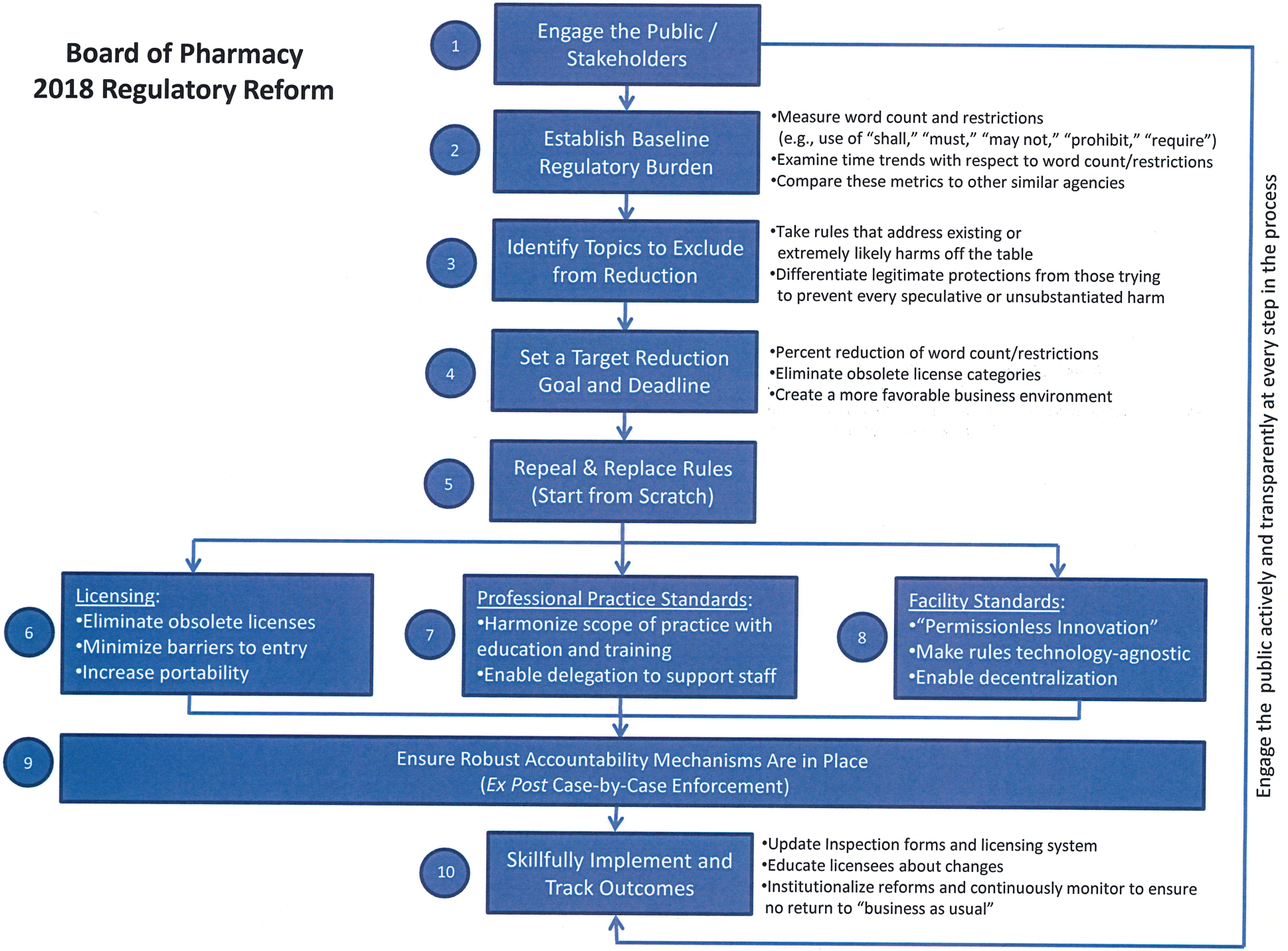
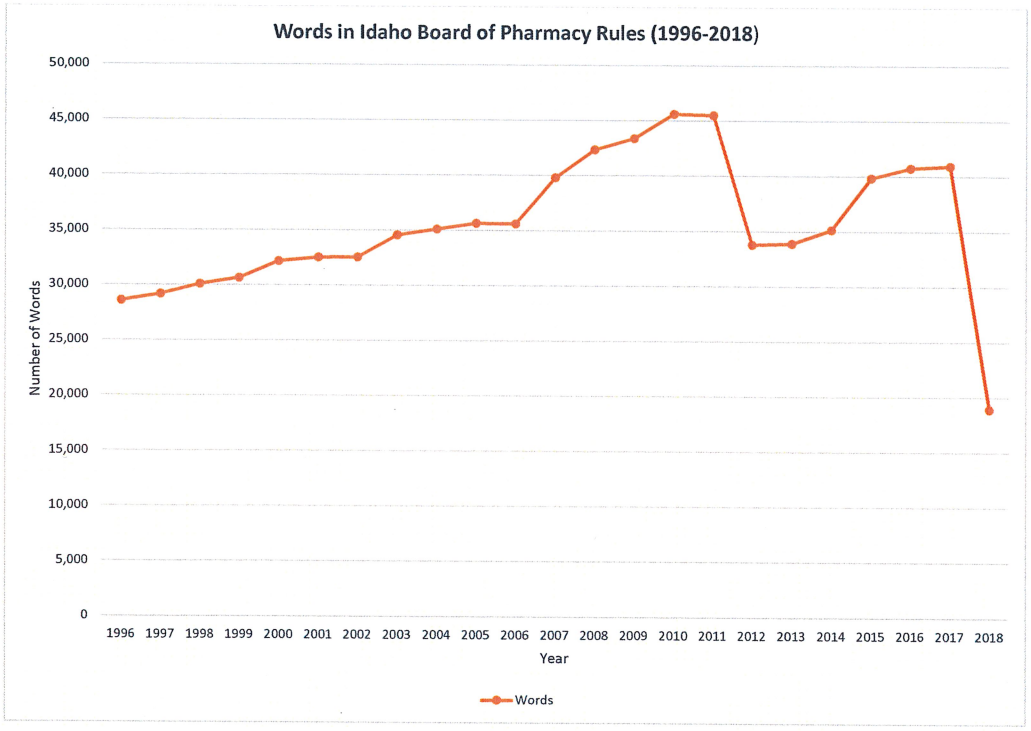
Board of Pharmacy
2018 Regulatory Reform

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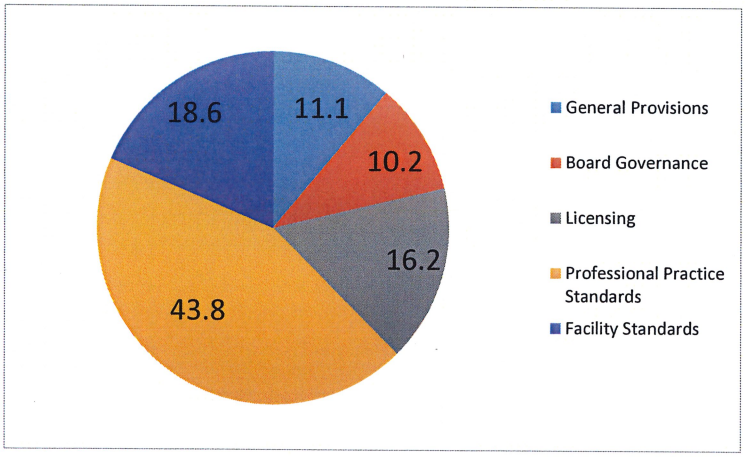
Composition of 2017 Board of Pharmacy Statutes & Regulations
18.6
11.1
10.2
16.2
43.8
General Provisions
Board Governance
Licensing
Professional Practice Standards
Facility Standards

THE PROCRUSTEAN PROBLEM WITH PRESCRIPTIVE REGULATION

Maureen K. Ohlhausen[1]

I. INTRODUCTION

Thank you to the board of the *CommLaw Conspectus* for asking me to write an introduction to this edition of the journal. Several articles in this edition examine the need for regulation of fast-changing industries. As a Commissioner of the Federal Trade Commission (FTC) for the past two and a half years, and as a regulatory lawyer in private and public practice before my nomination, I have had a close-up view of the effects and effectiveness of regulation. Thus, it seems apt to introduce this volume with my own thoughts based on those experiences.

I have one key message: prescriptive regulation, particularly of fast-changing industries, risks becoming procrustean. In Greek mythology, Procrustes was a rogue blacksmith, a son of the sea god Poseidon, who offered weary travelers a bed for the night. He built an iron bed especially for his tired guests, but there was a catch: if the visitor was too small for the bed, Procrustes would forcefully stretch the guest's limbs until they fit. If the visitor was too large for the bed, Procrustes would amputate limbs as necessary to fit the guest to the bed. Eventually, Procrustes met his demise at the hand of Greek hero Theseus, who fit Procrustes to his own bed by cutting off his head.

The story of Procrustes warns against our human tendency to squeeze com-

[1] Commissioner, U.S. Federal Trade Commission. The views expressed are the author's own and do not necessarily represent the views of the Federal Trade Commission.

plicated things into simple boxes, to take complicated ideas, technologies, or people, and force them to fit our preconceived models. We often do not recognize this backward fitting tendency, observes risk analyst Nassim Taleb, or are even oddly proud of our cleverness in reducing something complicated to something simple.[2]

Regulators should embrace the lesson of Procrustes. They should resist the urge to simplify, make every effort to tolerate complexity, and develop institutions that are robust in the face of complex and rapidly changing phenomena. Unfortunately, regulation too often is a procrustean bed for the regulated industry, due to the limits of regulators' knowledge and foresight. When the regulated industry is rapidly evolving, yesterday's comfortable regulatory bed can quickly become a torture rack for tomorrow's technologies.

The history of telecommunications regulation is largely a story of procrustean regulatory attempts to fit new technologies into an out-of-date regulatory model. From the 1913 Kingsbury Commitment to the 1996 Telecommunications Act and its subsequent implementation, Congress and the Federal Communications Commission (FCC) have constructed a bed of regulation that makes distinctions based on physical platform, business model, and geographic characteristics that are increasingly irrelevant. Consequently, when considering the converging technologies and overlapping business models of an IP-based world, the FCC has struggled to deploy its prescriptive *ex ante* regulation tool in a legally sustainable manner. The ongoing saga of net neutrality is a prime example of the legal, political, and practical problems of using prescriptive *ex ante* rulemaking to regulate a dynamic industry.[3]

To protect consumers effectively while still promoting innovation, regulators must embrace regulatory humility and focus on consumer harm. When considering the future of communications regulation, therefore, reformers should look for guidance to the FTC's successful, evolving approach to Internet-related issues, including its *ex post* enforcement of basic competition and consumer protection rules.

II. TWO KEY PRINCIPLES FOR REGULATORS

The lesson of Procrustes should lead all regulators of technology to embrace two fundamental principles. The first is regulatory humility. The second is a focus on evaluating consumer harm. Unless regulators follow these two prin-

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2 NASSIM N. TALIB, THE BED OF PROCRUSTES, xii (2010).

3 *See, e.g.*, Randolph May, *The Net Neutrality Hybrid Proposals: They Definitely Are Not Comfortable,* FREE STATE FOUND., *available at* http://bit.ly/1z60cRA (criticizing a recent round of proposed prescriptive net neutrality regulations).

ciples, even agencies with the best-designed statutory and regulatory structure will be less effective and could possibly make consumers worse off. On the other hand, regulators who embrace these principles can help limit the harms caused by the flaws that exist in all regulatory approaches. Practicing these principles is particularly important when the area to be regulated is rapidly changing and difficult to predict.

A. Principle 1: Regulatory Humility

It is exceedingly difficult to predict the path of technology and its effects on society. For example, the massive benefits of the Internet in large part have been a result of entrepreneurs' freedom to experiment with different business models. The best of these experiments have survived and thrived, even in the face of initial unfamiliarity and unease about the impact on consumers and competitors. For example, there was early widespread skepticism of online shopping. Now, online shopping is an every-day occurrence. Early skepticism does not predict potential consumer harm. Conversely, as the failures of thousands of dotcoms show, early enthusiasm does not predict consumer benefit.

Because it is so difficult to predict the future of technology, government officials, myself included, must approach new technologies and new business models with a significant dose of regulatory humility. This means we must work hard to educate ourselves and others about new developments. We must research the effects on consumers and the marketplace. We must identify benefits and any likely harm. If harms do arise, we must ask if existing laws and regulations are sufficient to address them, rather than assuming that new rules are required.

Finally, we must remain conscious of our limits. The success of the information economy allows regulators to gather a lot of data, but the possession of data is not the same as knowledge or wisdom. "Data-driven" decisions can be wrong. Even worse, data-driven decisions can *seem* right while being wrong. Political polling expert Nate Silver notes that "[o]ne of the pervasive risks that we face in the information age ... is that even if the amount of knowledge in the world is increasing, the gap between *what we know* and what *we think* we know may be widening."[4] Regulatory humility can help narrow that gap.

B. Principle 2: A Focus on Evaluating Consumer Harm

Equally important, we ought to focus on evaluating consumer harm. Before

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[4] NATE SILVER, THE SIGNAL AND THE NOISE: WHY SO MANY PREDICTIONS FAIL - BUT SOME DON'T 46 (Sept. 2012).

intervening, regulators must understand how new technologies and business models affect consumers, both positively and negatively. Doing so requires careful factual and economic analysis and serves as another check on action for the sake of action. As noted in the *FTC at 100 Report*, "[T]he improvement of consumer welfare is the proper objective of the agency's competition and consumer protection work."[5] Our consumer protection laws encourage us to focus on consumer harm, whether the cause of the harm is deception or unfairness. In analyzing a potentially deceptive practice or omission, the FTC asks if the deception is material; that is, absent the deception, would the consumer have made a different choice? As explained in our *Deception Statement*, "If different choices are likely, the [deceptive] claim is material, and injury is likely as well. Thus, injury and materiality are different names for the same concept."[6] The Commission's unfairness analysis relies even more explicitly on harm. The Commission deems a practice unfair if it causes substantial harm, which is not outweighed by any offsetting consumer or competitive benefits, and the consumer could not have reasonably avoided the harm.[7] The FTC's *Unfairness Statement* specifically identifies financial, health, and safety as varieties of harm that the Commission should consider substantial and further states that emotional impact and more subjective types of harm will not make a practice unfair.[8] I believe these clear statements as to what constitutes consumer harm have focused the FTC and made it more effective than it would be, for example, under a less specific public interest standard.

When the FTC exercises its competition authority, it also carefully evaluates consumer welfare (or, its corollary, consumer harm). The core mission of antitrust law is to improve consumer welfare by protecting vigorous competition and economic efficiency. The FTC has expressly acknowledged that its dual consumer protection and competition mandates are bound together by this single objective of improving consumer welfare.[9] This is in part why I have said that consumer welfare must be among the guiding lights for the FTC to apply its Section 5 authority to cases outside the reach of traditional antitrust laws.[10]

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[5] WILLIAM E. KOVACIC, FED. TRADE COMM'N, THE FEDERAL TRADE COMMISSION AT 100: INTO OUR 2ND CENTURY, THE CONTINUING PURSUIT OF BETTER PRACTICES iii (Jan. 2009), *available at* http://1.usa.gov/16uiZua.

[6] FED. TRADE COMM'N, FTC POLICY STATEMENT ON DECEPTION (1983), *available at* http://1.usa.gov/1hbciPe.

[7] FED. TRADE COMM'N, FTC POLICY STATEMENT ON UNFAIRNESS 3 (1980), *available at* http://1.usa.gov/1GRYWkc.

[8] *Id.*

[9] *See generally, About the FTC: What We Do*, FTC, http://1.usa.gov/1r1bmEC (last visited Mar. 18, 2014).

[10] *See, e.g.*, *In re* Motorola Mobility LLC & Google Inc., FTC File No. 121-0120 Dissenting Statement of Commissioner Maureen K. Ohlhausen, 4-5 & n.22, (Jan. 3, 2013),

In such cases, before taking action, the FTC ought to establish substantial harm to competition or the competitive process, and thus to consumers, relying on robust economic evidence that the challenged conduct is anticompetitive and reduces consumer welfare.[11]

By focusing on practices that are actually likely to harm consumers, the FTC has limited its forays into speculative harms, thereby preserving its resources to address clear violations. I believe this self-restraint has been important to the FTC's success in tackling a wide range of disparate problems without disrupting innovation. This is a model worth replicating.

III. THE PRESCRIPTIVE APPROACH AND ITS PROCRUSTEAN PROBLEM

Regulatory humility and a focus on evaluating consumer harm are both necessary to successfully protecting online consumers and competition. However, regulators also need the proper tools for the job. Although the FTC and the FCC share jurisdiction over the Internet, the tools they use are very different.

The FCC has traditionally regulated the communications industry using prescriptive *ex ante* regulation. The Communications Act and subsequent legislation established a system of classifications for various telecommunications providers or services.[12] Within that silo structure, the FCC has generally conducted Administrative Procedure Act rulemakings that classify entities as falling within a specific silo and then detail the procedures these various types of entities must follow. Friedrich Hayek, who spent a lot of time exploring the interaction between laws and liberty, would call these types of rules "commands" or "rules of organizations," as distinct from "rules of spontaneous orders" such as common law that arose organically and evolve over time.[13]

I believe the prescriptive *ex ante* approach is not well-suited to regulating

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available at http://1.usa.gov/1x0JB1E (objecting to use of Section 5 in case lacking evidence of substantial consumer harm, as opposed to perceived harm to particular competitors); *see generally,* Maureen K. Ohlhausen, Commissioner, Fed. Trade Comm'n, Section 5: Principles of Navigation, Remarks before the U.S. Chamber of Commerce (July 25, 2013), *available at* http://1.usa.gov/1wj8NOQ; Maureen K. Ohlhausen, *Section 5 of the FTC Act: Principles of Navigation*, J. ANTITRUST ENFORCEMENT (2013).

[11] *See id.* at 8 ("We must tie our UMC enforcement back to our core mission of promoting and protecting consumer welfare. In my view, then, our UMC authority should be used solely to address harm to competition or the competitive process, and thus to consumer"); *see also id.* at 13 ("[A]ny effort to expand UMC beyond the antitrust laws should be grounded in robust economic evidence that the challenged practice is anticompetitive and reduces consumer welfare.").

[12] Communications Act of 1934, *amended by* 47 U.S.C. § 151 *et seq.*

[13] *See* FRIEDRICH A. HAYEK, LAW, LEGISLATION, AND LIBERTY, 48-51 (1973).

the rapidly evolving Internet. Prescriptive *ex ante* regulation faces at least three significant knowledge-gathering challenges. First, a regulator must acquire knowledge about the present state and future trends of the industry being regulated. The more prescriptive the regulation, and the more complex the industry, the more detailed the knowledge the regulator must collect. Second, collecting such information is very time-consuming, if it is even possible, because such knowledge is generally distributed throughout the industry and may even be latent. Third, as a regulated industry continues to evolve, collected knowledge can quickly become stale. Obsolescence is a particular concern for fast-changing technological fields like telecommunications.

These knowledge problems can lead to negative consequences. First, because statutory, procedural, and resource constraints make it impossible for the regulator to continually update the rules, it is difficult for *ex ante* regulation to keep up with technological change. These problems may not be as acute if the regulated industry is slowly evolving over decades. However, in the Internet ecosystem, which is rapidly innovating and evolving, a prescriptive *ex ante* approach has resulted in significant mismatches between the rules and reality. Second, because *ex ante* regulations are an attempt at the virtually impossible task of predicting the future, some harms will occur that were unanticipated. Simultaneously, regulations may prevent harmless or even beneficial practices. Third, prescriptive *ex ante* regulations can hinder innovation. For example, if an innovative new project or service does not easily comport with a particular statutory or regulatory classification, the innovator may be uncertain about how to comply with the law. Such legal uncertainty exacerbates the already risky effort to develop something new, which discourages innovation.

IV. THE FTC'S *EX POST* ENFORCEMENT APPROACH

Given that the prescriptive *ex ante* regulatory approach faces such difficulties, what is the alternative? For consumer protection and competition issues, I have a significant amount of experience operating within the model we use at the Federal Trade Commission.

The FTC model is quite different from that of the FCC. Instead of a siloed statute, Section 5 of the FTC Act charges the FTC to prevent and punish "unfair methods of competition," and "unfair and deceptive acts."[14] The Act applies across all industries with a few exceptions. Where the FCC's regulations generally set the boundaries of what certain types of entities can do, the FTC's statute fences off deceptive or unfair practices for all entities, but generally

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[14] 15 U.S.C. § 45(a)(1) (2012).

permits everything else. The FTC's process is enforcement-centric rather than rulemaking-centric. As such, it is *ex post* rather than *ex ante* and case-by-case rather than one-size-fits-all. Since an enforcement action requires a complaint and a case to move ahead, the FTC's method typically focuses on actual, or at least specifically alleged, harms rather than attempt to predict future harms more generally.

Because of these structural differences, the FTC's enforcement process is less affected by the systemic knowledge problems of the FCC's prescriptive *ex ante* rulemaking approach. First, rather than having to collect detailed knowledge about an entire industry, the FTC need only gather enough information about the specific parties to the dispute and their behaviors in the relevant market. The FTC has significant investigatory authority to gather such information. Second, collecting such information is much simpler because the vast majority of the necessary information will be in the hands of the parties to the case. Third, even in rapidly changing industries, the FTC's decision on a case will bind only those parties to the specific case. The case will have precedential value, but when the FTC weighs that precedent in future cases, it can then consider any changes in the underlying facts.

Thus, the FTC's approach facilitates what Adam Thierer calls "permissionless innovation," or the "anti-precautionary principle" better than a prescriptive rulemaking approach.[15] The proof, as they say, is in the pudding. As the Internet – the most dynamic technological environment in history – has become an increasingly integral part of society, the FTC's enforcement-centric approach has enabled it to protect consumers and competition online even while industry has continued to innovate. In fact, the FTC is already addressing major Internet-centric concerns, including new issues in privacy, fraud, advertising and other consumer protection issues, along with competition issues.

Perhaps the most significant Internet issue the FTC has tackled is privacy. The FTC leads the federal effort to protect the privacy of consumers online. Online privacy is a very wide-ranging topic, covering spam email, data collection and security, safety of children, and online advertising. Hot new topics include the Internet of Things and big data. The FTC has been active in all of these areas. For example, the FTC has brought a broad selection of enforcement cases addressing consumer harms related to the Internet, including more than 100 spam and spyware cases and 50 data security cases.[16] The FTC has brought these cases against a wide range of defendants, including an interna-

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[15] *See generally*, Adam Thierer, *Permissionless Innovation: The Continuing Case for Comprehensive Technological Freedom*, MERCATUS CENTER (2014), http://bit.ly/1xrMurQ.

[16] FED. TRADE COMM'N, 2014 PRIVACY AND DATA SECURITY UPDATE (2014), *available at* http://1.usa.gov/13dnmI2 (last visited July 30, 2014).

tional hotel chain, a major data broker, a national drugstore chain, and the social media site, Twitter.[17] We also hold companies to the promises made in their privacy policies and have brought actions against companies such as Google[18] and Facebook[19] for violating those promises. Additionally, we have brought over 20 cases to enforce the Children's Online Privacy Protection Act and have collected more than $7 million in civil penalties.[20] And recently we filed a complaint against AT&T for misleading millions of its smartphone customers by charging them for unlimited data plans while "throttling" customer data speeds, reducing speeds by nearly 90 percent in some cases.[21] The FTC's strong enforcement record reflects the agency's readiness and capability to protect consumer privacy online in the face of technological change.

While enforcement is the cornerstone of our activity to protect consumers online, our enforcement efforts are supported by a wide range of other complementary tools that the FTC uses to promote consumer welfare and competition online. These tools include consumer[22] and business[23] education on privacy, data security, and fraud prevention. The FTC also has a strong policy research and development capability that it uses to stay abreast of new technologies and emerging issues. For example, the Commission has been closely studying the related issues of big data and the Internet of Things.[24] This research helps inform the FTC's *ex post* enforcement actions in emerging technologies.

V. CONCLUSION

A lot of energy will be spent over the next several years exploring how we can reshape our communications laws. Keeping in mind the lessons of Pro-

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17 *In the Matter of Twitter, Inc.*, Docket No. C-4316, FTC File No. 0923093,151 F.T.C. 162 (Mar. 2, 2011) (decision and order), *available at* http://1.usa.gov/1wjagoq (last visited July 30, 2014).

18 U.S. v. Google Inc., 2012 U.S. Dist. LEXIS 164401 (N.D. Cal. 2012).

19 *In the Matter of Facebook, Inc.,* Docket No. C-4365, FTC File No. 0923184, (July 27, 2012) (decision and order), *available at* http://1.usa.gov/PtOXNS.

20 *See generally,* Maureen K. Ohlhausen, Commissioner, Fed. Trade Comm'n, *Forum for EU-U.S. Legal- Economic Affairs*, Remarks at The FTC's Privacy Agenda for the 2014 Horizon (September 14, 2013), *available at* http://1.usa.gov/1J5io15

21 Press Release, *FTC Says AT&T Has Misled Millions of Consumers with 'Unlimited' Data Promises*, FTC (Oct. 28, 2014), http://1.usa.gov/1rS2DPN.

22 *See generally, Consumer Information*, FTC, http://1.usa.gov/1kCABbJ (last visited July 30, 2014).

23 *See generally, Bureau of Consumer Protection Business Center*, FTC, http://1.usa.gov/13dpLCw (last visited July 30, 2014).

24 *See generally, Internet of Things - Privacy and Security in a Connected World*, FTC, http://1.usa.gov/13dJvpi (last visited July 30, 2014).

crustes, thought leaders, legislators, and regulators should resist simple classifications and tolerate complexity, pursuing instead frameworks that are robust in the face of rapidly changing technologies and markets. During this process, I hope they will embrace regulatory humility and focus on evaluating and addressing actual consumer harm. They should also heed the demonstrated challenges of using *ex ante* approaches to regulate a fast-evolving technology like the Internet. As decision makers seek to update our laws to better serve Internet consumers, I urge them to consider the time-tested FTC model of successful *ex post* enforcement of competition and consumer protection rules.