

# NOTES

## ANTICOMPETITIVE MANIPULATION OF REMS: A NEW EXCEPTION TO ANTITRUST REFUSAL-TO-DEAL DOCTRINE

### TABLE OF CONTENTS

INTRODUCTION . . . . .	657
I. LEGISLATIVE ORIGINS OF REMS . . . . .	660
A. <i>The Hatch-Waxman Act</i> . . . . .	660
B. <i>The FDAAA</i> . . . . .	662
II. BRAND DRUG MANUFACTURERS' USE OF REMS TO BLOCK GENERIC ENTRY. . . . .	664
A. <i>Bioequivalence Testing and Generics' Lack of Access to         Samples</i> . . . . .	664
B. <i>REMS' Negative Effect on Generic Market Entry and         Subsequent Economic Harm.</i> . . . . .	665
III. INSTITUTIONAL FAILURE TO ADDRESS GENERICS' REMS CONCERNS. . . . .	666
A. <i>Repeated Congressional Inaction</i> . . . . .	667
B. <i>Absence of FDA Enforcement Against REMS Abuses.</i> . . . .	671
C. <i>REMS Enforcement: The Role of the FDA or the FTC?</i> . . . .	673
IV. AN ANTITRUST ANALYSIS OF REMS: THE REFUSAL-TO-DEAL DOCTRINE . . . . .	676
A. <i>Section 1 Is Not a Source of Brand Antitrust Liability.</i> . . . .	677
B. <i>Brands Hold Monopoly Power Under Section 2</i> . . . . .	677
C. <i>Jurisprudence of the Refusal-to-Deal Doctrine:         Otter Tail, Aspen Skiing, and Trinko.</i> . . . . .	679
D. <i>The "No Economic Sense" Test Protects Brands from         Violating Section 2</i> . . . . .	683
1. <i>Brand Manufacturers and Generic Competitors Have            No Prior Course of Dealing</i> . . . . .	684

2. <i>Brand Manufacturers Under REMS Regulation         Do Not Make Their Drugs Available to the Public . . . .</i>	686
3. <i>Fear of Tort Liability Serves as a Valid Business         Reason for Brands' Refusals to Deal with Generics. . . .</i>	689
4. <i>Under Current Antitrust Doctrine, Brands' Refusals         to Deal with Generics Do Not Fail the "No Economic         Sense" Test . . . . .</i>	692
V. COURTS SHOULD CREATE A NEW EXCEPTION TO THE REFUSAL-TO-DEAL DOCTRINE TO IMPOSE LIABILITY UPON BRANDS . . . . .	694
CONCLUSION . . . . .	698

## INTRODUCTION

Spending on pharmaceutical drugs in the United States is exorbitantly high, amounting to \$325 billion in 2015—just under 2 percent of GDP.<sup>1</sup> And this spending is rising: prescription drug spending is projected to increase by over 6 percent per year over the next decade.<sup>2</sup> One of the factors most responsible for these high medical and pharmaceutical costs is the price of brand drugs. Although branded drugs compose only 11 percent of prescriptions in the United States, that 11 percent is responsible for 73 percent of total American drug spending.<sup>3</sup> Soaring pharmaceutical costs are not a new problem, either; Congress's strongest attempt to decrease spending on pharmaceutical drugs occurred in 1984, when Congress passed the Hatch-Waxman Act<sup>4</sup> to encourage the entry of generic drugs into the pharmaceutical marketplace.<sup>5</sup> Generic drugs are often substantially cheaper than their branded counterparts, as their average cost across the industry is 80-85 percent lower than brand drugs.<sup>6</sup> Yet, when the Hatch-Waxman Act was enacted, approximately 150 brand drugs whose patent protection had expired faced no generic drug competition.<sup>7</sup> Therefore, it is no surprise that Congress, seeking to provide “low-cost, generic drugs for millions of Americans,”<sup>8</sup> targeted accelerating market entry of generic drugs as a way to decrease rising pharmaceutical costs.<sup>9</sup>

---

1. Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription Drug Spending*, BROOKINGS: UP FRONT (Apr. 26, 2017), <https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/> [<https://perma.cc/PQ8F-5GL7>].

2. *See id.*

3. *See Generic Drugs Facts*, U.S. FOOD & DRUG ADMIN. [hereinafter *Facts*], <https://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/genericdrugs/ucm167991.htm> [<https://perma.cc/XD5U-WFAM>] (last updated June 4, 2018).

4. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2012)).

5. *See* 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman) (the goal of the Act was to provide “low-cost, generic drugs for millions of Americans”).

6. *Facts*, *supra* note 3.

7. Michael A. Carrier & Brenna Sooy, *Five Solutions to the REMS Patent Problem*, 97 B.U. L. REV. 1661, 1663-64 (2017) (citing H.R. REP. NO. 98-857, pt. 1, at 17 (1984)).

8. 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman).

9. *See* Henry N. Butler, *REMS-Restricted Drug Distribution Programs and the Antitrust Economics of Refusals to Deal with Potential Generic Competitors*, 67 FLA. L. REV. 977, 981-82

The Hatch-Waxman Act has been fairly successful in encouraging generic competition.<sup>10</sup> But recently, generics have encountered an additional hurdle to entering the market. In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA), which granted the Food and Drug Administration (FDA) the authority to require drug manufacturers to create a Risk Evaluation and Mitigation Strategy (REMS) to ensure the safety of their products.<sup>11</sup> The drug manufacturer designs a REMS program to restrict the distribution of potentially dangerous drugs by limiting drug access to selected and approved distributors.<sup>12</sup> However, many brand-name drug manufacturers have designed their REMS programs in such a way that prevents generic drug manufacturers from obtaining access to the branded drugs.<sup>13</sup> Generic drug manufacturers need access to samples of the branded drugs to develop and test their generic drugs for bioequivalence with the branded drug, in order to qualify their products for fast-tracked regulatory approval through the FDA's Abbreviated New Drug Application (ANDA).<sup>14</sup> Without being able to test for bioequivalence, the generic drug manufacturers face significant barriers to market entry.<sup>15</sup> As generics are unable to enter the pharmaceutical product's market, the lack of competition leads to higher prices because the branded drug manufacturer retains a monopoly over the market, even if the company's patent has expired.<sup>16</sup> To overcome this regulatory side effect, generics have increasingly turned to the courts and antitrust law to enjoin brands to provide them with samples of the brand drugs.<sup>17</sup>

---

(2015); Donald S. Lee, *Pharmaceutical Manufacturers: Players or Pariahs in Health Care Reform?*, 3 KAN. J.L. & PUB. POL'Y 89, 90-91 (1993).

10. See *infra* text accompanying notes 34-38.

11. Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, § 505-1, 121 Stat. 823, 926-39 (2007) (codified at 21 U.S.C. § 355-1 (2012)).

12. See *infra* notes 39-45 and accompanying text.

13. See *infra* Part II.

14. See *infra* notes 22-27, 60-62 and accompanying text.

15. See *infra* Part II.

16. ALEX BRILL, MATRIX GLOBAL ADVISORS, LOST PRESCRIPTION DRUG SAVINGS FROM USE OF REMS PROGRAMS TO DELAY GENERIC MARKET ENTRY 1 (2014), [https://www.gphaonline.org/media/cms/REMS\\_Studyfinal\\_July2014.pdf](https://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf) [<https://perma.cc/UU5E-LVNF>].

17. See *infra* text accompanying note 151.

This Note argues that brand drug manufacturers have manipulated REMS to engage in anticompetitive behavior that undermines the purpose of the Hatch-Waxman Act and hurts the public interest by preventing market entry of generic competitors. Part I will give an overview of the Hatch-Waxman Act and the FDAAA to examine the legislative origins of Congress's regulations of the pharmaceutical industry affecting generic market entry. Part II will explain why brands' refusal to share samples with generics has anticompetitive effects, and will highlight the economic consequences that have resulted from this behavior.

Part III will address the legislative history behind the FDAAA, focusing on the limitation of REMS "block[ing]" behavior under § 355-1(f)(8),<sup>18</sup> and will detail how Congress has attempted to clarify brands' duties under REMS but has failed to issue firm legislation on the matter. Part III contends that this lack of clear congressional intent has played a large role in why the FDA has acted with extreme passivity towards generics' allegations of brands' uses of REMS to justify anticompetitive behavior. Part III will also argue that while the FDA has seemingly requested the Federal Trade Commission (FTC) to intervene on behalf of generics' antitrust claims, the FDA is better positioned to regulate REMS disputes in a way that relieves antitrust concerns and streamlines the ANDA approval process while appropriately resolving safety concerns.

Part IV will survey possible antitrust remedies available to generics, and will identify the refusal-to-deal doctrine under Section 2 of the Sherman Antitrust Act as the most appropriate avenue for judicial analysis. After analyzing Supreme Court jurisprudence on the refusal-to-deal doctrine, Part IV argues that current refusal-to-deal doctrine and analysis will not impose antitrust liability on brands because brands' refusals to deal are motivated by a legitimate business purpose of avoiding tort and product liability. Absent an evidentiary showing of anticompetitive motivation, generics' litigation against brands for their refusal to sell samples will likely prove unsuccessful.

However, Part V will explain why REMS provides an ideal context for courts to impose a new exception to the right of firms to

---

18. 21 U.S.C. § 355-1(f)(8) (2012).

refuse to deal with competitors. Under the analysis set forth by *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*,<sup>19</sup> the FDA and the REMS regulatory framework have fallen short of effectively providing a regulatory antitrust check. This failure has opened the door for the judiciary to intervene and apply antitrust principles to alleged anticompetitive uses of REMS. Part V will ultimately conclude that courts should step through this opening and apply antitrust scrutiny within the REMS context—an area of the pharmaceutical industry currently beset by a vacuum of anti-competitive liability.

## I. LEGISLATIVE ORIGINS OF REMS

Studying the origins and purposes behind the Hatch-Waxman Act and the FDAAA—which, respectively, created procedures governing generic manufacturer entry into the pharmaceutical market<sup>20</sup> and REMS<sup>21</sup>—lays the foundation of understanding why the status quo of brands' use of REMS is problematic.

### A. *The Hatch-Waxman Act*

The primary provision of the Hatch-Waxman Act<sup>22</sup> enabled a generic to circumvent the FDA's strict, time-consuming, and expensive testing requirements for a new drug<sup>23</sup> by permitting generics to file an Abbreviated New Drug Application (ANDA) instead of the typical New Drug Application (NDA).<sup>24</sup> ANDAs allowed generics to “piggy-back”<sup>25</sup> on a brand-name drug's successful application—including expensive safety and effectiveness studies<sup>26</sup>—if they showed their generic drug was bioequivalent to the brand drug.<sup>27</sup> In

---

19. 540 U.S. 398 (2004).

20. See *infra* Part I.A.

21. See *infra* Part I.B.

22. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 (2012)).

23. See Carrier & Sooy, *supra* note 7, at 1664.

24. See 21 U.S.C. § 355(j)(2)(A)(i)-(viii) (2012).

25. See Carrier & Sooy, *supra* note 7, at 1664-65.

26. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 676 (1990).

27. See FED. TRADE COMM'N, *GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY* 5 (2002), <https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry->

exchange for the increase in generic competition Congress created through ANDAs, the Act extended the patent term for brand drugs.<sup>28</sup>

In an ANDA application, the generic must certify one of the following four conditions: (I) a patent for the listed drug has not been filed; (II) the existing patent on the listed drug has expired; (III) the specific date on which a patent for a listed drug will expire; or (IV) the patent for the listed drug is invalid or will not be infringed by the generic's manufacture, use, or sale of the generic drug.<sup>29</sup> A filing under condition IV is called a "Paragraph IV certification,"<sup>30</sup> and the first successful Paragraph IV ANDA applicant is awarded 180 days of generic exclusivity on the market.<sup>31</sup> However, once a generic has filed a Paragraph IV certification with both the FDA and the brand drug manufacturer, the brand may file an infringement action against the generic,<sup>32</sup> which leads to an automatic thirty-month stay of the generic's ANDA approval.<sup>33</sup>

State drug product selection (DPS) laws, which are in effect in all fifty states, support the Hatch-Waxman Act's effort to aid generic market entry.<sup>34</sup> DPS laws allow—and often require—pharmacists to substitute generic drugs for prescribed brand drugs if the generic drug is rated by the FDA as bioequivalent to the brand drug.<sup>35</sup> DPS laws are critical for lowering consumers' pharmaceutical expenses, because even though branded drugs comprise only 11 percent of prescriptions in the United States, this 11 percent is responsible for 73 percent of drug spending.<sup>36</sup> Together, the Hatch-Waxman Act and state DPS laws have also been largely successful in increasing generic market entry: while generics constituted only 19 percent of the prescription drug market in 1984, as of 2014, they represented 89

---

prior-patent-expiration-ftc-study/genericdrugstudy\_0.pdf [https://perma.cc/XK8A-PSDG].

28. See Butler, *supra* note 9, at 982.

29. See § 355(j)(2)(A)(vii)(I)-(IV).

30. See Jordan Paradise, *REMS As a Competitive Tactic: Is Big Pharma Hijacking Drug Access and Patient Safety?*, 15 HOUS. J. HEALTH L. & POL'Y 43, 51 (2015).

31. See § 355(j)(5)(B)(iv).

32. See Paradise, *supra* note 30, at 51.

33. See § 355(j)(5)(B)(iii).

34. See Michael A. Carrier, *Sharing, Samples, and Generics: An Antitrust Framework*, 103 CORNELL L. REV. 1, 8 (2017).

35. See *id.*

36. See *Facts*, *supra* note 3.

percent of the market.<sup>37</sup> A study by the Generic Pharmaceutical Association calculated that generics led to savings of almost \$1.5 trillion for consumers between 2006 and 2015.<sup>38</sup>

### *B. The FDAAA*

Section 505-1(a)(1) of the FDAAA empowers the FDA to require drug manufacturers to comply with REMS for certain drugs the FDA deems sufficiently hazardous.<sup>39</sup> The FDA considers (1) the size of population likely to use the drug; (2) the seriousness of the disease the drug alleviates; (3) the drug's expected benefit to consumers; (4) the expected duration of treatment; (5) the seriousness of known or possible adverse effects; and (6) the drug's novelty, as factors affecting the need for a REMS program.<sup>40</sup> The FDA may require a REMS before a drug enters the market or after the drug has hit the market, if new evidence of risk appears.<sup>41</sup> Because the drug manufacturer uniquely designs each REMS according to FDA requirements based upon the drug's risks,<sup>42</sup> some REMS are therefore more restrictive than others.<sup>43</sup> REMS generally require a manufacturer to provide a medication guide for patients, communication to distributors and health care providers describing the drug's risks, "limitations on labeling, promotion, and prescribing [of the drug] in order to assure safe use by patients," and a REMS implementation plan.<sup>44</sup> More restrictive REMS programs involve elements to assure safe use (ETASU), which "restrict a drug's distribution and affect how it can be sold" and to whom.<sup>45</sup>

---

37. See GENERIC PHARM. ASS'N, 2016 GENERIC DRUG SAVINGS & ACCESS IN THE UNITED STATES REPORT 5 (2016), <http://www.gphaonline.org/media/generic-drug-savings-2016/index.html> [<https://perma.cc/J9HW-L3PV>].

38. See *id.* at 6.

39. See 21 U.S.C. § 355-1 (2012).

40. U.S. FOOD & DRUG ADMIN., A BRIEF OVERVIEW OF RISK EVALUATION & MITIGATION STRATEGIES (REMS), 6 (2007) <http://www.fda.gov/downloads/AboutFDA/Transparency/Basics/UCM328784.pdf> [<https://perma.cc/2BL3-5TTD>].

41. See *id.* at 5.

42. See § 355-1.

43. See Carrier, *supra* note 34, at 6.

44. See Paradise, *supra* note 30, at 46 (citing 21 U.S.C. §§ 355-1(c)-(f)).

45. See Carrier, *supra* note 34, at 7 (citing 21 U.S.C. § 355-1(f)(2)(D)(ii)).



Under the FDAAA, if a brand drug requires REMS, then any corresponding generic drugs seeking market entry under the expedited ANDA application must adhere to the brand's REMS program requirements.<sup>46</sup> The FDAAA's intent was that the brand and the generic would collaborate to create a single shared REMS program,<sup>47</sup> but that has rarely borne out in practice: "many generic companies are ... finding that brand manufacturers are unwilling to work with them on the development of single, shared REMS systems."<sup>48</sup> Fortunately, the FDAAA also grants discretion to the FDA Commissioner<sup>49</sup> to allow a generic to create its own REMS program when either (1) the burden of creating the single shared REMS system outweighs the benefits, or (2) the REMS program is protected by patent and the generic has been unsuccessful in attempts to acquire a license.<sup>50</sup>

REMS is quickly becoming a fairly common staple of the pharmaceutical industry: the FDA assigns REMS programs for approximately 40 percent of new drugs.<sup>51</sup> As of January 2017, there were seventy-six approved REMS programs, and forty-two involved ETASU.<sup>52</sup> However, a 2013 report from the Department of Health and Human Services Office of the Inspector General called into question "the overall effectiveness of the REMS program," as only seven of then-forty-nine REMS programs were meeting the FDA's goals for improving drug safety.<sup>53</sup>

Congress designed the Hatch-Waxman Act to ease generic drug entry into the market,<sup>54</sup> and Congress included provisions creating

---

46. See Paradise, *supra* note 30, at 59.

47. See *id.*; Carrier & Sooy, *supra* note 7, at 1669.

48. Paradise, *supra* note 30, at 68.

49. The text of the statute grants this discretionary power to the Secretary of the Department of Health and Human Services, 21 U.S.C. § 355-1(i)(1)(B) (2012), but in practice the decision to waive the shared REMS program lies with the FDA Commissioner. See Paradise, *supra* note 30, at 59.

50. See 21 U.S.C. § 355-1(i)(1)(B)(ii) (2012); Carrier & Sooy, *supra* note 7, at 1669.

51. See BRILL, *supra* note 16, at 2.

52. Carrier, *supra* note 34, at 7 (citing *Approved Risk Evaluation and Mitigation Strategies (REMS)*, U.S. FOOD & DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cder/remis/index.cfm?event=RemsDetails.page&REMS=17> [<https://perma.cc/SNH2-EACQ>]).

53. DEP'T OF HEALTH & HUMAN SERVS., OFFICE OF INSPECTOR GEN., FDA LACKS COMPREHENSIVE DATA TO DETERMINE WHETHER RISK EVALUATION AND MITIGATION STRATEGIES IMPROVE DRUG SAFETY 22 (2013).

54. See 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman).

REMS within the FDAAA to ensure the safety of hazardous drugs.<sup>55</sup> However, these policy goals have been either thwarted or overshadowed by brands' use of REMS to block generic entry into the pharmaceutical market.<sup>56</sup> A closer examination of how brands have manipulated REMS, and the effects of this manipulation upon generic competitors and the market at large, is warranted.

## II. BRAND DRUG MANUFACTURERS' USE OF REMS TO BLOCK GENERIC ENTRY

REMS programs are designed to limit access to potentially dangerous drugs.<sup>57</sup> However, brand drug manufacturers have used REMS' distribution limitations to deny generic competitors the access to samples of the brand drugs that generics need to achieve ANDA certification.<sup>58</sup> As a result, generics are unable to complete bioequivalence testing, which creates a barrier to generic entry into the market resulting in negative economic consequences for the general American public.<sup>59</sup>

### A. Bioequivalence Testing and Generics' Lack of Access to Samples

For both ANDA and DPS reasons, it is essential that generics prove that their generic drug is bioequivalent to the brand drug.<sup>60</sup> Bioequivalence occurs when the "rate and extent of absorption in the body" of the drug is equivalent between the brand and generic drug.<sup>61</sup> Generics must complete bioequivalence testing themselves, and are able to prove bioequivalence only after obtaining samples of the brand drug that they can test against their generic version of

---

55. See *supra* Part I.B.

56. See *infra* Part II.

57. See *supra* notes 39-40 and accompanying text.

58. See *supra* notes 41-45 and accompanying text.

59. See *infra* Parts II.A-B.

60. See *supra* text accompanying notes 27, 35.

61. Carrier, *supra* note 34, at 35 (citing U.S. FOOD & DRUG ADMIN., CTR. FOR DRUG EVALUATION & RESEARCH, APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (36th ed. 2016), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm> [<https://perma.cc/VQ8Y-75dd>]).

the drug.<sup>62</sup> Usually, generics are able to obtain samples of the brand drug for bioequivalence testing through normal purchase and distribution channels, such as the brand drug's wholesaler(s).<sup>63</sup> However, because a central purpose of REMS is to limit access to the potentially hazardous drug,<sup>64</sup> REMS often include "provisions barring distributors and wholesalers from selling the drug to entities without approval under the REMS."<sup>65</sup> As the brand drug manufacturer is responsible for creating and running their own REMS program,<sup>66</sup> generics must either get the brand to list them as approved entities, or ask to purchase samples of the drug from the brand manufacturer directly.<sup>67</sup> REMS therefore gives brand drug manufacturers tremendous power over the ability of their generic competitors to meet FDA market entry regulation requirements.

### *B. REMS' Negative Effect on Generic Market Entry and Subsequent Economic Harm*

Unsurprisingly, brands have taken advantage of this power to block or slow down their generic competition. A prime example of a brand using REMS to refuse to share samples occurred as early as 2008, when Celgene refused to sell samples of their brand drugs Thalomid and Revlimid to Lannett, a generic pharmaceutical manufacturer.<sup>68</sup> Both Thalomid and Revlimid were subject to extensive ETASU.<sup>69</sup> Although Lannett sued Celgene, alleging that Celgene's

---

62. See, e.g., Butler, *supra* note 9, at 983 (citing Roxane Laboratories, Inc.'s Answer, Affirmative Defenses, and Counterclaim Complaint at 22, Actelion Pharm. Ltd. v. Apotex Inc., No. 1:12-cv-05743-NLH-AMD (D.N.J. Nov. 27, 2012)).

63. See, e.g., Carrier, *supra* note 34, at 9.

64. See *supra* text accompanying notes 44-45.

65. Lauren Battaglia, *Risky Conduct with Risk Mitigation Strategies? The Potential Antitrust Issues Associated with REMS*, ANTITRUST HEALTH CARE CHRON., Mar. 2013, at 28, <https://www.hlregulation.com/files/2013/10/Lauren-Battaglia-article1.pdf> [<https://perma.cc/TV63-MQWA>].

66. See DEP'T OF HEALTH & HUMAN SERVS., *supra* note 53, at 1 n.3.

67. See Battaglia, *supra* note 65, at 28.

68. See Paradise, *supra* note 30, at 64.

69. See U.S. FOOD & DRUG ADMIN., THALOMID B (THALIDOMIDE) 1-7, <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM222649.pdf> [<https://perma.cc/67C7-KG5Y>] (last modified Sept. 2014); U.S. FOOD & DRUG ADMIN., REVLIMID R (LENALIDOMIDE) 1-7, <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM222644.pdf> [<https://perma.cc/R55S-WK6W>] (last modified Feb. 2015).

refusal to allow Lannett to buy samples violated antitrust law, the suit was never decided on the merits and ended in settlement.<sup>70</sup> Lannett's complaint was just the tip of the iceberg; as of June 2016, over 100 generics have complained that they have not been able to conduct bioequivalence testing due to lack of access to brand drug samples.<sup>71</sup> A 2014 study estimated that brand refusal to grant generics access to their drug samples under the auspices of REMS distribution limitations costs consumers \$5.4 billion per year.<sup>72</sup>

### III. INSTITUTIONAL FAILURE TO ADDRESS GENERICS' REMS CONCERNS

Given that brands' manipulative use of REMS both largely thwarts the purpose of the Hatch-Waxman Act and has resulted in economic harm to consumers,<sup>73</sup> it raises the question: has Congress or the FDA addressed and curtailed such behavior? While members, and even bodies of Congress have attempted to enact legislation that would close the REMS loophole,<sup>74</sup> the FDA has refrained from issuing any effective regulation on REMS abuses,<sup>75</sup> and has even tried to shirk adjudication and enforcement of alleged REMS manipulation onto the FTC.<sup>76</sup> This Part examines these repeated failures by both Congress and the FDA to sufficiently address generic manufacturers' concerns of brands' manipulation of REMS, and argues that the FDA is the designated REMS regulatory body, and is in a better position than the FTC to regulate all aspects of REMS, including alleged anticompetitive behavior.

---

70. See Paradise, *supra* note 30, at 64 (citing Erin Coe, *Lannett Cuts Deal with Celgene in Thalomid Antitrust Case*, LAW 360 (Dec. 7, 2011), <http://www.law360.com/articles/291483/lannett-cuts-deal-with-celgene-in-thalomid-antitrust-case>).

71. See Carrier, *supra* note 34, at 3.

72. See BRILL, *supra* note 16, at 1.

73. See *supra* Parts II.A-B.

74. See *infra* Part III.A.

75. See *infra* Part III.B.

76. See *infra* notes 133-35 and accompanying text.

### A. Repeated Congressional Inaction

Members of Congress are aware that brands are using REMS as a tactic to block or delay generic competition and market entry. Representatives and academics alike have argued that brands' refusal to provide samples contravenes the language of the FDAAA and the purpose of the Hatch-Waxman Act.<sup>77</sup> Many of these REMS critics point to § 355-1(f)(8) of the FDAAA as the source of their argument.<sup>78</sup> Section 355-1(f)(8) acts as a “[l]imitation” on REMS, stating that “[n]o holder of an approved covered application shall use any [ETASU] required by the Secretary under this subsection to block or delay approval of an [ANDA] application.”<sup>79</sup> However, the provision “does not construe the type of conduct that is considered to block or delay, nor does it include penalties for violations.”<sup>80</sup> Congress has repeatedly failed to enact legislation clarifying—or giving the FDA enforcement power upon—§ 355-1(f)(8).<sup>81</sup> In 2007, 2012, 2014, and 2016, Congress considered language requiring brands to provide or sell generics samples of their drugs for the purpose of bioequivalence testing; each time, Congress failed to enact any changes.<sup>82</sup>

In addition to containing § 355-1(f)(8),<sup>83</sup> House Bill 2900—the first version of the 2007 FDAAA that was passed by the House—would have explicitly required brands to sell their drug to generic companies at market price for the purposes of bioequivalence testing.<sup>84</sup> House Bill 2900 provided that if the generic agreed to pay market value for the samples and to abide by the drug's REMS and ETASU standards, then the brand had to sell “a sufficient quantity

---

77. See Carrier, *supra* note 34, at 36; Carrier & Sooy, *supra* note 7, at 1670-71; Paradise, *supra* note 30, at 46; Shashank Upadhye & Braden Lang, *The FDA and Patent, Antitrust, and Property Takings Laws: Strange Bedfellows Useful to Unblock Access to Blocked Drugs*, 20 B.U. J. SCI. & TECH. L. 84, 90 (2014); Christopher Megaw, Note, *Reviving Essential Facilities to Prevent REMS Abuses*, 47 COLUM. J.L. & SOC. PROBS. 103, 104-05 (2013); *infra* notes 97-99 and accompanying text.

78. See, e.g., Paradise, *supra* note 30, at 60-62, 61 nn.94-95, 62 n.99.

79. 21 U.S.C. § 355-1(f)(8) (2012).

80. Paradise, *supra* note 30, at 61.

81. See *infra* notes 83-110 and accompanying text.

82. See *infra* notes 83-110 and accompanying text.

83. § 355-1(f)(8).

84. See Carrier, *supra* note 34, at 11 n.57 (citing Food and Drug Administration Amendments Act of 2007, H.R. 2900, 110th Cong. § 505-1(f)(6) (2007)).

of drug to conduct bioequivalence testing.”<sup>85</sup> Although the House passed House Bill 2900 on July 11, 2007, the Senate took no action on it.<sup>86</sup> Two months later, on September 19, 2007, the House passed House Bill 3580.<sup>87</sup> House Bill 3580 was substantially similar to House Bill 2900, but it omitted the language explicitly obligating brands to sell drug samples to generics for bioequivalence testing.<sup>88</sup> The Senate passed House Bill 3580 without amendment, and it became law less than two weeks after its initial passage by the House.<sup>89</sup>

In 2012, Congress considered the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA).<sup>90</sup> The Senate version of the FDASIA, Senate Bill 3187, contained language ordering that “if a drug is a covered drug, no [ETASU] shall prohibit, or be construed or applied to prohibit, supply of such drug to any eligible drug developer for the purpose of conducting testing necessary to support an [ANDA] application.”<sup>91</sup> Although the Senate passed Senate Bill 3187 on May 24, 2012,<sup>92</sup> the language quoted above was dropped when the House made its revisions to the bill, and the Senate thereafter passed the House’s version of the FDASIA without the provision.<sup>93</sup> Notably, the Senate’s legislative history neither explains nor mentions that the Senate dropped the provision when it chose to pass the House’s version of the FDASIA.<sup>94</sup>

Two years later, a House bill introduced in September 2014 again sought to enact legislation that would clarify brands’ obligation to

---

85. H.R. 2900, 110th Cong. § 505-1(f)(6) (2007).

86. See *H.R. 2900 (110th): Food and Drug Administration Amendments Act of 2007*, GOVTRACK, <https://www.govtrack.us/congress/bills/110/hr2900> [<https://perma.cc/ZPE9-YCDS>].

87. *Id.*

88. Compare Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007), with H.R. 2900 § 505-1(f)(6).

89. See *H.R. 3580 (110th): Food and Drug Administration Amendments Act of 2007*, GOVTRACK, <https://www.govtrack.us/congress/bills/110/hr3580> [<https://perma.cc/S5R4-JAK7>].

90. See Food and Drug Administration Safety and Innovation Act, S. 3187, 112th Cong. (as passed by Senate, May 24, 2012).

91. *Id.* § 1131(a).

92. See *S. 3187 (112th): Food and Drug Administration Safety and Innovation Act*, GOVTRACK, <https://www.govtrack.us/congress/bills/112/s3187> [<https://perma.cc/8PN8-KVCX>].

93. See Megaw, *supra* note 77, at 116.

94. See Upadhye & Lang, *supra* note 77, at 99.

provide generics access to brand drugs for testing purposes.<sup>95</sup> Section 3(a) of House Bill 5657—the Fair Access for Safe and Timely Generics Act of 2014—proposed that a brand drug manufacturer may not “adopt, impose, or enforce” any condition of REMS “that restricts or has the effect of restricting the supply of such covered product to an eligible product developer for development or testing purposes.”<sup>96</sup> Additionally, House Bill 5657 empowered the FDA to grant injunctive relief and damages against a brand manufacturer should it violate the provision,<sup>97</sup> and it established “commercially reasonable, market-based prices” as the standard for sample purchases between brands and generics.<sup>98</sup> But yet again, Congress did not enact language of this kind into law, as no further action was taken on the bill after it was introduced and subsequently referred to the House Subcommittee on Health.<sup>99</sup>

In 2016, the Senate became the legislative body to most recently attempt to require brand drug manufacturers to provide generics with samples for testing.<sup>100</sup> The bill, known as the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2016, enlists the Secretary of Health and Human Services (HHS) to act as a middleman between the brand manufacturer and the generic seeking access to samples of the brand drugs.<sup>101</sup> If a generic has been denied access to a brand’s drugs because of REMS, the generic can apply to the HHS Secretary requesting access, and within ninety days the Secretary grants the generic authorization to obtain the drug samples if the generic has instituted sufficient safety precautions.<sup>102</sup>

In the hearing for the bill, Senators Leahy and Grassley explicitly called out brands’ refusal to share samples under REMS limitations,

---

95. See Fair Access for Safe and Timely Generics Act of 2014, H.R. 5657, 113th Cong. (2014).

96. *Id.* § 505-2(b).

97. See *id.* § 505-2(f)(2).

98. *Id.* § 505-2(c).

99. See *H.R. 5657 - FAST Generics Act of 2014*, CONGRESS.GOV, <https://www.congress.gov/bill/113th-congress/house-bill/5657/all-actions> [<https://perma.cc/UU7Z-BJDR>].

100. See CREATES Act of 2016, S. 3056, 114th Cong. (2016).

101. *Id.* § 3(b)(1)(B)(ii).

102. *Id.* §§ 3(b)(1)(B)(ii)(I)-(II).

with Senator Grassley labelling it a “misuse[ ]” of REMS.<sup>103</sup> According to Senator Leahy, brands’ refusal to provide samples to generics constituted a “simple delay tactic [that] uses regulatory safeguards as a weapon to block competition.”<sup>104</sup> Senator Grassley claimed this was “in violation of FDA regulations and the Hatch Waxman Act.”<sup>105</sup> Despite this vigor by members of the Senate,<sup>106</sup> however, Congress has taken no action on the bill in over a year, and it appears dead.<sup>107</sup>

Even though Congress has not enacted the CREATES Act, it is worth noting that in its findings, the Act cites the testimony of both the Director of the FDA’s Center for Drug Evaluation and Research<sup>108</sup> and the FTC Chairwoman<sup>109</sup> to demonstrate the problems that REMS has created for generic market entry. Furthermore, the text of the bill—while not discounting the potential of antitrust law to address the issue of brands blocking generic access to their drugs through REMS—finds that “a more tailored legal pathway”—such as congressional legislation—is the most efficient and effective way

---

103. *The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition: Hearing Before S. Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Judiciary Comm.*, 114th Cong. (2016) (statement of Sen. Chuck Grassley, Chairman, S. Judiciary Comm.), <https://www.judiciary.senate.gov/imo/media/doc/06-21-16%20Grassley%20Statement.pdf> [<https://perma.cc/UY4J-TJMB>].

104. *Id.* (statement of Sen. Patrick Leahy, Ranking Member, S. Judiciary Comm.), <https://www.judiciary.senate.gov/imo/media/doc/06-21-16%20Leahy%20Statement%202.pdf> [<https://perma.cc/9G5E-XQP6>].

105. *See id.* (statement of Sen. Patrick Leahy, Ranking Member, S. Judiciary Comm.).

106. The CREATES Act, introduced and sponsored by Senator Leahy, also had eleven cosponsors. *See S.3056 - CREATES Act of 2016*, CONGRESS.GOV, <https://www.congress.gov/bill/114th-congress/senate-bill/3056/cosponsors> [<https://perma.cc/7RC6-X3ZU>].

107. *See S.3056 - CREATES Act of 2016*, CONGRESS.GOV, <https://www.congress.gov/bill/114th-congress/senate-bill/3056/all-actions> [<https://perma.cc/V9PP-XJJ5>] (the last action on the bill was the previously cited hearing held on June 21, 2016 by the Senate’s Subcommittee on Antitrust, Competition Policy and Consumer Rights).

108. *See* CREATES Act of 2016, S. 3056, 114th Cong. § 2(6) (2016) (“The Director of the Center for Drug Evaluation and Research at the Food and Drug Administration has testified that some manufacturers of covered products have used REMS and distribution restrictions adopted by the manufacturer on their own behalf as reasons to not sell quantities of a covered product to generic product developers, causing barriers and delays in getting generic products on the market.”).

109. *See id.* § 2(7) (“The Chairwoman of the Federal Trade Commission has testified that the Federal Trade Commission continues to be very concerned about potential abuses by manufacturers of brand drugs of REMS or other closed distribution systems to impede generic competition.”).



to resolve this problem that REMS created and to improve generic entry and competition in the pharmaceutical marketplace.<sup>110</sup>

### *B. Absence of FDA Enforcement Against REMS Abuses*

Although more than 100 generics have filed complaints alleging that brands are using REMS to block their access to the brand's drug samples,<sup>111</sup> the FDA has consistently refrained from holding the position that the FDAAA requires the sale of samples between brand and generic drug manufacturers for generic bioequivalence testing and ANDA approval purposes.<sup>112</sup> The FDA has repeatedly written in REMS approval letters that brand manufacturers may not use REMS "to block or delay approval of an [ANDA]."<sup>113</sup> However, the FDA has been reluctant to elaborate upon what the aforementioned blocking or delaying approval looks like in practice within a brand's operation of its REMS program.<sup>114</sup>

Nevertheless, the FDA's position on this topic has slightly evolved. In response to Lannett's filing against Celgene<sup>115</sup>—one of the first complaints by a generic over restricted access to a brand's drug samples<sup>116</sup>—the FDA filed a letter taking the position that while Lannett would not be violating REMS safety measures by accessing the drugs once it received approval for its bioequivalence study, Celgene was not required to provide the requested samples.<sup>117</sup> In 2012, again in response to a generic's filing against Celgene, the FDA showed signs of possibly leaning toward supporting generics by stating that it "would not consider the provision of samples of

---

110. *Id.* § 2(9).

111. *See supra* text accompanying note 71.

112. *See, e.g.,* Paradise, *supra* note 30, at 62 ("The FDA has thus far declined to take a position on any of these [REMS] issues.").

113. Butler, *supra* note 9, at 984 (alteration in original) (quoting Letter from Judith A. Racoosin, Deputy Dir. for Safety, Ctr. for Drug Evaluation & Research, to Beth Connelly, Assoc. Dir. Regulatory Affairs, Purdue Pharma L.P. (Apr. 15, 2013), [http://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2013/019516Orig1s03ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/applletter/2013/019516Orig1s03ltr.pdf)).

114. *See supra* note 112.

115. *See supra* notes 68-70 and accompanying text.

116. *See* Paradise, *supra* note 30, at 64.

117. *See* Butler, *supra* note 9, at 986, 986 n.53 (citing Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to Kumar Sekar, Dr. Reddy's Labs., Inc. (Aug. 7, 2013), [http://www.fdalawyersblog.com/FDA\\_CDOR\\_to\\_Dr\\_Reddy's\\_Laboratories\\_Inc\\_Partial\\_Petition\\_Approval\\_and\\_Denial.pdf](http://www.fdalawyersblog.com/FDA_CDOR_to_Dr_Reddy's_Laboratories_Inc_Partial_Petition_Approval_and_Denial.pdf)).

a[] [REMS-regulated drug] to a generic manufacturer a REMS violation.”<sup>118</sup> The FDA justified this position because holding otherwise would “frustrate [the] Congressional intent”<sup>119</sup> set forth in the Hatch-Waxman Act to encourage generic market entry and competition.<sup>120</sup> Recent draft guidance released by the FDA has repeated this position.<sup>121</sup>

Currently, the FDA is continuing to evaluate whether it should issue general guidance and rulemaking on brands justifying their unwillingness to sell drug samples to generics through REMS.<sup>122</sup> Notably, before a Senate committee in 2016, the Director of the FDA’s Center for Drug Evaluation and Research admitted that brands have often used REMS to “block[] generic competition.”<sup>123</sup> While a statement like this may be encouraging for those who wish the FDA to identify brand behavior as violating § 355-1(f)(8), this statement did not lead to any new FDA rulemaking or enforcement of § 355-1(f)(8). Given that the FDA did not act after acknowledging the very “block[ing]” activity the FDAAA seeks to limit,<sup>124</sup> this signals that the FDA has no intention of evolving their position to the point where they would be actively enforcing § 355-1(f)(8) against brands that block generic access to their samples.

---

118. Paradise, *supra* note 30, at 66 (quoting Original Complaint at 12, Mylan Pharms. Inc. v. Celgene Corp., No. 14-2094 (D.N.J. Apr. 3, 2014)).

119. *See id.* at 66-67.

120. *See supra* Part I.A.

121. *See* Paradise, *supra* note 30, at 67 (citing FOOD & DRUG ADMIN., DRAFT GUIDANCE: HOW TO OBTAIN A LETTER FROM FDA STATING THAT BIOEQUIVALENCE STUDY PROTOCOLS CONTAIN SAFETY PROTECTIONS COMPARABLE TO APPLICABLE REMS FOR RLD (Dec. 2014), <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf>).

122. *See* Ed Silverman, *Share and Share Alike? Not If It's a REMS*, DRUGS.COM (Dec. 2013), [https://www.drugs.com/clinical\\_trials/share-share-alike-not-if-s-rems-16362.html](https://www.drugs.com/clinical_trials/share-share-alike-not-if-s-rems-16362.html) [<https://perma.cc/AW9F-E8WU>].

123. Carrier, *supra* note 34, at 44 (alterations in original) (quoting *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs: Hearing Before the S. Comm. on Health, Educ., Labor & Pensions*, 114th Cong. at 1:03:09-22 (2016), <https://www.c-span.org/video/?403817-1/hearing-generic-drug-approval-process-accessibility&start=3777> [<https://perma.cc/9AU8-38AU>] (statement of Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research)).

124. 21 U.S.C. § 355-1(f)(8) (2012).

*C. REMS Enforcement: The Role of the FDA or the FTC?*

Adding to the complexity of this issue within REMS—and likely an additional reason why the FDA has largely been inactive on this matter—is the uncertainty over what type of authority the FDA has to enforce § 355-1(f)(8) in the FDAAA.<sup>125</sup> While the FDAAA seeks to direct brands and generics to create a shared REMS program,<sup>126</sup> and (ostensibly) places limitations on brands’ use of REMS to “block or delay approval” of generic ANDAs,<sup>127</sup> the FDAAA lacks any remedial scheme.<sup>128</sup> The FDAAA “provides no direction” on “whether and to what extent the FDA has any authority” to achieve these aforementioned ends.<sup>129</sup> Commenting on the FDA’s authority under the FDAAA, a HHS Report noted that the FDA even lacks “the authority to take enforcement actions against sponsors that do not include all information requested in FDA [REMS] assessment plans.”<sup>130</sup> It is therefore no surprise the FDA remains hesitant to take an active enforcement role in a controversial REMS issue that touches on antitrust concerns far more than safety or health concerns.

Instead, the FDA has opted to shift resolution of generic manufacturers’ claims against brand manufacturers to the FTC. In August 2013, the FDA answered a citizen petition asking the FDA to, among other things, expand on § 355-1(f)(8) by explicitly issuing regulatory guidance that brands shall not use REMS to block or delay generic competition.<sup>131</sup> The FDA replied that § 355-1(f)(8) is not a “safety-related element[,]” and that “issues related to ensuring that marketplace actions ... do not block competition would be best addressed by the FTC.”<sup>132</sup> Two months later (October 2013), in response to a citizen petition over a different FDAAA REMS

---

125. See Paradise, *supra* note 30, at 61-62 (“It is unclear ... whether and what type of authority the FDA or the courts have to enforce the limitation in the statute.”).

126. See *supra* notes 46-50 and accompanying text.

127. § 355-1(f)(8).

128. See Carrier, *supra* note 34, at 36-37 (citing S. SPECIAL COMM. ON AGING, 114TH CONG., SUDDEN PRICE SPIKES IN OFF-PATENT PRESCRIPTION DRUGS: THE MONOPOLY BUSINESS MODEL THAT HARMS PATIENTS, TAXPAYERS, AND THE U.S. HEALTH CARE SYSTEM 117 n.733 (2016)).

129. Paradise, *supra* note 30, at 68-69; see also *supra* text accompanying notes 120-21.

130. DEP’T OF HEALTH & HUMAN SERVS., *supra* note 53, at 22.

131. Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to Kumar Sekar, Dr. Reddy’s Labs., Inc., *supra* note 117, at 1.

132. *Id.* at 7.

requirement,<sup>133</sup> the FDA wrote “[t]o the extent that ... there may be antitrust issues ... we suggest [the drug manufacturer] consult with the FTC.”<sup>134</sup>

The FDA’s continual inaction has indicated its desire to either wait for Congress to enact additional legislation relating to REMS, or to let the FTC handle any enforcement resulting from brands using REMS to block generic bioequivalence testing, ANDA approval, and eventual generic market entry.<sup>135</sup> Essentially, the FDA would doubt its authority to act even if it became certain that brand manufacturers were intentionally using REMS to block generics from receiving ANDA approval. The FDA has been too timid. The Hatch-Waxman Act granted the FDA general rulemaking authority to institute regulations furthering the goal of the Act: to ease generic drug entry into the pharmaceutical market.<sup>136</sup>

Additionally, the FDAAA’s focus on REMS and safety does not bind the FDA’s hands; as the FDA stated in its draft guidance to the industry, “the provision of samples of a[] [drug controlled by a REMS program] to a generic manufacturer” that meets corresponding safety requirements does not constitute a REMS violation.<sup>137</sup> REMS programs were created and required by the FDAAA to ensure that the drug’s benefits outweigh its safety risks.<sup>138</sup> So long as the generic meets the same safety standards as the brand does—which generics are required to do<sup>139</sup>—the FDA should have no worries about acting in accordance with the Hatch-Waxman Act and the FDAAA’s legislative purposes by prescribing regulations that require brands to sell their drug samples to generics for

---

133. The provision stated that, unless granted a waiver, brands and generics must establish a shared REMS program. *See* 21 U.S.C. § 355-1(a)(8)(i)(1)(B) (2012).

134. Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Research, to William Franzblau, Vice President, Prometheus Labs., Inc. 6 (Oct. 7, 2013), <https://www.regulations.gov/document?D=FDA-2013-P-0572-0003&attachmentNumber=1&contentType=pdf> [<https://perma.cc/ARB2-VWQS>].

135. *See supra* Part III.B.

136. *See* 130 CONG. REC. 24,427 (1984) (statement of Rep. Waxman) (expressing that the goal of the Act was to provide “low-cost, generic drugs for millions of Americans”).

137. Paradise, *supra* note 30, at 66 (citing Original Complaint at 12, Mylan Pharms. Inc. v. Celgene Corp., No. 14-2094 (D.N.J. Apr. 3, 2014)).

138. *See* Paradise, *supra* note 30, at 57.

139. *See id.* at 59 (“[T]he generic drug entering the market based on measures of bioequivalence to [the brand drug] must also adhere to the [brand’s] REMS.”).

bioequivalence testing and ANDA approval.<sup>140</sup> “Based on the strong legislative history, portraying a universal concern about anti-competitive behavior and the goal of a vibrant generic drug market, such regulation seems to be easily legally defensible.”<sup>141</sup>

Importantly, the FDA (or the FTC) does not decide the limits of FDA jurisdiction over REMS issues, even of those REMS issues which primarily center on anticompetitive concerns: Congress does.<sup>142</sup> Congressional intent regarding FDA regulatory and enforcement power over REMS abuses that frustrate generic ANDA applications is muddled by repeated Congressional failures to enact more specific language mandating generic access to brand drug samples,<sup>143</sup> and by the general lack of a remedial scheme governing REMS and FDAAA violations.<sup>144</sup> However, channeling the Supreme Court’s reasoning in *Credit Suisse Securities (USA) LLC v. Billing*, “the FDA has authority to enforce its own rules.”<sup>145</sup> The rule prescribed in § 355-1(f)(8) prohibits using REMS “to block or delay approval of an [ANDA] application,”<sup>146</sup> and this rule must necessarily be enforced by some governing institution. The FDA is better equipped than the FTC to enforce § 355-1(f)(8), to terminate brand manufacturer use of REMS in a way that blocks or delays generic testing and ANDA approval, and to increase safe, low-cost generic drug competition—the primary goals of the Hatch-Waxman Act and the FDAAA. Yet the FDA’s decision to remain inactive in enforcing § 355-1(f)(8) has pushed generics to seek remedies for alleged REMS abuses through the courts.<sup>147</sup>

Both Congress and the FDA have remained inactive in fixing REMS, which has resulted in limitations on generic market entry

---

140. *See id.* at 78.

141. *Id.*

142. *See* Butler, *supra* note 9, at 1002 (citing *Independent Agencies and Government Corporations*, USA.GOV., <http://www.usa.gov/Agencies/Federal/Independent.html>). This is because Congress “creates independent agencies and thus [sets] the extent of their jurisdictions.” *Id.* at 1002 n.199.

143. *See supra* Part III.A.

144. *See* Carrier, *supra* note 34, at 36-37 (citing S. SPECIAL COMM. ON AGING, *supra* note 128, at 117 n.733 (2016)).

145. Butler, *supra* note 9, at 1002; *see* 551 U.S. 264, 285 (2007).

146. 21 U.S.C. § 355-1(f)(8) (2012).

147. *See* Carrier, *supra* note 34, at 3, 3 n.2.

and economic harm to American consumers.<sup>148</sup> But, although the political and regulatory processes have left generics unsatisfied, generics have also sought reprieve through the court system.<sup>149</sup> Due to Congress's and the FDA's failures to remedy REMS' anticompetitive effects—or to at least create a regulatory pathway for effective adjudication of generics' concerns over brands' use of REMS—many generic manufacturers have turned to litigation and antitrust law as a means of acquiring the brand samples necessary to comply with ANDA requirements to enter the market.<sup>150</sup>

#### IV. AN ANTITRUST ANALYSIS OF REMS: THE REFUSAL-TO-DEAL DOCTRINE

As of June 2016, over 100 generics had complained that they had not been able to conduct bioequivalence testing due to lack of access to brand drug samples.<sup>151</sup> However, potential antitrust liability for brand refusal to provide samples for generic testing has only been analyzed by courts in seven of these cases,<sup>152</sup> and none of the cases moved past the motion-to-dismiss phase before settling under undisclosed agreements.<sup>153</sup> This Part analyzes the potential success of antitrust claims for anticompetitive REMS activity under both Section 1 and Section 2 of the Sherman Antitrust Act,<sup>154</sup> and concludes that current antitrust law is not an avenue to success for

---

148. See *supra* Parts III.A-B.

149. See *infra* notes 151-53 and accompanying text.

150. See *infra* notes 151-53 and accompanying text.

151. See Carrier, *supra* note 34, at 3, 3 n.2.

152. For a case-by-case analysis on the results of the seven cases, see *id.* at 12-20. For the seven cases themselves, see *In re Suboxone Antitrust Litig.*, No. 16-cv-563, 2017 WL 36371 (E.D. Pa. Jan. 4, 2017) [hereinafter *In re Suboxone II*]; Transcript of Oral Opinion at 18-19, *Mylan Pharm. v. Celgene Corp.*, No. 2:14-cv-02094-ES-MAH (D.N.J. Dec. 22, 2014); *In re Suboxone Antitrust Litig.*, 64 F. Supp. 3d 665 (E.D. Pa. 2014) [hereinafter *In re Suboxone I*]; *Natco Pharma Ltd. v. Gilead Scis., Inc.*, No. 14-3247(DWF/JSM), 2015 WL 5718398 (D. Minn. Sept. 29, 2015); *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997(KSH)(CLW), 2015 WL 9589217 (D.N.J. Oct. 29, 2015); *Actelion Pharm. Ltd. v. Apotex Inc.*, No. 12-5743(NLH/AMD), 2013 WL 5524078 (D.N.J. Sept. 6, 2013); Order Upon Consideration of Defendant Celgene Corp.'s Renewed Motion to Dismiss at 1, *Lannett Co. v. Celgene Corp.*, No. 2:08-cv-03920-TJS (E.D. Pa. Mar. 30, 2011) [*Lannett v. Celgene*].

153. See Carrier, *supra* note 34, at 12.

154. 15 U.S.C. §§ 1-2 (2012).

generics in their search for acquiring brand samples for bioequivalence testing.

### A. Section 1 Is Not a Source of Brand Antitrust Liability

There are two primary bases for non-merger antitrust claims in the United States: Sections 1 and 2 of the Sherman Antitrust Act.<sup>155</sup> Section 1 makes illegal any agreement in restraint of trade<sup>156</sup> when the agreement's anticompetitive effects<sup>157</sup> are significant and outweigh any procompetitive justifications.<sup>158</sup> However, Section 1 is an unlikely and ineffective source of liability for REMS actions. A generic's claim under Section 1 would likely argue that the brand manufacturer entered into an agreement with its distributors to withhold samples from the generic in restraint of trade.<sup>159</sup> But because REMS (and ETASU in particular) itself requires these restrictions upon distribution of the drugs,<sup>160</sup> courts could not reasonably conclude that the brands have created an agreement with the distributor for the anticompetitive goal of restraining trade, for the REMS "restrictions on wholesale distribution ... are therefore not imposed by the brand company at all."<sup>161</sup>

### B. Brands Hold Monopoly Power Under Section 2

Section 2 claims, on the other hand, warrant much closer attention and analysis. Indeed, most antitrust cases involving denying samples to generics arise under Section 2.<sup>162</sup> Section 2 prohibits monopolization in restraint of trade,<sup>163</sup> which requires the brand to both have monopoly power and to engage in exclusionary conduct to obtain or maintain the monopoly.<sup>164</sup> The Supreme Court has defined

---

155. *Id.*

156. *Id.* § 1.

157. At their core, anticompetitive effects are the three "evils" of increased prices, reduced output, and/or reduced quality. *See* *Standard Oil Co. v. United States*, 221 U.S. 1, 52 (1911).

158. *See* *Carrier*, *supra* note 34, at 21; *Megaw*, *supra* note 77, at 124.

159. *See* *Megaw*, *supra* note 77, at 123.

160. *See supra* notes 43-45 and accompanying text.

161. *Megaw*, *supra* note 77, at 123. *But see* *Carrier*, *supra* note 34, at 20-21.

162. *See* *Carrier*, *supra* note 34, at 20.

163. *See* 15 U.S.C. § 2 (2012).

164. *See* *United States v. Grinnell Corp.*, 384 U.S. 563, 570-71 (1966).

monopoly power as “the power to control prices or exclude competition,”<sup>165</sup> and courts have looked to an entity’s market share and the barriers to entry into that market to determine whether a defendant holds sufficient monopoly power to constitute antitrust liability.<sup>166</sup> In clarifying the scope of “market,” the Court held that “as a matter of law, a single brand of a product ... [can] be a relevant market under the Sherman Act,”<sup>167</sup> a holding that lower courts have applied to include a single branded drug.<sup>168</sup> Because the patent system itself purposefully institutes artificial and complete barriers to entry,<sup>169</sup> and as such a patented drug should in theory hold 100 percent market share, it therefore seems fairly clear that the brand manufacturers holding patented REMS drugs would have monopoly power under current antitrust law.<sup>170</sup>

It is worth noting, however, that this may not always be the case. There may be another drug that is sufficiently similar in terms of demand-side substitutability such that courts will find that the two (or more) drugs constitute the same product market.<sup>171</sup> The existence of substitutability only occurs rarely, though, when the drugs still have active patent protection.<sup>172</sup> But in these rare cases when

---

165. *United States v. E. I. du Pont de Nemours & Co.*, 351 U.S. 377, 391 (1956).

166. *See Carrier*, *supra* note 34, at 21.

167. *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481 (1992).

168. *See Carrier*, *supra* note 34, at 22, 22 n.152; *see also* *Geneva Pharms. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 496 (2d Cir. 2004) (defining the product market as only the generic version of a drug, excluding even the brand version); *New York v. Actavis, PLC*, No. 14 Civ. 7473, 2014 WL 7015198, at \*35 (S.D.N.Y. Dec. 11, 2014) (“[C]ourts have found a single brand-name drug and its generic equivalents to be a relevant product market in cases where the challenged conduct involves a branded drug manufacturer’s effort to exclude generic competition.”).

169. *See, e.g.*, Thomas Meyers, Address at the Boston University Journal of Science and Technology Law Symposium: Biotech Materials and Medical Devices in the New Millennium (2000) (transcript available at 6 B.U. J. SCI. & TECH. L. 3, ¶ 19 (2000)).

170. This is not true as a matter of law, *see* *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 37 n.7 (1984) (O’Connor, J., concurring) (“[A] patent holder has no market power in any relevant sense if there are close substitutes for the patented product.”); *In re Indep. Serv. Orgs. Antitrust Litig.*, 203 F.3d 1322, 1325 (Fed. Cir. 2000) (“A patent alone does not demonstrate market power.”), but rather a matter of practice. *See infra* notes 172-73 and accompanying text.

171. *See Brown Shoe Co. v. United States*, 370 U.S. 294, 325 (1962) (ruling that a product market is defined by measuring the “cross-elasticity of demand” between the product and potential substitutes for it).

172. *See, e.g.*, M. Howard Morse, *Product Market Definition in the Pharmaceutical Industry*, 71 ANTITRUST L.J. 633, 650 (2003) (summarizing that in all recent FTC challenges to patented



sufficient substitutes do exist, the REMS drug will not have a 100 percent market share. Nevertheless, in such cases where substitutes exist, it is plausible—if not likely—that the brand still will be considered a monopolist under Section 2. This is because even when substitutes do exist for patented drugs, the product market remains highly concentrated, and so it remains likely that the brand will retain a high enough market share to possess market power.<sup>173</sup>

This inquiry into product market definition and market power is an essential hurdle for any generic to pass over in its antitrust claim.<sup>174</sup> This is particularly true because the burden of proving market power falls on the plaintiff,<sup>175</sup> who in REMS antitrust cases will invariably be the generic. However, because product market definition is a largely factual inquiry,<sup>176</sup> and in order to analyze the more pressing issue of how courts should view brands' use of REMS as exclusionary conduct, the remainder of this Note will assume that a generic has established a *prima facie* showing of the brand's market power under Section 2.

### *C. Jurisprudence of the Refusal-to-Deal Doctrine: Otter Tail, Aspen Skiing, and Trinko*

Monopoly power alone is not illegal under antitrust law. As Justice Scalia noted in *Verizon Communications Inc. v. Law Offices of Curtis V. Trinko, LLP*, “[t]he mere possession of monopoly power ... is not only not unlawful; it is an important element of the free-

---

drugs, “the product market definition alleged [was] ... limited to the pioneer drug and its generic equivalents”).

173. See PATRICIA M. DANZON, COMPETITION AND ANTITRUST ISSUES IN THE PHARMACEUTICAL INDUSTRY 26 (2014), <https://faculty.wharton.upenn.edu/wp-content/uploads/2017/06/Competition-and-Antitrust-Issues-in-the-Pharmaceutical-IndustryFinal7.2.14.pdf> [<https://perma.cc/RV4A-LEZD>] (“Although the US pharmaceutical market as a whole is unconcentrated, the product market definition used for on-patent drugs is usually the therapeutic class or indication, and at this level concentration can be a significant concern.”). The steep decline in price that occurs following every additional generic entrant into the market is also strong evidence of the high market concentration of patented brand drugs. See *Generic Competition and Drug Prices*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm> [<https://perma.cc/XC78-88LX>] (last updated Nov. 28, 2017).

174. See, e.g., Morse, *supra* note 172, at 652.

175. See *id.* at 656.

176. See *id.* at 634 (“[M]arket definition issues are intensely factual.”).

market system.... [M]onopoly power will not be found unlawful unless it is accompanied by an element of anticompetitive *conduct*.<sup>177</sup> This second prong of Section 2 antitrust claims—that the entity must wield its monopoly power in restraint of trade by engaging in exclusionary conduct—is governed in the REMS context by the refusal-to-deal doctrine.<sup>178</sup> The refusal-to-deal doctrine represents the principle that there is generally no obligation upon an entity to contract or deal with another party, including a competitor.<sup>179</sup> The Supreme Court has stated that refusal-to-deal cases imposing liability exist only at the “outer boundary” of Section 2 liability.<sup>180</sup> However, the Supreme Court has also established that there are certain recognized exceptions to the refusal-to-deal doctrine that withdraw a monopolist’s protection from Section 2 liability and *would* obligate a monopolist to deal with another party.<sup>181</sup> The three seminal Supreme Court cases explaining when monopolistic companies are required to deal with their competitors due to antitrust concerns are *Otter Tail Power Co. v. United States*,<sup>182</sup> *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*,<sup>183</sup> and *Trinko*.<sup>184</sup>

*Otter Tail* involved an electric utility company that had monopolized the retail distribution of electricity in its service area, and had then used its monopoly power to prevent a competitor electricity distribution system from entering the retail market.<sup>185</sup> Specifically, *Otter Tail* refused to either sell its own energy to the competitor at wholesale or to “wheel power” to the competitor from other suppliers of wholesale energy.<sup>186</sup> *Otter Tail* thereby prevented its competitor from acquiring access to any electrical power, and so the competitor was unable to provide power to its potential service communities.<sup>187</sup> The Court held this exclusionary conduct violated Section 2 of the

---

177. 540 U.S. 398, 407 (2004).

178. *See, e.g., Carrier, supra* note 34, at 20, 22-23.

179. *See Megaw, supra* note 77, at 126.

180. *Trinko*, 540 U.S. at 409.

181. *See id.* at 408-09 (“The leading case for § 2 liability based on refusal to cooperate with a rival ... is *Aspen Skiing*”).

182. 410 U.S. 366 (1973).

183. 472 U.S. 585 (1985).

184. 540 U.S. 398 (2004).

185. *See Otter Tail*, 410 U.S. at 368.

186. *Id.* at 371.

187. *See id.*

Sherman Act.<sup>188</sup> The Court required Otter Tail to deal with its competitor despite Otter Tail's claims of self-interest, stating that "[t]he promotion of self-interest alone does not invoke the rule of reason to immunize otherwise illegal conduct" when the self-interest at stake is merely an interest in acquiring greater or continued monopolistic control over the market.<sup>189</sup> Notably, the Court found that Otter Tail violated Section 2 even when Otter Tail had not engaged in any prior dealings with the competitor, and the competitor was only a mere "potential entrant[]" into the market.<sup>190</sup>

In *Aspen Skiing*, the Court significantly expanded upon the rationale behind the refusal-to-deal doctrine.<sup>191</sup> *Aspen Skiing* revolved around Aspen Skiing Company (Ski Co.) and Aspen Highlands Skiing Corporation (Highlands), two competing ski resorts in Aspen, Colorado, where Ski Co. held monopoly power over the skiing market.<sup>192</sup> Prior to the initiation of the lawsuit by Highlands, Ski Co. and Highlands had contracted with one another to provide a joint ski pass ticket that allowed customers to ski in Aspen resorts owned by either company.<sup>193</sup> However, after a dispute over revenue sharing, Ski Co. discontinued the joint ticket.<sup>194</sup> Furthermore, Ski Co. refused to sell Highlands any Ski Co. ticket passes that Highlands could sell to its customers who wished to purchase multiple-resort passes, and refused to accept customers' vouchers (paid for by Highlands) that were equal to the price of a Ski Co. ticket.<sup>195</sup> Despite restating the "high value that we have placed on the right to refuse to deal with other firms,"<sup>196</sup> the Court held that Ski Co.'s refusal to deal was not motivated by "efficiency" concerns or "valid business reasons," but constituted "predatory" action that violated Section 2.<sup>197</sup> Analyzing the evidence, the Court specifically pointed out that not only would selling Highland tickets and accepting Highland customers' vouchers have come at no cost to Ski Co., but also that

---

188. *Id.* at 380-81.

189. *Id.* at 380 (quoting *United States v. Arnold, Schwinn & Co.*, 388 U.S. 365, 375 (1967)).

190. *Id.* at 377.

191. *See Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610-11 (1985).

192. *Id.* at 587-88.

193. *See id.* at 589.

194. *See id.* at 592.

195. *See id.* at 592-94.

196. *Id.* at 601.

197. *Id.* at 605.

Ski Co. was actually avoiding “immediate benefits” by refusing to deal with Highlands.<sup>198</sup> Furthermore, Ski Co. refused to accept ticket vouchers from its competitor despite simultaneously voluntarily (and thus presumably profitably)<sup>199</sup> accepting the same tickets from other members of the public.<sup>200</sup> While legitimate business reasons can exist in a refusal to deal that turns down immediate benefits, the Court made clear that a monopolist “forgo[ing] ... short-run benefits because it was ... motivated entirely by a decision to avoid providing any benefit to [a competitor]” violates Section 2.<sup>201</sup>

*Trinko* involved a complaint that Verizon, a local exchange carrier regulated by the Telecommunications Act of 1996,<sup>202</sup> had “denied interconnection services to rivals in order to limit entry.”<sup>203</sup> According to the complaint, Verizon had discriminated against competing local carriers when it did not grant them access to its local loop, and thereby prevented them from potentially serving customers.<sup>204</sup> But before getting to the merits of the antitrust claim, the Court first determined that Verizon was not given implied immunity from antitrust scrutiny by the “detailed regulatory scheme” created by the 1996 Act,<sup>205</sup> as the Act included a provision specifically precluding an interpretation of implied immunity.<sup>206</sup> Returning to the merits, the Court referred to the anticompetitive activity in *Aspen Skiing* as being “at or near the outer boundary of § 2 liability,”<sup>207</sup> since Ski Co.’s decisions to unilaterally terminate profitable prior dealing with a competitor and to (against its own non-monopolistic self-interest) refuse to sell its competitor’s goods that it otherwise held available to the public were clear Section 2 violations.<sup>208</sup> Unlike Ski Co., Verizon had no prior course of dealing with its competitors and

---

198. *Id.* at 610.

199. *See, e.g.*, *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004). For additional insight into the presumption of profitability, see *infra* notes 222-23.

200. *See Aspen Skiing*, 472 U.S. at 609-10.

201. *Id.* at 608, 610.

202. *Trinko*, 540 U.S. at 401; *see* Telecommunications Act of 1996, Pub. L. No. 104-104, 110 Stat. 56 (1996) (codified as amended in scattered sections of 47 U.S.C. § 152 (2012)).

203. *Trinko*, 540 U.S. at 407.

204. *See id.* at 404-05.

205. *Id.* at 406.

206. *Id.* (citing Telecommunications Act of 1996).

207. *Id.* at 409.

208. *See supra* text accompanying notes 191-98.

did not offer the sought-after services to the public.<sup>209</sup> Therefore, the Court held that Verizon's refusal to deal did not fall within the "limited exception" to the right to refuse to deal established in *Aspen Skiing*.<sup>210</sup>

Furthermore, the Court in *Trinko* chose not to impose liability upon Verizon's behavior by adding an exception to the general freedom to refuse to deal<sup>211</sup> because the FCC regulatory system overseeing the industry was an "effective steward of the antitrust function"<sup>212</sup> that was built into the regulatory structure for antitrust concerns.<sup>213</sup> The final factor the Court considered was the practical ability of a court to supervise any duty to deal it may impose: "No court should impose a duty to deal that it cannot explain or adequately and reasonably supervise. The problem should be deemed irremedia[ble] by antitrust law when compulsory access requires the court to assume the day-to-day controls characteristic of a regulatory agency."<sup>214</sup>

#### *D. The "No Economic Sense" Test Protects Brands from Violating Section 2*

*Otter Tail*, *Aspen Skiing*, and *Trinko* establish that the critical determination in refusal-to-deal cases is whether the alleged exclusionary conduct had a legitimate business purpose other than furthering monopoly power.<sup>215</sup> This determination has become known

---

209. See *Trinko*, 540 U.S. at 409-10.

210. See *id.* at 409. Further, courts should be "very cautious" in recognizing exceptions to the general principle that firms have no obligation to deal due to the "uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm." *Id.* at 408.

211. See *id.* at 411.

212. *Id.* at 413.

213. When a

regulatory structure designed to deter and remedy anticompetitive harm ... exists, the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny. Where, by contrast, "[t]here is nothing built into the regulatory scheme which performs the antitrust function," the benefits of antitrust are worth its sometimes considerable disadvantages.

*Id.* at 412 (quoting *Silver v. N.Y. Stock Exch.*, 373 U.S. 341, 358 (1963)).

214. *Id.* at 415 (quoting Phillip Areeda, *Essential Facilities: An Epithet in Need of Limiting Principles*, 58 ANTITRUST L.J. 841, 853 (1989)).

215. See *supra* Part IV.C.

as the “no economic sense” test,<sup>216</sup> and is the standard favored by scholars, agencies, and courts.<sup>217</sup> But what seems to make “economic sense” can be imprecise and debatable, and therefore lead to differing interpretations on the outcome of antitrust liability for particular types of alleged exclusionary conduct.<sup>218</sup> Merging the holdings and rationales behind the Court’s evolution of the refusal-to-deal doctrine in *Otter Tail*, *Aspen Skiing*, and *Trinko*, however, reveals an analytical framework that should guide courts’ determinations of whether brands’ refusal to share samples with generics in the REMS context makes economic sense.

*Otter Tail*, *Aspen Skiing*, and *Trinko* identify three primary factors that inform courts whether the refusal to deal in the REMS context has a valid business justification or is unlawful anticompetitive conduct.<sup>219</sup> The first factor (and the one easiest to determine) is whether the monopolist and its competitor have engaged in a prior course of dealing.<sup>220</sup>

### *1. Brand Manufacturers and Generic Competitors Have No Prior Course of Dealing*

In *Aspen Skiing*, the Court found liability in strong part because Ski Co. had terminated its dealings with Highlands before engaging in the disputed conduct.<sup>221</sup> Due to its voluntary nature, a prior

---

216. See, e.g., *Carrier*, *supra* note 34, at 27.

217. See *id.*

218. Differing scholarly opinions on the outcome of the no economic sense test are apparent in this very issue surrounding brand manufacturers’ refusal to sell samples to generic manufacturers under REMS. Compare *Butler*, *supra* note 9, at 980 (arguing that brands have many legitimate business justifications for refusing to provide samples to generics), with *Carrier*, *supra* note 34, at 38-41 (arguing that brands’ denial of samples makes no economic sense).

219. Brands’ refusal to provide generics with samples clearly constitutes the kind of exclusionary conduct that would violate Section 2 absent a valid business reason; as a result of brands’ decision to refuse to deal with generics, generics are unable to meet ANDA requirements and enter the market. See *supra* Part II. It is not possible for generics to obtain the necessary sample of drugs through another source due to REMS regulations restricting access to the drugs apart from authorization from the brand in accordance with methods defined by the REMS program for that drug. See *supra* Part II.A.

220. See *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 608, 610-11 (1985).

221. See *id.* at 593.

course of dealing is presumably profitable.<sup>222</sup> Thus, unilateral termination of the course of dealing and subsequent exclusionary conduct by the monopolist is presumably *unprofitable*, excluding profit derived from long-term anticompetitive gains. Therefore, a course of dealing existing prior to the alleged exclusionary conduct by itself “is *sufficient*, but not *necessary*, to show conduct that lacks economic sense” and fails the test.<sup>223</sup>

Applying this first factor to REMS cases, when brand manufacturers refuse to deal with generic manufacturers and provide samples for generic ANDA testing, there should, in theory, never be a preexisting relationship between the brand and the generic regarding provision of samples of the brand drug. This is because the generic needs the brand drug samples to enter the market;<sup>224</sup> if the generic has not been in the market previously, there should be no prior commercial relationship. And if the generic had previously dealt with the brand for samples of the drug, it would no longer need a sample. Although no prior course of dealing exists in REMS refusal-to-deal cases, the absence of this factor does not preclude antitrust liability by implying that the *absence* of dealing is

---

222. See, e.g., *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 409 (2004); see also ROBERT H. BORK, *THE ANTITRUST PARADOX* 156 (1978) (“In any business, patterns of distribution develop over time; these may reasonably be thought to be more efficient than alternative patterns of distribution that do not develop. The patterns that do develop and persist we may call the optimal patterns. By disturbing optimal distribution patterns one rival can impose costs upon another, that is, force the other to accept higher costs.”).

223. Carrier, *supra* note 34, at 51. In the vast majority of cases, this conclusion that a prior course of dealing is profitable will likely prove correct. However, this Note’s author believes that a prior course of dealing should not be an irrefutable indicator of economic sense. A long-term contract creates a prior course of dealing that, while voluntary at its outset, may no longer be profitable given changes in the market. Similarly, fluctuations in demand or in the costs of inputs can cause a prior profitable course of dealing to suddenly become unprofitable. Mere nonrenewal, or even an efficient breach, of a contract by a monopolist should not automatically create a sufficient finding that a refusal to deal lacks economic sense. Therefore, this Note contends that if a plaintiff alleging a refusal-to-deal violation shows a prior course of dealing, the court should allow the defendant the opportunity to rebut the presumption of profitability and lacking economic sense. This would be done by introducing evidence that shows why the prior dealings were either involuntary and/or had recently become unprofitable. While the third factor of the no-economic-sense test generally produces this same type of evidence and the first two factors serve primarily as proxies for the third factor anyway, see *infra* text accompanying notes 228-29, it is important to clarify that a legitimate business justification should rebut any cessation of a prior course of dealing.

224. See *supra* Part II.

profitable; as mentioned previously, prior dealing is a “*sufficient*, but not *necessary*” factor.<sup>225</sup>

## *2. Brand Manufacturers Under REMS Regulation Do Not Make Their Drugs Available to the Public*

The second factor is whether the goods or services denied by the monopolist to the plaintiff were otherwise made available to the public.<sup>226</sup> In both *Otter Tail* and *Aspen Skiing*, the monopolist “was already in the business of providing a service to certain customers ... [but] refused to provide the same service to certain other customers.”<sup>227</sup> This factor operates as a proxy for economic sense comparable to that of the prior course of dealing<sup>228</sup>: that the monopolist is willing to sell its goods or services to the public, but not to its competitor, creates a logical presumption that the monopolist is leaving profitable dealings on the table by its refusal to deal.<sup>229</sup> The refusal to deal must apparently be “motivated entirely by a decision to avoid providing any benefit to [its smaller competitor],”<sup>230</sup> precluding legitimate business motivations in the refusal to deal, and therefore constituting a Section 2 antitrust violation.

At first glance, this factor seems to weigh heavily towards a result of Section 2 liability falling upon brand drug manufacturers. Under

225. Carrier, *supra* note 34, at 51. This proposition is supported by *Otter Tail*, in which the Court found Otter Tail’s exclusionary conduct violated Section 2 despite there being no prior course of dealing, *Otter Tail Power Co. v. United States*, 410 U.S. 366, 377 (1973), and by *Trinko*, in which the Court continued its analysis even after finding there was no prior course of dealing. See 540 U.S. at 409-10.

226. In *Trinko*, the Court distinguished the case before it from *Otter Tail* and *Aspen Skiing* by noting that the defendants in those cases were refusing to deal with competitors as to goods and services that they were otherwise holding out to public consumers. See *Trinko*, 540 U.S. at 410 (“In the present case, by contrast, the services allegedly withheld are not otherwise marketed or available to the public.”). The Court emphasized this point by later adding that the services requested from Verizon by its competitors were not only denied to the public, but offering them to rivals would come at “considerable expense and effort. New systems [would have to] be designed and implemented simply to make that access possible.” *Id.*

227. See *id.* (comparing the actions of Verizon to those of Otter Tail and Ski Co.).

228. See *supra* notes 223-25 and accompanying text.

229. See *Trinko*, 540 U.S. at 409 (“The unilateral termination of a voluntary (*and thus presumably profitable*) course of dealing suggested a willingness to forsake short-term profits to achieve an anticompetitive end.”).

230. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610 (1985).



REMS and ETASU programming, many brands have contracted with distributors to make their drug safely available to the public, but have refused to sell their drug to their generic rivals.<sup>231</sup> And when a corporation turns down a proposal to sell at its own retail price,” the presumption is that this decision could only be justified by “a calculation that its future monopoly retail price would be higher.”<sup>232</sup> This straightforward analysis implies the kind of singular anticompetitive motivation that the Court has repeatedly held violates Section 2.<sup>233</sup> However, the REMS regulatory program introduces several elements that warp any application of this second factor to brands’ refusal to deal with generics.

Like Verizon’s services in *Trinko*, the products denied to generic competitors are not available to the public, but are shared with select entities under obligations and restrictions governed by a regulatory scheme.<sup>234</sup> Branded drugs under REMS are not marketed or available to the public at all; they are only made available to select distributors following extensive communication and planning regarding compliance with REMS safety requirements.<sup>235</sup> Unlike Ski Co.’s marketing scheme in *Aspen Skiing*, in which it “made a deliberate effort to discourage its customers from doing business with its smaller rival,”<sup>236</sup> brands do not make a deliberate effort to *exclude* generics—they just make no deliberate efforts to *include* generics. Additionally, drugs subject to ETASU require brands to conduct intensive investigation on the purchaser before they can sell the drug, in order to ensure safe handling of the drug.<sup>237</sup> While the eventual goal is to market the drugs to the consuming public, brands under REMS are required to discriminatorily restrict their provision of drugs.<sup>238</sup> A brand’s decision to not provide generic competitors with the brand drugs is arguably merely one of many calculated decisions to refrain from providing others with their drugs due to safety and liability concerns.

---

231. See *supra* text accompanying note 71.

232. See *Trinko*, 540 U.S. at 409.

233. See *supra* notes 219-22 and accompanying text.

234. See *Trinko*, 540 U.S. at 410; *supra* note 226.

235. See *supra* note 44 and accompanying text.

236. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610 (1985).

237. See *supra* note 45 and accompanying text.

238. See *supra* text accompanying notes 44-45.

Additionally, implementing a REMS program is not cheap,<sup>239</sup> and there are many procedures to account for before the drug can be distributed.<sup>240</sup> As a result, requiring brands to work with generics to supply generics with samples of REMS-regulated drugs would be costly, and would require the companies to design and implement new systems in a manner very similar to what the Court in *Trinko* stated they did not want to occur.<sup>241</sup> For these reasons, it becomes much more difficult to discern whether a brand that refuses to deal with a generic competitor is actually “sacrific[ing] short-run benefits and consumer goodwill in exchange for a perceived long-run impact on its smaller rival.”<sup>242</sup>

Therefore, not only is the REMS-regulated drug more comparable to the regulated services in *Trinko* not available to the public,<sup>243</sup> but brands’ frequent and required discrimination as to recipients of their drug also significantly weakens the presumption that the refusal to deal is only due to a motivation to harm the potential rival. Unless a generic can proffer specific evidence that the brand’s refusal to deal is distinguishable from other discriminatory judgments the brand makes in restricting access to its drugs due to anticompetitive motivations,<sup>244</sup> this factor weighs against Section 2 liability for refusals to deal tied to REMS.

---

239. See, e.g., Amee Sarpatwari et al., *Using a Drug-Safety Tool to Prevent Competition*, 370 NEW ENG. J. MED. 1476, 1476 (2014) (REMS are “sometimes criticized for being onerous and costly to manufacturers”).

240. See *supra* text accompanying notes 44-45.

241. See *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 410 (2004); *supra* note 226.

242. *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 610-11 (1985).

243. See *supra* note 227 and accompanying text.

244. One way for generics to accomplish this without uncovering explicit indicia of anticompetitive intent could be to introduce evidence that the brand has provided samples to comparable but noncompeting research organizations. See *Carrier*, *supra* note 34, at 52. However, inferring an anticompetitive motivation unto a brand for providing samples to research organizations would likely result in the negative externality of diminishing research organizations’ access to samples. It is therefore debatable whether courts should use this evidentiary path to adjudge anticompetitive intent, even if such intent exists and would be revealed through this approach.

### 3. *Fear of Tort Liability Serves as a Valid Business Reason for Brands' Refusals to Deal with Generics*

The third factor the Court identified in its string of refusal-to-deal precedent is whether the monopolist refused to deal for a valid business reason, or refused with singularly anticompetitive intent.<sup>245</sup> This third factor is the most important, but also the most complicated factor to decipher. Ideally, the first or second factors would serve as proxies to reveal the monopolist's motivations and aid a court in this determination. However, in the case of brand refusal-to-deal under REMS, the first two factors have been largely inapplicable.<sup>246</sup> Applying this third factor to the REMS context, this Note concludes that brands do currently have a valid business justification for their refusal to deal with their generic competitors: legitimate concerns over potential tort liability—even if that liability is unlikely to be realized.

Within the REMS context specifically, brand drug samples turned over to generics for testing can give rise to liability for the brand manufacturer.<sup>247</sup> Generics rely on the brand and its REMS program to properly communicate the drug's scientific and safety information, and are required by the FDAAA to have an identical REMS in place to the brand's REMS.<sup>248</sup> If injuries result from the generic testing process, brands could be liable because, under REMS, a REMS program creator and operator (the brand) is deemed responsible for ensuring safety of the drug in testing and compliance with REMS provisions when the drug is distributed.<sup>249</sup> Pharmaceutical product liability is not cheap in itself, but liability for violations involving REMS drugs is particularly expensive; REMS violations

---

245. See Butler, *supra* note 9, at 1004-05 (“As ... reflected in all of the Supreme Court’s refusal-to-deal cases, no refusal to deal by a monopolist is deemed anticompetitive for purposes of antitrust liability if it is justified by ‘valid business reasons.’” (quoting *Aspen Skiing Co.*, 472 U.S. at 597)).

246. See *supra* Parts IV.D.1-2.

247. See Butler, *supra* note 9, at 1007.

248. See Carrier, *supra* note 34, at 49.

249. See Butler, *supra* note 9, at 1007 (“Third parties’ failure to follow the meticulous use provisions could result in liability litigation against the branded manufacturer.” (quoting Glenn G. Lammi, *Is FTC Becoming an All-Purpose Health Care Cost Regulator?*, FORBES (May 31, 2012, 1:00 PM), <http://www.forbes.com/sites/wlf/2012/05/31/is-ftc-becoming-an-all-purpose-health-care-cost-regulator>)).

can culminate in up to \$10 million fines.<sup>250</sup> Although a generic's safety and effectiveness testing "typically does not expose brands to product liability claims because it 'generally [does] not require[] ... clinical (human) data'"<sup>251</sup> under ANDA requirements,<sup>252</sup> bioequivalence is determined through human testing of the generic drug,<sup>253</sup> often involving at least twenty-four to thirty-six individuals.<sup>254</sup> REMS creates the legitimate potential for brands to incur significant liability if they provide brand drug samples for generic testing.

Liability concerns also exist broadly across the pharmaceutical industry for brands with generic competitors. Current tort and product liability over brand and generic drugs reaffirms, for the most part, the axiom that "a manufacturer of a product is not liable for injuries to a user of another manufacturer's product."<sup>255</sup> This principle is known as competitor liability,<sup>256</sup> and has widespread support in courts across the nation.<sup>257</sup> However, two recent Supreme Court cases—*Wyeth v. Levine*<sup>258</sup> and *PLIVA, Inc. v. Mensing*<sup>259</sup>—have cast doubts about the strength of this principle against competitor liability in cases involving brand and generic pharmaceuticals.<sup>260</sup> While in *Wyeth* the Court held that injured consumers could sue brand manufacturers for failing to warn about the risks of taking brand drugs,<sup>261</sup> *PLIVA* held that injured consumers could not bring failure-to-warn claims for injuries caused by

---

250. See Butler, *supra* note 9, at 1006.

251. Carrier, *supra* note 34, at 59 n.397 (quoting *Abbreviated New Drug Application (ANDA): Generics*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/>).

252. See Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 FORDHAM L. REV. 1835, 1842-43 (2013).

253. See 21 U.S.C. §§ 355(j)(2)(A)(iv), (j)(8) (2012).

254. Schwartz et al., *supra* note 252, at 1843.

255. Carrier, *supra* note 34, at 59 (quoting Kenneth Sills, Annotation, *Liability of Name Brand Drug Manufacturer for Injury or Death Resulting from Use of Prescription Drug's Generic Equivalent*, 56 A.L.R. 6TH 161 (2010), <https://advance.lexis.com/api/permalink/4be255e7-0355-4edf-b732-Oe79c5bfc37a/?context=1000516>).

256. See, e.g., Schwartz et al., *supra* note 252, at 1849.

257. See *id.* at 1852 ("[M]ore than sixty courts have rejected [competitor] liability.").

258. 555 U.S. 555 (2009).

259. 564 U.S. 604 (2011).

260. See Schwartz et al., *supra* note 252, at 1852.

261. See *Wyeth*, 555 U.S. at 558-59.

FDA-approved generic pharmaceuticals because the Court determined that generics had no control over the labels on their drugs.<sup>262</sup> These two holdings have created an apparent “dichotomy” in liability between brands and generics, in which claims against generic manufacturers may be precluded when claims against brands are not.<sup>263</sup> While this does not overturn competitor liability,<sup>264</sup> it encourages plaintiffs, as well as courts (likely motivated by equitable concerns), to search for avenues to find brands liable even when the product consumed was the generic version of the drug.<sup>265</sup> One court has already done just this: the Supreme Court of Alabama in *Wyeth, Inc. v. Weeks*.<sup>266</sup> In *Weeks*, the court held that a brand could be held liable for fraud or misrepresentation made in connection with drug labeling even when the consumer was injured by the generic version of the drug.<sup>267</sup> While Alabama remains an outlier,<sup>268</sup> brands likely see the decision as unlocking and opening Pandora’s Box, as their expanded liability has been opened.<sup>269</sup>

Even if brands are never actually held liable again under competitor liability, the mere *risk* of very costly liability has increased dramatically.<sup>270</sup> Now, every generic drug consumed has the realistic potential of leading to liability for brands, which creates strong incentives for brands to minimize generic manufacture of their drug. These incentives arise not because of prohibited monopolistic pricing motivations, but because of legitimate business concerns about costly future tort and product liability (particularly if generic versions

---

262. See *PLIVA*, 564 U.S. at 624. Generics are required to have identical labeling to that of the brand drug. See 21 U.S.C. § 355(j)(2)(A)(v) (2012).

263. See Schwartz et al., *supra* note 252, at 1854, 1857.

264. See *id.* at 1857.

265. See *id.* at 1852.

266. 159 So. 3d 649 (Ala. 2014).

267. See *id.* at 676-77.

268. See Schwartz et al., *supra* note 252, at 1860 (“Overall, nearly two dozen courts have assessed competitor liability theories since *Mensing* was decided. Other than the Supreme Court of Alabama, all have held that *Mensing* does not alter state law principles that brand-name drug manufacturers cannot be liable for harms caused by their generic competitors.”).

269. See Monee Hanna & Nicholas Janizeh, *Innovator Liability: A Pandora’s Box For Pharma Cos.?*, LAW 360 (Apr. 2, 2018, 1:30: PM), <https://www.law360.com/articles/1028345> [<https://perma.cc/MN55-ZZEH>].

270. See *Weeks*, 159 So. 3d at 685 (Murdock, J., dissenting) (commenting that the majority’s decision to expand liability to brands “creates a precedent that poses danger for the prescription-medicine industry and, by extension, for all industry”).

of the brand's drugs are consumed in Alabama).<sup>271</sup> Furthermore, brands are required by the NDA process to report on any significant development in the scientific understanding of the drug, and to change the labeling of the product if the safety or effectiveness of the product changes.<sup>272</sup> These monitoring, reporting, and labeling requirements placed solely on the brand manufacturer extend past the expiration of the brand's patent and continue indefinitely so long as a generic version remains in the market.<sup>273</sup>

This creates significant monitoring and potential liability costs for brands that are unrelated to monopolistic pricing motivations like those seen in *Otter Tail*<sup>274</sup> or *Aspen Skiing*.<sup>275</sup> Even though *Otter Tail* also operated under a highly regulated industry,<sup>276</sup> their exclusionary activity was not tied to concerns over liability.<sup>277</sup> Unlike *Otter Tail*, which "had already incurred the cost of the required infrastructure and, other than the ability to limit the development of future rivals, would have nothing to lose from complying with its regulatory obligation to 'wheel' the power of municipal power providers,"<sup>278</sup> brands face significant potential losses from dealing with their competitors, and thus brands' refusal to deal makes economic sense.

#### 4. *Under Current Antitrust Doctrine, Brands' Refusals to Deal with Generics Do Not Fail the "No Economic Sense" Test*

Absent the presence of a prior course of dealing (factor one), or the availability of the product to the public but not a competitor (factor two), the standard under the "no economic sense" test of a legitimate business reason appears fairly difficult to meet. Apart from the signals given by the proxy determinations of intent through factors one and two, it is difficult to determine the motivation

---

271. See *supra* notes 266-69 and accompanying text.

272. See Schwartz et al., *supra* note 252, at 1844.

273. See *id.* at 1844-45 (citing 21 C.F.R. §§ 314.3(a)-(c) (2018)).

274. See *Otter Tail Power Co. v. United States*, 410 U.S. 366, 377-78 (1973).

275. See *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585, 604 (1985).

276. Butler, *supra* note 9, at 994.

277. See *Otter Tail*, 410 U.S. at 378.

278. Butler, *supra* note 9, at 994.

behind a refusal to deal. Faced with this arduous task, courts reasonably have placed the burden of proving anticompetitive intent upon the plaintiff.<sup>279</sup> This is consistent with the tone the Court has struck regarding the established right of firms to refuse to deal, and the Court's views on monopolists in general. In *Aspen Skiing*, the Court noted the "high value that we have placed on the right to refuse to deal with other firms,"<sup>280</sup> and reminded courts that "even a firm with monopoly power has no duty to engage ... with a competitor."<sup>281</sup> A refusal to deal in itself does not have "evidentiary significance"<sup>282</sup> apart from an additional showing of monopolistic intent.<sup>283</sup> Because the opportunity to acquire and possess monopoly power "induces risk taking that produces innovation and economic growth," the Court has expressed the desire to "safeguard" legal monopolies by only imposing liability when there is anticompetitive conduct with anticompetitive intent;<sup>284</sup> "it is necessary to prove a 'specific intent' to accomplish the forbidden [monopolistic] objective."<sup>285</sup> Although the need to prove monopolistic intent itself creates a high bar for finding antitrust liability,<sup>286</sup> a legitimate, non-anticompetitive business reason behind the alleged exclusionary action remains the best defense, as a valid business purpose "will generally succeed in defending even a suspicious refusal to deal against an alleged antitrust violation."<sup>287</sup>

While brands that refuse to sell their REMS-regulated drug samples to generics are electing to forgo the short-run benefits of a sale, brands are doing so for the long-run business reason of minimizing

---

279. In *Actelion v. Apotex*, a case dealing with a REMS refusal-to-deal, the court stated that if the defendants can *prove* that the plaintiffs are "motivated not so much by safety concerns but instead ... by the desire to use [REMS] ... to maintain and extend a monopoly," then Section 2 liability is in order. Carrier, *supra* note 34, at 14 (quoting Transcript of Motions Hearing at 116, *Actelion Pharm. Ltd. v. Apotex, Inc.*, No. 1:12-cv-05743, 2013 WL 5524078 at \*117 (D.N.J. Oct. 17, 2013)).

280. *Aspen Skiing Co.*, 472 U.S. at 601.

281. *Id.* at 600.

282. *Id.* at 585.

283. *See Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004).

284. *Id.*

285. *Aspen Skiing*, 472 U.S. at 602.

286. *See Butler*, *supra* note 9, at 1000.

287. *Id.* (citing *Areeda*, *supra* note 214, at 852).

costly tort and product liability claims.<sup>288</sup> There is no “prior conduct” by the brands that would “shed[] light upon the motivation of its refusal to deal,” and thus courts must defer to a shown legitimate business reason for the refusal to deal and not impute “anticompetitive malice” to the monopolist.<sup>289</sup> Therefore application of the “no economic sense” test in the REMS context reveals that, absent an evidentiary showing of monopolistic motivation superseding a legitimate business reason, there are legally insufficient antitrust concerns to impose Section 2 liability upon brand manufacturers for refusing to deal with their generic competitors.

#### V. COURTS SHOULD CREATE A NEW EXCEPTION TO THE REFUSAL-TO-DEAL DOCTRINE TO IMPOSE LIABILITY UPON BRANDS

Brands should not face Section 2 liability in the REMS context under current refusal-to-deal doctrine because their refusal to deal with generic competitors makes economic sense.<sup>290</sup> However, the Court in *Trinko* noted that if “traditional antitrust principles justify adding the present case to the few existing exceptions” to the general right to refuse to deal with competitors, then courts should create a new exception and impose antitrust liability.<sup>291</sup> In analyzing whether a new exception is appropriate, the crux of the Court’s determination centered on whether the regulatory structure overseeing the monopolist’s behavior “was an effective steward of the antitrust function.”<sup>292</sup> If the regulatory structure was already “designed to deter and remedy anticompetitive harm,” then there would be no need for additional antitrust review, as “the additional benefit to competition provided by antitrust enforcement will tend to be small, and it will be less plausible that the antitrust laws contemplate such additional scrutiny.”<sup>293</sup>

Brand refusals to deal with generics due to REMS is an appropriate context for courts to create a new exception to the right of refusal to deal. First, the FDAAA did not create a “regulatory structure

---

288. *See supra* Part IV.D.3.

289. *Trinko*, 540 U.S. at 409.

290. *See supra* Part IV.D.4.

291. *Trinko*, 540 U.S. at 411.

292. *Id.* at 413.

293. *Id.* at 412.



designed to deter and remedy anticompetitive harm”<sup>294</sup> resulting from REMS.<sup>295</sup> Section 355-1(f)(8) of the FDAAA auspices to act as a “[l]imitation” on REMS, stating that “[n]o holder of an approved covered application shall use any [ETASU] required by the Secretary under this subsection to block or delay approval of an [ANDA] application.”<sup>296</sup> However, the language in § 355-1(f)(8) “does not construe the type of conduct that is considered to block or delay, nor does it include penalties for violations,”<sup>297</sup> and the FDAAA as a whole “provides no direction” on “whether and to what extent the FDA has any authority” to enforce this section.<sup>298</sup>

While the FDA has repeatedly written that brand manufacturers may not use REMS “to block or delay approval of an [ANDA],”<sup>299</sup> the FDA has been reluctant to elaborate upon what the aforementioned blocking or delaying approval looks like in practice within a brand’s operation of its REMS program.<sup>300</sup> Even if § 355-1(f)(8) was designed to deter and remedy anticompetitive harm, it does not do so in practice. The FDA seems to think that it has no clear authority to punish anticompetitive behavior,<sup>301</sup> and thus is an ineffective steward of any antitrust function within the FDAAA, if it exists.

Comparing the FDA and the FDAAA regulatory scheme to that in *Trinko* further reveals how lacking the FDAAA is in creating an antitrust function to govern REMS cases. The regulatory framework in *Trinko* “significantly diminishe[d] the likelihood of major anti-trust harm”<sup>302</sup> by requiring Verizon to be “on good [competitive] behavior” in its local market and to satisfy a “competitive checklist” before it could enter the long-distance market regulated by the FCC.<sup>303</sup> But there is no such requirement of prior pro-competitive

---

294. *Id.*

295. *See supra* Parts I.B., III.B.

296. 21 U.S.C. § 355-1(f)(8) (2012).

297. *Paradise, supra* note 30, at 61.

298. *Id.* at 68-69; *see supra* text accompanying notes 120-21.

299. *Butler, supra* note 9, at 984 (quoting Letter from Judith A. Racoosin, Deputy Dir. for Safety, Ctr. for Drug Evaluation & Research, to Beth Connelly, Assoc. Dir. Regulatory Affairs, Purdue Pharma L.P., *supra* note 299).

300. *See supra* note 11.

301. *See supra* text accompanying notes 119-21, 130.

302. *Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 412 (2004) (quoting *Town of Concord v. Bos. Edison Co.*, 915 F.2d 17, 25 (1st Cir. 1990)).

303. *Id.* at 412.

conduct required from brands to enter NDA and REMS programming. The Court in *Trinko* also looked for specific evidence that the regulatory framework was effective in practice, and deemed examples from the regulatory response to the alleged antitrust violation by Verizon relevant to determine whether the regulatory framework necessitated judicial intervention over antitrust matters.<sup>304</sup> Noting that the FCC and the New York Public Service Commission “responded” to the antitrust complaints, “concluded” that Verizon had violated the regulatory provision, and then “imposed” penalties and remedial reporting requirements, the Court found that the regulatory structure had effectively performed its designated antitrust function.<sup>305</sup> In the REMS context, however, the FDA has inconsistently *responded* to anticompetitive claims by generics regarding alleged REMS abuses.<sup>306</sup> The FDA has not *concluded* that a brand was in breach of the FDAAA for its failure to share drug samples with generics, despite the language of § 355-1(f)(8) possibly giving the FDA grounds to find otherwise.<sup>307</sup> While “generic manufacturers’ dissatisfaction with the pace and level of FDA action is not an argument that the agency is failing to actively regulate,”<sup>308</sup> the FDA has in fact gone beyond failing to regulate; it has attempted to shift all resolution of the antitrust elements of generics’ claims (and possible *imposition* of penalties) against brands for their refusal to provide samples to the FTC.<sup>309</sup>

Even under a *Trinko* analysis that is rightfully “cautious” in creating new exceptions to the right to refuse to deal with competitors,<sup>310</sup> the FDA is not serving as an effective steward of the antitrust function. As a result, there have been over 100 claims made by generics against brands for anticompetitively refusing to provide

---

304. *See id.* at 413.

305. *Id.*

306. *See, e.g.,* Carrier, *supra* note 34, at 49 n.366 (“FDA sometimes ‘sat on ... [letter] requests for years and never responded to them.’” (alteration in original) (quoting Transcript of Motions Hearing at 57, Actelion Pharm. Ltd. v. Apotex, Inc., No. 1:12-cv-05743, 2013 WL 5524078, at \*117 (D.N.J. Oct. 17, 2013))).

307. *See supra* notes 142-46 and accompanying text.

308. Butler, *supra* note 9, at 1002.

309. *See supra* Part III.C.

310. *Trinko*, 540 U.S. at 408 (“We have been very cautious in recognizing such exceptions [to the refusal-to-deal right], because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct by a single firm.”).

them samples of drugs,<sup>311</sup> but none have been resolved by the FDA using its regulatory authority by punishing the brand's anticompetitive behavior and requiring the brand to sell the samples to the generic. Traditional antitrust principles are endangered by brands' refusal to provide samples to generics, which thwarts competition by preventing generics from completing the ANDA process and entering the pharmaceutical market.<sup>312</sup> In regulating REMS provisions, the FDA is focused on ensuring safety, not competition.<sup>313</sup> Because the FDA has not been an effective steward of the FDAAA regarding alleged REMS abuses,<sup>314</sup> the benefits of imposing judicial antitrust scrutiny are significant.<sup>315</sup>

Congress and the FDA have essentially abandoned generic manufacturers in their quest to complete the ANDA process and enter the market. But that does not mean courts are bound to do likewise. Although brands' refusals to deal with their generic competitors does not implicate established exceptions to the right of firms to refuse to deal, "[a]ntitrust analysis must always be attuned to the particular [regulatory] structure and circumstances of the industry at issue."<sup>316</sup> While the regulatory scheme surrounding REMS and the pharmaceutical industry at large is extensive, it has not served as an effective steward of antitrust principles.<sup>317</sup> Building on a line of other Supreme Court cases, notably *Silver v. New York Stock Exchange*,<sup>318</sup> *Trinko* established that courts could impose antitrust scrutiny and liability when traditional antitrust principles justify its implementation because the current regulatory framework is not, in design or in practice, remedying major antitrust harm.<sup>319</sup> Therefore, to properly enforce the traditional antitrust principles that establish and empower Section 2, courts should not turn a blind eye to brands' anticompetitive manipulation of REMS. Instead, courts should create a new exception to the refusal-to-deal doctrine

---

311. See *supra* note 71 and accompanying text.

312. See *supra* Part II.

313. See *supra* Part I.B.

314. See *supra* Parts III.A-B.

315. See *Trinko*, 540 U.S. at 412.

316. *Id.* at 411.

317. See *supra* notes 294-301 and accompanying text.

318. See 373 U.S. 341, 358-59 (1963).

319. See *Trinko*, 540 U.S. at 411-13.

for brands' refusal to share samples due to asserted REMS justifications. Failing to do so would "defeat the congressional policy reflected in the antitrust laws"<sup>320</sup> while also defeating the procompetitive purposes of the Hatch-Waxman Act.<sup>321</sup>

### CONCLUSION

Brand drug manufacturers have manipulated REMS to engage in anticompetitive behavior that undermines the purpose of the Hatch-Waxman Act and hurts the public interest by preventing the entry to market of generic competitors.<sup>322</sup> Congress has given indications of its intent to make REMS abuses of this nature unlawful, both through § 355-1(f)(8) of the FDAAA and subsequent attempts, but has as of yet failed to do so.<sup>323</sup> The FDA has been likewise passive in responding to generics' concerns about brands' use of REMS to shield their anticompetitive behavior from regulatory scrutiny.<sup>324</sup> While current refusal-to-deal doctrine does not support imposing antitrust liability upon brands' use of REMS to restrict generics from accessing samples of brand drugs,<sup>325</sup> the ineffectiveness of the regulatory structure overseeing REMS creates a need for courts to intervene and apply antitrust scrutiny to prevent further significant anticompetitive harm.<sup>326</sup>

Until Congress intervenes and makes brand refusal to provide samples to generics due to asserted REMS concerns explicitly unlawful, or clarifies the FDA's power to regulate and punish anticompetitive uses of REMS, a vacuum of antitrust scrutiny will continue to exist in the pharmaceutical industry. Guided by *Trinko* and public policy,<sup>327</sup> courts should apply traditional antitrust principles in the area of REMS regulation and impose antitrust

---

320. *Silver*, 373 U.S. at 360.

321. *See supra* Part I.A.

322. *See supra* Part II.

323. *See supra* Part III.A.

324. *See supra* Part III.B.

325. *See supra* Part IV.

326. *See supra* Part V.

327. *See supra* Part V.

liability upon brands' anticompetitive refusals to provide samples to generics.

*Tyler A. Garrett\**

---

\* J.D. Candidate 2019, William & Mary Law School; B.A. 2016, Wheaton College (IL). I would like to thank the staff and editors of the *William & Mary Law Review*, particularly Michael Byrnes, Julie Cascino, Emma Vignali, Eric Lynch, and Tessa Tilton, for doing so much to help prepare this Note for publication. I also would like to express my deep gratitude towards my family for their constant support and encouragement in all I do, and for their willingness to listen to me ramble about antitrust issues as I went about researching and writing this Note.