

2018

# A Prescription for Pharmaceutical's Future: Balancing Industry and Consumer Concerns in Pharmaceutical Drug Development

Caroline Bressman

Follow this and additional works at: <https://scholarship.law.umn.edu/mlr>

Part of the [Law Commons](#)

---

## Recommended Citation

Bressman, Caroline, "A Prescription for Pharmaceutical's Future: Balancing Industry and Consumer Concerns in Pharmaceutical Drug Development" (2018). *Minnesota Law Review*. 127.  
<https://scholarship.law.umn.edu/mlr/127>

This Article is brought to you for free and open access by the University of Minnesota Law School. It has been accepted for inclusion in Minnesota Law Review collection by an authorized administrator of the Scholarship Repository. For more information, please contact [lenzx009@umn.edu](mailto:lenzx009@umn.edu).

## Foreword

# A Prescription for Pharmaceutical's Future: Balancing Industry and Consumer Concerns in Pharmaceutical Drug Development

Caroline Bressman\*

Prescription drug pricing is an explosive issue for contemporary Americans.<sup>1</sup> Despite intense calls to action, few changes have followed. After years of protest, why is there no solution?

Tackling these issues head on, *Minnesota Law Review* hosted its annual Symposium—entitled “A Prescription for Pharmaceutical's Future: Balancing Industry and Consumer Concerns in Pharmaceutical Drug Development”—on October 27, 2017. Professors, industry insiders, consumer advocates, and federal regulators gathered to discuss the thorny issues surrounding drug pricing.

Ralph Hall, J.D., professor of practice at the University of Minnesota Law School, launched the Symposium's discussion by describing why drug pricing is such a key issue for individuals and for societal structures. Professor Hall outlined the many areas of law, market dynamics, and social values that drug pricing traverses. Moreover, he described how the rise of precision medicine profoundly impacts drug pricing. When the cost of developing drugs increases yet the number of people *using* such drugs

---

\* Symposium Articles Editor, *Minnesota Law Review* Volume 102. I am deeply grateful to Professor Ruth L. Okediji and Professor Ralph Hall for providing invaluable counsel in curating the Symposium. Special thanks also to the University of Minnesota Law School for furnishing the resources to make the Symposium a success. Lastly, I thank *Minnesota Law Review's* Lead Editors and Professor Kristin Hickman for constant support throughout the Symposium development process. Copyright © 2018 by Caroline Bressman.

1. See Ashley Kirzinger, Bryan Wu, & Mollyan Brodie, *Kaiser Health Tracking Poll—March 2018: Views on Prescription Drug Pricing and Medicare-for-all Proposals*, KAISER FAMILY FOUND. (Mar. 23, 2018), <https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-march-2018-prescription-drug-pricing-medicare-for-all-proposals>.

decreases, then that dynamic raises drug prices. At the same time, medical professionals would consider that dynamic good medicine. After considering these diverse implications, Professor Hall raised the deceptively simple question, "What is a 'fair' price?"

Next, Michelle M. Mello, Ph.D., J.D., professor of law at Stanford Law School and professor of health research and policy at Stanford University School of Medicine, described why, out of the many problems in health policy, drug pricing is the most difficult problem to solve. Professor Mello described the various market, moral, and political factors that render solving the drug pricing issue uniquely difficult. She characterized the fundamental difficulty as American society's uncertainty about the core tradeoff between affordability and availability of innovative therapies. She explained why drug pricing has egregious issues with transparency. She elucidated the many examples of perverse incentives that abound the prescription drug market. She noted that pharmaceutical pricing and development issues lack an ethical framework, largely due to the cognitive dissonance between innovation and access. Finally, she argued that the current political atmosphere, particularly with its emphasis on pharmaceutical company scandals, makes cool-headed deliberation about solutions even more challenging.

Joanne Chan, J.D., assistant general counsel for the Pharmaceutical Research and Manufacturers of American (PhRMA), then outlined the issue of drug pricing from the perspective of the pharmaceutical industry. She provided context on the importance of research and development and its resource-intensiveness in terms of person-power and financing. Ms. Chan further explained that many actors influence how a drug is priced and that the system includes a framework for negotiating discounts and rebates on top of a foundation of competition in the supply chain. Lastly, she highlighted the need for a collective solution to rising drug prices that would include the interests of innovators, supply chain players, and patients.

The Symposium then moved into its first panel discussion, entitled "Investigating the Pricing Equation: A Law and Economics Analysis," moderated by Thomas F. Cotter, M.S., J.D., Briggs and Morgan professor of law at the University of Minnesota Law School. The panel's first speaker, Arti K. Rai, J.D., Elvin R. Latty professor of law at Duke University Law School, addressed the intersection of biopharmaceutical regulation and

antitrust. She first contrasted pharmaceutical drugs with biologics in terms of how competition operates differently and how the Hatch-Waxman Act differs from the Biologics Price Competition and Innovation Act of 2010 in terms of patent litigation frameworks. Professor Rai also argued that this sector-specific regulatory regime is not sufficiently attentive to competition and that the U.S. Supreme Court's decision in *FTC v. Actavis*, in which the Court reasoned that reverse payment deals are subject to significant antitrust scrutiny, was the correct decision. Professor Rai argued that even though antitrust should not be excluded, it should also not act as the sole remedy for the lack of competition that may emerge from regulatory dysfunction. She provided cases in which she argued that reliance on antitrust is dubious, such as in the case of product hopping.

The panel's second speaker, Christopher Robertson, Ph.D., J.D., professor of law and associate dean for research and innovation at the University of Arizona College of Law, presented aspects of a forthcoming book project. Professor Robertson's talk focused on the consumer side of the pharmaceutical drug pricing equation, and suggested that health insurance can sometimes compound the challenges around drug affordability. He outlined a major issue in health policy: if one exposes consumers to healthcare costs, then access to healthcare is undermined. At the same time, though, one cannot rule out the problem of moral hazard waste in health insurance. To examine the issue of health insurance creating waste while also creating consumer access, Professor Robertson presented pilot data of a vignette study that used indemnity insurance as a lodestar for comparison. The patient, or the homeowner in the indemnity insurance framework, may decide how to spend insurance checks, while also retaining access to services.

Next, Rachel Sachs, M.P.H., J.D., associate professor of law at Washington University School of Law, delivered a discussion of the relationship between FDA approval and insurance impact, along with that relationship's impact on drug pricing. Although many policymakers often do not recognize this relationship, Professor Sachs explained that significant overlap of the FDA approval standard and coverage of drugs by public insurance programs (such as Medicare) exists. She then queried what might happen if the FDA approval process and insurance reimbursement was completely delinked and hypothesized that a reduction in access to drugs would occur. Professor Sachs concluded by de-

scribing possible options short of full delinkage that could address both drug pricing and access issues.

Finally, Stephen Schondelmeyer, Pharm.D., Ph.D., chair of the Department of Pharmaceutical Care and Health Systems and director of the PRIME Institute at the University of Minnesota, described signals of market failure in the pharmaceutical market and potential fixes for the future. First, he outlined the major categories of market failure signals—market structural issues, reverse and perverse incentives, extraordinary prices and extraordinary price changes, occasional irrational prescribing, and market inefficiencies—and described these signals as characteristics of the pharmaceutical market. Professor Schondelmeyer noted the uniqueness of the pharmaceutical market: as prices increase, the value of a drug and a consumer's health state does not necessarily increase in turn. In concluding his talk, Dr. Schondelmeyer argued that increased transparency of pricing information, accountability for drug prices charged by pharmaceutical companies, and targeted rewards for significant innovations are necessary reforms for the pharmaceutical market.

The Symposium's keynote speaker was Dr. Jonathan Jarow, senior medical advisor to the director of the FDA's Center for Drug Evaluation and Research. Dr. Jarow delivered an address on the FDA's mission and its actions with respect to pharmaceutical drug development. He noted that the Agency's core mission constitutes a balance between protecting the public and spurring innovation, and, with respect to drug development, balancing safety and access in a field with limited resources. Dr. Jarow provided the opioid epidemic as an example of the FDA applying its mission to an immensely challenging situation and taking unprecedented actions to meet its mission. He emphasized that although the FDA has not directly regulated drug pricing during its history, the Agency has recently changed its policy by taking actions that indirectly affect drug pricing as a means of rendering drugs more accessible to the public.

The Symposium's second panel, titled "Safe and Effective' or 'Now and Cheap?': Finding the Right Role for the FDA," was moderated by Professor Ralph Hall. Amy Kapczynski, M.A., J.D., professor of law and faculty director of the Global Health Justice Partnership at Yale Law School, opened the discussion by analyzing the FDA's mission and recent backlash efforts from groups that argue that the government should not regulate what

drugs are available. She provided three examples of these backlash efforts: (1) so-called right to try legislation; (2) provisions from the 21st Century Cures Act; and (3) First Amendment litigation regarding drug marketing. Professor Kapczynski defined the FDA's mission as both a producer of balanced information about drugs and a validator of information on drugs, both functions at which the market often fails. She argued that calls to decrease the FDA's role must be preceded by more consideration of the reliability of FDA decision making on accelerated timelines and with less evidence. She then pointed out that information generation and validation could operate in other manners, such as with publicly funded clinical trials and mandates for data transparency.

Next, Jordan Paradise, J.D., professor of law at Loyola Chicago School of Law, spoke on regulatory silence at the FDA. First, she described what the FDA is and what its general authority is regarding drugs and biologics regulation. Significantly, she emphasized that Congress has authorized the FDA to act, without requiring specific action, on patent law issues. She then described the complex relationship between the FDA, the Federal Trade Commission, and the U.S. Patent and Trademark Office. She provided two examples of the FDA's inaction regarding patent-related procedural mechanisms within legislation: risk evaluation and mitigation strategies for drugs and biologics and the Biologics Price Competition and Innovation Act. Finally, she described potential costs associated with the Agency's decision not to act, including litigation costs, delayed market entry, increased drug costs, decreased competition, and adverse patient outcomes.

W. Nicholson Price II, J.D., Ph.D., assistant professor of law at University of Michigan Law School, then concluded the panel by analyzing how the tools of a learning health system could help with the balancing of gaining access to drugs early with less information or gaining access later with more information. Professor Price described how clinical trials are not the best method of learning a drug's efficacy and safety. Instead, a learning health system model would provide opportunities for a cycle of constant information collection and improvement of pharmaceutical drugs. Professor Price outlined two examples—observational studies and interventional studies with electronic health record systems—that could be incorporated in the drug approval regime. Despite these possibilities, however, Professor Price also explained how the legal frameworks of research and clinical

care, specifically with each framework's rules on privacy and informed consent, would hamper a learning health system model.

The third and final panel, titled "Pharmaceuticals Around the Globe: Access and Delivery Issues for Consumers," was moderated by Fred L. Morrison, Ph.D., J.D., Popham, Haik, Schnobrich/Lindquist & Vennum professor of law at the University of Minnesota Law School. James Love, director of Knowledge Ecology International, delivered a talk on the balance of innovation and affordability tradeoffs and the "delinkage" of a pharmaceutical market that does not rely on high prices. He described how current calls for delinkage emphasize competition, such as by creating a prize fund with a mechanism to compete for shares of this fund, based on evidence of efficacy relative to competing drugs. Mr. Love also argued that inquiries on drug prices should not be based solely on value, but should focus on how much money a company needs to do what consumers want it to do. Finally, Mr. Love provided an example of how a remuneration and innovation fund could apply to CAR T-cell therapy in the treatment of some kinds of cancer.

Next, Jerome J. Reichman, J.D., Bunyan S. Womble professor of law at Duke University Law School, presented on compulsory licensing of pharmaceutical drugs under the Agreements on Trade Related Aspects of Intellectual Property Rights (TRIPS) of 1994. Professor Reichman described how prices for patented medicines remain high in most developing countries because of TRIPS and how he has previously argued that developing countries should consider pooled procurement strategies to gain access to essential medicines. Professor Reichman then described how the recent Marrakesh Treaty provides a framework for cross-border action that suspends the ordinary rules of territorial intellectual property laws in the service of human rights. The Marrakesh Treaty may serve as an analogy to pharmaceutical access, in which governments in pharmaceutical producer countries would issue compulsory licenses solely for the export of such pharmaceuticals to requesting countries under Article 31*bis* of TRIPS.

Finally, Margo A. Bagley, J.D., Asa Griggs Candler professor of law at Emory University School of Law, described the increasing interest in several countries for legitimizing traditional medical systems in healthcare. She explained the differences between traditional medicines and scientific medicines and that the former remains the primary source for healthcare for many people, particularly in developing countries. Although the two

systems have similarities, Professor Bagley explained that countries should not push traditional medicines as a substitute for scientific medicine when the efficacy of traditional medicine has not been proven, particularly since information gathering and validation of traditional medicines proves burdensome. However, if traditional medicines are as efficacious as scientific medicines, then the former's integration into a healthcare system could lower the overall pharmaceutical cost burden. Finally, Professor Bagley described the importance of reconceptualizing a broader concept of access to medicines, which would include issues such as lifestyle changes regarding diet and exercise as access to medicines issues.

*Minnesota Law Review's* 2017 Symposium discussions illustrated why pharmaceutical drug pricing is one of the most complex legal and policy issues today. Common themes resonated among many of the speaker's talks, such as the uniqueness of the pharmaceutical market and its constant battle between access and innovation, yet each speaker focused on a discrete aspect of the market and its regulation in offering novel solutions to today's astronomical drug pricing issues. The following pieces provide a deeper look into the Symposium's discussions. No single prescription exists as a panacea to drug pricing issues today, but sustained conversation of ideas raised at this Symposium provides a foundation for pharmaceutical's future.



\*\*\*