

Written Statement of Professor Robin Feldman, Director
of the Institute for Innovation Law, University of
California Hastings College of the Law

House of Representatives, Judiciary Subcommittee on
Regulatory Reform, Commercial & Antitrust Law

Hearing on Treating the Opioid Epidemic: The State of
Competition in the Markets for Addiction Medicine

September 22, 2016

Mr. Chairman and esteemed members of the Committee, I am Professor Robin Feldman of the University of California Hastings, and it is an honor to testify before you today on competition issues in the addiction treatment market. Open and vigorous competition is the backbone of the U.S. market, but that is not what we are seeing in the market for treating opioid addiction. Instead of vigorous competition, drug companies have engaged in legal and regulatory games to block entry into the market, stringing these games out, one after another, while competition languishes on the sidelines. The games come in two baskets: one set involves manipulating the Hatch-Waxman system for expedited entry of generic drugs when the patent expires; and the other set involves manipulating the system of non-patent exclusivities.

I have studied both areas in depth, including conducting an empirical study using more than a decade of FDA data. Below are three papers that identify and describe the games pharmaceutical companies are currently playing:

- *Drug Wars: A New Generation of Generic Pharmaceutical Delay*, Harvard Journal on Legislation (Summer 2016), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2659308

This article presents a comprehensive overview of three generations of games pharmaceutical companies play to keep generics off the market and maintain monopoly pricing. The first two generations were dominated by anticompetitive collusion. With the third generation, the industry has moved toward obstruction, using administrative processes, regulatory schemes and drug modifications to prevent generics from entering the market. The paper describes behavior in the opioid addiction treatment market in key examples throughout.

- *Regulatory Property: The New IP*, Columbia Journal of Law & the Arts (forthcoming), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2815667

This article describes a sprawling system of regulatory property which has developed alongside traditional intellectual property over the past thirty

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years, and which pharmaceutical companies have been relying on to gain market advantage. Appendix A, a chart aggregating all thirteen regulatory regimes in one place, may be particularly helpful.

- *Empirical Evidence of Drug Pricing Games: A Citizen's Pathway Gone Astray*, Stanford Technology Law Review (forthcoming), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2833151

This article presents an empirical study we conducted using more than a decade of FDA data. The study found that pharmaceutical companies are systemically using the FDA's citizen petition process to delay approval of generic competitors. The timing of citizen petition filings suggests that companies are using them as a last-ditch effort to maintain market monopoly.

While the spotlight today is on the market for treating opioid abuse, the behavior is endemic to the pharmaceutical industry. One sees the same baskets of behavior throughout, including manipulation of the Hatch-Waxman system and manipulation of non-patent exclusivities. It is critical to understand all of these systems as single, unified organism. Only if we analyze them as a coherent whole can we hope to understand how all of the pieces fit together and address the places where systemic dysfunctions are arising. Without that, society will continue to pay the cost in the form of higher taxes (to compensate for soaring Medicare costs), higher insurance premiums, higher treatment costs, and more suffering for those who cannot afford to pay. Nowhere is this more apparent than in the opioid addiction treatment market.