contracts between drug companies and the middle players are closely guarded secrets. PBM customers, including Medicare, private insurers, and even their auditors, generally are not permitted access to the terms. And the middle players are not alone; everyone is feeding at the trough.

Our work has documented a full picture of incentive structures in which higher-priced drugs receive favorable treatment, and patients are channeled towards more expensive medicines.[15] In exchange for financial incentives structured in different ways to appeal to hospitals, insurers, doctors, and even patient advocacy groups, drug companies ensure that lower-priced substitutes cannot gain a foothold. It is a win-win for everyone, except of course for taxpayers and society.

In particular, one critical mechanism within health insurance reimbursement for restraining drug prices is the formulary tiering system. Although tiering should reflect the cost of a drug—and reward patients who choose less-expensive drugs—something is seriously amiss in this system, too. Unfortunately, brand companies use volume rebates to induce health plans and PBM middle players to disfavor generic drugs. Using again Medicare claims data from roughly one million patients between 2010 and 2017, we documented the troubling amounts of distorted tiering and wasted cost.[16] Increasingly, generics are shifted to more expensive—and therefore less accessible—tiers. The percentage of generics on the least expensive tier dropped from 73% to 28%; the percentage of drugs on inappropriate tiers rose from 47% to 74%.[17] Considering only costs paid by patients and the federal Low-Income Subsidy program, tier misplacement cumulatively costs society $13.25 billion over the time period studied.[18]

Trade secret overreach. Trade secret law represents the next frontier of pharmaceutical manipulation of intellectual property law to hide pricing practices and maintain market dominance. Specifically, to shield pricing arrangements in the pharmaceutical supply chain from scrutiny by regulators and the public, pharmaceutical companies have turned to bold claims that prices, in and of themselves, are trade secrets and thus immune from regulatory disclosure. Our work[19] challenges that notion and argues that promoting pricing transparency is in the interests of consumers. Ultimately, our work provides grounds for rejecting claims that "naked prices" in the pharmaceutical supply chain are trade secrets based on contemporary conceptions of the trade secret—and we borrow from copyright law to advance a new concept of "thin" trade secret

protection amenable to appropriate regulatory challenges yet still protective of price transparency.

Pay-for-delay, patent evergreening, formulary manipulation, and trade secret overreaching represent the tip-of-the-iceberg of behaviors used by pharmaceutical companies and documented extensively in our work. I am grateful for the opportunity to share this research and encouraged by the Committee's willingness to address the problems that are pushing drug prices ever higher and blocking access to affordable medications for patients.

Warmest regards,
Robin Feldman

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[1] Portions of this submission are excerpted and adapted from the following works, which contain extensive analyses of these issues: Robin Feldman, The Price Tag of "Pay-for-Delay" (May 12, 2021) (available at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3846484) [hereinafter Feldman, Price Tag]; Robin Feldman, *The Devil in the Tiers*, 8 OXFORD J.L. & BIOSCI. no. 1 (2021), available at https://academic.oup.com/jlb/article/8/1/lsaa081/6103567?login=true [hereinafter Feldman, *Devil*]; Robin Feldman, *May Your Drug Price Be Evergreen*, 5 OXFORD J.L. & BIOSCI. 590 (2018), available at https://academic.oup.com/jlb/article/5/3/590/5232981 [hereinafter Feldman, *Evergreen*]; ROBIN FELDMAN & EVAN FRONDORF, DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET (2017) [hereinafter FELDMAN & FRONDORF, DRUG WARS]; Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Pharmaceutical Delay*, 53 HARV. J. ON LEGIS. 499 (2016), available at https://repository.uchastings.edu/faculty_scholarship/1528/ [hereinafter Feldman & Frondorf, *Drug Wars*].

[2] Feldman, *Devil*, *supra* note 1, at 19. The RAND Corporation found in 2021 that the price of brand-name prescription drugs in the United States is 256% of the prices in thirty-two OECD countries combined, ranging from 170% of prices in Mexico to 779% of prices in Turkey (ANDREW W. MULCAHY, CHRISTOPHER WHALEY, MAHLET G. TEBEKA, DANIEL SCHWAM, NATHANIEL EDENFIELD & ALEJANDRO U. BECERRA-ORNELAS, RAND CORP., INTERNATIONAL PRESCRIPTION DRUG PRICE COMPARISONS: CURRENT EMPIRICAL ESTIMATES AND COMPARISONS WITH PREVIOUS STUDIES 26 (2021), https://www.rand.org/content/dam/rand/pubs/research_reports/RR2900/RR2956/RAND_RR2956.pdf).

[3] Feldman, *Devil*, *supra* note 1, at 2–3 (citing Kaiser Family Foundation, *Public Opinion on Prescription Drugs and Their Prices* fig.5 (Oct. 16, 2020), https://www.kff.org/slideshow/public-opinion-on-prescription-drugs-and-their-prices/).

[4] JEAN FUGLESTEN BINIEK & WILLIAM JOHNSON, HEALTH CARE COST INST., SPENDING ON INDIVIDUALS WITH TYPE 1 DIABETES AND THE ROLE OF RAPIDLY INCREASING INSULIN PRICES 2 (2019), https://healthcostinstitute.org/images/easyblog_articles/267/HCCI-Insulin-Use-and-Spending-Trends-Brief-01.22.19.pdf; Lisa L. Gill, *The Shocking Rise of Prescription Drug Prices*, CONSUM. REP. (Nov. 26, 2019), https://www.consumerreports.org/drug-prices/the-shocking-rise-of-prescription-drug-prices/.

[5] *See generally* Feldman, Price Tag, *supra* note 1.

[6] *See generally* Robin Feldman & Connie Wang, *A Citizen's Pathway Gone Astray—Delaying Competition from Generic Drugs*, 376 N. ENG. J. MED. 1499 (2017), available at https://repository.uchastings.edu/cgi/viewcontent.cgi?article=2557&context=faculty_scholarship; Robin Feldman, *The Burden on Society from Eleventh-Hour "Citizen Petitions" Filed to Slow Generic Drugs*, 79 MD. L. REV. ONLINE 1 (2020), available at https://digitalcommons.law.umaryland.edu/endnotes/61/.

[7] *See generally* FELDMAN & FRONDORF, DRUG WARS, *supra* note 1; Feldman & Frondorf, *Drug Wars*, *supra* note 1.

[8] *See generally* FELDMAN & FRONDORF, DRUG WARS, *supra* note 1, at 13–19.

[9] *See generally id*. at 19–23.

[10] *See* Feldman, Price Tag, *supra* note 1.

[11] FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS 2 (2010), https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.
[12] Feldman, *Evergreen*, *supra* note 1. The Evergreen Drug Patent Search database of the Center for Innovation's research into patent protection extensions is available to the public at https://sites.uchastings.edu/evergreensearch/.
[13] Feldman, *Evergreen*, *supra* note 1, at 597.
[14] *Id*.
[15] Robin Feldman, *Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills*, 57 HARV. J. ON LEGIS. 303 (2020), available at https://harvardjol.com/wp-content/uploads/sites/17/2020/05/R.-Feldman_Perverse-Incentives.pdf.
[16] *See* Feldman, *Devil*, *supra* note 1.
[17] *Id*. at 19.
[18] *Id*.
[19] *See* Robin Feldman & Charles Tait Graves, *Naked Price and Pharmaceutical Trade Secret Overreach*, 22 YALE J.L. & TECH. 61 (2020), available at https://yjolt.org/sites/default/files/22_yale_j.l._tech._61_naked_price.pdf.