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Written Testimony of Professor Robin Feldman,  
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Before the  
U.S. House of Representatives, Committee on the Judiciary  
Subcommittee on Antitrust, Commercial & Antitrust Law

Hearing on Treating the Problem:  
Addressing Anticompetitive Conduct and Consolidation in Health Care Markets  
April 29, 2021

Open and vigorous competition is the backbone of U.S. markets, but we are not seeing that in pharmaceutical markets.<sup>1</sup> Rather, drug companies are engaging in regulatory games, stringing these out, one after another, while competition languishes on the sidelines.

We know pharmaceutical markets are not working because we can see monopoly pricing extend beyond the statutory grant of exclusivity, to the detriment of patients and taxpayers. And we can see the harms of monopoly pricing when, for example, diabetic patients are forced to skip or ration their life-saving insulin.<sup>2</sup> Although discovered almost a century ago, this drug still costs Medicare patients an average of more than \$800 out-of-pocket each year.<sup>3</sup>

In general, Americans pay an average of 4 times more for prescription drugs in comparison to other industrialized nations.<sup>4</sup> For certain drugs, the price can be more than 60 times greater, even

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<sup>1</sup> Portions of these comments are derived from the following works of mine, which contain additional, in-depth explorations of the issues: Robin Feldman & Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, 53 HARV. J. LEGIS. 500 (2016); ROBIN FELDMAN & EVAN FRONDORF, *DRUG WARS: HOW BIG PHARMA RAISES PRICES AND KEEPS GENERICS OFF THE MARKET* (Cambridge University Press, 2017); Robin Feldman, Evan Frondorf, Andrew K. Cordova & Connie Wang, *Empirical Evidence of Drug Pricing Games—A Citizen’s Pathway Gone Astray*, 20 STAN. TECH. L. REV. 39 (2017); Robin Feldman, *May Your Drug Price Be Evergreen*, 5 OXFORD J.L. & BIOSCI. 590 (2018); Robin Feldman, *Drug Companies Keep Merging. Why That’s Bad for Consumers*, WASH. POST (Apr. 6, 2021), <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/>; Mark A. Lemley & Robin Feldman, *Atomistic Antitrust*, UC Hastings Research Paper Forthcoming, available at SSRN: <https://ssrn.com/abstract=3793809> or <http://dx.doi.org/10.2139/ssrn.3793809>.

<sup>2</sup> See COLO. DEPT. OF LAW, *PRESCRIPTION DRUG PRICING REPORT 2* (2020) (40% of Coloradans using insulin reported having to skip or ration doses at least once a year).

<sup>3</sup> *Id.* at 38.

<sup>4</sup> STAFF OF H.R. WAYS & MEANS COMM., 116<sup>TH</sup> CONG., *A PAINFUL PILL TO SWALLOW: U.S. VS. INTERNATIONAL PRESCRIPTION DRUG PRICES 3* (2019).

after rebates.<sup>5</sup> It is tough to tell patients in Chicago to pay hundreds of dollars for a drug when their cousin in Toronto pays \$30.

Although expensive specialty drugs are causing their fair share of pain, the out-of-pocket costs for the majority of top-selling prescription drugs have increased by more than 50% over the last decade, and many have more-than-doubled in price.<sup>6</sup> At some point, these price increases are unsustainable. After all, every budget—even the government’s—has a breaking point. But how did we get here in the first place, and how do we fix it?

Quite simply, competition is the key to a prescription drug market that is innovative and accessible. To this end, the federal government has created a crucial system of incentives—in the form of patents and other exclusivities—that encourage drug innovation, research, and development. In theory, we should see a cycle of innovation and reward, followed by generic companies entering the market, bringing down prices to competitive levels. That is the bargain between drug-makers and society. This design, however, is a far cry from what is actually happening.

Instead, pharmaceutical companies are gaming the system to protect and extend their monopolies. Companies do this through anticompetitive schemes to block generic entry, including product hopping, pay-for-delay, and citizen petition abuse. This committee has an historic opportunity to alleviate the problem by enacting legislation that will help improve access to affordable prescription drugs for patients.

The temptation for companies to engage in anticompetitive gaming is quite strong. As a drug patent nears expiration and generic competition looms on the horizon, a brand-name company can face the loss of hundreds of millions of dollars in revenue. With so much at stake, pharmaceutical companies have entered into pay-for-delay agreements with generic drug-makers.<sup>7</sup> It is an ingenious approach in which the brand-name drug company shares a portion of its monopoly profits with the generic in exchange for the generic agreeing to stay out of the market for a specified period of time. It’s a win-win for both the generic and the brand company, unfortunately, at the expense of everyone else.

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<sup>5</sup> *Id.*

<sup>6</sup> Nathan E. Wineinger et al., *Trends in Prices of Popular Brand-Name Prescription Drugs in the United States*, 2 JAMA NET. OPEN (2019), doi: [10.1001/jamanetworkopen.2019.4791](https://doi.org/10.1001/jamanetworkopen.2019.4791).

<sup>7</sup> See generally FELDMAN & FRONDORF, *DRUG Wars*, *supra* note 1, at 34; see also C. Scott Hemphill, *Paying for Delay: Pharmaceutical Patent Settlement as a Regulatory Design Problem*, 81 N.Y.U. L. REV. 1553 (2006); C. Scott Hemphill, *An Aggregate Approach to Antitrust: Using New Data and Rulemaking to Preserve Drug Competition*, 109 COLUM. L. REV. 629 (2009); Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009); Steve D. Shadowen, Keith B. Leffler & Joseph T. Lukens, *Anticompetitive Product Changes in the Pharmaceutical Industry*, 41 RUTGERS L.J. 1 (2009); Matthew Avery & Mary Nguyen, *The Roadblock for Generic Drugs: Declaratory Judgment Jurisdiction for Later Generic Challengers*, 15 N.C. J.L. & TECH. 1 (2013); Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry*, 108 COLUM. L. REV. 1471 (2008).

The 2013 Supreme Court decision in *Actavis*<sup>8</sup> paved the way for antitrust scrutiny of pay-for-delay. In response, companies simply have made these agreements more complex and convoluted. Today, there are numerous indications of complex value transfers in exchange for generic drugs staying off the market.<sup>9</sup> When competitors shake hands and agree that the less-expensive drug should stay off the market, it is bad for consumers.

Pay-for-delay is only one of the anticompetitive strategies in the vast arsenal that pharma companies launch against lower-priced competitors. Some of these games blatantly serve to delay the entry of competition. For example, The Food and Drug Administration's citizen petition process was created in the 1970s as a mechanism for ordinary citizens to raise concerns about food, drugs, and FDA regulations. That process, however, has clearly gone astray. In many cases, the concerned citizen is actually a large drug company raising frivolous or questionable claims. In some years, out of all citizen petitions filed at the FDA—including ones concerning tobacco, food, dietary supplements, and medical devices—one in five involves a pharma company attempting to block a competitor.<sup>10</sup> Nearly 40% of these petitions are filed a year or less before the FDA approves a generic, suggesting that many of these are last-ditch efforts to maintain higher prices as long as possible.<sup>11</sup> Although the FDA denies 90% of these petitions,<sup>12</sup> the process takes time. These abusive filings force the FDA to spend its limited resources reviewing petitions, rather than approving safe and effective medications.

Product-hopping is another strategic game deployed to block competitors.<sup>13</sup> Product-hopping involves modifying a drug, often just before the patents expire. The company then pushes doctors and health plans to favor the new version or removes the old one from the market altogether. If successful, there is no market for the old drug—just a market for the new one, protected by shiny new patents.

These additional patents may cover changes to a drug's dosage, formulation, or delivery system, such as whether it comes in pill or capsule form. Although the initial patent on a drug might cover the basic chemical or biologic molecule, the fifth patent might cover a change that has a negligible benefit to the patient.

In fact, much of the patenting activity these days relates to extending protection for existing medications. Specifically, 78% of the drugs associated with new patents are not new drugs coming on the market, but existing ones.<sup>14</sup>

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<sup>8</sup> Fed. Trade Comm'n v. *Actavis, Inc.*, 133 S. Ct. 2223, 2227 (2013).

<sup>9</sup> See generally Laura Karas, Gerald F. Anderson, Robin Feldman, *Pharmaceutical "Pay-for-Delay" Reexamined: A Dwindling Practice or a Persistent Problem?*, 71 HASTINGS L.J. 959 (2020); Robin C. Feldman & Prianka Misra, *The Fatal Attraction of Pay-for-Delay*, 18 CHI.-KENT J. INTELL. PROP. 249, 253-254 (2019).

<sup>10</sup> Feldman et al., *Citizen's Pathway*, *supra* note 1, at 44.

<sup>11</sup> See *id.*

<sup>12</sup> See Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 AM. U. L. REV. 305, 332-33, 333 (table 4) (2016) (finding that between 2011 and 2015, the FDA denied 92% of section 505(q) citizen petitions, the type most often employed to oppose generic entry).

<sup>13</sup> See generally FELDMAN & FRONDORF, *DRUG Wars*, *supra* note 1, at 69.

<sup>14</sup> Feldman, *May Your Drug Price*, *supra* note 1, at 590.

These “secondary” patents are often quite weak. And when generics fully challenge such patents, the generic wins in court about three-quarters of the time.<sup>15</sup> A patent challenge may take years, however, during which competition is thwarted, and prices stay high. This is especially true for brand drugs fortified with dozens or even hundreds of secondary patents.

Science sometimes moves in small increments and sometimes in large leaps. The question isn’t whether increments are important. The question is whether market incentives are sufficient or whether government should intervene in the market. When a company makes a secondary change to a drug—such as adjusting a drug’s dosage—the R&D investment is generally far less than required for the drug’s initial innovation. If that change is valuable to patients, a company should be able to earn its reward in the market for the modification. It is the massive investment in new research for which government needs to put its thumb on the scale and give the company a significant number of years of protection.

Against this backdrop of strategic behaviors, the pharmaceutical industry has become increasingly consolidated in recent decades, which lessens the chance of disruption and competition. Between 1995 and 2015, the 60 leading pharmaceutical companies merged to only 10.<sup>16</sup> Moreover, in 2017, just four companies produced more than 50% of all generic drugs.<sup>17</sup>

Consolidation has not been good for innovation. Rather, due to stagnating research results,<sup>18</sup> large pharma now outsources R&D, generally by buying startup after startup. In the process, innovation has shifted into lucrative, so-called “orphan drugs.” Thus, although more new molecules are emerging, they help fewer people, and the price is extraordinary.

Consolidation also can enable drug-makers to directly quell competition. In what are known as “killer acquisitions,” pharmaceutical companies acquire innovative companies solely to stop a potential future competitor.<sup>19</sup>

The consolidated industry structure raises other concerns. A small group of powerful drug manufacturers are responsible for shuttling new drugs through late-stage regulatory processes, leaving startup innovators with little choice other than acquisition or partnership with an entrenched firm.<sup>20</sup> The public regulatory process for drug development is rooted in concerns for patient safety. However, when large pharmaceutical companies serve as a secondary gatekeeper to FDA approval, they have every financial incentive to focus on maintaining their market position, not safeguarding the public interest.

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<sup>15</sup> See C. Scott Hemphill & Bhaven Sampat, *Drug Patents at the Supreme Court*, 339 SCIENCE 1386, 1387 (2013) (showing that 89% of patents in settled litigation disputes are secondary patents, which courts usually (68% of the time) find invalid or not infringed).

<sup>16</sup> OPEN MARKETS INSTITUTE, HIGH DRUG PRICES & MONOPOLY, <https://www.openmarketsinstitute.org/learn/drug-prices-monopoly> (last visited Apr. 27, 2021).

<sup>17</sup> Robert Coopman, *Generics Industry’s Rise*, CHAIN DRUG REV. (Sept. 25, 2017).

<sup>18</sup> See Kenneth I. Kaitin, *Deconstructing the Drug Development Process: The New Face of Innovation*, 87 CLIN. PHARMACOL. THER. 356, 356 (2010) <https://pubmed.ncbi.nlm.nih.gov/20130565/>.

<sup>19</sup> See Colleen Cunningham, Florian Ederer & Song Ma, *Killer Acquisitions*, 129 J. POL. ECON. 649, 649 (2021).

<sup>20</sup> See Barak Richman, Will Mitchell, Elena Vidal, Kevin Schulman, *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L.J. 787, 787 (2017).

To compound the problem, antitrust law has not kept up, either with the behaviors that repeatedly block competition or with the waves of mergers and buy-ups. Instead, courts and agencies tend to focus on a single behavior or a single startup purchase, often missing the forest for the trees.<sup>21</sup> This atomistic focus is misplaced. Companies and markets don't focus on one particular act to the exclusion of all else. Business strategy emphasizes holistic, integrated planning; market outcomes aren't determined by a single act, but by the result of multiple acts in the overall context of the market.

Consider a dominant firm that buys 100 companies. The likelihood that any one purchase harms competition may be low. However, the likelihood that the pattern of acquisitions harms competition is much greater.<sup>22</sup>

Similarly, a drug company may take a number of actions to block competition. In the context of pharmaceutical regulation, those actions work together to prevent competition that would otherwise have occurred, not because of a genuine effort to persuade the government or the courts but because of the combined effect of multiple obstacles to generic competition.<sup>23</sup>

Antitrust law often misses these perspectives. For example, in deciding whether pharma company actions before courts and agencies can be considered antitrust violations, some courts have concluded that each action in a series must be evaluated separately.<sup>24</sup> Such approaches are misguided. One would miss the intricate harmonies of a symphony if the notes were considered separately. And so it is with antitrust. By adopting an overly atomistic approach, modern antitrust law frequently misses the power of actions in concert.

This committee has the opportunity to address anticompetitive behavior in the pharmaceutical arena, and I would like to highlight three actions that are important for reaching this goal. First, I respectfully suggest the committee approve pending bills related to citizen petition abuse, pay-for-delay, and product hopping. These are essential steps for improving access to affordable prescription drugs for patients. Second, various legislative actions can be taken to encourage a comprehensive, rather than an atomistic, application of antitrust law.<sup>25</sup> This would encourage courts and agencies to consider the effects of behaviors as a whole.

Third, I recommend what I call a robust "Second Look" policy. Most law is backward-looking, asking whether a defendant breached a contract, committed a tort, infringed a patent, etc. Merger analysis, however, is designed to prevent future harm, requiring a court or agency to predict what would happen with and without the merger.

The law struggles with this predictive task. Thus, we should rely, not only on the crystal ball predictions of a merger's effects, but also on an examination of what actually happens to competition in the future. Economic models are great, but the marketplace is where the rubber

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<sup>21</sup> See generally Lemley & Feldman, *Atomistic Antitrust*, *supra* note 1.

<sup>22</sup> See *id.*

<sup>23</sup> See *id.* at 3; see also Stacey L. Dogan & Mark A. Lemley, *Antitrust Law and Regulatory Gaming*, 87 TEX. L. REV. 685 (2009).

<sup>24</sup> See *id.* at 19-21 (discussing disagreement among the federal circuits).

<sup>25</sup> See *id.* at 63-78 (discussing prospective solutions to the limiting focus of antitrust law).

hits the road. With this in mind, competition agencies should establish a robust system of post-merger review to ensure that predictions related to the competitive effects of pharmaceutical mergers and acquisitions were accurate.

Much of this monopoly gaming has blossomed just in the last 15 years. It is not age-old, and it is not inevitable. I am tremendously encouraged to see bipartisan efforts to address these critical issues affecting patient access to affordable drugs.