



CENTER FOR INNOVATION (C4i)

The Law & Medicine Initiative Recent Evidence in Health Care Policy February 2020

Health care is one of the most pressing issues facing Americans today. According to a January 2020 Gallup poll, **81% of Americans cited health care as extremely or very important to them in the upcoming presidential election**, outranking every other issue.¹

The non-partisan Law & Medicine Initiative at the UC Hastings Center for Innovation (C4i) aims to:

- Improve affordability, access, and quality in health care systems while protecting innovation and ensuring that markets are fair, efficient, and transparent;
- Generate the data and information that policymakers need to improve health care systems;
- Increase understanding of complex topics in law and medicine; and
- Develop a stable of solutions.

This advisory memo highlights recent evidence on four main challenges in health care systems and policy recommendations, along with a list of resources from the Law & Medicine Initiatives.

Please let us know if we can provide additional information.

¹ Gallup Poll. (2020). ["Importance of Issues to U.S. Adults' Voters in 2020 Presidential Election."](#)

DRUG COMPANY EVERGREENING

- Rather than creating new medicines, pharmaceutical companies largely recycle and repurpose old ones. From 2005-2015, for example, [78% of drugs with new patents were not new drugs but ones already on the market.](#)

With evergreening, companies refresh their market monopoly by slightly modifying a drug's dosage, delivery, or other characteristics to obtain additional exclusivities, blocking low-cost generics and driving up drug prices.

The statistics are from the peer-reviewed article, "[May Your Drug Price Be Evergreen.](#)" *Oxford Journal of Law and the Biosciences*, in which our researchers studied drugs on the market between 2005 and 2015 and tracked every time a company extended its protection cliff.

THE ROLE OF HEALTH INSURANCE FORMULARIES

Health plan tiering should reflect the cost of a drug, as well as reward patients who choose generics over brands. However, [a new C4i study analyzing Medicare claims from 1 million patients over an eight-year period \(2010 to 2017\) shows widespread formulary manipulations:](#)

- From 2010-2017, the percentage of generics on the most-preferred tier dropped from 73% to 28%.
- During the same period, the percentage of drugs placed on inappropriate tiers in relation to drugs with the same active ingredient increased from 47% to 74%.
- The average out-of-pocket cost triples in Medicare plans from the most-preferred tier to the next, which hurts patients. Yet we found that the health plans pay roughly the same amount for generics on both tiers. Thus, by moving generic onto pricier tiers, health plans are pocketing more money, for drugs that cost them the same amount.
- Considering nothing but patient out-of-pocket costs and payments from the federal low-income-subsidy program, these formulary abuses wasted \$13.25 billion dollars over the eight-year period, with the waste rising significantly across time.

The full study can be accessed at "[The Devil in the Tiers.](#)"

PBMs AND REBATE SCHEMES

By offering lucrative payments to pharmacy benefit manager middle players (PBMs), as well as to doctors and hospitals, drug companies ensure that inexpensive drugs never gain traction.

In her book, [*Drugs, Money, & Secret Handshakes*](#), C4i Director Professor Feldman analyzes the complex and secretive pharmaceutical industry and shows how higher-priced drugs receive favorable treatment and patients are channeled toward the most expensive medicines. The well-received book provides a strong foundation for understanding the PBM and rebate systems, along with the challenges to improving the health care system and potential policy solutions.

The book provides insights into the type and extent of these problems, which lawsuits have helped illuminate, including:

- After patent protection expired on Remicade, Johnson & Johnson's rheumatoid arthritis drug, **the company created a scheme that induced hospitals and health plans to exclude the lower-priced biosimilar.**
- Walgreens and CVS pharmacies **charged patients with health insurance more than the uninsured when purchasing certain generic drugs as part of a scheme to ensure higher payments to the middle players and enhance the brand drugs' market position.**
- In the vaccine market, **Sanofi charged prices up to 34.5% higher unless buyers agreed to purchase Sanofi's vaccines exclusively, blocking out cheaper competitors.**
- The majority of patient advocacy groups receive significant support from drug and device companies, which may influence the groups to advocate for policies favorable to the companies. When companies donate their drugs, they are particularly tax advantaged, receiving a deduction above the cost of the drug. **Today, patient assistance programs are 10 of the largest 15 charitable foundations in the US.**

The scholarly paper on which the book is based can be found online: "[Perverse Incentives: Why Everyone Prefers High Drug Prices -- Except for Those Who Pay the Bills](#)" (forthcoming, *Harvard Journal on Legislation*.)

THE MISUSE OF TRADE SECRET LAW TO HIDE DRUG PRICING

In the pharmaceutical industry, drug companies and PBM middle players shield prices from the public and regulators by misusing trade secret law. This drives up drug prices and distorts the drug market.

Our work, "[Naked Price and Pharmaceutical Trade Secret Overreach](#)," forthcoming from *Yale Journal of Law and Technology*, provides a legal road map showing how drug pricing does not constitute a protectable trade secret. **This road map is essential so that policymakers can make bold changes in the health care system without shying away due to threats of potential trade secret rights.**

POLICY SOLUTIONS AND RECOMMENDATIONS

The Law & Medicine Initiative's resources section below, as well as other works from C4i, provide rich solutions to the distortions driving health care pricing. Our primary recommendations include:

- Implement a "one-and-done" approach to pharmaceutical patent law in which each drug receives one—and only one—period of market protection.
- Make list price determine each drug's placement on formulary tiers. List price—that badly maligned, roundly dismissed figure—should become the holy grail for health insurer drug pricing. Using list price would decrease the incentive-distorting rebate schemes while recognizing that many people already pay full list price.
- Use value-based pricing *only* when the value of a drug is measured in relation to the nation's overall health needs, considers all diseases, and weighs the long-term, evidence-based outcomes. Value-based pricing cannot mean "the sky's the limit."
- Ruthlessly simplify. In the case of the Hatch-Waxman and Biologics Act systems for approval of cheaper drugs, with their complicated patent challenge systems, they have spawned too many opportunities for manipulation. In contrast, a simplified, slimmed-down system would provide fewer opportunities for clever gamesmanship and require fewer resources as a whole.
- Improve transparency of drug pricing information across industry and governmental health care agencies. From peeling back the veil on rebate deals and actual drug prices to expanding the Federal Drug Administration's (FDA) disclosure of drug application information and data, there is much to be improved. Greater clarity will thwart abuses and support public accountability of the health care system.

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ADDITIONAL RESOURCES

Selected Recent Works by Professor Robin Feldman, Director of C4i

- [Drugs, Money, & Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices](#) (Cambridge)
- [Drug Wars: How Big Pharma Raises Prices and Keeps Generics off the Market](#) (Cambridge)
- [May Your Drug Price Be Evergreen](#) (*Oxford Journal of Law and the Biosciences*)
- [Naked Price and Pharmaceutical Trade Secret Overreach](#) (forthcoming, *Yale Journal of Law and Technology*)
- [Perverse Incentives: Why Everyone Prefers High Drug Prices—Except for Those Who Pay the Bills](#) (forthcoming, *Harvard Journal on Legislation*)
- [Artificial Intelligence: The Importance of Trust & Distrust](#) (*Green Bag*)
- [The Cancer Curse: Regulatory Failure by Success](#) (forthcoming, *Columbia Science & Technology Law Review*)
- [A Citizen's Pathway Gone Astray](#) (*New England Journal of Medicine*)

Op Eds

- [President Trump's Coronavirus Response Highlights a Flawed Drug Pricing System](#) (*Washington Post*)
- [How Big Pharma is Hindering Treatment of the Opioid Addiction Epidemic](#) (*The Conversation*)
- ['One-and-Done' for New Drugs Could Cut Patent Thickets and Boost Generic Competition](#) (STAT)
- [The Perils of Value-Based Pricing for Prescription Drugs](#) (*Washington Post*)
- [Why the Cancer Moonshot Has Been So Disappointing](#) (*Washington Post*)
- [Why Prescription Drug Prices Have Skyrocketed](#) (*Washington Post*)

Data

[C4i's "Orange Book" database of prescription drug patent protections](#)

Congressional and Regulatory Agency Testimony

- [Promoting Competition to Lower Medicare Drug Prices](#) (House Ways & Means Subcommittee on Health testimony) (March 2019) (opening remarks at 8:10; answers to questions at 36:23, 56:50, 1:03:05, 1:11:45, 1:17:46, 1:21:00, 1:27:15, 1:30:08, 1:40:26, 1:50:29, 1:57:46, 2:03:05);
- House Ways & Means Subcommittee on Health (closed-door briefing for Members and staff) (March 2019);
- House Judiciary Committee (closed-door bipartisan staff briefing on pharmaceutical pricing) (March 2019);
- Senate Committee on Health, Education, Labor, and Pensions (written expert statement on competition and drug pricing provided at request of Chairman Lamar Alexander) (March 2019);
- [California Pay-for-Delay Bill](#) (Assembly Judiciary Committee testimony) (April 2019) (opening remarks at 27:25);

- [Treating the Opioid Epidemic: The State of Competition in the Markets for Addiction Medication](#) (House Judiciary Subcomm. on Regulatory Reform testimony) (opening remarks at 1:06:30);
- [The CREATES ACT: Ending Regulatory Abuse, Protecting Consumers, & Ensuring Competition](#) (Senate Judiciary Subcomm. on Antitrust testimony) (opening remarks at 50:36);
- [Capitol Insights: Soaring Drug Prices and What State Governments Can Do](#) (Nov. 9, 2017) (opening remarks at 34:09);
- [Competition Issues Related to Algorithms, Artificial Intelligence, and Predictive Analytics](#) (FTC Hearings November 14, 2018) (opening question at 22:40);
- [FDA Comments for Public Meeting on Ensuring a Balance Between Innovation & Access](#) (September 19, 2017).

ABOUT ROBIN FELDMAN

Robin Feldman is the Arthur J. Goldberg Distinguished Professor of Law and Director of the Center for Innovation at the University of California Hastings.

She is an award-winning scholar whose work has been called “absolutely remarkable” and a “must read.” Professor Feldman has published 4 books and more than 50 articles in law journals including at Harvard, Yale, and Stanford, as well as in the *American Economic Review* and the *New England Journal of Medicine*. Professor Feldman testifies frequently before Congress and federal and state agencies. Her empirical work has been cited by the White House, along with numerous courts and agencies.



Professor Feldman participated in the GAO’s report to Congress on AI, the Army Cyber Institute’s threat casting exercise on weaponization of data, and the National Academies of Sciences roundtable on AI and life sciences. In addition to her scholarship, Professor Feldman runs the Startup Legal Garage, which provides free legal work to 60 early-stage technology and life science companies each year and focuses on women entrepreneurs.

ABOUT UC HASTINGS CENTER FOR INNOVATION

The Center for Innovation (C4i) at UC Hastings promotes data-driven law-making and seeks to empower policymakers and regulators to make informed, evidence-based decisions, particularly at the intersection of law and technology.

More than a think tank, C4i is an action tank invested in identifying implementable solutions to today’s problems. Research initiatives and classroom components are integral to the Center as it identifies and advances the knowledge, tools, and skills necessary to foster innovation in the practice and development of law and policy.

Three primary programs comprise the Center’s work: The Law & Medicine Initiative, Startup Legal Garage, and The AI & Capital Markets Initiative.

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