

SHAMING BIG PHARMA

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The FDA recently published a list of top branded drug companies that are suspected of purposely blocking competition from the generic drug industry. Calling out big pharma by “naming and shaming” them into good behavior is an innovative, still largely experimental, regulatory tool designed to harness public opinion and build on pharma’s reputational sensitivities. This Essay analyzes the FDA’s new initiative as a form of regulation by shaming, points to crucial flaws in the agency’s use of the tactic, and suggests key points for improvement.

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INTRODUCTION

Novartis, Mylan, Roche, Pfizer, Celgene, Actelion—all these are examples of mega pharmaceutical companies that were recently “named and shamed” by the Food and Drug Administration (FDA).¹ This “shaming list,” which was uploaded to the FDA’s website, includes the names of more than 50 branded drug companies that allegedly tried to block competition from generic drug

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1. See *Reference Listed Drug (RLD) Access Inquiries*, U.S. FOOD & DRUG ADMIN. (FDA), <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm> [https://perma.cc/K3E5-C9DZ] (last visited Aug. 27, 2018) [hereinafter FDA list]. The list was published on May 17, 2018. See *FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., On New Agency Efforts to Shine Light on Situations Where Drug Makers May Be Pursuing Gaming Tactics to Delay Generic Competition*, U.S. FOOD & DRUG ADMIN. (FDA), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm607930.htm> [https://perma.cc/SA29-QNAN] [hereinafter *Statement from FDA Commissioner*].

companies.² The drugs that these generics are trying to produce and sell for a more affordable price to patients range from acne medication to blood thinners, pain killers, antipsychotic drugs, and drugs prescribed for treating cancer and other serious diseases.³ FDA Commissioner Scott Gottlieb has stated that he hopes that the publication of the list will discourage this type of bad behavior by branded drug companies.⁴ This initiative is indicative of the growing interest of the FDA and other health regulators in adopting “naming and shaming” tactics toward drug companies.⁵ Can such “regulation by shaming” work?

In general, the term “shaming” is often perceived negatively, causing shaming to be regarded as illegitimate.⁶ However, shaming can be useful when applied properly by regulatory agencies. In this Essay, I discuss the concrete characteristics and theoretical framing of the innovative regulation recently employed by the FDA, and I argue that, generally, shaming pharma can work but not in the manner in which it was executed in the case of the recent pharmaceutical company “shame list.” I explain how, in this instance, the FDA employed shaming tactics ineffectively, as it failed to convey the message to the public in a comprehensible and accessible manner. In conclusion, I suggest guidelines for successful regulatory shaming that the FDA can administer in the future, drawing on the regulatory shaming tactics employed by regulators in other fields and on regulatory shaming theory and principles.⁷

I. NAMING AND SHAMING BY THE FDA

“Naming and shaming” tactics have been used by the FDA with regards to the pharma industry in recent years, mainly through online publication of non-compliance and warning letters.⁸ For example, the FDA posted on its website a table listing companies that failed to meet the regulatory requirements of the Pediatric Research Equity Act (PREA),⁹ primarily the obligation to conduct

2. *See id.*; FDA list, *supra* note 1.

3. *See id.*

4. *See Statement from FDA Commissioner, supra* note 1.

5. *See, e.g., FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., On New Agency Actions to Further Deter ‘Gaming’ of the Generic Drug Approval Process by the Use of Citizen Petitions*, U.S. FOOD & DRUG ADMIN. (FDA), Oct. 2, 2018, <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm622252.htm> [<https://perma.cc/H9XB-K9N3>].

6. *See, e.g.,* James Q. Whitman, *What Is Wrong with Inflicting Shame Sanctions?*, 107 YALE L.J. 1055, 1055-56 (1998).

7. *See* Sharon Yadin, *Regulatory Shaming*, 49 ENVTL. L. (forthcoming 2019), <https://ssrn.com/abstract=3290017> (developing the theory and basic principles of “regulatory shaming”).

8. *See, e.g., Warning Letters and Notice of Violation Letters to Pharmaceutical Companies*, U.S. FOOD & DRUG ADMIN. (FDA), <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/EnforcementActivitiesbyFDA/WarningLettersandNoticeofViolationLetterstoPharmaceuticalCompanies/default.htm> [<https://perma.cc/VDJ6-FSFR>] (last visited Aug. 30, 2018).

9. Pediatric Research Equity Act of 2007, Pub. L. No. 110-85, 121 Stat. 866 (codified as amended in 21 U.S.C. § 301).

pediatric studies, along with copies of non-compliance letters issued by the agency and the companies' responses to these letters.¹⁰ According to the FDA, when a company fulfills the requirement to conduct relevant studies, the date it does so is added by the agency to the last column of the table,¹¹ and thus this online database is kept updated.

It now seems that the FDA is interested in further exploring and experimenting with this approach. Only a few months ago, in May 2018, the agency published an online "black list," in which it named dozens of branded drug companies that are supposedly using unlawful or unethical means to attempt to impede competition from generic drug companies.¹²

"Generics" are the unbranded versions of branded drugs that appear after the latter have lost patent and regulatory protection.¹³ Generics contain the same active ingredients, but not necessarily the same inactive ingredients, as branded drugs.¹⁴ As generics are not based on the expensive research and development efforts invested in the branded drugs, they cost between 80% and 85% less than the brand-name equivalent.¹⁵ Thus, generic drugs can provide an affordable alternative for patients in need.

According to the FDA, potential applicants for generic drug approval are being prevented from obtaining samples of certain branded products named in the list, which are necessary for attaining FDA approval of generic drugs.¹⁶ Branded drug samples are vital for generic applicants because the applicants need to demonstrate to the FDA that their version of the product is bioequivalent to the branded drug.¹⁷ A generic drug developer generally needs 1,500 to 5,000 units of the branded drug to perform studies needed to gain FDA approval.¹⁸

The list names branded drug companies that failed to provide the necessary samples despite requests from prospective generic applicants, and despite the fact that no regulatory restrictions with regard to the samples' safety and distribution were imposed.¹⁹ Generally, the FDA may impose distribution limitations on branded products, as part of an FDA safety program called REMS

10. See *Non-Compliance Letters under 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act*, U.S. FOOD & DRUG ADMIN. (FDA), <https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/ucm343203.htm> [<https://perma.cc/9ETR-C7EK>] (last visited Aug. 30, 2018).

11. See *id.*

12. See *Statement from FDA Commissioner*, *supra* note 1.

13. See Kathleen Craddock, *Improving Generic Drug Approval at the FDA*, 7 MICH. J. ENVTL. & ADMIN. L. 421, 423 (2018).

14. See Cheryl Spector, *Generic Copies: Are They New Drugs*, 3 CARDOZO L. REV. 131, 131 (1981).

15. See Shyam Goswami, *Windfall Profits and Failed Goals of the Bayh-Dole Act*, 19 J. GENDER RACE & JUST. 375, 382 (2016).

16. See FDA list, *supra* note 1.

17. See *Statement from FDA Commissioner*, *supra* note 1.

18. See FDA list, *supra* note 1.

19. See *id.*

(Risk Evaluation and Mitigation Strategy).²⁰ But according to the FDA, some companies are falsely arguing that safety issues prevent them from distributing drug samples to generic companies.²¹ For example, according to the list, one branded drug company (Celgene) that was authorized by the agency to distribute samples to generic companies was nevertheless the subject of 13 complaints received by the FDA from generic companies that were unable to receive such samples.²²

The FDA's publication included open condemnation of big pharma conduct. In the text accompanying the list of companies, the agency explained that "'gaming' tactics were being used to delay generic competition,"²³ and in a statement, the FDA Commissioner asserted that the pharma companies on the list "have potentially been blocking access to the samples of their branded products."²⁴ Despite efforts made by the Commissioner to stress that publishing the list was merely an attempt to promote transparency,²⁵ the data, the accompanying text, and the statement made to the press are all indicative of shaming.²⁶

Indeed, this step was clearly intended to draw public attention to big pharma misconduct. As the FDA Commissioner stated regarding the list, "We'll continue to look at more ways we can expand upon today's action and call public attention to situations where the careful balance that Congress sought between product innovation and access may be being disrupted."²⁷ The Commissioner also stated that the agency's decision to publish the list was rooted in the idea that "no patients should be priced out of medicines they need to support their health" and that it was intended to "increase competition as a way to help make drugs more affordable and improve access."²⁸

It is worth noting that the FDA's efforts to maintain competition in the pharma industry are somewhat secondary to, or even beyond, its main mandate. Overall, the agency—which is located within the Department of Health and Human Services—is responsible for regulating drugs for safety and effectiveness and is thus considered "the gatekeeper of the American pharmaceutical marketplace." Meanwhile, the main agency responsible for addressing

20. See *Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN. (FDA), <https://www.fda.gov/Drugs/DrugSafety/REMS/default.htm> [<https://perma.cc/M9VL-VKK4>] (last visited Nov. 3, 2018).

21. See FDA list, *supra* note 1.

22. See *id.*

23. See *id.*

24. See *Statement from FDA Commissioner, supra* note 1.

25. See *id.* See also Beth Mole, *Shame, Shame, Shame — FDA has Named Names of Pharma Companies Blocking Cheaper Generics*, ARSTECHNICA (May 17, 2018), <https://arstechnica.com/science/2018/05/fda-to-start-naming-names-of-pharma-companies-blocking-cheaper-generics> [<https://perma.cc/EW6Y-XUPS>].

26. See also *infra* Part II; Yadin, *supra* note 7 (discussing the difference between shaming and transparency).

27. See *Statement from FDA Commissioner, supra* note 1.

28. See *id.*

anticompetitive business practices is the Federal Trade Commission (FTC). This possible tension was addressed directly by the FDA Commissioner, who stated that the agency's efforts to improve generic drug competition aimed to improve access and affordability and that the FDA will cooperate in this with the FTC.

The existence of generic drug companies, ensuring fair competition in the market, is in the public interest and is therefore a regulatory goal. Laws such as the Federal Food, Drug and Cosmetic Act (FDCA)²⁹ and the Drug Price Competition and Patent Term Restoration Act (“Hatch-Waxman”)³⁰ aim to strike a balance between the need to encourage the development of new drugs, which is typically an expensive and lengthy process,³¹ and the need to make these drugs affordable to all patients. As long as the branded drug company enjoys exclusivity in marketing, based on its patent, the price of the drug can remain as high as the pharma company desires in order to recoup its research and development costs and make a profit.³² The term of a new patent is generally twenty years from the date on which the application was filed with the Patent and Trademark Office, which can occur anytime during the development of a drug.³³ When a branded drug company no longer enjoys exclusivity in the market, generic drug companies can enter the market and supply patients with cheaper versions. In reality, though, branded drug companies constantly deploy various means to impede competition from generics—from filing frivolous drug patents and citizen petitions to engaging in various other anti-competitive strategies, such as paying generic manufacturers to delay their entry into the market, reaching anti-competitive agreements, shifting market demand to a new formulation of a drug, and withholding samples.³⁴ These practices are an ongoing concern of legislators and regulators in the health industry.

II. REGULATION BY SHAMING

Shaming is often perceived negatively as a phenomenon that needs to be eradicated³⁵ in which citizens, and sometimes even the state in the criminal

29. 21 U.S.C. § 301 (2015).

30. Pub. L. 98-417, 98 Stat. 1585 (1984).

31. See, e.g., Margaret Gilhooly, *FDA and the Adaptation of Regulatory Models*, 49 ST. LOUIS U. L.J. 131, 132 (2004); Jordan Paradise, *Regulatory Silence at the FDA*, 102 MINN. L. REV. 2383, 2395 (2018).

32. See Craddock, *supra* note 13, at 425-26; Christine S. Paine, *Brand-Name Drug Manufacturers Risk Antitrust Violations by Slowing Generic Production through Patent Layering*, 33 SETON HALL. L. REV. 479, 480-81 (2003).

33. See 35 U.S.C. § 154(a)(2). For more information see *Frequently Asked Questions on Patents and Exclusivity*, U.S. FOOD & DRUG ADMIN. (FDA), <https://www.fda.gov/drugs/developmentapprovalprocess/ucm079031.htm#howlongpatentterm> [<https://perma.cc/XU3P-EH5R>] (last visited Sep. 2, 2018). There are also “exclusivity periods,” given for six months to seven years upon approval of certain drugs, regardless of a patent. See *id.*

34. See Paine, *supra* note 32, at 479-81; Paradise, *supra* note 31, at 2398.

35. See, e.g., Whitman, *supra* note 6, at 1055-56.

context,³⁶ shame other citizens.³⁷ It is often regarded as a despicable act that can cause irreparable harm to individuals.³⁸ Civilian shaming may be based on nothing more than false accusations or insults³⁹ designed to humiliate and inflict pain.⁴⁰ But administrative shaming is something different. It can achieve regulatory goals effectively, since it is cheaper and faster than other forms of regulatory sanctions, either criminal or administrative, and when designed properly it can efficiently deter organizations from non-compliance.⁴¹ Unlike civilian shaming, regulatory shaming is subject to public law norms; it does not aim to humiliate or hurt individuals' feelings, but to inflict reputational harm on business organizations⁴² and nudge them in the right direction. Regulation by shaming adds to a growing toolkit of innovative regulatory apparatuses that are meant to enforce norms without relying solely on "command and control."⁴³ Much like its sibling—disclosure regulation⁴⁴—regulatory shaming takes place in the "expressive space" of regulation,⁴⁵ in which the regulator conveys messages and "speaks" to the public. Shaming is not to be confused with the concept of transparency, as it is designed to encourage action by third parties against a non-compliant firm, and it focuses on a condemning rather than an informative message.⁴⁶

Shaming initiatives by regulatory agencies are becoming more and more common.⁴⁷ These policies take many forms, including "naming and shaming," star ratings, color ratings, league tables, public statements, publication of enforcement actions, and publication of inspection results.⁴⁸ All of them aim to harm the reputation of companies that fail to comply with regulations or that are thwarting regulatory goals in some other way. Shaming highlights actions by these regulated entities that may be illegal or unethical and allows the

36. In criminal contexts, the government, mostly through the judiciary, shames offenders by publishing information about crimes and criminals after crimes are committed. *See, e.g.*, Dan M. Kahan, *What Do Alternative Sanctions Mean?*, 63 U. CHI. L. REV. 591, 631-32 (1996).

37. *See generally* Kristine L. Gallardo, *Taming the Internet Pitchfork Mob: Online Public Shaming, the Viral Media Age, and the Communications Decency Act*, 19 VAND. J. ENT. & TECH. L. 721 (2017); Kate Klonick, *Re-Shaming the Debate: Social Norms, Shame, and Regulation in an Internet Age*, 75 MD. L. REV. 1029 (2016).

38. *See, e.g.*, JOHN BRAITHWAITE, CRIME, SHAME, AND REINTEGRATION 68 (1989); DANIELLE KEATS CITRON, HATE CRIMES IN CYBERSPACE 11 (2014).

39. *See, e.g.*, Emily Chiang, *Institutional Reform Shaming*, 120 PENN ST. L. REV. 53, 84 (2015).

40. *See id.*

41. *See* Yadin, *supra* note 7.

42. *See id.*

43. *See id.* The legal concept of "regulation" is often perceived as control or constraint. *See* Barak Orbach, *What is Regulation?*, 30 YALE J. ON REG. ONLINE 1, 4 (2012).

44. Disclosure regulation focuses on requiring manufacturers and service providers to actively reveal information about their products. *See* Yadin, *supra* note 7.

45. *See generally* Alex Geisinger, *Reconceiving the Internal and Social Enforcement Effects of Expressive Regulation*, 58 WM. & MARY L. REV. ONLINE 1, 8-9 (2016).

46. *See* Yadin, *supra* note 7.

47. *See id.*

48. *See infra* Part III. *See also* Yadin, *supra* note 7.

administrative agency to publicly condemn a specific action (or non-action) of a named company or companies. For instance, regulators shame companies for non-compliance with workplace safety regulations, environmental regulations, or health regulations.⁴⁹ They also shame companies for “gaming the system” through legally grey area tactics,⁵⁰ and for overly high salaries paid to CEOs.⁵¹

The idea of regulatory shaming is to convey a message to a shaming community—such as employees, investors, peers, consumers, interest groups, politicians, or the general public—which will then act in accordance with the negative feelings invoked by the adverse publication.⁵² The shaming community can feel betrayed, disgusted, appalled, outraged,⁵³ or otherwise disappointed with the shamed organization or with its behavior. But the main point is that these feelings are translated into action. Without some form of response from the public or other third parties, regulatory shaming cannot work. Customers can protest, file complaints, or boycott the products sold by the condemned regulatee; shareholders may withdraw their investment; employees can demonstrate or even strike; peers and competitors may refuse to engage in any kind of business ventures with the company; and suppliers may refuse to work with it.

Regulation by shaming harnesses firms’ sensitivity to reputational damage. A qualitative research study into environmental regulation found that corporate officials care not only about complying with formal regulations but also with their “social license,” that is, public expectations with regard to environmental performance.⁵⁴ Public opinion, influenced by a trustworthy organ of the state that openly condemns a company’s actions, can cause financial damage to firms.⁵⁵ Adverse publications made by administrative agencies can thus become a powerful tool in regulatory enforcement endeavors.⁵⁶

But in order for regulatory shaming to work, there are several essential components to the shaming process:

1. Choosing a topic for regulatory shaming that third parties (shaming communities) will be interested in or passionate about
2. Identifying the right shaming group—those people who can and will act in order to influence the company’s behavior

49. *See id.*

50. As discussed in the FDA example which is the focus of this Essay.

51. The Securities and Exchange Commission (SEC) recently adopted a shaming strategy through a regulation that requires companies to disclose the compensation ratio between their median employee (by salary) and their CEO. *See* 15 U.S.C. § 78I note (2012); 17 C.F.R §§ 229, 240, 249 (2015).

52. *See* Yadin, *supra* note 7.

53. *See generally* Cass R. Sunstein, *Growing Outrage*, BEHAVIOURAL PUBLIC POLICY (Aug. 30, 2018), <https://www.cambridge.org/core/journals/behavioural-public-policy/article/growing-outrage/07A7377940D8BA0E503DDB8C10EEC70F#.W4lw6NdmaBE> [<https://perma.cc/27Z7-CU3U>].

54. *See* Dorothy Thornton et al., *General Deterrence and Corporate Environmental Behavior*, 27 LAW & POL’Y 262, 264 (2005).

55. *See, e.g.*, Andrea A. Curcio, *Painful Publicity—An Alternative Punitive Damage Sanction*, 45 DEPAUL L. REV. 341, 372-76 (1996).

56. *See generally* Yadin, *supra* note 7.

3. Taking a regulatory moral stand that is non-controversial and that the shaming community can easily agree with

4. Properly shaping a shaming message that is well-communicated and specifically designed for the chosen shaming group

5. Disseminating the shaming message through suitable media channels

These are important steps that need to be carefully implemented in order for the shaming action to fulfill its public interest goal. Shaming initiatives that fail may cause more harm than good. Regulators that do not succeed in correcting market failures through adverse publications may suffer all kinds of consequences.⁵⁷ For example, they may themselves be scolded by the targeted companies or by third parties, including the intended shaming community. They may harm their relationship with the industry in general and with the shamed entity in particular, causing irreparable damage to regulatory goals and hurting industry willingness to cooperate and comply with regulations and with the regulator in general. They may jeopardize their reputations as professional regulators, and they may become entangled in costly and prolonged legal battles with the shamed regulatees.⁵⁸

III. WHAT'S WRONG WITH THE FDA'S SHAMING TACTIC?

Generally, shaming big pharma can be an effective part of the FDA's regulatory agenda with regards to fair competition in the drug market, for several reasons.

First, the public can easily identify with the need to keep drugs affordable and can be expected to react strongly to branded companies' attempts to manipulate the market.⁵⁹ Obviously, patients who depend on a specific drug cannot afford to boycott it. However, public attention to adverse behavior of specific drug companies can, in principal, deter the drug industry in general (as well as specific companies) from engaging in unethical or illegal practices. For instance, Eli Lilly, one of three companies in the world that hold a patent for insulin, was recently the target of harsh public criticism and outrage due to a very

57. See generally Barak Orbach, *What is Government Failure?*, 30 YALE J. ON REG. ONLINE 44 (2012) (discussing the concept of "regulatory failure").

58. Regulatory shaming may sometimes be legally problematic. Examples of possible illegality of regulatory shaming include harsh reputational damage; publication of citations prior to final orders, which implicates due process; and lack of statutory authority to sanction by public shaming. See, e.g., Eric J. Conn & Casey M. Cosentino, *Hot Off the Press: Two Attorneys Argue That OSHA's Enforcement Press Releases Violate the Federal Administrative Procedure Act*, EHSTODAY (Sep. 1, 2011), <http://www.ehstoday.com/standards/osha/hot-off-press-0901> [<https://perma.cc/EV8Z-TDPD>]. Since shaming practices vary from one agency to another, and even within the same agency, each with a different legal basis, a complex generalized analysis in this regard will remain outside the scope of this Essay.

59. See *supra* Part II (Items 1-3).

steep increase in its product prices.⁶⁰ It was subject to protests outside its Indianapolis headquarters, as well as calls for tighter regulation and more transparency, and for greater affordability and accessibility of insulin, from advocacy groups such as Patients for Affordable Drugs and the American Diabetes Association.⁶¹ Consequently, the House of Representatives is conducting an inquiry into insulin pricing, with the intent of eventually introducing legislation.⁶² Furthermore, many pharma companies, including those listed in the FDA’s shame list, also sell generics⁶³ and are thus in competition with other companies in a manner that facilitates consumer leverage. Therefore, though medication is clearly different from sportswear in terms of consumer choice, regulatory shaming that is directed towards patients and patient advocacy groups can certainly be effective.

There are also other effective shaming audiences that the FDA can reach, such as potential investors and current shareholders in the pharma industry, and pharma employees. These stakeholders can also play an important role in the “private regulation” process being advanced by the FDA. For example, many investors are unwilling to invest in companies with whose values, actions, and goals they cannot identify,⁶⁴ a common phenomenon with tobacco, alcohol, and arms companies.⁶⁵ Sometimes, such investors are driven by fear that investing in such companies may in turn cause them to be personally shamed by others who consider such investments immoral.⁶⁶ These issues are central to an approach known as “corporate social responsibility” (CSR), which now plays a prominent role in investors’ considerations.⁶⁷ Under the terms of CSR, the corporate entity is understood through a communitarian prism, which focuses on the social and moral aspects of the corporation’s community activities, rather than its own individualistic interests.⁶⁸ FDA shaming of pharmaceutical companies for intentionally manipulating the market in order to keep prices high, and hurting patients in need, may trigger a similar effect with pharma shareholders and

60. See Nathaniel Weixel, *Skyrocketing Insulin Prices Provoke New Outrage*, THE HILL (June 21, 2018), <https://thehill.com/policy/healthcare/393378-skyrocketing-insulin-prices-provoke-new-outrage> [<https://perma.cc/W44W-PTEG>].

61. See *id.*; John Russell, *Lilly Insulin Prices Come Under Microscope*, IBJ (Aug. 26, 2017), <https://www.ijb.com/articles/65163-lilly-insulin-prices-come-under-microscope> [<https://perma.cc/ZL8K-PMFQ>].

62. See Weixel, *supra* note 60.

63. See, e.g., Sheila Kaplan, *F.D.A. Names and Shames Drug Makers to Encourage Generic Competition*, NY TIMES (May 17, 2018), <https://www.nytimes.com/2018/05/17/health/drug-prices-generics-fda.html> [<https://perma.cc/7DLY-29C4>].

64. See, e.g., Douglas M. Branson, *Corporate Social Responsibility Redux*, 76 TUL. L. REV. 1207, 1219 (2002).

65. See *id.*

66. See *id.*

67. See *id.*

68. See *id.* at 1217. See also Oren Perez, Reuven Cohen & Nir Schreiber, *Governance through Global Networks and Corporate Signaling*, REG. & GOVERNANCE (forthcoming 2019), <https://ssrn.com/abstract=3265793> [<https://perma.cc/XV4L-Q365>] (discussing the reasons why companies adopt CSR schemes) (manuscript at 4-5).

potential investors. Additionally, pharma employees who learn that their company is acting in a way that is not considered socially responsible may elect to strike, thus causing the company not only indirect reputational harm but also direct financial losses.

The second reason why shaming can be an important tool for the FDA's regulatory agenda is that the big pharma companies named in the FDA's list generate annual revenues of billions of dollars.⁶⁹ With such large sums at the disposal of the regulatees, monetary sanctions may well be an ineffective form of regulatory enforcement and deterrence.⁷⁰ Indeed, drug prices have been and still remain a major concern of public health regulators and legislators, who have been largely unable to restrain rising drug prices.⁷¹ It is thus worth considering other, more sophisticated sanctions, even if only as a complementary measure. Furthermore, since this shaming is mostly directed toward big drug companies, the risk of over-deterrence and of causing disproportionate reputational damages is relatively small.⁷²

Finally, because the drug industry is heavily regulated,⁷³ it is familiar with regulatory intervention and is therefore less likely to be hostile to regulatory endeavors to enforce regulation, minimizing the regulatory risks of shaming.⁷⁴

Therefore, in theory, shaming big pharma can work. However, the FDA's recent list of shame was lacking in both form and in substance, failing to include items 4 and 5 (and possibly 2) in the list of critical stages for successful regulatory shaming, as presented in the previous section.⁷⁵ The FDA's shaming list is extremely uncommunicative in both the language used and in the ways in which the data has been processed, organized, and presented, and it was not distributed through appropriate channels for effective impact. These findings suggest that the agency has not fully considered the shaming process, its relevant participants, and its intended results and effects.

69. For instance, Roche grossed more than \$42.2bn in 2017; Pfizer—\$52bn; Novartis—\$49bn; and Bayer—\$29.1bn. See Vasanthi Vara, *The World's Biggest Pharmaceutical Companies by Revenue in 2018*, PHARMACEUTICAL TECHNOLOGY (June 20, 2018), <https://www.pharmaceutical-technology.com/features/worlds-biggest-pharmaceutical-companies-2018> [https://perma.cc/PAY3-D3QA].

70. Between 1991 and 2015, financial penalties imposed amounted to just five percent of the \$711 billion in net profits made by the eleven largest global drug companies during just ten of those twenty-five years (2003-2012). See *Twenty-Five Years of Pharmaceutical Industry Criminal and Civil Penalties: 1991 Through 2015*, PUBLICCITIZEN (March 31, 2016), <https://www.citizen.org/our-work/health-and-safety/twenty-five-years-pharmaceutical-industry-criminal-and-civil-penalties-1991-through-2015> [https://perma.cc/6EBH-97YL].

71. See generally U.S. DEP'T. OF HEALTH & HUMAN SERVS., AMERICAN PATIENTS FIRST: THE TRUMP ADMINISTRATION BLUEPRINT TO LOWER DRUG PRICES AND REDUCE OUT-OF-POCKET COSTS (May 2018), <https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf> [https://perma.cc/ZAQ7-YLSQ].

72. See Yadin, *supra* note 7.

73. See, e.g., Adrian Towse & Patricia M. Danzon, *The Regulation of the Pharmaceutical Industry*, in THE OXFORD HANDBOOK OF REGULATION 548, 548 (Robert Baldwin, Martin Cave & Martin Lodge eds., 2010).

74. See *supra* Part II.

75. See *id.*

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Figure 1 below shows the FDA’s list (for convenience, only the first few rows are presented).⁷⁶ A quick glance reveals that the list is not at all designed to be easily accessible for the general public, which is not fluent with the pharma regulation terminology used by the FDA both in the table itself and in the “explanatory” text in the webpage in which the table appears.

Figure 1: Excerpt from the FDA’s Pharma “Shame List” (2018)

RLD Access Inquiries

Product	RLD Sponsor ^{4,5}	Number of Inquiries Received by FDA	Does the product have a REMS with ETASU Impacting Distribution?	For Products with REMS with ETASU Impacting Distribution: Date(s) of Safety Determination Letter(s) Issued (if applicable)
Absorica (isotretinoin)	RANBAXY INC/SUN PHARMACEUTICAL INDUSTRIES INC	5	Yes	12/9/2015
Abstral (fentanyl citrate)	GALENA BIOPHARMA	1	Yes	
Accutane (isotretinoin)	ROCHE PALO ALTO LLC	2	Yes	6/23/2009
Adempas (riociguat)	BAYER HEALTHCARE PHARMACEUTICALS INC	2	Yes	9/27/2016; 5/2/2017
Afinitor (everolimus)	NOVARTIS PHARMACEUTICALS CORP	1	No	N/A
Amnesteem (isotretinoin)	MYLAN PHARMACEUTICALS INC	3	Yes	
Ampyra (dalfampridine)	ACORDA THERAPEUTICS INC	4	No	N/A
Brilinta (ticagrelor)	ASTRAZENECA LP	1	No	N/A
Claravis (isotretinoin)	TEVA PHARMACEUTICALS USA	4	Yes	

For instance, terms like RLD, REMS, and ETASU are used as the building blocks for this table, which is even called “RLD Access Inquiries.”⁷⁷ Of the five columns in the table, only the names of the companies and the names of the drugs in columns 1 and 2 are easily understood. Footnotes to the accompanying text which attempt to explain some technical terms only add to the confusion by using

76. See FDA list, *supra* note 1.

77. REMS stands for “Risk Evaluation and Mitigation Strategy”; ETASU, for “Elements to Assure Safe Use”; RLD for “Reference Listed Drug”.

even more pharma jargon.⁷⁸ The table is thus immediately comprehensible only to people within the pharma industry; for a person from outside the pharma industry to understand it would require reading and re-reading the accompanying text (over 2,000 words) as well as the data provided in the table.

Even for those who are able to decipher the lingo in which the FDA describes the condemned behavior of big pharma, the data is very confusing. It includes both pharma companies on which regulatory restrictions on sharing drug samples have been imposed (for safety reasons) and companies that have no such restrictions. However, in an accompanying statement, the FDA Commissioner explains that branded drug companies should always make available “a path to securing samples of brand drugs for the purpose of generic drug development.”⁷⁹ Also, different kinds of anti-competitive behaviors are described by the agency in the explanatory text, including contractual restraints imposed by branded drug companies on sellers, such as pharmacies.⁸⁰

Thus, the FDA publication obscures, diffuses, and dilutes its main message, and thereby fails to realize the full potential of regulatory shaming of the pharma industry.

Examples of regulatory shaming by other regulatory agencies show how the FDA could have done a much better job of shaping its message and making it comprehensible to relevant shaming communities. For example, the webpage in which the FDA lengthily explains the idea of the list and its complex database uses dense pharma regulation terminology and lacks any graphic support besides the table itself.⁸¹ By contrast, the Department of Health and Human Services provides an online rating of nursing homes that is based on a highly intuitive five-star scale, incorporating an easily understood graphic measuring tool (see Figure 2).⁸² In this form of regulation by shaming, each rated facility is assigned a star rating based on its weighted score from recent health inspections, its staff-resident ratio, and clinical data, saving the public the task of wading through the underlying data and navigating technical language.⁸³ The star ratings are posted online, which can shame poorly rated nursing homes into doing better in the inspected areas.

78. Such as GDUFA II, ANDA, and RS. See FDA list, *supra* note 1. GDUFA stands for “The Generic Drug User Fee Act”; ANDA for “Abbreviated New Drug Application”; and RS for “Reference Standard.”

79. See *Statement from FDA Commissioner, supra* note 1.

80. See FDA list, *supra* note 1.

81. See *id.*

82. See *Nursing Home Compare, CTRS. FOR MEDICARE & MEDICAID SERVS.*, <https://www.medicare.gov/nursinghomecompare/search.html> [<https://perma.cc/74WB-QGVS>] (last visited Aug. 27, 2018). Figure 2 is an example of a low-star rating given to a specific nursing home in New York.

83. See *id.*

Figure 2: Medicare, “Nursing Home Compare”



Another example is the Environmental Protection Agency’s (EPA) Toxics Release Inventory (TRI) program (see Figure 3), in which the agency publishes facility-based information regarding air, water, and land pollution, as well as compliance status.⁸⁴ Here, significantly non-compliant facilities are marked red, while compliant facilities are marked blue.

Figure 3: EPA Toxics Release Inventory Program



The methods used by the Department of Health and Human Services and the EPA, in which data are formulated and presented in a clear and communicative manner, can be very effective in soliciting public attention and facilitating corporate shaming to achieve regulatory goals.

84. See *Toxics Release Inventory (TRI) Program*, ENVTL. PROT. AGENCY, <http://www.epa.gov/toxics-release-inventory-tri-program> [<https://perma.cc/X4YG-NWHT>] (last visited Aug. 27, 2018). Figure 3 is an example of a rating that signals non-compliance, including significant non-compliance of a specific company found in the EPA’s database.

The chosen distribution methods for the FDA’s message were also flawed. The list of pharma companies was only mentioned on a few of the FDA’s Twitter accounts,⁸⁵ with a concise informative notification (see Figure 4) referring the readers to the FDA Commissioner’s statement.⁸⁶

Figure 4: FDA Tweet about its “Shame List”



This relative paucity of communication is particularly surprising given that the FDA has a fairly heavy social media presence and conducts extensive interactive media activity. The agency sends out email alerts to subscribers and provides RSS feeds and also maintains a Facebook page in both English and in Spanish, a Pinterest page with dozens of infographics, more than 20 Twitter accounts, a blog, a YouTube channel, and a Flickr page, most of which are updated daily, even several times a day.⁸⁷

By contrast, an example from the Occupational Safety and Health Administration (OSHA) shows how social media, as well as administrative agencies’ webpages and news releases, can be properly harnessed for regulatory shaming. Figure 5 below is an example of OSHA’s almost daily tweets on enforcement actions taken against companies that violate workplace safety regulations.⁸⁸ The tweet links to a webpage (news release) in which the agency clearly and concisely explains the case,⁸⁹ without unnecessary OSHA jargon or undecipherable data (see Figure 6).

85. See, e.g., FDA Media Affairs (@FDAMedia), TWITTER (May 17, 2018, 6:57 AM), <https://twitter.com/FDAMedia/status/997113935747829760> [<https://perma.cc/WLS7-RX5R>].

86. In the statement page, another link provides access to the table itself.

87. See *Interactive Media*, FDA, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/NewsEvents/InteractiveMedia/default.htm> [<https://perma.cc/Z63B-Q99P>] (last visited Aug. 28, 2018).

88. See OSHA (@OSHA_DOL), TWITTER (June 29, 2018, 7:50 AM), https://twitter.com/OSHA_DOL/status/1012709797282680832 [<https://perma.cc/M8YD-LQEK>].

89. Meanwhile, the FDA Commissioners’ statement was 1,200 words long. See *Statement from FDA Commissioner*, *supra* note 1

Figure 5: OSHA Shaming Tweet



Figure 6: OSHA News Release



In short, the FDA's efforts at shaming big pharma would be much more effective if it was to follow the five-step process laid out in this Essay.⁹⁰ First, it must choose a topic that people are interested in or passionate about. Drug companies' behavior can generally be considered a fitting subject for shaming since patients are dependent on these companies for their health. Therefore, issues that relate to illegal or unethical practices of pharmaceutical companies, such as price gouging, exclusion of competitors, or poor transparency regarding their activities, can be considered good candidates for regulatory shaming. Second, the FDA should carefully identify the right shaming audience, and consider patients, health advocacy groups, investors in the pharma sector, pharma employees, and the pharma industry in general. Defining the right target group will improve the effectiveness of any regulatory shaming effort. Third, the FDA should consider whether its moral stand regarding the pharma industry is fully shared by the targeted shaming communities. In all of these first three steps, the FDA's regulatory shaming of big pharma is on fairly solid ground, though some improvements may be needed in step two.

The final two steps, however, need significant improvement if the FDA's shaming tactics are to achieve more effective results. The fourth step is that the

90. See *supra* Part II.

FDA must shape its shaming message in a much more communicative manner. The message needs to be simple and direct. Instead of lengthy text embedded with pharma jargon, or undecipherable charts and data, use should be made of short statements; infographics; easily digestible numbers, scores, and ratings; and intuitive and attractive design. Messages of this type are far more suited to most shaming audiences, as well as to the media, and thus can be much more effective in changing drug companies' behavior. In this regard, short messages that name specific companies can be more effective than general sector-wide shaming; and converting data into simple ratings and scores can offer a more straightforward message for widescale dissemination.

And fifth, proper use of social media and digital media in general is crucial for regulatory communication with the public in today's world. Short shaming messages and related graphics are highly suited for platforms such as Facebook and Twitter. The FDA should harness multiple media outlets that have high visibility in order to disseminate the message as broadly as possible, and can issue repeated publications as needed. These communications can also include reports to the public on how FDA shaming efforts have helped change pharma companies' behavior, thus encouraging further public participation in "private regulation" based on regulatory shaming.

CONCLUSION

The FDA has been accused by some commentators of being an agency that engages in "regulatory silence"—that is, it is reluctant to take action that may be viewed as aggressive or outside the clear scope of product safety and efficiency.⁹¹ But in fact, the FDA has shown real initiative in the regulatory tools arena, experimenting with "naming and shaming" of drug companies that engage in anti-competitive behavior to impede competition from generics. Though some may consider shaming to be "soft" rather than "hard" regulation, it is definitely not passive or neutral, and it is a clear example of "thinking outside the box." Naming and shaming practices are most certainly an embodiment of the FDA's regulatory philosophy, developed in the 1970s, which advocates achieving the general objectives of the law in creative ways that do not violate statutory restrictions.⁹²

The rising prices of drugs across the country are currently a major public policy problem, one with which regulators are still grappling.⁹³ Under these circumstances, there is a great need for creative regulatory solutions. Only recently, the Department of Health and Human Services proposed requiring that TV ads for prescription drugs include their list price, in order to incentivize drug

91. See Paradise, *supra* note 31, at 2409-10; Carl Tobias, *FDA Regulatory Compliance Reconsidered*, 93 CORNELL L. REV. 1003, 1004, 1009 (2008).

92. See Gilhooley, *supra* note 31, at 132.

93. See generally American Patients First, *supra* note 71.

companies to lower their prices.⁹⁴ Officials in the Department have also declared that they intend to shame drug companies that do not comply with the new rule once it is passed.⁹⁵

It therefore seems that in the health industry, regulatory shaming is more relevant than ever. But can shaming big pharma work? Can it efficiently achieve regulatory goals, such as enhancing competition in the pharma industry and bringing down drug prices? Can shaming by the FDA in other regulatory fields work as well? And can it also work for other health regulators? The answer to all these questions, in my opinion, is yes.⁹⁶ But first, the regulatory agency has to properly identify the intended shaming group (the general public, the pharma industry, investors, etc.) and then both correctly formulate the shaming message and select the appropriate media channels, so as to communicate its message in an efficient and accessible manner.

Although this Essay has focused on deficiencies in the implementation of the regulatory shaming approach by the FDA, some elements of its approach were entirely correct. One of the smartest things the FDA did was to publicly notify, in advance, that regulatory shaming was going to take place in a certain subject area. In fact, the head of the FDA stated almost a year in advance that the agency had identified that “gaming tactics” were being employed by branded drug companies to impede competition from generics and that the agency planned to publicize the letters it had received from authorized generics that had requested samples from branded drug companies and were denied.⁹⁷ Announcing regulatory shaming ahead of time can create deterrence in the drug industry and reduce unwanted behaviors by big pharma companies, even before the shaming itself takes place.

In conclusion, regulatory shaming holds great promise for curtailing bad behavior by big pharma. Regulators in health and other sectors, as well as legal scholars, should further develop this interesting and innovative approach to regulation.

94. See *What You Need to Know about Putting Drug Prices in TV Ads*, HHS.GOV, (Oct. 15, 2018), <https://www.hhs.gov/about/news/2018/10/15/what-you-need-to-know-about-putting-drug-prices-in-tv-ads.html> [https://perma.cc/J7PE-4ZA3].

95. See Amy Goldstein & Carolyn Y. Johnson, *Drugmakers May Have to Disclose Prices of Medicine in Television Ads*, WASH. POST (Oct. 15, 2018), https://www.washingtonpost.com/national/health-science/tv-ads-for-drugs-will-send-patients-to-websites-with-pricing-information/2018/10/15/b74ac344-d090-11e8-b2d2-f397227b43f0_story.html?utm_term=.47f67cc81e3a [https://perma.cc/69E9-9BFP].

96. These, of course, warrant additional study. *But see generally* Yadin, *supra* note 7.

97. See Jayne O’Donnell, *FDA Chief Says Drug Makers Are Gaming the System to Slow Generic Competition; Vows Action*, USA TODAY (Aug. 15, 2017), <https://www.usatoday.com/story/news/politics/2017/08/15/fda-chief-says-drug-makers-gaming-system-slow-generic-competition-vows-action/568698001> [https://perma.cc/A8ZX-KXQ4].