

# Cats at the Christening: Bundled Rebates, Doctrinal Blind Spots, and the Risks of Antitrust Under-Enforcement in the Biologic Pharmaceutical Market

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## I. INTRODUCTION

The biologic pharmaceutical industry represents a “new frontier”<sup>1</sup> in antitrust law, which has for decades hammered out its place in a policy sphere that seeks to mold a careful balance between innovation incentives and anticompetitive extension of statutorily-granted market exclusivity. The rising cost of prescription drugs has been a target for Republican and Democratic administrations alike,<sup>2</sup> but policymakers who wish to elevate antitrust doctrine in the pharmaceutical market should prepare to engage with an advantage held by incumbent firms due to certain characteristics of the biologic industry. Commentators have observed how existing policy fails to account for a number of

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1. Michael A. Carrier & Carl J. Minniti, III, *Biologics: The New Antitrust Frontier*, 2018 U. ILL. L. REV. 1.

2. See, e.g., Jayne O’Donnell, *Trump’s Push to Reduce Drug Prices in State of the Union Boosts Hope for Action This Year*, USA TODAY (Feb. 6, 2020, 4:14 PM) <https://www.usatoday.com/story/news/health/2020/02/06/trump-and-drug-prices-state-of-the-union-prescription-reform-pass/4470776002/>; Peter Sullivan, *Obama Administration Scraps Controversial Drug Pricing Proposal*, THE HILL (Dec. 15, 2016, 9:06 PM), <https://thehill.com/policy/healthcare/310681-obama-administration-scraps-controversial-drug-pricing-proposal>.

potentially anticompetitive complications posed by biologics and urged antitrust authorities and policymakers to be clear-eyed about these possibilities.<sup>3</sup> As a number of key patents for blockbuster biologic drugs begin to expire,<sup>4</sup> courts and antitrust enforcement agencies should prepare for unique contours of the biologic marketplace to generate new antitrust conundrums that are unlikely to be resolved with existing antitrust doctrines.<sup>5</sup> The recent antitrust litigation over the biologic pharmaceutical “Remicade” previews one of these new battlegrounds: rebate bundles in the biologic marketplace.

In 2017, the pharmaceutical company Pfizer accused rival Johnson & Johnson (“J&J”) of anticompetitive conduct in the biologics market.<sup>6</sup> J&J introduced Remicade, the brand name for a biologic product Infliximab, in 1999.<sup>7</sup> The Food and Drug Administration (“FDA”) approved Remicade’s treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Chron’s disease, and plaque psoriasis.<sup>8</sup> In 2016, Pfizer received FDA approval to launch Inflectra as the first follow-on biologic (also known as a “bio-similar”) to Remicade.<sup>9</sup> The FDA approved Inflectra for all of Remicade’s indications but one: pediatric ulcerative colitis.<sup>10</sup> Remicade and Inflectra are administered in a clinical setting and are covered by a

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3. E.g., Thomas Cotter, *On Unknown Opportunities and Perils: Reflections on Carrier and Minniti’s “Biologics: The New Antitrust Frontier,”* 2018 U. ILL. L. REV. ONLINE 72, 80; Simone Rose & Tracea Rice, *The Biosimilar Action Plan: An Effective Mechanism for Balancing Biologic Innovation and Competition in the United States?*, 51 U. PAC. L. REV. 539, 551 (2020); John Thomas, *The Frontier Within: Thoughts on Carrier & Minniti*, 2018 U. ILL. L. REV. ONLINE 99, 122.

4. Comment, *Blockbuster Immunology Drugs Facing Patent Expiry and Biosimilar Competition*, PHARM.-TECH. <https://www.pharmaceutical-technology.com/comment/blockbuster-immunology-drugs-facing-patent-expiry-biosimilar-competition/> (last updated Apr. 24, 2018, 11:09).

5. E.g., Carrier & Minniti, *supra* note 1; Cotter, *supra* note 3; Rose & Rice, *supra* note 3; Thomas, *supra* note 3.

6. Flora Southey, *Motion to Dismiss Inflectra Case Denied, but J&J Insists ‘Pfizer’s Lawsuit Is Without Merit’*, BIOPHARMA-REP. (Aug. 14, 2018), <https://www.biopharma-reporter.com/Article/2018/08/14/Motion-to-dismiss-Inflectra-case-denied-but-J-J-insists-Pfizer-s-lawsuit-is-without-merit>.

7. Pfizer Inc. v. Johnson & Johnson, 333 F. Supp. 3d 494, 497 (E.D. Pa. 2018).

8. *Id.* at 497–98.

9. *Id.* at 498.

10. *Id.*

patient's medical-benefit insurance (rather than traditional pharmacy-benefit insurance coverage).<sup>11</sup>

Pfizer alleged that J&J's exclusive dealing arrangements and bundled rebates were anticompetitive.<sup>12</sup> Pfizer claimed that J&J bundled rebates in two different ways. First, J&J required insurers to purchase Remicade for new patients in order to secure rebates for existing Remicade patients.<sup>13</sup> Existing patients were considered inelastic because it was extremely unlikely they could switch their biologic product in the middle of treatment.<sup>14</sup> Second, J&J bundled Remicade rebates together with rebates for other brand name biologic products, such as Simponi, Simponi Aria, and Stelara.<sup>15</sup> Pfizer believed it could not offer competitive alternatives to these biologics.<sup>16</sup>

On a motion to dismiss, Judge Joyner determined that J&J's multi-product bundles did not present an antitrust concern.<sup>17</sup> Judge Joyner reasoned that Pfizer, a pharmaceutical company with an extremely diverse product inventory, was free to offer its own competitive multi-product bundles.<sup>18</sup> On the other hand, Judge Joyner upheld Pfizer's claim that J&J's decision to bundle rebates for new and existing Remicade patients was anticompetitive.<sup>19</sup> If existing-patient demand was truly inelastic, Judge Joyner reasoned, "[T]his could fall into a traditional bundling case where J&J has bundled its power over existing Remicade patients to break the competitive mechanism and deprive new Infliximab patients (and their insurers) of the ability to make a meaningful choice between Remicade and its biosimilars."<sup>20</sup>

Judge Joyner credited the fact that Remicade's list price (also known as the "Wholesale Acquisition Cost")<sup>21</sup> continued to rise even though J&J faced competition from Pfizer. "Accepting as true Pfizer's allegations that existing Remicade patients will not switch to a

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11. *Id.*

12. *Id.* at 498–500.

13. *Id.* at 498–99.

14. *Id.* at 499.

15. *Id.*

16. *Id.*

17. *Id.* at 504.

18. *Id.*

19. *Id.*

20. *Id.*

21. *Id.* at 505.

biosimilar despite price competition,” Judge Joyner reasoned, “the *increasing penalties* that payors may face for exiting patients may effectively force payors into accepting J&J’s exclusionary terms for all patients.”<sup>22</sup>

To understand the potential anticompetitive effects of rebate bundles in the biologic market, it is necessary to parse out how rebates and rebate bundles can create the penalties identified by Judge Joyner. The realities of this marketplace create hidden penalties that may be combined with steep costs of biosimilar entry to “break the competitive mechanism.” This is particularly true with regards to cross-indication rebate bundles that may take advantage of indication asymmetry in the biologic market. With that understanding in place, it becomes clear that existing antitrust doctrine is inadequate to address this conduct. Policymakers, antitrust enforcement agencies, and industry participants should be prepared to evaluate cross-indication rebate bundles in the biologic market in order to best facilitate biosimilar competition.

To that end, this Article begins with an exploration of the nature of biologics and the difficulties associated with competition in the biologic marketplace in Part II. Then, in Part III, it discusses the role of rebates and pharmacy benefit managers (“PBMs”) in the prescription pharmaceutical marketplace. Part IV explains how a “rebate risk dynamic” may create hidden costs that help to break the competitive mechanism in the biologic market. Finally, Part V expounds on the inapplicability of current antitrust doctrine to cross-indication rebate bundling.

## II. BIOLOGICS AND THE NATURE OF BIOSIMILAR COMPETITION

Before we can discuss the dynamics of the pharmaceutical marketplace, we must understand how the nature of biologic development creates steep entry costs for potential competitors. To grasp these realities, it is necessary to examine the basic science of biologics and follow-on biologic development and how that science can result in unequal regulatory approvals among competitive biologics. To further illuminate the problems faced by potential competitors, it is helpful to examine how public policy for competitive entry of biologic follow-

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22. *Id.* at 505 (emphasis added).

ons differs from policies designed to foster generic competition among traditional pharmaceuticals.

### A. *Biologics and Biosimilars*

Biologic pharmaceuticals are therapeutic drugs derived from biologic sources, such as proteins, nucleic acids, or a combination of different living cells or tissues.<sup>23</sup> Biologics differ significantly from traditional small-molecule compounds such as ibuprofen.<sup>24</sup> The ibuprofen in your home was created through the process of chemical synthesis; several chemical ingredients were combined in a certain order to create the drug.<sup>25</sup> The result is a highly stable and predictable product and the chemical synthesis is known to create ibuprofen every time.<sup>26</sup> Further, once the drug is put together, it is relatively easy to break it down into its parts, analyze its chemical structure, and determine how to put it back together again.<sup>27</sup> A generic manufacturer of ibuprofen uses this information to combine the same active ingredients in the same form, concentration, and route of administration to market a generic version of the brand name drug.<sup>28</sup> This is why a generic version of ibuprofen sits next to the brand name product on the pharmacy shelf or a generic prescription drug can be substituted for a prescription brand name medication behind the counter.

A biologic is far more complex. It is often impossible to evaluate a finished biologic drug and determine what went into the

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23. FED. TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 3 n.1 (2009), <https://www.ftc.gov/sites/default/files/documents/reports/emerging-health-care-issues-follow-biologic-drug-competition-federal-trade-commission-report/p083901biologicsreport.pdf>.

24. *Id.* at 5.

25. *See What's the Difference Between Brand-Name and Generic Prescription Drugs?*, SCI. AM. (Dec. 13, 2004), <https://www.scientificamerican.com/article/whats-the-difference-betw-2004-12-13/>.

26. *See, e.g.,* Rose & Rice, *supra* note 3 (“Small molecule drugs are developed through predictable chemical synthesis processes. The final chemical compound is always the same and easily verified . . .”).

27. *Id.*

28. *See, e.g.,* *Generic Drugs: Questions and Answers*, FDA, <https://www.fda.gov/drugs/questions-answers/generic-drugs-questions-answers> (last visited Mar. 19, 2021).

production of that product.<sup>29</sup> Unlike chemical compounds, certain aspects of a biologic can be absorbed into the process and are not immediately apparent in post hoc analyses of the finished product.<sup>30</sup> Further, it is extremely difficult to analyze a finished biologic to learn about the complex processes (as opposed to just chemical formula) that resulted in its final form.<sup>31</sup> Because biologics are engineered using living organisms, they can be sensitive to minor variations in the process of formulation.<sup>32</sup> Indeed, biologics are often described using the phrase: “the product is the process.”<sup>33</sup> For these reasons, it is exceedingly difficult or impossible for a follow-on producer to develop an exact replica of a biologic; therefore, regulatory authorities cannot rely on safety and efficacy studies of the original drug to approve follow-ons.<sup>34</sup>

Because of the physical challenges that face biosimilar developers, the process can take as long as five to nine years and cost between \$100 million and \$250 million.<sup>35</sup> By way of contrast, generic entry for traditional small-molecule pharmaceuticals typically takes two years and costs between \$1 million and \$2 million.<sup>36</sup>

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29. See, e.g., Carrier & Minniti, *supra* note 1, at 7.

30. *Id.*

31. Curtis Triplitt et al., *How Similar Are Biosimilars? What Do Clinicians Need to Know About Biosimilar and Follow-On Inuslins?*, 35 *CLINICAL DIABETES* 209, 210 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5669137/pdf/209.pdf>.

32. WENDY H. SCHAT & JOHN R. THOMAS, CONG. RSCH. SERV., R41483, FOLLOW-ON BIOLOGICS: THE LAW AND INTELLECTUAL PROPERTY ISSUES 15 (2012), [https://www2.law.umaryland.edu/marshall/crsreports/crsdocuments/R41483\\_01242012.pdf](https://www2.law.umaryland.edu/marshall/crsreports/crsdocuments/R41483_01242012.pdf).

33. Carrier & Minniti, *supra* note 1, at 7.

34. *Id.*

35. Erwin A. Blackstone & Joseph P. Fuhr, Jr., *The Economics of Biosimilars*, 6 *AM. HEALTH DRUG BENEFITS* 469, 471 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/pdf/ahdb-06-469.pdf>.

36. *Biosimilars vs. Generics: What's the Difference?*, PFIZER [https://www.pfizer.com/sites/default/files/investors/financial\\_reports/annual\\_reports/2018/our-innovation/progressing-our-science/biosimilars-vs-generics/index.html](https://www.pfizer.com/sites/default/files/investors/financial_reports/annual_reports/2018/our-innovation/progressing-our-science/biosimilars-vs-generics/index.html) (last visited Mar. 19, 2021).

*B. Indication Asymmetry and Cross-Indication Rebate Bundles*

Because of the difficulty associated with biosimilar development, a biologic and a biosimilar may have asymmetrical indications.<sup>37</sup> An indication is the disease, condition, or symptom for which the drug has received FDA approval to treat.<sup>38</sup> For example, peptic ulcer disease is one indication for protein-pump inhibitors.<sup>39</sup> An original (or “pioneer”) biologic may have five indications while a biosimilar may only be approved for three or four.<sup>40</sup> Although there is a process by which biosimilars may gain FDA approval for indications not directly studied,<sup>41</sup> the number of indications nevertheless may differ.<sup>42</sup>

Throughout the following discussion regarding rebates and drug pricing, it is important to keep in mind that this asymmetry may allow pioneer biologic incumbents to bundle rebates across all approved indications to disadvantage rival biosimilars with fewer approved indications. As we will see, this cross-indication rebate bundle may require insurers to prioritize a biologic for all of the biologic’s indications, including those indications with available competitive biosimilars, in order to receive rebates on any one indication, particularly those without competitor biosimilar alternatives. This is the method by which biosimilar incumbents may be able to raise rivals’ costs. Because rebates are the method by which biologics and biosimilars compete on price,

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37. James G. Stevenson, *Challenges with the Introduction of Biosimilars in the US*, PHARMACY TIMES (June 21, 2016), [https://www.pharmacytimes.com/publications/ajpb/2016/AJPB\\_MayJune2016/challenges-with-the-introduction-of-biosimilars-in-the-us](https://www.pharmacytimes.com/publications/ajpb/2016/AJPB_MayJune2016/challenges-with-the-introduction-of-biosimilars-in-the-us).

38. U.S. FOOD & DRUG ADMIN., INDICATIONS AND USAGE SECTION OF LABELING FOR HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS—CONTENT AND FORMAT: GUIDANCE FOR INDUSTRY 2 (2018), <https://www.fda.gov/media/114443/download>.

39. See, e.g., *Generic Drugs: Questions and Answers*, *supra* note 28.

40. See, e.g., U.S. FOOD & DRUG ADMIN., LABELING FOR BIOSIMILAR PRODUCTS: GUIDANCE FOR INDUSTRY 7–8 (2018), <https://www.fda.gov/media/96894/download>.

41. See, e.g., *Biosimilar Development, Review, and Approval*, FDA, <https://www.fda.gov/drugs/biosimilars/biosimilar-development-review-and-approval#indication> (last updated Oct. 20, 2017).

42. CONG. RSCH. SERV., R44620, BIOLOGICS AND BIOSIMILARS: BACKGROUND AND KEY ISSUES 17 (2019), <https://fas.org/sgp/crs/misc/R44620.pdf>.



cross-indication rebate bundles may put biosimilars with fewer indications at a significant disadvantage.

### C. *Current Public Policy to Facilitate Biosimilar Entry*

Given the scientific limitations, the challenges of market entry for follow-on biosimilars is fundamentally different than those associated with generic production of traditional small-molecule pharmaceuticals. Public policy designed to encourage and accelerate generic competition for traditional pharmaceuticals cannot easily be applied to biologics and biosimilars.<sup>43</sup>

Before Congress passed the Hatch-Waxman Act in 1984, generic producers of traditional small-molecule pharmaceuticals were required to undertake lengthy safety and efficacy studies, as any new drug would.<sup>44</sup> This process could take several years.<sup>45</sup> Additionally, because the trials themselves constituted infringement of the original patent, generic producers could not begin these trials until after the expiration of the original patent.<sup>46</sup> Together, these two hurdles combined to create a de facto extension of the life of the original patent, as generic entry could not practically occur until, at the earliest, several years after the patent's expiration.

To promote generic entry, the Hatch-Waxman Act addressed both of these hurdles.<sup>47</sup> First, the Act codified an experimental use exception to patent infringement claims against generic drug producers seeking FDA approval during the original patent's lifetime.<sup>48</sup> Second, the Act created the Abbreviated New Drug Application ("ANDA") process whereby generic drug producers can bypass the costly FDA approval process. Instead, generic drug producers can "piggyback" on original safety and efficacy studies to demonstrate that the generic product is "bioequivalent" to the relevant brand name drug.<sup>49</sup> Additionally, to incentivize more rapid generic entry and ward off a collective action problem, the Hatch-Waxman Act grants 180 days of generic

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43. See Carrier & Minniti, *supra* note 1, at 15–16.

44. *Id.* at 11–14.

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.* (codified at 35 U.S.C. § 271(e)(1)).

49. *Id.*

exclusivity for the first generic producer to file an ANDA.<sup>50</sup> Together, these statutory creations seek to promote generic entry and price competition as close as possible to the moment that original patents expire.

The Hatch-Waxman Act was able to promote generic entry thanks largely to a fundamental premise underlying generic production of small-molecule compounds: the chemical process of small-molecule pharmaceutical creation allows generic producers to create therapeutically equivalent replicas of brand named drugs at relatively low cost. Unlike small-molecule compounds, biologics are not built on predictable chemical processes.<sup>51</sup> Instead, “the product is the process.”<sup>52</sup> Because a biosimilar is inherently not the same product, the justification for relying on previous showings of safety and efficacy, which is a major justification for the ANDA process, does not apply.<sup>53</sup>

Given this difference, Congress could not afford biosimilar producers the same pathway afforded to generic small-molecule compounds in the Hatch-Waxman Act.<sup>54</sup> To facilitate that pathway for biologics, Congress passed the Biologics Price Competition and Innovation Act (“BPCIA”) in 2010.<sup>55</sup> As with Hatch-Waxman, the BPCIA provides an abbreviated pathway for biosimilars.<sup>56</sup> A follow-on biologic is able to skip traditional drug approval if it meets five requirements.<sup>57</sup> Approval as a biosimilar qualified for abbreviated approval means the follow-on product is “highly similar to the reference

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50. *Id.* at 12.

51. WENDY H. SCHACT & JOHN R. THOMAS, CONG. RSCH. SERV., R41483, FOLLOW-ON BIOLOGICS: THE LAW AND INTELLECTUAL PROPERTY ISSUES 2 (2012), [https://www2.law.umaryland.edu/marshall/crsreports/crsdocuments/R41483\\_01242012.pdf](https://www2.law.umaryland.edu/marshall/crsreports/crsdocuments/R41483_01242012.pdf).

52. Carrier & Minniti, *supra* note 1, at 7.

53. *Id.* at 15–16.

54. *Id.* at 14.

55. *Id.* at 3 (citing Patient Protection and Affordable Care Act (“ACA”), Pub. L. No. 111-148, 124 Stat. 119, 804 (2010) (codified as amended in scattered sections of the U.S. Code) (BPCIA was enacted under Title VII of ACA)).

56. *Id.* at 15.

57. 42 U.S.C. § 262(k)(2)(A)(i). The follow-on biologic must (I) meet the statutory definition of a “biosimilar”; (II) utilize the same mechanism or mechanisms of action as the reference biologic unless the reference product’s mechanism of action is unknown; (III) have the same labeling as the approved reference biologic; (IV) utilize the same route of administration, dosage form, and strength as the reference biologic; and (V) meet manufacturing facility safety standards. *Id.*

product notwithstanding minor differences in clinically inactive components” without “clinically meaningful differences . . . in terms of the safety, purity, and potency of the product.”<sup>58</sup> The follow-on product may gain the status of an “interchangeable biologic” if it meets two additional criteria. First, the follow-on must be “expected to produce the same clinical result as the reference product in any given patient,” and, second, must be shown to be safely alternated with the reference product for existing patients.<sup>59</sup>

Although the BPCIA does provide an accelerated pathway for competitive biosimilars, there are some important differences between the BPCIA and the Hatch-Waxman Act.<sup>60</sup> First, exclusivity is only granted to those biosimilars approved as “interchangeable.”<sup>61</sup> Second, exclusivity lasts for a single year,<sup>62</sup> during which the FDA may approve additional biosimilars.<sup>63</sup>

#### *D. Danger Ahead: An Anticompetitive Troika*

Albeit an imperfect remedy,<sup>64</sup> the BPCIA seeks to carve an abbreviated pathway for follow-on biologic products to spur competition in the biologic market space.<sup>65</sup> However, characteristics of the healthcare industry may create an opportunity for biologic incumbents to raise the cost of entry for competitive biosimilars.<sup>66</sup> Policymakers should apply lessons learned from recent history to emerging questions surrounding antitrust and the biologic industry.

Over time, various aspects of the Hatch-Waxman Act were leveraged by some pharmaceutical companies to artificially delay generic

58. 42 U.S.C. § 262(i)(2)(A)–(B).

59. 42 U.S.C. § 262(k)(4)(A)–(B).

60. Carrier & Minniti, *supra* note 1, at 15.

61. *Id.*

62. 42 U.S.C. § 262(k)(6)(A).

63. Carrier & Minniti, *supra* note 1, at 16.

64. See, e.g., Yaniv Heled, *Follow-on Biologics Are Set Up to Fail*, 2018 U. ILL. L. REV. ONLINE 113, 115–24.

65. Carrier & Minniti, *supra* note 1, at 15–16.

66. See Daryl Lim, *Biologics as the New Antitrust Frontier: Reflections, Rিপোষ্ট, and Recommendations*, 2018 U. ILL. L. REV. ONLINE 209, 227 (2018) (“Despite the BPCIA’s thoughtful construction, antitrust law has a gap-filling role.”).

entry and protect brand name drug profits.<sup>67</sup> The law's Paragraph IV "first-to-file exclusivity" was exploited by brand name producers to settle disputes with first-to-file generics on anticompetitive terms that guaranteed later entry and preserved monopolistic margins.<sup>68</sup> Similarly, the Act's automatic thirty-month stay, originally intended to balance brand name drug interests and promote resolution of patent disputes, has been triggered by baseless claims intended to delay generic competition.<sup>69</sup>

Antitrust law stepped in to neutralize these loopholes and stop anticompetitive patent exclusivity achieved with pay-for-delay settlements and sham litigation. In this way, antitrust law served to block pharmaceutical companies from thwarting the purpose of the Hatch-Waxman Act: the promotion of competition in the prescription drug market. Today, biologic producers have an opportunity to combine the inherent difficulty of creating biosimilars with indication-asymmetry and market dynamics to impede a major policy goal: competition from biosimilar pharmaceuticals. When these three factors merge, a biologic producer may bundle rebates across indications to leverage much more than traditional cost competitiveness. In effect, the incumbent biologic producer may be able to harness this troika to stymie biosimilar competition and extend their market exclusivity beyond what may occur but for the use of rebates bundled across indications.

To understand the power of rebate bundles in the biologic marketplace, it is necessary to first cover, in broad terms, the mechanics of the distribution chain for prescription pharmaceuticals and who the stakeholders are. We can then see how rebates may be leveraged to

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67. *See, e.g.,* Fed. Trade Comm'n v. Actavis, Inc., 570 U.S. 136, 153–54 (2013) (finding that a reverse settlement payment "in effect amounts to a purchase by the patentee of the exclusive right to sell its product, a right it already claims but would lose if the patent . . . were held invalid or not infringed by the generic product"); Fed. Trade Comm'n v. AbbVie Inc., 329 F. Supp. 3d 98, 126 (E.D. Pa. 2018) (finding that defendants engaged in sham litigation to trigger automatic thirty-month stay under Hatch-Waxman Act), *rev'd on other grounds*, 976 F.3d 327 (3d Cir. 2020) (holding that the district court lacked the authority to order disgorgement but affirming that the suit was a sham); *see also* FED. TRADE COMM'N, GENERIC DRUG ENTRY PRIOR TO PATENT EXPIRATION: AN FTC STUDY 1 (2002), [https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/generic-drug-entry-prior-patent-expiration-ftc-study/genericdrugstudy_0.pdf).

68. *See Actavis*, 570 U.S. at 137–38.

69. *See generally AbbVie Inc.*, 329 F. Supp. 3d at 126.

create a hidden “rebate risk dynamic” within a prescription drug’s journey from the manufacturer to a consumer and how this dynamic may serve to break the competitive mechanism in the biologic market.

### III. THE ROLE OF PHARMACY BENEFIT MANAGERS AND REBATES IN THE BIOLOGIC MARKETPLACE

The nature of biologic development and necessary regulatory requirements means that potential biosimilar competitors must overcome steep challenges to enter the biologic marketplace. In addition to costly scientific hurdles, these competitors face market dynamics that may add additional costs as they seek to enter the market. This is in large part because the sale of a pharmaceutical product generally involves a complex distribution chain filled out by several intermediary stakeholders with intertwining interests. To better understand how these market dynamics may be leveraged, it is important to consider how pharmacy benefit managers and insurers work together and how they create payment structures known as “drug formularies.” Additionally, it is helpful to consider how specialty pharmacies fit into the biologic marketplace.

#### *A. Pharmacy Benefit Managers and the Drug Distribution Dynamic*

A PBM is an entity that operates, either internally or by contract, to administer prescription drug programs for insurance entities such as commercial health plans, employer insurance plans, Medicare Part D plans, and federal and state employee health plans.<sup>70</sup> Originally, PBMs fulfilled an administrative role that was outsourced by the insurance plans.<sup>71</sup> A pharmacy would fill a prescription and collect a co-payment.<sup>72</sup> The paper claim would be sent to the PBM, who would sort it, collect the fee from the insurer, and pass the full payment on to the

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70. See Joanna Shepherd, *Is More Information Always Better? Mandatory Disclosure Regulations in the Prescription Drug Market*, 99 CORNELL L. REV. ONLINE 1, 2 (2013).

71. See Michael Ollove, *Drug-Price Debate Targets Pharmacy Benefit Managers*, PEW (Feb. 12, 2019), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2019/02/12/drug-price-debate-targets-pharmacy-benefit-managers>.

72. *Id.*

pharmacy.<sup>73</sup> The PBM then charged the insurer a small administrative fee each time this service was performed.<sup>74</sup> As their use became more widespread, PBMs began to offer more than just claim-processing services, including drug utilization review, pharmacy networking, and formulary development.<sup>75</sup> As the value of PBMs increased, their large client-rosters morphed into significant bargaining power in price negotiations with drug manufacturers.<sup>76</sup> This allowed PBMs to extract rebates from manufactures and, in turn, created more value in the eyes of insurer-clients. Today, PBMs handle approximately 75% of the estimated 6 billion prescriptions dispensed in the United States annually.<sup>77</sup> Further, PBMs handle 74% of Medicare Part D drug benefit management services.<sup>78</sup>

There are two types of structural relationships between insurers and PBMs: “carve-in” and “carve-out.”<sup>79</sup> Under the “carve-in” model, PBMs may be included within an integrated health system, such as Cigna or Kaiser Health Plan.<sup>80</sup> Under this arrangement, the insurer and PBM operate under the same umbrella.<sup>81</sup> Additionally, insurers and PBMs may have sub-contractual or partnership relationships.<sup>82</sup> Under a partnership arrangement, some of the PBMs functions are controlled

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73. *Id.*

74. Brittany Hoffman-Eubanks, *The Role of Pharmacy Benefit Managers in American Health Care: Pharmacy Concerns and Perspectives: Part 1*, PHARMACY TIMES (Nov. 14, 2017 1:00 PM), <https://www.pharmacytimes.com/news/the-role-of-pharmacy-benefit-mangers-in-american-health-care-pharmacy-concerns-and-perspectives-part-1>.

75. *Id.*

76. *See id.*

77. *Pharmacy Benefit Managers, Explained*, ADVISORY BD. (Nov. 13, 2019), <https://www.advisory.com/daily-briefing/2019/11/13/pbms>.

78. *See* U.S. GOV. ACCOUNTABILITY OFF., GAO-19-498, USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION 14 n.29 (2019), <https://www.gao.gov/assets/710/700259.pdf>.

79. Statement of the Fed. Trade Comm’n Concerning the Proposed Acquisition of Medco Health Solutions by Express Scripts, Inc. FTC File No. 111-0210 (Apr. 2, 2012), [https://www.ftc.gov/sites/default/files/documents/public\\_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf](https://www.ftc.gov/sites/default/files/documents/public_statements/statement-commission-concerning-proposed-acquisition-medco-health-solutions-express-scripts-inc./120402expressmedcostatement.pdf).

80. Helene L. Lipton et. al., *Pharmacy Benefit Management Companies: Dimensions of Performance*, 20 ANN. REV. PUB. HEALTH 361, 369 (1999).

81. *See id.* at 369–70.

82. *Id.* at 370.

by the insurer (e.g., formulary development).<sup>83</sup> Alternatively, PBM functions can be performed by a PBM that operates as a wholly-owned subsidiary.<sup>84</sup> In the “carve-out” model, PBMs are wholly separate, financially independent entities that contract directly with employers to provide PBM services.<sup>85</sup> Prior to its merger with Cigna, Express Scripts was an example of a standalone PBM.<sup>86</sup>

There is a significant amount of concentration in the PBM space. In 2018, around 75% of prescription claims handled by PBMs were processed by the three biggest firms: CVS Health, Express Scripts, and OptumRX.<sup>87</sup> Further, around 95% of these prescription claims are processed by just six PBMs.<sup>88</sup> Vertical integration between PBMs and insurers has also become the norm, as most major health insurers own or operate a PBM in some form.<sup>89</sup> Concentrating a large number of covered beneficiaries underneath one PBM umbrella benefits beneficiaries because it increases the PBM’s bargaining power with drug manufacturers. However, PBMs have become powerful players in the distribution dynamic, and scrutiny of behavior that leverages that power should be especially mindful of a PBM’s incentives.

### B. *PBMs and Manufacturer Rebates*

To understand the role and value of a PBM, step back and look at what happens when an insured person fills a prescription at the

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83. *Id.*

84. *Id.*

85. *Id.*

86. See, e.g., Eric Sagonowsky, *Bye-bye, Solo Express Scripts: What Does The Cigna Buyout Mean for Pharma?*, FIERCE PHARMA (Mar. 8, 2018, 11:45 AM), <https://www.fiercepharma.com/m-a/cigna-picks-up-standalone-pbm-express-scripts-54b-deal>.

87. Adam J. Fein, *CVS, Express Scripts, And The Evolution of The PBM Business Model*, DRUG CHANNELS (May 29, 2019), <https://www.drugchannels.net/2019/05/cvs-express-scripts-and-evolution-of.html>; Michael Hiltzik, Column, *How ‘Price Cutting’ Middlemen Are Making Crucial Drugs Vastly More Expensive*, L.A. TIMES (June 9, 2017, 12:00 PM), <https://www.latimes.com/business/hiltzik/la-fi-hiltzik-pbm-drugs-20170611-story.html>.

88. Fein, *supra* note 87.

89. Alia Paavola, *The Top Insurers All Have PBMs: Here’s Who They Are*, BECKER’S HOSP. REV. (Apr. 10, 2019), <https://www.beckershospitalreview.com/pharmacy/the-top-insurers-all-have-pbms-here-s-who-they-are.html>.

pharmacy. Typically, filling a prescription at the pharmacy involves two separate but codependent journeys. The first is the journey of the actual drug. This journey is relatively straightforward: the manufacturer sells the drug to a wholesaler, who sells the drug to the pharmacy, who dispenses the drug to the patient.<sup>90</sup> The original sale of the drug to the wholesaler reflects the “list price” (or “Wholesale Acquisition Cost”).

The second journey is that of the payment that ultimately reaches the manufacturer who produced the drug. This journey is significantly more complicated. Two steps occur before the prescription is ever filled. First, the PBM negotiates the net cost of the drug with the manufacturer.<sup>91</sup> The drug is already in the hands of the pharmacy, which paid for the drug based on the list price. To do this, the PBM and the manufacturer look at the list price, which must ultimately be reimbursed to the pharmacy, and negotiate over the rebate that results in the net price collected by the manufacturer at the end of the day. Second, the PBM contracts with a pharmacy to fill prescriptions for those beneficiaries of the PBM client-insurer.<sup>92</sup>

Third, the prescription is filled at the pharmacy. At this step, the patient pays the pharmacy a co-payment.<sup>93</sup> This represents a fraction of the drug’s total list price. The pharmacy is now owed money because they paid the wholesaler based on the list price of the drug. Fourth, the PBM collects the balance of that price from the client-insurer, plus an administrative fee for managing this process.<sup>94</sup> Fifth, the PBM reimburses the pharmacy for the remainder of the drug’s cost, plus whatever dispensing fees the pharmacy is contractually owed; this makes the pharmacy whole plus a profit.<sup>95</sup> Sixth, the manufacturer pays the PBM the agreed-upon rebate (from step one). The manufacturer’s net gain is now the list price paid by the wholesaler, minus distribution fees, minus the rebate paid to the PBM.<sup>96</sup> Seventh, the PBM

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90. Adam J. Fein, *Follow the Dollar: The U.S. Pharmacy Distribution and Reimbursement System*, DRUG CHANNELS (Feb. 3, 2016), <https://www.drugchannels.net/2016/02/follow-dollar-us-pharmacy-distribution.html>.

91. *See id.* at 2 fig.1.

92. *See id.*

93. *See id.* at 4.

94. *See id.* at 2 fig.1.

95. *See id.*

96. *See id.*



passes the rebate back to the insurer, minus a small fraction (depending on its contract with the insurer).<sup>97</sup>

On the financial journey between a drug manufacturer and a drug consumer, the PBM acts as a hub through which money flows between the manufacturer and insurer in the form of rebates and between the insurer and the pharmacy in the form of list-price payments.<sup>98</sup> With one hand, the PBM coordinates the list price and rebates that fill out this map. With the other hand, the PBM coordinates formulary access to the beneficiary that kicks off the dance when they fill a prescription at the pharmacy with their prescription drug insurance coverage.

### C. PBMs and the Rebate Revenue Stream

PBMs now have three revenue streams: traditional administrative fees, spread-pricing, and rebate share.<sup>99</sup> A PBM benefits from spread-pricing when they charge insurer-clients the cost of a drug based on the drug's average wholesale price, then pay the pharmacy the maximum allowable cost and pocket the difference.<sup>100</sup> Though spread-pricing is controversial, it is outside the scope of this Article.

Through the rebate stream, the PBM reimburses the pharmacy a negotiated rate for a prescription medication after the beneficiary pays a co-payment.<sup>101</sup> The insurer pays the net cost of the drug (the negotiated drug cost plus pharmacy dispensing fees minus the beneficiary co-payment) to the PBM along with an administrative fee.<sup>102</sup> The

97. *See id.*; *see also* Neeraj Sood et al., *Flow of Money Through the Pharmaceutical Distribution System*, USC HEALTH POL'Y & ECON. 1 (June 2017), [https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC\\_Flow-of-MoneyWhitePaper\\_Final\\_Spreads.pdf](https://healthpolicy.usc.edu/wp-content/uploads/2017/06/USC_Flow-of-MoneyWhitePaper_Final_Spreads.pdf).

98. *The Prescription Drug Landscape, Explored*, PEW (Mar. 8, 2019), <https://www.pewtrusts.org/en/research-and-analysis/reports/2019/03/08/the-prescription-drug-landscape-explored>.

99. Hoffman-Eubanks, *supra* note 74.

100. Robert Langreth et al., *The Secret Drug Pricing System Middlemen Use to Rake in Millions*, BLOOMBERG (Sept. 11, 2018), <https://www.bloomberg.com/graphics/2018-drug-spread-pricing/>.

101. Sood et al., *supra* note 97.

102. *Pharmacy Benefit Managers and Their Role in Drug Spending*, COMMONWEALTH FUND (Apr. 22, 2019), <https://doi.org/10.26099/njmh-en20>.

manufacturer then gives the PBM the negotiated rebate, which the PBM then passes back to the insurer but may retain a share of the rebate.<sup>103</sup> That share represents the PBMs revenue gained through the rebate stream.

#### D. PBMs and the Drug Formulary

Today, much of a PBM's importance derives from the drug formulary. A formulary, at its base, includes a list of drugs that are covered by your insurer.<sup>104</sup> There are several types of formularies. With an "open" formulary, all drugs are covered by your insurance, meaning your insurer will pay a portion of your prescription regardless of what drug is dispensed.<sup>105</sup> On the other end of the spectrum, a "closed" formulary means your insurance covers only certain drugs, to the exclusion of others.<sup>106</sup> If your insurance is on a closed formulary, you will pay the full cost of excluded drugs unless you successfully obtain a formulary override.<sup>107</sup>

In between the "open" and "closed" models, a formulary can implement "incented" co-payments.<sup>108</sup> This means the formulary builds in a preference for certain drugs over others within a common therapeutic class.<sup>109</sup> A formulary signals that preference to

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103. *Id.*

104. *A Consumer Guide to Drug Formularies: Understanding the Fundamentals of Behavioral Health Medications*, PARITYTRACK, [https://www.paritytrack.org/issue\\_briefs/a-consumer-guide-to-drug-formularies-understanding-the-fundamentals-of-behavioral-health-medications/](https://www.paritytrack.org/issue_briefs/a-consumer-guide-to-drug-formularies-understanding-the-fundamentals-of-behavioral-health-medications/) (last visited Mar. 19, 2021).

105. See Richard H. Parish II, *What Is a Formulary, Anyway? Part 2*, PHARMACY 1 (July 23, 2018), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6165227/pdf/pharmacy-06-00072.pdf>.

106. *See id.*

107. See, e.g., Steve Miller, *How We Build a Formulary*, EXPRESS SCRIPTS (Nov. 12, 2018), <https://www.express-scripts.com/corporate/articles/how-we-build-formulary>. A formulary override or formula exception is a process by which an insured person asks their insurer to bypass the formulary and approve a non-formulary medication.

108. Vittorio Maio et al., *Pharmacy Utilization and the Medicare Modernization Act*, 83 MILBANK Q. 101, 116–17 (2005), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690380/pdf/milq0083-0101.pdf>.

109. David H. Kreling, *Cost Control for Prescription Drug Programs: Pharmacy Benefit Manager (PBM) Efforts, Effects, and Implications*, ASPE (Aug. 8,

beneficiaries and their physicians through the use of tiers.<sup>110</sup> Tiered formularies incentivize beneficiaries to choose Tier 1 options over Tier 2 through the use of lower co-payments.<sup>111</sup> For example, if the formulary prefers a therapeutically equivalent generic version over a branded drug, it will signal that to the beneficiary with placement on Tier 1 and the lowest available co-payment.<sup>112</sup> The preferred brand name drug would be placed on Tier 2 with a higher co-pay.<sup>113</sup> A non-preferred brand name drug may appear on Tier 3.<sup>114</sup>

There is an additional variation among formularies that utilize the incented model. Formularies may structure the tiers based on either “drug classes” or “indications.” A “drug class” is used to group together similar drugs based on their mechanism of action, physiologic effect, or chemical structure.<sup>115</sup> For example, proton-pump inhibitors are a drug class based on their common mechanism of action on a stomach’s enzyme production.<sup>116</sup> Drugs within a common drug class may have different modes of administration or side effects.<sup>117</sup> A drug’s “indication” is the disease, condition, or symptom for which the drug has

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2009), <https://aspe.hhs.gov/cost-control-prescription-drug-programs-pharmacy-benefit-manager-pbm-efforts-effects-and-implications> (background report prepared for a Department of Health and Human Services conference on pharmaceutical pricing).

110. *Id.*

111. *Id.*

112. *See, e.g., Formulary Development and Management at CVS Caremark, CVS CAREMARK 3*, <https://www.caremark.com/portal/asset/FormDevMgmt.pdf> (last visited Mar. 19, 2021); EXPRESS SCRIPTS, WHITE PAPER: FORMULARY DEVELOPMENT AT EXPRESS SCRIPTS, <https://www.express-scripts.com/aboutus/formularyinformation/development/formularyDevelopment.pdf> (last updated Dec. 2020).

113. *See* Kreling, *supra* note 109.

114. *Id.*

115. Michael Bihari, *Drug Classes: Making Sense of Medication Classification*, VERYWELL HEATH, <https://www.verywellhealth.com/drug-classes-1123991> (last updated Mar. 26, 2020).

116. Michael M. Phillips, *Proton Pump Inhibitors*, MEDLINE PLUS, <https://medlineplus.gov/ency/patientinstructions/000381.htm> (last updated Mar. 27, 2019).

117. Haiden A. Huskamp et al., *The Impact of a Three-Tier Formulary on Demand Response for Prescription Drugs*, 14 J. ECONS. & MGMT. STRATEGY 729, 731 (2005), [http://www.pitt.edu/~ytzhang/zhang\\_JEMS2005.pdf](http://www.pitt.edu/~ytzhang/zhang_JEMS2005.pdf).

received FDA approval to treat.<sup>118</sup> For example, peptic ulcer disease is one indication for proton-pump inhibitors.<sup>119</sup>

When a formulary is based on drug classes, rebates and discounts are negotiated simply for a drug's inclusion or preference.<sup>120</sup> Although an included drug may have several different indications, the terms are set for any time a beneficiary purchases that drug, regardless of its use.<sup>121</sup> An indication-based formulary forces the manufacturer to jockey for position within each of that drug's indications.<sup>122</sup> Under this model, a drug may appear in a Tier 1 slot for one indication, a Tier 2 slot for another, and may be excluded for a third indication.<sup>123</sup> This may be because it is deemed more or less clinically effective by the Pharmacy and Therapeutics ("P&T") Committee, because of rebate competition, or because of some combination of the two. In 2018, the Center for Medicare Services ("CMS") (a federal agency within the Department of Health and Human Services) permitted the use of indication-based formularies for Medicare Part D providers.<sup>124</sup>

Broadly speaking, there are two phases of formulary creation: one medical and one business. In the medical phase, a P&T Committee—an independent collection of doctors, pharmacists, and other specialists—reviews FDA guidelines, clinical data, and other evidence, to

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118. U.S. FOOD & DRUG ADMIN., *supra* note 38.

119. See Daniel S. Strand et al., *25 Years of Proton Pump Inhibitors: A Comprehensive Review*, 11 GUT & LIVER 27, 33 tbl.3 (Nov. 14, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5221858/pdf/gnl-11-027.pdf>.

120. Troy Brennan, *Aligning Drug Prices with Value*, CVS HEALTH 3 (July 11, 2017), [https://payorsolutions.cvshealth.com/sites/default/files/cvs-payor-solutions-aligning-drug-prices-with-value-insights-briefing\\_jul-2017.pdf](https://payorsolutions.cvshealth.com/sites/default/files/cvs-payor-solutions-aligning-drug-prices-with-value-insights-briefing_jul-2017.pdf).

121. *A Consumer Guide to Drug Formularies*, *supra* note 104.

122. *Indication-Based Formularies: A New Tool in Drug Cost Management*, BEN MEDICA (Dec. 17, 2018), <https://www.benmedica.com/articles/2018/12/17/indication-based-formularies-a-new-tool-in-drug-cost-management>; see also Mari Edlin, *Indication-Based Formulary Design Chases Medicare Market*, MANAGED HEALTHCARE EXEC. (June 12, 2019), <https://www.managedhealthcareexecutive.com/managed-care-pharmacy-survey/indication-based-formulary-design-chases-medicare-market>.

123. See generally Emily Sutton, *Indication-Based Pricing: What Are the Opportunities and Challenges?*, REMAP CONSULTING (Apr. 27, 2018), <https://remapconsulting.com/indication-based-pricing-opportunities-challenges/>.

124. *Indication-Based Formulary Design Beginning in Contract Year (CY) 2020*, CMS.GOV (Aug. 29, 2018), <https://www.cms.gov/newsroom/fact-sheets/indication-based-formulary-design-beginning-contract-year-cy-2020>.

create the list of drugs that should or should not be included, as well as specifics regarding a drug's utilization.<sup>125</sup> The P&T Committee does not consider drug price in this phase.<sup>126</sup> In the business phase, the PBM will negotiate with manufacturers of those drugs included by the P&T Committee for inclusion or preference on the formulary.<sup>127</sup>

#### *E. Formulary Placement and Asymmetrical Indication Labels*

Drug manufacturers are aware that exclusion from a formulary deprives them of access to a large number of sales at the pharmacy and will compete on cost with rebates for inclusion and preferable formulary placement.<sup>128</sup> In theory, this competition allows PBMs to lower overall costs for their insurer-clients.<sup>129</sup> Whether or not preferable formulary placement is based truly on therapeutic value and cost-efficiency, rather than the PBMs self-interest in rebate capture,<sup>130</sup> it is clear that stakes are high for formulary placement and drug manufacturers can leverage the interests of PBMs and insurers against competitor manufacturers.

One way to leverage these interests may be a cross-indication rebate bundle. If a drug formulary is indication-based, a drug with multiple indications may condition rebates for each of the drug's indications on preferable formulary placement for all indications. In either a class-based or indication-based formulary, a competitive drug with fewer indications will be at a significant disadvantage when it

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125. *A Consumer Guide to Drug Formularies*, *supra* note 104.

126. *See, e.g., Formulary Development and Management at CVS Caremark*, *supra* note 112; EXPRESS SCRIPTS, *supra* note 112; *see also* Joshua Cohen, *Are P&T Committees Wielding More Influence and Driving Larger Drug Rebates?*, FORBES (May 20, 2019, 8:04 AM), <https://www.forbes.com/sites/joshuacohen/2019/05/20/are-pt-committees-wielding-more-influence-and-driving-larger-drug-rebates/#82f68512f892> (discussing the possibility of including cost as a factor in formulary development).

127. Cohen, *supra* note 126.

128. Sood et. al., *supra* note 94.

129. *Id.*

130. *See, e.g.,* John Arnold, Opinion, *Are Pharmacy Benefit Managers the Good Guys or Bad Guys of Drug Pricing?*, STAT (Aug. 27, 2018), <https://www.statnews.com/2018/08/27/pharmacy-benefit-managers-good-or-bad/>.

negotiates rebates for preferred formulary placement.<sup>131</sup> As discussed later, this disadvantage may be made more severe by aspects of the pharmaceutical marketplace that create hidden costs and may deter competitive entry in the biologic marketplace.<sup>132</sup>

#### F. PBMs and Drug Distribution Through Specialty Pharmacies

Prescription pharmaceuticals may also be distributed through a “specialty pharmacy.” A specialty pharmacy is a state-licensed pharmacy equipped to administer prescriptions for highly complex, high-cost treatments, such as cancer, hepatitis C, organ transplant treatment, and others.<sup>133</sup> These treatments may require that prescription medications be administered, handled, or stored according to special procedures.<sup>134</sup> While this avenue was typically utilized for some injectable or infused products, oral medications have also been distributed through specialty pharmacies.<sup>135</sup>

Specialty drugs, once a relatively small sub-market within the pharmaceutical universe, have grown to become the largest revenue-generating sub-market.<sup>136</sup> The specialty-pharmacy market is highly consolidated and expected to remain so.<sup>137</sup> In 2019, more than 70% of specialty-pharmacy revenues were generated by the top four specialty

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131. See, e.g., Amanda Cole et al., *Value, Access, and Incentives for Innovation: Policy Perspectives on Alternative Models for Pharmaceutical Rebates*, INST. FOR CLINICAL & ECON. REV. 1 (2019), <https://www.ohe.org/system/files/private/publications/Cole%20et%20al.%20%20ICER%20OHE%20White%20Paper%20on%20Rebates.pdf>.

132. See *infra* Part IV.

133. Michelle Byrne, *The Ins and Outs of Specialty Pharmacy*, PHARMACY TIMES (Dec. 6, 2018, 4:11 PM), <https://www.pharmacytimes.com/news/the-ins-and-outs-of-specialty-pharmacy>.

134. *Id.*

135. See, e.g., Indu V. Pillai, *The Changing Specialty Drug Reimbursement Landscape*, DECISION RES. GRP. (June 17, 2019), <https://decision-resourcesgroup.com/blog/changing-specialty-drug-reimbursement-landscape/>.

136. *Id.*

137. Adam J. Fein, *The Top 15 Specialty Pharmacies of 2019: PBMs Stay on Top*, DRUG CHANNELS (Apr. 28, 2020), <https://www.drugchannels.net/2020/04/the-top-15-specialty-pharmacies-of-2019.html>.

pharmacy companies.<sup>138</sup> Moreover, most specialty pharmacy companies have been purchased by PBMs and insurers.<sup>139</sup>

As with traditional prescription pharmaceuticals, PBMs negotiate with drug manufacturers for rebates and formulary placement.<sup>140</sup> For example, in 2014, AbbVie launched a specialty hepatitis C treatment to rival Gilead's blockbuster Sovaldi drug.<sup>141</sup> PBMs Express Scripts and CVS/Caremark, both of which own specialty pharmacies, capitalized on this competition to negotiate favorable rebates for either treatment in exchange for favorable formulary placement.<sup>142</sup>

### *G. Summary: PBMs, Rebates, and the Drug Formulary*

In sum, individual insurer-clients benefit from the bargaining power PBMs derive from their massive rosters of insured persons. PBMs benefit from the rebate model because they retain portions of rebates as they are passed from manufactures to insurers. Unsurprisingly, there is counterbalancing bargaining power on the side of drug manufacturers. For PBMs and their insurer-clients, rebates often represent much more than just a discount, and drug manufacturers know this. The following discussion illustrates how rebates fit into PBM-insurer contracts, the Medicare Part D system, and a regulation known as the "medical loss ratio" under the Affordable Care Act ("ACA"), and how this dynamic can be leveraged through the use of cross-indication rebate bundling to raise rivals' costs and deter competitive entry in the biologics market.

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138. *Id.*

139. *Id.*

140. *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, VISANTE 4 (Feb. 2016), [https://spcma.org/wp-content/uploads/2015/10/Visante\\_PBM\\_Savings\\_Study-2016.pdf](https://spcma.org/wp-content/uploads/2015/10/Visante_PBM_Savings_Study-2016.pdf).

141. Adam J. Fein, *How PBMs Profit from the Hepatitis C Formulary Wars . . . and What It Means for Specialty's Future*, DRUG CHANNELS (Jan. 8, 2015), <https://www.drugchannels.net/2015/01/how-pbms-profit-from-hepatitis-c.html>.

142. *Id.*

#### IV. THE “REBATE RISK DYNAMIC” AND HIDDEN PENALTIES IN REBATE BUNDLING

With a basic understanding of the science of biologics and the dynamics of contracting in the pharmaceutical marketplace, the power of indication asymmetry and bundled rebates in the biologic marketplace comes into focus. Traditionally, a monopolist may be able to impose penalties on consumers who forgo bundled rebates and concurrently raise rivals' costs when it raises the unbundled price of products consumers otherwise buy separately.<sup>143</sup> This is a “bundled-rebate penalty.” Analysis of bundled discounts for anticompetitive harm examines the cost-savings for consumers against the possibility of foreclosure of competition.<sup>144</sup> In the Remicade litigation, Judge Joyner identified such a penalty in the loss of rebates for existing Remicade patients: insurers that would opt for the competitive option for new patients would lose rebates on prescriptions filled for existing Remicade patients.<sup>145</sup>

Like a sink hole in the road, rebate penalties in the pharmaceutical market can be deeper than meets the eye. Incentives built into the system by the nature of how PBMs and insurers utilize rebates can create a “rebate risk dynamic” that adds additional depth to the penalties identified by Judge Joyner in the Remicade litigation. The nature of how PBMs and insurers utilize rebates gives rise to systemic incentives and dynamic risk calculations that add hidden depth to the type of penalty traditionally associated with discount bundling in antitrust doctrine. In this way, the rebate risk dynamic illuminates how market contours may create additional costs imposed upon biosimilars.

Before exploring how PBM incentives can contribute to the rebate risk dynamic, Section A will set the stage with a brief summary of how incumbents may foreclose competition by increasing the cost of entry. Section B we will examine how the rebate risk dynamic may deepen the cost of entry by leveraging certain aspects of PBM-insurer contracts. Section C will discuss additional costs of the rebate risk

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143. See, e.g., Einer Elhauge, *Tying, Bundled Discounts, and the Death of the Single Monopoly Profit Theory*, 123 HARV. L. REV. 397, 472 (2009).

144. *Id.*; see also Herbert Hovenkamp, *Implementing Antitrust's Welfare Goals*, 81 FORDHAM L. REV. 2471, 2486–89 (2013).

145. *Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494, 504 (E.D. Pa. 2018).



dynamic associated with Medicare Part D. Finally, Section D will explore how bundled-rebate penalties may have been steeper for insurers because of accounting aspects associated with the medical loss ratio reporting requirements under the ACA.

*A. The Rebate Risk Dynamic in Perspective: Incumbent Firms Set the Terms of Competition*

Before we survey the three elements of the rebate risk dynamic, it is helpful to put the relevant potential foreclosure effect in perspective. The penalties associated with cross-indication rebate bundles and the rebate risk dynamic can be considered in relation to those penalties identified by Philippe Aghion and Patrick Bolton in their 1987 paper, *Contracts as a Barrier to Entry*.<sup>146</sup> Aghion and Bolton challenged the assumption that exclusive dealing contracts (whereby an incumbent firm imposes a penalty on buyers who switch to competitors) cannot deter entry without conceding compensation to buyers for the loss of competitive alternatives.<sup>147</sup> According to Aghion and Bolton, incumbent firms use these contractual penalties to set entrance fees for potential competitors who must compensate consumers for the penalties imposed by the contracts.<sup>148</sup> In this way, incumbent firms have the power to manipulate the terms of competition beyond simple measurement of competitor costs, extract surplus from entrants, and block entry of more efficient rivals.<sup>149</sup>

Professor Barry Nalebuff has summarized how this phenomenon may occur through the use of product bundles when an incumbent monopolist wards off entry at no cost to itself by simultaneously raising the unbundled cost of an uncontested product and offering to bundle it together with a contested product.<sup>150</sup> In this way, customers who forgo the bundle are assessed a penalty that must be borne by entrants in the market for the contested product because they must persuade

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146. Philippe Aghion & Patrick Bolton, *Contracts as a Barrier to Entry*, 77 AM. ECON. REV. 388 (1987).

147. *Id.*

148. *Id.* at 389.

149. *Id.*

150. See Barry Nalebuff, *Exclusionary Bundling*, 50 ANTITRUST BULL. 321, 323–25 (2005).

consumers to forgo the bundle.<sup>151</sup> Professor Scott Morton and Zachary Abrahamson have summarized how this phenomenon may occur through the use of loyalty rebates.<sup>152</sup> The following discussion highlights how contours of the pharmaceutical market may be leveraged to impose similar penalties that translate to costs of entry borne by potential biosimilar entrants.

### *B. PBM-Insurer Contracts and the Rebate Risk Dynamic*

PBMs and insurers can assign liability by contract to guarantee that benefits of manufacturer rebates are passed to insurers. How a PBM contracts with client-insurers to assign rebate liability contributes to how the rebate risk dynamic affects a PBM's incentives when faced with a pioneer incumbent's cross-indication rebate bundle. An analysis of the anticompetitive effects of these bundles must take into account the nature of these contractual commitments and how they increase the burden faced by competitor biosimilars.

PBM-insurer contracts typically follow one of four models with regards to how manufacturer rebates will pass back to insurers.<sup>153</sup> The first model requires 100% of rebates to pass through a PBM to its insurer-client.<sup>154</sup> A second model guarantees an insurer will receive a minimum dollar amount per formulary prescription.<sup>155</sup> A third model requires only that a certain percentage of the rebate pass through to the insurer.<sup>156</sup>

A fourth model of these PBM-insurer rebate contracts includes both a guaranteed percentage and minimum pass-through requirement. Under this structure, client-insurers require a PBM to pass through a minimum percentage of rebates but simultaneously guarantee a

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151. *Id.*

152. Fiona M. Scott Morton & Zachary Abrahamson, *A Unifying Analytical Framework for Loyalty Rebates*, 81 ANTITRUST L.J. 777, 787–88 (2017).

153. FED. TRADE COMM'N., PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 57–58 (2005), [https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitrpt_0.pdf).

154. *Id.*

155. *Id.*

156. *Id.*

minimum dollar amount per formulary prescription.<sup>157</sup> If the percentage is less than the total required minimum, the PBM is liable to the insurer-client for the difference.<sup>158</sup> For example, such a contract may require a PBM to pass through 90% of total rebates.<sup>159</sup> At the same time, the client-insurer requires a guaranteed minimum of \$2.50 per prescription of the preferred brand. If the total of 90% of rebates is less than the total guaranteed minimum, then the PBM is liable to the client-insurer for the difference.

This contractual arrangement adds some visibility to the true depth of the rebate risk dynamic. In this contractual arrangement, the PBM is highly incentivized to minimize risk by obtaining rebates at least equal to the guaranteed minimum across all indications. If a biosimilar with fewer indications competes on rebates with an incumbent biologic with more indications, it may be required to increase rebates to cover the cost of the PBM's risk. Even if a biosimilar entrant can offer rebates above the combined bundled rebate for one indication, if prescriptions on those indications without rebates begin to outnumber prescriptions on the competitive indication, the PBM's guaranteed minimum liability can eventually outpace rebates earned on the competitive indication.

This risk is illustrated in the following scenarios. In both scenarios, the list price for each prescription on any indication is \$100. A pioneer biologic offered a cross-indication bundled rebate of \$3.00 for Indication A, \$3.00 for Indication B, and \$10.00 for Indication C. A competitive biosimilar with only Indication C was able to offer a rebate of \$17.00 to compete with the total bundled rebate. The PBM's contract with its insurer-client requires a 90% rebate pass-through with a guaranteed minimum of \$2.50 per prescription.

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157. *Id.*

158. *Id.*

159. *Id.*

**Table 1**

Indication	List price per Rx	Pioneer Rebates (bundled)	Competitor Biosimilar Rebate
A	\$100	\$3	N/A
B	\$100	\$3	N/A
C	\$100	\$10	\$17

If the PBM chooses the competitive biosimilar rebate over the bundled rebate, it is possible that per-prescription liability will outpace rebates earned. In this illustration, prescriptions for Indications A and B surpassed the number of prescriptions for Indication C. This drives the PBM's minimum per-prescription liability up while rebate totals lag behind. To compensate, the PBM could price in this risk by extracting even more rebates for Indication C. This further exacerbates the difficulty faced by the biosimilar competitor.

**Table 2**

Competitive Rebate						
Indication	List price per Rx	Rebate per Rx	Minimum Liability per Rx	Number of Rx	Rebates Earned (total)	Minimum Liability (total)
A	\$100	\$0	\$2.50	400	\$0	\$1,000
B	\$100	\$0	\$2.50	200	\$0	\$500
C	\$100	\$17	\$2.50	50	\$850	\$125
<b>Total Rebates Earned:</b>	<b>\$850</b>					
<b>90% Liability</b>	\$765					
<b>Minimum Liability:</b>	<b>\$1,625</b>					

Alternatively, if the PBM chooses the bundled rebate over the competitor's offer, the per-prescription liability cannot outpace total rebates earned. So long as the rebates in non-competitive indications

remain above the minimum per-prescription liability, the PBM is not at risk of losing penalty amounts on this contract.

**Table 3**

Cross-Indication Bundled Rebate						
Indication	List price per Rx	Rebate per Rx	Minimum Liability per Rx	Number of Rx	Rebates Earned (total)	Minimum Liability (total)
A	\$100	\$3	\$2.50	400	\$1,200	\$1,000
B	\$100	\$3	\$2.50	200	\$600	\$500
C	\$100	\$10	\$2.50	50	\$500	\$125
<b>Total Rebates Earned:</b>	<b>\$2,300</b>					
<b>90% Liability</b>	\$2,070					
<b>Minimum Liability:</b>	<b>\$1,625</b>					

In 2015, the Pharmacy Benefit Management Institute published a report on PBM plans and contracts.<sup>160</sup> An analysis of that report determined that, of those contracts that required some form of pass-through, 39% of contracts required 100% of rebates to pass through, around 30% of contracts received the flat monetary amount per prescription, 16% required a certain percentage without a guaranteed minimum, and 16% required a certain percentage with a set minimum.<sup>161</sup>

This type of guaranteed-minimum rebate contract illustrates how the rebate risk dynamic increases the value biosimilar entrants must offer PBMs and insurers in order to compete with incumbent rebate bundles. In order to convince PBMs to accept zero rebates on other indications, biosimilars may need to offer larger rebates on their indications in order to cover the PBMs' risk of liability. If PBMs

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160. See Adam J. Fein, *Solving the Mystery of Employer-PBM Rebate Pass-Through*, DRUG CHANNELS (Jan. 14, 2016), <https://www.drugchannels.net/2016/01/solving-mystery-of-employer-pbm-rebate.html>.

161. *Id.*

beholden to this contract structure choose to price in the risk that their per-prescription liability will outpace total rebates, biosimilar competitors with asymmetrical indications may be forced to increase rebates steeply. At the end of the day, the steep rebates required to account for the priced-in risk may not be feasible for biosimilar competitors that seek to recoup the enormous costs associated with biosimilar development.

Antitrust enforcement agencies, courts, and policymakers should be aware of the rebate risk dynamic as they attempt to fashion a rule fit to address this potential foreclosure effect. While vertical integration among PBMs and their insurer-clients may abrogate the need for these guaranteed-minimum contracts, the integrated entities may still seek to extract concessions from biosimilars to cover these opportunity costs. Two additional aspects of the rebate system contribute to this rebate risk dynamic: Medicare Part D providers and the ACA's Medical Loss Ratio.

### *C. Medicare Part D and the Rebate Risk Dynamic*

A unique aspect of the Medicare Part D system and how rebates are structured into that system may contribute to how the rebate risk dynamic increases the penalties and entry costs attached to rebates and rebate bundles. As with guaranteed-minimum PBM-insurer contracts, the Part D system and the incentives it creates may add risk-based costs to biosimilar competitors with asymmetrical indication labels.

Under Medicare Part D, CMS contracts with private insurance companies to provide prescription drug benefit coverage to Medicare beneficiaries.<sup>162</sup> Under this arrangement, the private insurance companies (known as "Part D sponsors") collect both premiums from beneficiaries (at rates determined by CMS) and payments from CMS for certain beneficiaries with higher health risk.<sup>163</sup> Additionally, CMS directly subsidizes premiums for certain low-income beneficiaries.<sup>164</sup>

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162. SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R40611, MEDICARE PART D PRESCRIPTION DRUG BENEFIT 2 (2020), <https://fas.org/sgp/crs/misc/R40611.pdf>.

163. Francesco Decarolis et al., *Subsidy Design in Privately-Provided Social Insurance: Lessons from Medicare Part D 4–5* (Nat'l Bureau of Econ. Rsch., Working Paper No. 21298, 2015), <https://www.nber.org/papers/w21298.pdf>.

164. SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R40611, MEDICARE PART D PRESCRIPTION DRUG BENEFIT 26 (2020), <https://fas.org/sgp/crs/misc/R40611.pdf>.

Beneficiaries are able to shop for plans, and in 2019, 46 million Medicare beneficiaries were enrolled in Part D plans.<sup>165</sup>

Low-income beneficiaries that do not select a plan are randomly assigned to sponsor plans by CMS.<sup>166</sup> This process is also known as “auto-enrollment.”<sup>167</sup> Crucially, to be eligible to score beneficiaries through auto-enrollment, Part D sponsors must offer a premium below a threshold determined by CMS.<sup>168</sup> Out of 46 million Medicare beneficiaries enrolled in Part D plans,<sup>169</sup> an estimated 13 million received the low-income subsidy in 2020.<sup>170</sup> The low-income subsidy is considered a major source of sponsor revenue,<sup>171</sup> and auto-enrollment generates an incentive to keep premiums below the qualifying threshold.<sup>172</sup> For example, qualification for auto-enrollment can simultaneously increase revenue and lower marketing costs.<sup>173</sup>

As with commercial insurance, PBMs operate between sponsor plans and pharmaceutical manufacturers and negotiate rebates on behalf of those sponsor plans they represent.<sup>174</sup> Because of a particular

165. *An Overview of the Medicare Part D Prescription Drug Benefit*, KAISER FAM. FOUND. (Oct. 14, 2020), <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>.

166. SUZANNE M. KIRCHHOFF, CONG. RSCH. SERV., R40611, *MEDICARE PART D PRESCRIPTION DRUG BENEFIT 13* (2020), <https://fas.org/sgp/crs/misc/R40611.pdf>.

167. *Id.*

168. Francesco Decarolis, *Medicare Part D: Are Insurers Gaming the Low Income Subsidy Design?*, 105 AM. ECON. REV. 1, 2 (2014), [http://people.bu.edu/fdc/Decarolis\\_MedPartD.pdf](http://people.bu.edu/fdc/Decarolis_MedPartD.pdf).

169. *An Overview of the Medicare Part D Prescription Drug Benefit*, *supra* note 162.

170. *Id.*

171. Decarolis, *supra* note 168.

172. Mary Ellen Stahlman, *A Closer Look at the Medicare Part D Low-Income Benchmark Premium: How Low Can It Go?*, NAT'L HEALTH POL'Y F., Aug. 2, 2006, at 14–15, [https://www.nhpf.org/library/issue-briefs/IB813\\_LowIncomeBenchmark\\_08-02-06.pdf](https://www.nhpf.org/library/issue-briefs/IB813_LowIncomeBenchmark_08-02-06.pdf).

173. *Id.*

174. U.S. GOV. ACCOUNTABILITY OFF., GAO-19-498, *MEDICARE PART D USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION 12* (2019), <https://www.gao.gov/assets/710/700259.pdf>; *see also* Ann VanBoxtel, *How PBMs Make Money in the Medicare Part D Market—A GAO Report Analysis*, THE BURCHFIELD GRP. (Sept. 19, 2019), <https://www.burchfield-group.com/health-plan-insurer-blog/how-pbms-make-money-in-the-medicare-part-d-market-a-gao-report-analysis>.

quirk within the Part D system, however, sponsors have an incentive to opt for high-price/high-rebate drugs over lower-cost/lower-rebate alternatives. To understand why, it is necessary to understand some of the fundamentals of how Part D sponsors shift costs within the system.

Under current regulations, cost-sharing liability for a beneficiary's prescription is spread among the beneficiary, the sponsor plan, and the government.<sup>175</sup> The division of liability is calculated based on the point-of-sale price (the price paid to the pharmacy when the drug is dispensed to the beneficiary).<sup>176</sup> Importantly, the point-of-sale price does not reflect rebates negotiated between manufacturers and plan sponsors.<sup>177</sup> When the point-of-sale price is set higher because of a high-cost/high-rebate option, the high price is spread across the beneficiary, the sponsor plan, and the government, but only the liability of the plan sponsor is offset by the rebate, which is not passed on to the beneficiary or the government.<sup>178</sup> Moreover, higher out-of-pocket costs for beneficiaries means those individuals move more rapidly to the "catastrophic" phase of cost-sharing.<sup>179</sup> At this event, "reinsurance" kicks in, beneficiary liability drops to 5%, Medicare's liability reaches its highest (80%), and sponsor plan liability reaches its lowest (15%).<sup>180</sup> A recent CMS report summarized this system as one that creates little or no incentive for sponsor plans "to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available."<sup>181</sup>

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175. *Phases of Part D Coverage*, MEDICAREINTERACTIVE.ORG <https://www.medicareinteractive.org/get-answers/medicare-prescription-drug-coverage-part-d/medicare-part-d-costs/phases-of-part-d-coverage> (last visited Mar. 19, 2021).

176. ERIN TRISH ET AL., HEALTH POL'Y, HOW WOULD SHARING REBATES AT THE POINT-OF-SALE AFFECT BENEFICIARY COST-SHARING IN MEDICARE PART D? 2 (2020), <https://healthpolicy.usc.edu/research/how-would-sharing-rebates-at-the-point-of-sale-affect-beneficiary-cost-sharing-in-medicare-part-d/>.

177. See, e.g., U.S. GOV. ACCOUNTABILITY OFF., GAO-19-498, MEDICARE PART D USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION 13 (2019), <https://www.gao.gov/assets/710/700259.pdf>.

178. *Id.*

179. *Id.*

180. *Id.* at n.28.

181. Adam J. Fein, *Will CMS Pop the Gross-to-Net Bubble in Medicare Part D with Point-Of-Sale Rebates?*, DRUG CHANNELS (Nov. 21, 2017),



However, there is more to this rebate capture than meets the eye. While plan sponsors do capture rebates at the expense of high-need beneficiaries and tax-payer dollars, they use those additional revenues to lower the cost of premiums for lower-need beneficiaries.<sup>182</sup> Because of this, Part D has been described as a “reverse insurance program,” where those beneficiaries who require the most expensive medications subsidize the premiums of healthier seniors.<sup>183</sup> A recent Government Office of Accountability (“GAO”) study determined that, in 2016, \$18 billion worth of rebates passed through PBMs to Part D sponsors.<sup>184</sup>

It may be that this system facilitates lower premiums to the benefit of a large number of beneficiaries.<sup>185</sup> Remember, though, that to qualify for low-income beneficiary auto-enrollment, plans need to keep premiums below a certain threshold. Further, this distribution represents a large source of revenue that sponsors may forgo if they opt against this type of subsidization. In that light, it is clear that a plan sponsor, faced with a cross-indication rebate bundle, has much more on their mind than immediate discounts. The rebates themselves (regardless of immediate cost saving) factor into their ability to subsidize lower premium levels and qualify for low-income beneficiary auto-enrollment.

This dynamic is similar to the issue created by guaranteed-minimum payment contracts to insurer-clients. If a plan sponsor forgoes

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<https://www.drugchannels.net/2017/11/will-cms-pop-gross-to-net-bubble-in.html> (quoting Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Program for Contract Year 2019, 82 Fed. Reg. 56336 (proposed Nov. 27, 2017) (to be codified at 42 C.F.R. pts. 405, 417, 422, 423, 460, and 498)).

182. *Id.*

183. *Id.*

184. *See, e.g.*, U.S. GOV. ACCOUNTABILITY OFF., GAO-19-498, MEDICARE PART D USE OF PHARMACY BENEFIT MANAGERS AND EFFORTS TO MANAGE DRUG EXPENDITURES AND UTILIZATION 16 (2019), <https://www.gao.gov/assets/710/700259.pdf>.

185. Whether or not Part D sponsors should be required to pass rebates directly to beneficiaries, and what effect that would have on the cost of premiums overall, is still an open question. As it stands, the negotiated cost structure continues to incentivize plans to choose high-cost/high-rebate drugs. Even the CMS proposal sought input with regards to a requirement that sponsors pass through only a share of the rebates to beneficiaries at the point-of-sale. If sponsors could no longer subsidize lower premiums with rebates collected, they may still be able to collect some share of rebates as they pass through to the negotiated point-of-sale price.

rebates on certain indications in favor of a competitive biosimilar for one indication, it may need to calculate whether the competitive indication will satisfy its need to capture enough rebate value to adequately subsidize premiums to reach the auto-enrollment threshold. The price of this risk may be reflected in rebates extracted from biosimilar competitors with asymmetrical indications. While a biosimilar's competitive rebate for some indications may be enticing, it may not be enough to offset forgone rebates on indications not covered by that biosimilar. Further, the steep rebates required to compete with this aspect of the rebate risk dynamic may not be feasible for competitors that must recoup the enormous development costs associated with biosimilar development.

*D. The Medical Loss Ratio and the Rebate Risk Dynamic*

The rebate risk dynamic may also be at play from the perspective of insurers obligated to comply with the ACA's "Medical Loss Ratio" requirement ("MLR") (also known as the "80/20" rule). The MLR requires insurers in small-group markets to spend 80% of premiums (80 cents out of every premium dollar) on medical claims or costs that improve your quality of care.<sup>186</sup> 20% (20 cents out of every premium dollar) may be spent on administrative, overhead, and marketing costs.<sup>187</sup> In large-group markets, the medical loss ratio is less forgiving, at 85/15. Plans that exceed the maximum percentage of administrative costs are deemed to be either inefficient or excessively profitable and must return a percentage of premiums to their clients in the form of a rebate.<sup>188</sup> In 2019, insurers were required to pay \$1.37 billion in rebates to 9 million consumers.<sup>189</sup>

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186. *Medical Loss Ratio*, CMS.GOV, <https://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Market-Reforms/Medical-Loss-Ratio> (last visited Mar. 19, 2021).

187. *Id.*

188. Charles Roehrig, *The Impact of Prescription Drug Rebates on Health Plans and Consumers*, ALTARUM 18–19 (Apr. 2018), [https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report\\_April-2018.pdf](https://altarum.org/sites/default/files/Altarum-Prescription-Drug-Rebate-Report_April-2018.pdf).

189. Louise Norris, *ACA's 2019 Medical Loss Ratio Rebates*, HEALTHINSURANCE.ORG (Apr. 20, 2020), <https://www.healthinsurance.org/obamacare/acas-2019-medical-loss-ratio-rebates/>.

Typically, an administrative fee paid to a PBM for processing a prescription payment would fall into an insurer's administrative column.<sup>190</sup> However, a PBM retains a portion of a rebate as it passes through, in lieu of an administrative fee.<sup>191</sup> While the money obtained by either side is ultimately the same, this allows the insurer to manipulate the MLR favorably as costs are moved from the administrative column into the health care column.<sup>192</sup> As one study explained, "This boosting of the MLR will benefit health plans struggling to meet the required MLR thresholds."<sup>193</sup>

As with guaranteed-minimum PBM-insurer contracts and Medicare Part D auto-enrollment, the MLR contributes to the rebate risk dynamic when it potentially increases the rebates biosimilar entrants must offer PBMs and insurers to compete with incumbent rebate bundles. Medicare Part D providers may price this risk into rebates extracted from biosimilar competitors with asymmetrical indications. This may work against biosimilar entrants that seek to recoup biosimilar development costs and may contribute to a foreclosure effect. This represents another way bundled-rebate penalties increase the costs of potential biosimilar entrants. Antitrust enforcers, courts, and policymakers should be aware of this dynamic as they grapple with the possible foreclosure effects of bundled rebates.

In 2020, CMS released a final rule that amended how insurers may calculate their medical loss ratio.<sup>194</sup> Starting in 2022, insurers must deduct rebates in their total medical benefit costs.<sup>195</sup> Similarly, insurers must deduct any share of rebates retained by the PBM (in lieu of an administrative fee) from the medical benefit total, though this is still not added to administrative costs.<sup>196</sup> This change applies to medical loss ratios reported in 2023, but courts and antitrust enforcers should be aware that this rebate risk dynamic existed prior to the CMS reforms.

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190. Roehrig, *supra* note 188.

191. *Id.*

192. *Id.*

193. *Id.* at 19.

194. Katie Keith, *The 2021 Final Payment Notice, Part 1: Insurer Provisions*, HEALTH AFFS. (May 8, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200508.974523/full/>.

195. *Id.*

196. *Id.*

V. *LEPAGE'S, PEACEHEALTH*, AND THE INADEQUACY OF EXISTING  
ANTITRUST BUNDLING DOCTRINE

Contemporary antitrust doctrine attempts to simultaneously appreciate the potential anticompetitive effects of bundled discounts but also minimize the risk that over-enforcement may chill legitimate price-competition.<sup>197</sup> The Third Circuit and Ninth Circuit have both adopted approaches along these lines.<sup>198</sup> Both approaches risk false negatives in administrative and judicial scrutiny of bundled discounts and rebates in the biologic industry.

First, Section A will first briefly explain the two approaches. Next, Section B will explain how the hidden costs associated with the rebate risk dynamic in the biologic marketplace render these approaches inadequate to guard against firms that elect to engage in these anticompetitive business practices in order to artificially extend market exclusivity for biologic drugs.

A. *Two Tests for Exclusionary Discount Bundling*

Contemporary antitrust doctrine has generated two tests for exclusionary conduct in discount bundling.<sup>199</sup> In 2003, the Third Circuit set forth its disproportionate product diversity test in *LePage's v. 3M*.<sup>200</sup> Five years later, the Ninth Circuit declined to endorse the Third Circuit's approach and adopted its own price-cost test in *Cascade Health Solutions v. PeaceHealth*.<sup>201</sup>

1. *LePage's* and Disproportionate Product Diversity

In *LePage's v. 3M*, the Third Circuit endorsed the idea that bundled rebates may cause anticompetitive harm by way of exclusionary

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197. See, e.g., Christopher R. Leslie, *Predatory Pricing and Recoupment*, 113 COLUM. L. REV. 1695, 1746 (2013).

198. See *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008); *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003).

199. See *PeaceHealth*, 515 F.3d at 910; *LePage's Inc. v. 3M*, 324 F.3d at 156.

200. 324 F.3d at 156.

201. 515 F.3d at 910.

conduct.<sup>202</sup> 3M and LePage's competed in the market for transparent tape.<sup>203</sup> 3M offered rebate bundles to customers who purchased from an array of products offered by the manufacturer.<sup>204</sup> 3M conditioned rebates for six different products, including transparent tape, on minimum "target growth rates" for each product.<sup>205</sup> If a customer failed to meet a target for any one of the six products, it would forfeit rebates across the entire sextet of products.<sup>206</sup>

LePage's, which did not manufacture as diverse a product group, alleged that 3M used the bundled rebate conditions to leverage its diverse catalog to exclude LePage's from the transparent tape market.<sup>207</sup> The Third Circuit agreed that this disproportionate product diversity, leveraged by a monopolist with bundled rebates, could have an anticompetitive effect.<sup>208</sup> The Third Circuit observed a "powerful incentive . . . to purchase 3M tape rather than LePage's in order not to forego [sic] the maximum rebate 3M offered."<sup>209</sup> "The principal anticompetitive effect of bundled rebates as offered by 3M," the Third Circuit concluded, "is that when offered by a monopolist they may foreclose portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer."<sup>210</sup> Under this test, if a market leader bundles multiple products in such a way that a single-product seller cannot compete, there may be a cognizable antitrust harm.

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202. 324 F.3d at 155; *see also* *Eisai, Inc. v. Sanofi Aventis U.S., LLC*, 821 F.3d 394, 405 (3d Cir. 2016) (quoting *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 274 n.11 (3d Cir. 2012)) (explaining that the *LePage's* rule has been narrowed "to cases in which a single-product producer is excluded through a bundled rebate program offered by a producer of multiple products . . ."); *Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 552–58 (2019) (dismissing claims that bundled rebates were anticompetitive).

203. *LePage's Inc.*, 324 F.3d at 144.

204. *Id.* at 154.

205. *Id.*

206. *Id.*

207. *Id.* at 144.

208. *Id.* at 154.

209. *Id.*

210. *Id.* at 155.

## 2. *PeaceHealth* and a Price-Cost Rule

In *Cascade Health Solutions v. PeaceHealth*, the Ninth Circuit addressed bundled discounts and opted instead for a price-cost rule designed to protect against false-positives.<sup>211</sup> PeaceHealth, one of two hospital-care providers in Lane County, Oregon, bundled together discounts for primary, secondary, and tertiary care services offered to insurers.<sup>212</sup> Rival provider McKenzie could offer only primary and secondary services.<sup>213</sup> McKenzie alleged that PeaceHealth had leveraged its monopoly power over tertiary-care services to coerce insurers to prefer PeaceHealth for primary and secondary services.<sup>214</sup>

The Ninth Circuit declined to impose liability merely because PeaceHealth mixed its exclusive tertiary service with the competitive market for primary and secondary services.<sup>215</sup> The district court had instructed the jury that PeaceHealth would be liable for exclusionary conduct if it leveraged monopoly power in one market to offer a bundled discount in a competitive market that its rival could not match.<sup>216</sup> The Ninth Circuit appreciated that bundled discounts can work to operate like an illegal tying arrangement and effectively coerce purchasers to accept bundled products.<sup>217</sup> At the same time, the Ninth Circuit worried that the *LePage's* standard might “protect a less efficient competitor at the expense of consumer welfare.”<sup>218</sup> To resolve these concerns the case was remanded to determine liability under a new test that would require a plaintiff to show that, “after allocating the discount given by the defendant on the entire bundle of products to the competitive product or products, the defendant sold the competitive product or products below its average variable cost of producing them.”<sup>219</sup> By this

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211. 515 F.3d 883, 910 (9th Cir. 2008).

212. *Id.* at 891.

213. *Id.*

214. *Id.* at 892.

215. *Id.* at 903 (“Given the endemic nature of bundled discounts in many spheres of normal economic activity, we decline to endorse the Third Circuit’s definition of when bundled discounts constitute the exclusionary conduct proscribed by § 2 of the Sherman Act.”).

216. *Id.* at 898.

217. *Id.* at 900–01.

218. *Id.* at 899.

219. *Id.* at 910.

reasoning, if a defendant sells the competitive product below its average variable cost of production, it leverages monopoly power “to exclude a hypothetical equally efficient producer of the competitive product.”<sup>220</sup> This price-cost test is designed both to guard against false-positives and provide defendants with a workable test to engage in bundled discounts without uncertainty regarding antitrust liability.<sup>221</sup>

### 3. *PeaceHealth* and Tying Arrangements

In *PeaceHealth*, the plaintiffs argued that PeaceHealth’s bundled discount constituted an illegal tying arrangement.<sup>222</sup> At summary judgment, the district court determined that PeaceHealth had not leveraged the tying product (tertiary services) to coerce customers to purchase the tied product (primary and secondary services).<sup>223</sup> The district court relied heavily on the fact that the sale of tertiary services was not strictly conditioned on the purchase of primary and secondary services.<sup>224</sup> The Ninth Circuit overturned this summary judgment determination, holding instead that a reasonable trier of fact could find that the bundled discount was an illegal tying arrangement, and that “the evidence shows genuine factual disputes about whether PeaceHealth forced insurers either as an implied condition of dealing or as a matter of economic imperative through its bundled discounting, to take its primary and secondary services if the insurers wanted tertiary services.”<sup>225</sup> The Ninth Circuit left it to the district court, on remand, to decide whether the plaintiffs were required to show below-cost prices to establish the coercion element of a tying claim.<sup>226</sup>

#### B. *The Risk of False Negatives and Underenforcement in the Biologic Marketplace*

There is considerable risk of false negatives and underenforcement if antitrust enforcers and courts opt to apply the *PeaceHealth*

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220. *Id.* at 906.

221. *Id.* at 896.

222. *Id.* at 912.

223. *Id.*

224. *Id.* at 914.

225. *Id.*

226. *Id.* at 916 n.27.

price-cost rule or the narrowed *LePage's* disproportionate product diversity rule to rebate bundles in the biologic marketplace.<sup>227</sup> In both rules, effective antitrust analysis requires real appreciation for the costs associated with the rebate risk dynamic. Further, neither test for exclusionary conduct asks whether incumbent discount or rebate schemes truly foreclose the possibility of competitive entry. In light of challenges regarding administrability of such analyses, policymakers should eschew existing tests in favor of a “foreclosure paradigm” set forth in recent scholarship.

In the wake of the *LePage's* decision, commentators noted that the Third Circuit's approach would result in false positives that protect less-efficient competitors to the detriment of consumers.<sup>228</sup> While a strict application of the *LePage's* rule could cause overenforcement in cases involving multi-product bundles and single-product competitors, the Third Circuit's subsequent interpretation of that rule shows that the rule's analysis is far shallower than is necessary in the pharmaceutical space. This approach has already failed to account for the rebate risk dynamic in the recent Remicade litigation.<sup>229</sup> Judge Joyner noted the potential harm caused by J&J's bundling of existing and new patients but dismissed Pfizer's claim that J&J's multi-product rebate-bundle caused anticompetitive harm.<sup>230</sup> Although J&J had bundled rebates across products for which Pfizer had no competitive alternative biosimilar, Judge Joyner declined to apply the test from *LePage's*.<sup>231</sup> Instead, Judge Joyner noted that the Third Circuit had narrowed *LePage's* rule to cases “in which a single-product producer is excluded through a bundled rebate program . . . .”<sup>232</sup> “Pfizer, of course, is not a single-product

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227. See, e.g., Bradley Pollina, *False Negatives Under a Discount Attribution Test for Bundled Discounts*, 22 COMM'LAW CONSPECTUS 74 (2014).

228. See, e.g., Richard A. Epstein, *Monopoly Dominance or Level Playing Field? The New Antitrust Paradox*, 72 U. CHI. L. REV. 49, 71–72 (2005); John B. Kirkwood, *The Essence of Antitrust: Protecting Consumers and Small Suppliers from Anticompetitive Conduct*, 81 FORDHAM L. REV. 2425, 2461–62 (2013); Timothy J. Muris & Vernon L. Smith, *Antitrust and Bundled Discounts: An Experimental Analysis*, 75 ANTITRUST L.J. 399, 426 (2008).

229. For a summary of the Remicade litigation, see *supra* Part I.

230. *Pfizer, Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494, 504 (E.D. Pa. 2018).

231. *Id.*

232. *Id.* (quoting *Eisai, Inc. v. Sanofi Aventis U.S., L.L.C.*, 821 F.3d 394,405 (3d Cir. 2016)).



producer,” Judge Joyner reasoned.<sup>233</sup> “Moreover, Pfizer has not alleged any facts suggesting that J&J is hindering its ability to compete with J&J’s multi-product bundles by offering their own multi-product bundles.”<sup>234</sup>

Judge Joyner was correct to observe that Pfizer is capable of creating its own multi-product rebate bundle out of its extremely diverse product line. However, what the simplicity and administrability of the rule offers comes at the risk of significant underenforcement in the pharmaceutical market. Together, the scientific barriers that cause asymmetrical indication labels, the significant costs of biologic development, and the rebate risk dynamic built into PBM and insurer incentives work together to slash the possibility that a biosimilar can overcome cross-indication rebate bundling merely with a separate bundle cobbled together with that company’s product line. An effective anti-trust analysis of biologic rebate bundles should examine not whether the competitor can offer any competitive bundle, but instead whether the total costs associated with biosimilar development and the rebate risk dynamic could feasibly allow for biosimilar entry in the face of cross-indication rebate bundling.

As with the *LePage’s* rule, the *PeaceHealth* price-cost rule, while administrable, presents steep risk of underenforcement in the biologic market. With knowledge about the true cost of the rebate risk dynamic, biologic manufacturers can set cross-indication rebate bundles at well above the average variable cost of production at a level that still deters potential biosimilar competition. As explained above, the biosimilar competitor with a less comprehensive indication label may be forced to price in the risk in order to offer PBMs and insurers a competitive option. Those pressures may become irreconcilable with the costs of biosimilar development. Nevertheless, the biosimilar competitor may find no remedy if the *PeaceHealth* price-cost rule is adhered to.

Lower courts have already noted the inadequacy of the *PeaceHealth* price-cost rule in the pharmaceutical marketplace. In the Northern District of California, Judge Wilken in *Meijer, Inc. v. Abbott Laboratories* declined to apply the *PeaceHealth* price-cost rule to allegations that defendant Abbott Laboratories had excluded rivals in a

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233. *Id.*

234. *Id.*

competitive market for protease inhibitor drugs when it combined its own protease inhibitor (“PI”) with its exclusive antiviral drug, Norvir, to create a single product.<sup>235</sup> Abbott had priced its exclusive drug at \$17.14 and its combination product at \$18.78.<sup>236</sup> Because protease inhibitors were sold to boost the antiviral properties of Norvir, Plaintiffs alleged that this combination forced them to price below the difference of \$1.64.<sup>237</sup>

A straightforward application of the *PeaceHealth* price-cost rule would have asked whether Abbot’s average variable cost of producing the competitive product is greater than \$1.64.<sup>238</sup> Instead, Judge Wilken observed that the rule, while adequate to promote efficient manufacture of a drug, was ill-suited to address the total costs associated with the introduction of competitive pharmaceuticals.<sup>239</sup> She notes, “An appropriate antitrust rule here should have the effect of prohibiting Abbott’s pricing practices if a hypothetical equally efficient *developer* of an equally effective PI would not be able to profit if it introduced that PI to the market at a price of \$1.64.”<sup>240</sup> Judge Wilken declined to require the plaintiffs to show the price was below average variable cost and noted that *PeaceHealth* “implicitly acknowledges that some atypical cases may fall outside of the situation where only below-cost pricing will have the effect of inhibiting competition.”<sup>241</sup> To find room for this exception, Judge Wilken relied on the Ninth Circuit’s language that the Supreme Court’s predatory-pricing jurisprudence suggests that “in the *normal case*, above-cost pricing will not be considered exclusionary conduct for antitrust purposes.”<sup>242</sup>

With this, Judge Wilken correctly identified the importance of dynamic price considerations in the pharmaceutical market and the inadequacy of the *PeaceHealth* price-cost rule in this space. Judge Wilken was astute in her observation that a proper test for exclusionary

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235. *Meijer, Inc. v. Abbott Laboratories*, 544 F. Supp. 2d 995, 1003–04 (N.D. Cal. 2008).

236. *Id.* at 1003.

237. *Id.*

238. *Id.*

239. *Id.* at 1004.

240. *Id.* (emphasis added).

241. *Id.* at 1003.

242. *Id.* (quoting *Cascade Health Solutions v. PeaceHealth*, 515 F.3d 883, 901 (9th Cir. 2008)).

conduct would ask whether incumbent discount or rebate schemes foreclose the possibility of profit for potential competitive entrants. Any such analysis must factor in the total costs associated with the rebate risk dynamics discussed herein.

*C. Not Losing the Forest for the Trees: Embracing Professor Salop's Foreclosure Paradigm*

Recent scholarship provides another paradigm through which enforcement agencies and courts may scrutinize rebate bundles in the biologic marketplace. With regard to conditional pricing practices such as bundled discounts, Professor Salop has argued that a model that focuses on foreclosure caused by raising rivals costs is often more appropriate than a price-cost model.<sup>243</sup> This is because these practices, analyzed under the predatory-pricing paradigm underlying the *PeaceHealth* rule, may lose the forest for the trees and overlook foreclosure in light of lower nominal prices. “Conditional discounts may lead to lower *nominal* prices,” writes Professor Salop, “[b]ut the attached conditions also can raise rivals’ costs and erect barriers to entry.”<sup>244</sup> As Professor Salop explains: “Once these exclusionary effects are taken into account, particularly in monopoly or dominant firm markets, even the nominally discounted prices may exceed the *unconditional* prices that would be charged in the market if the [conditional pricing practices] were prohibited by antitrust law.”<sup>245</sup>

Professor Salop observed how a price-cost test for conditional discounts can create a risk of false negatives.<sup>246</sup> One reason for this is that, in the case of a dominant incumbent firm bidding for customers, incentives differ significantly from those in traditional price competition on the merits.<sup>247</sup> Indeed, “[t]he incumbent firm is bidding with the purpose of maintaining market power rather than simply competing for scarce distribution . . . .”<sup>248</sup> With this in mind, Professor Salop’s

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243. Steven C. Salop, *The Raising Rivals’ Cost Foreclosure Paradigm, Conditional Pricing Practices, and the Flawed Incremental Price-Cost Test*, 81 ANTITRUST L.J. 371, 399 (2017).

244. *Id.*

245. *Id.*

246. *Id.* at 400.

247. *Id.*

248. *Id.*

foreclosure paradigm would eschew a price-cost test in favor of “a more conventional rule of reason approach.”<sup>249</sup> This approach would scrutinize the conditional discounts for negative effect on consumers and competition.<sup>250</sup>

Cross-indication rebate bundles are prime candidates for a rule of reason analysis that focuses on foreclosure through measures that may raise rivals’ costs. As discussed above, these rebate bundles can leverage scientific barriers, market dynamics, and development costs to exacerbate penalties while maintaining net prices well above an incumbent firm’s costs.<sup>251</sup> Under a rule of reason approach, enforcement authorities and private plaintiffs can make fact-specific inquiries about the foreclosure effects of bundled rebates in light of biosimilar development costs and the types of hidden penalties discussed here. This approach would also require a determination of whether consumer benefits are greater in total than they would be absent cross-indication rebate bundling and with more indication-specific biosimilar competition.

## VI. CONCLUSION

Biologic and biosimilar pharmaceuticals unlock potential breakthroughs in medical treatment at enormous cost of development. Scientific limitations in biosimilar development create unique barriers to pharmaceutical companies that seek to introduce competitive alternatives to steeply expensive pioneer biologic therapies. In addition to the scientific limitations that can result in asymmetrical indication labels, cross-indication rebate bundles impede competitive entry of firms that manage to overcome the difficulties associated with biosimilar development. The nature of how PBMs and insurers utilize rebates gives rise to systemic incentives and a “rebate risk dynamic” that adds hidden depth to the type of penalty traditionally associated with discount bundling in antitrust doctrine. Biologic incumbents have an opportunity to harness a troika of steep development costs, indication asymmetry, and market dynamics to artificially extend their exclusivity and block price competition through the use of cross-indication rebate bundles.

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249. *Id.* at 401.

250. *Id.*

251. *See supra* Parts IV and V.

Policymakers and industry participants who wish to promote competition in the biologic market should be aware that courts and antitrust enforcement agencies may struggle to apply existing doctrine to bundled rebates in the pharmaceutical market. Existing antitrust doctrine regarding discount or rebate bundles creates considerable risk of false negatives and underenforcement in the biologic marketplace. Indeed, neither of the existing tests fully address whether incumbent discount or rebate schemes foreclose the possibility of successful biosimilar entry. Therefore, policymakers, enforcement authorities, and courts should eschew these doctrines in favor of the “foreclosure paradigm” articulated by Professor Salop in his scholarship. Further, any test of exclusionary rebate bundles that examines such a possibility must account for the rebate risk dynamic.

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