

**INTERACTION OF HUMAN RIGHTS LAW AND  
COMPETITION LAW: THE RIGHT TO ACCESS TO  
MEDICINES AND CONSUMER WELFARE IN THE U.S.  
PHARMACEUTICAL SECTOR**

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ABSTRACT

*Access to essential medicines as public goods arguably forms an integral part of fundamental human rights. The current pharmaceutical industry faces serious challenges to access to medicines that result from anticompetitive business activities and structural shortcomings. Competition and human rights policies, though historically and theoretically following divergent paths, have vigorously interacted with each other, partly sharing policy goals one way or another. While such interaction occurs throughout a wide range of industries, those two policies commonly seek to safeguard and promote economic interests of consumers in the pharmaceutical industry. The right to access to medicines has a normative point of contact with consumer welfare in the competition context, inasmuch as both right and welfare can receive sustainable protection particularly when the pharmaceutical industry effectively functions in a way to ensure the public equal and full access to lower-cost and higher-quality medicines.*

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## INTRODUCTION

In these advanced times, when modern conveniences are at hand and easily and readily enjoyable, access to essential medicines as public goods arguably forms an integral part of fundamental human rights.<sup>1</sup> Indeed, access to medicines is well-founded in international law.<sup>2</sup> It is generally recognized as a first or second generation human right.<sup>3</sup> Thus, access to medicines may fall under the right to life as provided for in the International Covenant on Civil and Political Rights (ICCPR) or the right to health as set out in the International Covenant on Economic, Social and Cultural Rights (ICESCR).<sup>4</sup>

Notably, competition and human rights policies, though historically and theoretically following divergent paths, have

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1. JOO-YOUNG LEE, A HUMAN RIGHTS FRAMEWORK FOR INTELLECTUAL PROPERTY, INNOVATION AND ACCESS TO MEDICINES 204 (2015) (“The right to access to medicines is an essential element of the right to health and the right to life.”).

2. See Alicia Ely Yamin, *Not Just a Tragedy: Access to Medications as a Right Under International Law*, 21 B.U. INT’L L.J. 325, 329–51 (2003) (providing an overview of the norms relating to access to medications under international human rights law).

3. See LEE, *supra* note 1, at 204 (illustrating that medical access constitutes an integral component of “the right to health and the right to life”); see also Karel Vasak, *A 30-Year Struggle: The Sustained Efforts to Give Force of Law to the Universal Declaration of Human Rights*, UNESCO COURIER, Nov. 1977, at 29 (defining negative rights, such as the right to life as enshrined in the International Covenant on Civil and Political Rights, as first-generation human rights, and rights that require positive action, such as the right to health as enshrined in the International Covenant on Economic, Social and Cultural Rights, as second-generation human rights).

4. International Covenant on Civil and Political Rights art. 6, ¶ 1, *adopted* Dec. 19, 1966, 999 U.N.T.S. 14668 (entered into force Mar. 23, 1976); G.A. Res. 2200A (XXI), International Covenant on Economic, Social and Cultural Rights, art. 12, ¶ 1 (Dec. 16, 1966).

vigorously interacted with each other, partly sharing policy goals one way or another.<sup>5</sup> While such interaction occurs throughout a wide range of industries, those two policies commonly seek to safeguard and promote economic interests of consumers in the pharmaceutical industry.<sup>6</sup> The right to access to medicines has a normative point of contact with consumer welfare in the competition policy context, inasmuch as both right and welfare can be properly and sustainably protected, particularly when the pharmaceutical industry effectively ensures the public equal and full access to lower-cost and higher-quality medicines.<sup>7</sup>

The pharmaceutical industry, however, has encountered a surge of challenges to the right to access to medicines and to robust competition. A myriad of corporate practices have led to substantial consumer harm—resulting in a serious deterioration in access to medicines.<sup>8</sup> With this recognition, this article is aimed at unveiling and clarifying the nature of corporate responsibilities to respect the right to access to medicines and abstain from engaging in business practices to lessen competition and injure consumer welfare with particular emphasis on the U.S. pharmaceutical sector. This sector is arguably marked by the lack of pricing transparency controversially attributed to the excessive market power of pharmacy benefit managers as well as a well-known loophole in the Hatch-Waxman Act, which leads to anticompetitive abuses by means of pay-for-delay collusions. That being said, the article posits that the U.S. pharmaceutical market is not fully competitive, resulting in higher medicine prices than would prevail in a fully competitive market. First, the article examines the nature of the right to access to medicines as widely recognized in various international instruments.

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5. Cf. J. Janewa OseiTutu, *Human Development as a Core Objective of Global Intellectual Property*, 105 KY. L.J. 1, 7 (2016) (“[I]ntellectual property rights play an increasingly important role in society . . . where information and technology have tremendous social and financial value.”).

6. See, e.g., *id.* (examining the role of technology and intellectual property rights in the food, social media, and education industries).

7. See *id.* at 43 (arguing that patent protection should promote access to medicine due to the intersectionality of intellectual property protection and human development).

8. See, e.g., DUNCAN MATTHEWS & OLGA GURGULA, *THE IMPORTANCE OF COMPETITION LAW IN FACILITATING ACCESS TO MEDICINES* 11–12 (2016), [https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/5755bda2d51cd4f6f57d96af/1465236909052/Submission+to+the+UN+HLP\\_on+competition++policy\\_final%255b1%255d.pdf](https://static1.squarespace.com/static/562094dee4b0d00c1a3ef761/t/5755bda2d51cd4f6f57d96af/1465236909052/Submission+to+the+UN+HLP_on+competition++policy_final%255b1%255d.pdf) (outlining the corporate practice of defensive patenting, which interferes with the development of new medicines, thereby reducing access).

Second, the article provides an analysis of the normative interaction of access to medicines and consumer welfare in the U.S. pharmaceutical sector. Specifically, it investigates the nature of corporate responsibilities in relation to access to medicines, and subsequently discusses normative implications of corporate human rights responsibilities for safeguarding consumer welfare in the pharmaceutical sector. Consumer welfare discussions focus on how corporate practices—especially patent dispute settlements between pioneer drug manufacturers and generic drug manufacturers—and structural shortcomings in the pharmaceutical industry distort competition in the market, and thereby harm consumer welfare in relation to access to medicines.<sup>9</sup> The article concludes with policy suggestions to counterbalance the imperfections of the structure of the pharmaceutical market, which destabilizes accessibility and affordability of health care.

#### I. THE NATURE OF THE RIGHT TO ACCESS TO MEDICINES IN A NUTSHELL

Access to medicines is a fundamental human right well recognized in international law.<sup>10</sup> Access to medicines is an essential condition for the human enjoyment of sustainable life and health.<sup>11</sup> Thus, the right to access to medicines represents a legal norm that is derived from the right to life as a first generation human right and the right to health as a second generation right.<sup>12</sup> This characterization of the right to access to medicines creates State obligations to ensure public access to essential medicines both under the right to health and under the right to life.<sup>13</sup> This Section provides an overview of the nature of the human right to access to medicines as unequivocally manifested in a variety of international instruments.

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9. *See id.* at 7–8 (providing an overview of the landscape of patent dispute settlements as an anticompetitive practice that extends market exclusivity by preventing generic medicines from entering the market).

10. LEE, *supra* note 1, at 125, 134 (concluding that the right to access to medicines forms an essential element of the right to health and the right to life: two well-recognized doctrines of international law).

11. *Id.* at 121.

12. *Id.* at 204.

13. *Id.* at 125–32 (defining the responsibilities of States to ensure the right to access to medicines and the norms of international law that govern such obligations).

*A. Access to Medicines as the Right to Health*

The Constitution of the World Health Organization (WHO), adopted in 1946, provides the foundation for the right to health.<sup>14</sup> The preamble of the WHO Constitution provides that “[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.”<sup>15</sup> Article 25.1 of the Universal Declaration of Human Rights (UDHR), adopted in 1948, affirms access to medicines as an element of the right to health by laying down that “[e]veryone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.”<sup>16</sup> Furthermore, Article 12 of the ICESCR, adopted in 1966, assures “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health” and calls upon States to take appropriate steps necessary to achieve the progressive and full realization of the right of health.<sup>17</sup>

Notably, General Comment 14 of the UN Committee on Economic, Social and Cultural Rights, adopted in 2000, provides for four interrelated elements essential to the right to public health facilities, goods, and services, including essential medicines as defined by the WHO Programme on Essential Drugs.<sup>18</sup> First, functioning public health facilities, goods, and services must be available in sufficient quantities.<sup>19</sup> Second, health facilities, goods, and services must be accessible to everyone without discrimination.<sup>20</sup> This means that everyone should be able to physically access, and economically afford, health facilities, goods, and services and further

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14. CONSTITUTION OF THE WORLD HEALTH ORGANIZATION DOCUMENTS, WORLD HEALTH ORGANIZATION [WHO] 1 (2016), [http://www.who.int/governance/eb/who\\_constitution\\_en.pdf](http://www.who.int/governance/eb/who_constitution_en.pdf).

15. *Id.*

16. G.A. Res. 217 (III) A, Universal Declaration of Human Rights, art. 25, ¶ 1 (Dec. 10, 1948).

17. G.A. Res. 2200A (XXI), *supra* note 4, ¶¶ 1–2(d).

18. Comm. on Econ., Soc. & Cultural Rights, Rep. of the Econ. & Soc. Council on Its Twenty-Second, Twenty-Third and Twenty-Fourth Sessions, U.N. Doc. E/C.12/2000/21, Supp. 2, annex IV, ¶ 12 (2001). The WHO releases the model lists of essential medicines on a biennial basis since 1977. See MODEL LISTS OF ESSENTIAL MEDICINES: 20TH LIST, WORLD HEALTH ORGANIZATION [WHO] (2017), <http://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1> (detailing a core list of medicine needed for a basic health-care system).

19. Comm. on Econ., Soc. & Cultural Rights, *supra* note 18, ¶ 12(a).

20. *Id.* ¶ 12(b).

receive and impart information concerning health issues.<sup>21</sup> Third, health facilities, goods, and services must be deferential to medical ethics and culturally appropriate.<sup>22</sup> Fourth, “health facilities, goods and services must also be scientifically and medically appropriate and of good quality.”<sup>23</sup>

While numerous resolutions of the UN Human Rights Council (HRC), the former Commission on Human Rights, by and large echo the common principles set forth in the foregoing provisions, Resolution 12/24, adopted in 2009, emphasizes that access to medicines is an integral part of the right to health by reiterating that “access to medicines as one of the fundamental elements in achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”<sup>24</sup>

### B. Access to Medicines as the Right to Life

The right to life is one of the basic human rights and “is a prerequisite to the realisation of all other human rights.”<sup>25</sup> Article 3 of the UDHR and Article 6 of the ICCPR, adopted in 1966, proclaim the inherent right to life.<sup>26</sup> The right to life in a broad context is construed as including the right not to be arbitrarily deprived of one’s life by lack of access to essential medicines.<sup>27</sup> General Comment 6 of the UN Human Rights Committee, adopted in 1982, precludes the right to life from being narrowly interpreted in any event.<sup>28</sup> It recommends that “States [desirably] take all possible measures to

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21. *See id.* (explaining that everyone should have physical access to and ability to afford health care).

22. *Id.* ¶ 12(c).

23. *Id.* ¶ 12(d).

24. Human Rights Council Res. 12/24, U.N. Doc. A/HRC/RES/12/24, ¶ 7 (Oct. 12, 2009).

25. LEE, *supra* note 1, at 132.

26. G.A. Res. 217 (III) A, *supra* note 16, art. 3; International Covenant on Civil and Political Rights, *supra* note 4, art. 6, ¶ 1.

27. G.A. Res. 217 (III) A, *supra* note 16, art. 3 (declaring that “[e]veryone has the right to life, liberty and the security of person”); International Covenant on Civil and Political Rights, *supra* note 4, art. 6, ¶ 1 (declaring that “[e]very human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life”).

28. Human Rights Comm., General Comment No. 6, art. 6, The Right to Life, ¶ 5, U.N. Doc. HRI/GEN/1/Rev.9 (Vol. I) (Apr. 30, 1982).

reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics.”<sup>29</sup>

*C. Resistance to Conceptualizing Access to Medicines as a Fundamental Human Right*

In reality, the perspective conceptualizing access to medicines as a fundamental human right has often encountered external obstacles arising from misaligned interests between pharmaceutical companies and consumers. This is particularly so in cases of brand-name drugs. Branded drug manufacturers tend to prioritize a patent as a more important right, arguing that the protection of a patent is imperative to ensure that they enjoy a sufficient economic incentive for new drug research and development.<sup>30</sup> Indeed, a patent may serve as an effective drive for pharmaceutical innovation, and the properly regulated patent enforcement system may contribute to the promotion of access to medicines from an institutional perspective.<sup>31</sup> However, given that in practice, the business judgment of pharmaceutical companies is more likely driven by a profit motive, such incentive-based justification for deferring to intellectual property rights with more weight and de-categorizing access to medicines from a set of fundamental human rights may be deemed farfetched and unwarranted.<sup>32</sup> In general, pharmaceutical companies are highly profit-oriented so that they have often engaged in anticompetitive patent practices in which they abuse the patent-conferred right to exclude others from commercial exploitation of the invention.<sup>33</sup> In fact, patent-holding manufacturers are in a position to exert monopoly power during the valid patent term by overcharging drug prices.<sup>34</sup>

Moreover, pharmaceutical companies tend to overstate the costs of drug research and development to justify the need for higher economic incentives and appropriate them for developing such drugs as used to treat an illness that is less life-threatening but more

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29. *Id.*

30. DEBRA L. DELAET, *THE GLOBAL STRUGGLE FOR HUMAN RIGHTS: UNIVERSAL PRINCIPLES IN WORLD POLITICS* 113 (2d ed. 2014).

31. *Id.*

32. *Id.* at 114.

33. *Id.*

34. *Id.*

lucrative.<sup>35</sup> Hence, the rationale behind pharmaceutical companies' resistance to the perspective advocating access to medicines as a fundamental human right overall seems ill-founded and, therefore, unable to be vindicated.

## II. NORMATIVE INTERACTION OF ACCESS TO MEDICINES AND CONSUMER WELFARE IN THE PHARMACEUTICAL SECTOR

Facilitating access to medicines as the right to health or life warrants the vigorous implementation of the competition policy in the pharmaceutical sector with a view to protect consumer welfare.<sup>36</sup> The full realization of access to medicines may be assumedly conducive to the maximization of consumer welfare in the pharmaceutical sector.<sup>37</sup> The better access consumers have to lower-cost medicines of like quality, the more likely consumer savings are to increase.<sup>38</sup> General Comment 14 makes it clear that States are obligated to protect the right to health by means of taking all necessary measures to safeguard consumers against human rights infringements by third parties.<sup>39</sup> These measures include, *inter alia*, preventing pharmaceutical companies from engaging in practices detrimental to health.<sup>40</sup> Apart from States' obligations, General Comment 14 outlines the significance of human rights responsibilities of non-State actors.<sup>41</sup> It states that all members of society, including individuals and the private business sector, are accountable for the realization of the right to health.<sup>42</sup> This section examines the nature of corporate responsibilities in relation to the right to access to medicines and their normative implications for

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35. *Id.*

36. U.N. Dev. Programme [UNDP], Issue Brief on Using Competition Law to Promote Access to Medicines and Related Health Technologies in Low- and Middle-Income Countries, at 7, U.N. Doc. Issue Brief (Aug. 2017).

37. *See generally* LEE, *supra* note 1 (examining various frameworks that could help reach full realization of access to medicines and the benefits consumers would incur within the pharmaceutical market from such access).

38. *See* FTC v. Actavis, Inc., 570 U.S. 136, 154 (2013) (discussing how increased competition leads to lower priced medication that directly benefits consumers).

39. Comm. on Econ., Soc. & Cultural Rights, *supra* note 18, ¶ 51.

40. *See id.* (noting that these necessary measures include stopping pharmaceutical companies from engaging in practices that are harmful to health).

41. *See id.* ¶ 12(b) (adding that General Comment 14 outlines the importance of non-State actors' responsibility to human rights).

42. *Id.* ¶ 42.



safeguarding consumer welfare in the pharmaceutical sector, which underpins competition law and policy.

*A. The Nature of Corporate Responsibilities in Relation to Access to Medicines*

In 2008, John Ruggie, the UN Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, proposed the human rights framework of *Protect, Respect and Remedy*, comprised of three core principles: the State duty to protect against human rights abuses by non-State actors, including businesses; the corporate responsibility to respect human rights; and access to appropriate and effective remedies.<sup>43</sup> A central notion underlying this framework is that while it is incumbent on both States and corporations to defer to human rights, their human rights obligations are by nature, distinct.<sup>44</sup> Ruggie notes that “as economic actors, companies have unique responsibilities.”<sup>45</sup> “While corporations may be considered organs of society, they are specialized economic organs, not democratic public interest institutions. As such, their responsibilities cannot and should not simply mirror the duties of States.”<sup>46</sup>

He characterizes the corporate responsibility to respect human rights as the “baseline responsibility,” that is “the baseline expectation for all companies in all situations.”<sup>47</sup> He interprets the responsibility to respect rights as “essentially mean[ing] not to infringe on the rights of others – put simply, to do no harm.”<sup>48</sup> This responsibility requires companies to maintain due diligence by complying with national laws and managing the risk of human rights infringement.<sup>49</sup> The due diligence expected of companies is determined “by the context in which a company is operating, its

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43. John Ruggie (Special Representative on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises), *Protect, Respect and Remedy: A Framework for Business and Human Rights*, ¶¶ 18, 23, 26, U.N. Doc. A/HRC/8/5 (Apr. 7, 2008) [hereinafter Ruggie Rep. 2008].

44. Suerie Moon, *Respecting the Right to Access to Medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry*, 15 HEALTH & HUM. RTS. J. 32, 35 (2013).

45. Ruggie Rep. 2008, *supra* note 43, ¶ 6.

46. *Id.* ¶ 53 (internal quotations omitted).

47. *Id.* ¶¶ 24, 54.

48. *Id.* ¶ 24.

49. *Id.* ¶ 25.

activities, and the relationships associated with those activities.”<sup>50</sup> But he conceives additional corporate responsibilities arising “where [companies] perform certain public functions, or because they have undertaken additional commitments voluntarily.”<sup>51</sup>

In his 2011 report, Ruggie further developed the *Protect, Respect and Remedy* framework by advancing the UN Guiding Principles on Business and Human Rights, which later the HRC unanimously endorsed in 2011—Resolution 17/4.<sup>52</sup> The HRC, for the first time, emphasized the importance of establishing “a global standard for preventing and addressing the risk of adverse impacts on human rights linked to business activity.”<sup>53</sup> It recognized the Guiding Principles as playing a role in the authoritative global guidance “that will contribute to enhancing standards and practices with regard to business and human rights, and thereby contribute to a socially sustainable globalization, without foreclosing any other long-term development, including further enhancement of standards.”<sup>54</sup> The Ruggie Principles elaborate how the *Protect, Respect and Remedy* Framework applies to corporations and provide recommendations for the Framework’s implementation.<sup>55</sup> A set of guiding principles ensure that corporations do not violate human rights in the course of their transactions and provide appropriate redress when they encroach on those rights.<sup>56</sup>

The Ruggie Principles as general standards, however, set out horizontal human rights commitments that apply to all business activities in all industrial sectors.<sup>57</sup> Hence, the Ruggie Principles

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50. *Id.*

51. *Id.* ¶ 24.

52. John Ruggie (Special Representative on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises), *Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework*, U.N. Doc. A/HRC/17/31, annex (Mar. 21, 2011) [hereinafter Ruggie Rep. 2011]; Human Rights Council Res. 17/4, U.N. Doc. A/HRC/RES/17/4, ¶ 1 (July 6, 2011) [hereinafter H.R.C. Res. 17/4].

53. U.N. Human Rights Off. of the High Comm’r, Special Representative of the Secretary-General on Human Rights and Transnational Corporations and Other Business Enterprises, <http://www.ohchr.org/EN/Issues/Business/Pages/SRSGTransCorpIndex.aspx> (last visited Nov. 25, 2018).

54. H.R.C. Res. 17/4, *supra* note 52, ¶ 4; U.N. News, U.N. Human Rights Council Endorses Principles to Ensure Businesses Respect Human Rights (June 16, 2011), <https://news.un.org/en/story/2011/06/378662>.

55. Ruggie Rep. 2011, *supra* note 52, annex.

56. *Id.*

57. Joo-Young Lee & Paul Hunt, *Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines*, 40 J.L. MED. & ETHICS 220, 224 (2012).

themselves do not provide clear normative implications for the pharmaceutical sector. The 2008 Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines as presented by UN Special Rapporteur on the Right to Health, Paul Hunt may serve as the useful supplement to the Ruggie Principles. The Hunt Guidelines articulate specific norms regarding corporate responsibilities in the pharmaceutical sector.<sup>58</sup> They affirm the notion of General Comment 14: that while the ICESCR provides for the progressive realization of the right to health, States are obligated to immediately make essential medicines available.<sup>59</sup> According to the Hunt Guidelines, the policies and practices of pharmaceutical companies in relation to pricing, intellectual property, research and development, clinical trials, and marketing may have negative effects on access to medicines by “constitut[ing] obstacles to States’ implementation of the right to the highest attainable standard of health and, in particular, their endeavours to enhance access to medicines.”<sup>60</sup>

In his 2009 report, Hunt streamlined the structure of the right-to-health responsibilities of pharmaceutical companies, including innovator, generic, and biotechnology companies.<sup>61</sup> He noted that all pharmaceutical companies assume the common corporate responsibility to ensure the public fair and full access to medicines in terms of availability, accessibility, acceptability, quality, transparency, and monitoring and accountability, whereas patent-holding pharmaceutical companies have distinctively special obligations since “the ‘social expectations’ of a company holding a patent on a life-saving medicine are different from a pharmaceutical company that does not hold such a patent.”<sup>62</sup>

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58. Paul Hunt (Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health), *The Right to Health*, ¶¶ 26, 29–30, U.N. Doc. A/63/263 (Aug. 11, 2008) [hereinafter Hunt Rep. 2008].

59. Comm. on Econ., Soc. & Cultural Rights, *supra* note 18, ¶ 30; Moon, *supra* note 44, at 36.

60. Hunt Rep. 2008, *supra* note 58, ¶ 23.

61. Paul Hunt (Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health), *Promotion and Protection of all Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development*, ¶¶ 5, 8, 20, U.N. Doc. A/11/12/Add.2, annex (May 5, 2009) [hereinafter Hunt Rep. 2009].

62. *Id.* ¶¶ 18, 36. (“Society has legitimate expectations of a company holding the patent on a life-saving medicine. In relation to such a patent, the right-to-health framework helps to clarify what these terms, and expectations, are. Because of its critical social function, a patent on a life-saving medicine places important right-to-health responsibilities on the patent holder. These responsibilities are

Although the Ruggie Principles and Hunt Guidelines have different focal points for the right-to-health responsibilities, the underlying notions in both works are not at much variance with each other, but they rather complement each other. A close look at the Hunt Guidelines through the lens of the Ruggie Principles provides meaningful insight into the nature of corporate responsibilities in relation to access to medicines. Thus, all pharmaceutical companies, whether generic or brand-name drug manufacturers, have the baseline corporate responsibility to respect the right to access to medicines, which is predicated upon “social expectations – as part of what is sometimes called a company’s social licence to operate.”<sup>63</sup> But patent-holding, brand-name drug manufacturers have additional responsibilities beyond the corporate responsibility outlined in Ruggie’s *Protect, Respect and Remedy* Framework because these manufactures perform public functions by researching and developing innovative drugs that are crucial and essential to the human enjoyment of sustainable health and life.<sup>64</sup> But it should be noted that additional responsibilities cannot substitute for the corporate responsibility to respect.<sup>65</sup> Thus, pharmaceutical companies that have engaged in business practices thwarting legitimate patent and competition policies “cannot compensate for human rights harm by performing good deeds elsewhere,” such as offering a voluntary price discount on their newly patented drugs.<sup>66</sup>

*B. Normative Implications of Corporate Human Rights  
Responsibilities for Safeguarding Consumer Welfare in the  
Pharmaceutical Sector*

Access to medicines is an essential element of consumer welfare protection in the pharmaceutical industry.<sup>67</sup> The human rights policy to safeguard access to medicines well complements the competition policy to protect the economic interest of consumers in seeking to

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reinforced when the patented life-saving medicine benefited from research and development undertaken in publicly funded laboratories.”).

63. Ruggie Rep. 2008, *supra* note 43, ¶ 54.

64. Moon, *supra* note 44, at 37.

65. *Id.* at 35.

66. *Id.* at 37.

67. See *supra* Parts I & I.A (outlining the nature of the human right to access to medicines and explaining that this responsibility applies to all pharmaceutical companies).

obtain cheaper, generic versions of patented pioneer drug products.<sup>68</sup> These two policies pursue a common goal of enhancing economic and social welfare of consumers in need of essential medicines.<sup>69</sup> However, a close look at the pharmaceutical industry reveals that the consumer welfare policy often tends to be impeded by anticompetitive practices by pharmaceutical companies, sometimes in collusion with other market participants in the pharmaceutical supply chain.<sup>70</sup> For example, a certain collusive practice between a patent-holding branded manufacturer and a generic manufacturer may constitute anticompetitive joint conduct that substantially harms consumers by restricting their access to cheaper medicines.<sup>71</sup> As noted below, in this case, consumer harm occurs where a patent-holding branded manufacturer pays a generic manufacturer to delay market entry, which forecloses robust generic competition.<sup>72</sup>

Also, pharmaceutical companies may engage in horizontal conspiracies with market participants to fix prices and allocate markets for their drugs.<sup>73</sup> The collusion between pharmaceutical companies and so-called pharmacy benefit managers (PBMs) is precipitated by the strong anticompetitive incentive to buy off the pivotal and dominant role of PBMs in the pharmaceutical supply chain, which has been facilitated by structural shortcomings of the pharmaceutical industry, as proven by lack of transparency leading to the asymmetry of price information.<sup>74</sup> A close look at the full spectrum of the PBM-centric distribution chain clearly vindicates that they work as a negative force toward realizing access to medicines as human rights by exerting a substantial leverage over the pricing dynamics that are richly rewarding themselves and pharmaceutical

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68. *See supra* notes 36–38 and accompanying text (explaining that competition policy complements human rights policy by supporting consumer access to low-cost medicines).

69. *See supra* notes 63–66 and accompanying text (discussing the interaction between the corporate responsibility to respect and competition policy).

70. *See infra* notes 89–90, 147–49 and accompanying text (introducing anticompetitive practices within the U.S. pharmaceutical industry and potential collusive practices in the pharmaceutical supply chain).

71. *See infra* notes 89–100 and accompanying text (describing pay-for-delay settlements in the U.S. and how they can harm consumer access to affordable medicines).

72. *See infra* notes 106–07 and accompanying text (summarizing the European Commission's findings that pay-for-delay settlements reduce industry competition and harm consumers).

73. *See infra* notes 139–49 and accompanying text (describing how PBMs collude with other pharmaceutical supply chain members to control prices and markets).

74. *See infra* notes 125, 139–49 and accompanying text (highlighting PBMs' pivotal role in the industry and explaining their collusive practices).

companies in collusion, *inter alia* patent holding branded firms which the Hunt Guidelines quite appropriately target for special responsibilities.<sup>75</sup> In sum, anticompetitive company behavior coupled with structural drawbacks pervasive in the industry results in market failure that eventually harms consumers, hindering them from accessing essential medicines.<sup>76</sup>

Therefore, while the regulatory overhaul compelling corporate responsibilities to respect the right to access to medicines may significantly contribute to the resolution of social and economic inequality in people's pursuing the right to health, it cannot exclusively and fully settle this human rights infringement concern.<sup>77</sup> The proper understanding of the nature of the right to access to medicines and its interaction with the competition policy centering on consumer welfare warrants the introduction of both behavioral and structural remedies as a long-term and fundamental solution.<sup>78</sup> The following discussions profoundly unveil the mechanics of how certain corporate behavior and structural shortcomings in the pharmaceutical industry seriously impair the right to access to medicines and consumer welfare.

### 1. Corporate Behavior Against Access to Medicines and Consumer Welfare: Pay-for-Delay Patent Dispute Settlements

Competition law and policy seek to establish a level playing field in the market and thereby protect consumer welfare.<sup>79</sup> While the regulatory reach of competition law extends over a wide range of industries, including agriculture, communication, energy, financial institutions and markets, health care, insurance, organized labor, sport, and transportation, the regulatory reach especially came into

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75. See *infra* notes 125–66 and accompanying text (analyzing the pivotal role of PBMs in the pharmaceutical supply process).

76. See *infra* notes 160–66 and accompanying text (explaining that both structural and behavioral shortcomings in the pharmaceutical industry harm consumers).

77. See *infra* notes 160–66 and accompanying text (emphasizing the need for both structural and behavioral remedies to reduce PBMs' monopoly power).

78. See *infra* notes 160–66 and accompanying text (demonstrating the effectiveness of behavioral and structural remedies).

79. See 2 ABA SECTION OF ANTITRUST LAW, ANTITRUST LAW DEVELOPMENTS 1091 (8th ed. 2017) (demonstrating that Congress enacted the Hatch-Waxman Act to allow generic drug manufacturers to compete with branded drug manufacturers, inevitably driving down drug prices for the consumers).

vivid and dynamic play in the pharmaceutical sector in 1984. The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, was enacted in 1984 to strike a balance between conflicting interests between pioneer drug manufacturers, and generic drug manufacturers and consumers that benefit from increased generic competition in the market.<sup>80</sup> In representing this hard-fought compromise, the Hatch-Waxman Act, on the one hand, provides incentives for brand-name drug manufacturers to make the investments necessary to research and develop new drug products by allowing them to enjoy longer effective patent life, which encourages them to assume the increased costs of research and development.<sup>81</sup>

On the other hand, the Act streamlines the procedure for obtaining U.S. Food and Drug Administration (FDA) approval for generic drugs (bioequivalents of brand-name, or innovator, drugs) that do not infringe valid patents.<sup>82</sup> Thus, the Act establishes a regulatory scheme that enables generic manufacturers to challenge the patents held by branded manufacturers to bring their cheaper generics to market as quickly as possible.<sup>83</sup> Pursuant to the regulatory process, a patent-holding branded manufacturer must file a New Drug Application for FDA approval of their pioneer drug.<sup>84</sup> “A would-be competitor seeking to market a generic bioequivalent must submit an Abbreviated New Drug Application (ANDA) for FDA approval.”<sup>85</sup> The ANDA filer seeking to market before the patent expires must certify that the relevant patent is invalid or that the generic drug will not infringe the patent.<sup>86</sup> If a patent holder brings a patent infringement action against the potential generic entrant in a timely manner, the FDA approval of the generic drug is stayed for 30 months, which means the patent holder obtains an automatic preliminary injunction against the sale of the competing generics.<sup>87</sup>

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80. *See id.* at 1090 (describing the background behind the Hatch-Waxman Act’s enactment to resolve conflicts between branded drug manufacturers and generic drug manufacturers).

81. ABA SECTION OF ANTITRUST LAW, PHARMACEUTICAL INDUSTRY ANTITRUST HANDBOOK 81 (2009).

82. 2 ABA SECTION OF ANTITRUST LAW, *supra* note 79, at 1471.

83. *See id.* (describing how the Hatch-Waxman Act gives generic drug manufacturers ways to market their drugs as quickly as possible).

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.* at 1090–91.

However, the first ANDA filer retains the right to market its generic versions without competition from other generics for a 180-day period of exclusivity beginning on the date of the first commercial marketing.<sup>88</sup>

Problematically, branded manufacturers have sought a way to manipulate this Hatch-Waxman regulatory mechanism by engaging in various types of patent practices.<sup>89</sup> Among other things, they have settled patent infringement disputes with generic manufacturers in anticompetitive ways, including posing contractual limitations on generic manufacturers in return for offering inducements to accept those limitations.<sup>90</sup> Thus, branded manufacturers unsure of prevailing in patent infringement litigation tend to pay generic competitors to stay out of the market for a negotiated term.<sup>91</sup> Large payments may serve as a strong incentive for generic competitors to delay market entry.<sup>92</sup> Horizontal agreements of this kind are referred to as “reverse payment” or “pay-for-delay” settlements.<sup>93</sup>

Patent dispute settlements that simply authorize a patent holder to practice a patent in exchange for a specified royalty do not create antitrust concerns.<sup>94</sup> Pay-for-delay settlements, however, are subject to antitrust scrutiny because they aim to allocate markets and thwart competition to the detriment of other bona fide generic competitors and consumers.<sup>95</sup> Where the first ANDA-filing generic challenger does not enter the market, 180-day exclusivity is not triggered from the outset, which blocks the entry of other generic competitors waiting in the wings.<sup>96</sup> Furthermore, consumers are locked between the brand name drug and the generic version of the successful ANDA filer, and forfeit the right to access to other, cheaper generics.<sup>97</sup> Therefore, pay-for-delay settlements are simply characterized as

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88. *Id.* at 1472.

89. *See id.* at 1091 (demonstrating how branded drug manufacturers negotiate deals with generic drug manufacturers to get around the Hatch-Waxman Act).

90. *See id.* (describing how branded drug manufacturers settle with generic drug manufacturers to impose contractual limitations of delaying sales of generic drugs).

91. *Id.*

92. *Id.*

93. *Id.*

94. HERBERT HOVENKAMP, FEDERAL ANTITRUST POLICY: THE LAW OF COMPETITION AND ITS PRACTICE 326 (5th ed. 2016).

95. *Id.*

96. *Id.* at 326–27.

97. *See id.* at 327 (describing effective bilateral monopolies arising between ANDA filers and brand-name drug manufacturers).



exclusion arrangements and constitute a *per se* antitrust violation.<sup>98</sup> Notably, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) contributed to mitigating regulatory concerns that statutory 180-day exclusivity was vulnerable to arbitrary manipulation through pay-for-delay settlements.<sup>99</sup> The MMA set forth, *inter alia*, the exclusivity forfeiture provision, granting a certain period of time for the generic ANDA filer to begin marketing its generics, or otherwise forfeit exclusivity.<sup>100</sup>

The MMA's significant impact, notwithstanding antitrust concerns over pay-for-delay settlements, persists because they, though less incentivized, may occur outside the Hatch-Waxman context.<sup>101</sup> Indeed, the European Union does not have a regulatory system equivalent to the Hatch-Waxman Act, which provides a framework for patent dispute settlements between pioneers and generics.<sup>102</sup> Pay-for-delay settlements, however, have been perceived as a critical antitrust challenge to the pharmaceutical sector in the European Union.<sup>103</sup>

The European Commission carried out an extensive sector inquiry to investigate the reasons for lack of competition in Europe's market for human medicines.<sup>104</sup> In its final report issued in 2009, the Commission found competition in the pharmaceutical market not properly functional because of structural shortcomings requiring lengthy market authorization and, more importantly, corporate

98. *Id.* at 326.

99. See Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, § 1102(a)(1), 117 Stat. 2066, 2458–59 (2003) (defining an agreement with another applicant, the listed drug application holder, or a patent holder as an event that forfeits the 180-day exclusivity period).

100. 2 ABA SECTION OF ANTITRUST LAW, *supra* note 79, at 1472.

101. See, e.g., Damien Geradin, Douglas H. Ginsburg & Graham Safty, *Reverse Settlements in the European Union and the United States*, in COMPETITION AND PATENT LAW IN THE PHARMACEUTICAL SECTOR: AN INTERNATIONAL PERSPECTIVE 125, 137 (Giovanni Pitruzzella & Gabriella Muscolo eds., 2016) (discussing an example where reverse settlements occur outside of the Hatch-Waxman context).

102. *Id.*

103. *Pharmaceuticals & Health Services: Antitrust*, EUR. COMM'N: DIRECTORATE GEN. FOR COMPETITION, [http://ec.europa.eu/competition/sectors/pharmaceuticals/antitrust\\_en.html](http://ec.europa.eu/competition/sectors/pharmaceuticals/antitrust_en.html) (last updated Mar. 20, 2017).

104. DIRECTORATE GEN. FOR COMPETITION, EUR. COMM'N, FINAL REP. ON THE PHARMACEUTICAL SECTOR INQUIRY, ¶ 14 (July 8, 2009), [http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff\\_working\\_paper\\_part1.pdf](http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf).

practices typified by pay-for-delay settlements.<sup>105</sup> The Commission stated that through pay-for-delay settlements a branded manufacturer sought to lessen competitive pressure from generic drugs simply by sharing its monopoly profits with potential generic competitors.<sup>106</sup> The Commission concluded that those settlements constituted anticompetitive collusion causing substantial consumer harm.<sup>107</sup> The Commission has adopted a number of decisions against pharmaceutical companies in pay-for-delay cases including *Lundbeck*, *Servier*, and *Fentanyl*.<sup>108</sup>

As the U.S. Federal Courts of Appeals were divided with respect to the legal approach for evaluating pay-for-delay settlements, the theoretical and normative controversy surrounding these anticompetitive settlements remained unsolved, which invited heated discussions from antitrust scholars and practitioners.<sup>109</sup> It was 2013 when this controversy was eventually resolved by the highest authority. The Supreme Court, in its landmark decision *FTC v. Actavis*, held that the legality of pay-for-delay settlements should be examined under the standard “rule-of-reason” analysis, which requires a detailed factual inquiry into the nature and the effect of the practice concerned and market circumstances.<sup>110</sup>

The *Actavis* Court found that pay-for-delay settlements were “to maintain supracompetitive [profits] to be shared among the patentee and the challenger rather than face what might have been a competitive market—the very anticompetitive consequence that underlies the claim of antitrust unlawfulness.”<sup>111</sup> The *Actavis* Court contributed to resolving the circuit split by providing a well-marked roadmap by which factfinders could properly navigate in investigating the legality of pay-for-delay settlements.<sup>112</sup> The Court, however, declined to establish the specific framework for the proper rule-of-reason analysis, and mandated the lower courts to “structure

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105. *Id.* ¶¶ 1365, 1372; Eur. Comm’n, Memo on Antitrust: Commission Enforcement Action in Pharmaceutical Sector Following Sector Inquiry, at 1, U.N. Doc. MEMO/13/56 (Jan. 31, 2013) [hereinafter Eur. Comm’n Memo 2013].

106. *Id.*

107. *Id.*

108. *Id.* at 2.

109. *See infra* notes 110–13 and accompanying text (discussing a split court decision in regard to pay-for-delay settlements and complex unresolved issues).

110. *FTC v. Actavis, Inc.*, 570 U.S. 136, 158–59 (2013).

111. *Id.* at 157.

112. *Id.* at 153–58.

antitrust litigation so as to avoid, on the one hand, the use of antitrust theories too abbreviated to permit proper analysis, and, on the other, consideration of every possible fact or theory irrespective of the minimal light it may shed on the basic question.”<sup>113</sup> Hence, the Court’s finding left more complex issues behind for further discussions about how the rule-of-reason should be applied in the pay-for-delay context on a case-by-case basis.

*Actavis* merits special attention, particularly in that the Court took the consumer welfare approach when examining the legality of pay-for-delay settlements.<sup>114</sup> In other words, the Court structured an antitrust analysis by answering the cardinal question of whether the settlements at issue create, maintain, or strengthen the patentee’s monopoly to the detriment of consumers.<sup>115</sup> *Actavis* holds that the anticompetitive nature and effects of pay-for-delay settlements are attributed to their adverse impacts on competition in terms of consumer welfare, not total welfare.<sup>116</sup> By contrast, the total welfare approach examines *all* welfare effects in the market.<sup>117</sup> Thus, a bright line exists between the consumer welfare approach and the total welfare approach.<sup>118</sup> Where pay-for-delay settlements harm consumers by increasing drug prices, but benefit producers by lowering manufacturing costs, the consumer welfare approach may identify consumer loss as a degree of the anticompetitive effect of settlements, while the total welfare approach may generate the net competitive effect by having consumer loss offset by producer profits.<sup>119</sup>

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113. *Id.* at 159–60.

114. *See id.* at 154 (observing that pay-for-delay settlements benefit the patentees and the generic challengers while hurting consumers). Likewise, in his dissenting opinion, Chief Justice Roberts states that “[t]he point of antitrust law is to encourage competitive markets to promote consumer welfare.” *Id.* at 161 (Roberts, C.J., dissenting).

115. *See id.* at 154 (holding that large, unjustified reverse payments seeking to bring about anticompetitive consequences may be subject to antitrust liability).

116. *See id.* (emphasizing how settlements acting as “payment[s] in return for staying out of the market” benefit the patentee and the generic challenger to the detriment of consumers).

117. *See id.* (stating that pay-for-delay settlements benefit the parties by producing monopoly returns for the branded form that the generic shares, which otherwise would flow to consumers but for the settlements).

118. *See id.* (focusing on the detrimental effects that unjustified reverse settlements’ anticompetitive consequences cause consumers in deciding potential antitrust liability).

119. Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court’s Actavis Decision*, 15 MINN. J.L. SCI. & TECH. 3, 7 (2014); Aron Edlin, Scott Hemphill, Herbert Hovenkamp & Carl Shapiro, *Activating Actavis*, 28 ANTITRUST 16, 17 (2013).

Notably, although a branded manufacturer and a generic manufacturer are both subject to antitrust liability of a similar nature for pay-for-delay settlements under competition law, they may have different human rights responsibilities.<sup>120</sup> Both branded and generic manufacturers have the common baseline responsibility to respect access to medicines under the social expectation as laid down in the Ruggie Principles.<sup>121</sup> As previously noted, the Hunt Guidelines describe this basic corporate responsibility as maintaining due diligence by properly assuring the public that medicines are available, accessible, acceptable, of good quality, and all business activities in relation to access to medicines are transparent.<sup>122</sup> On another note, unlike a generic manufacturer, a branded manufacturer holding a patent on an essential medicine has additional responsibilities to safeguard the right to access to medicines because it performs a public function mandated by society for the public health by researching and developing innovative drugs.<sup>123</sup> Therefore, while the competition policy condemns pay-for-delay settlements for injuring consumer welfare and imposes antitrust responsibilities of the same nature on branded and generic manufacturers, the human rights policy may treat them differently by making a branded manufacturer assume additional responsibilities.

## 2. Structural Shortcoming Against Access to Medicines and Consumer Welfare: Functional Abuse of the Pivotal Role of PBMs in the Pharmaceutical Supply Process

The pharmaceutical supply market where the prescription drugs are distributed and dispensed to patients is a highly complex structure mainly attributed to the existence of multiplayers who operate at a different level of the supply chain, but interact with one another.<sup>124</sup>

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120. See Hunt Rep. 2008, *supra* note 58, annex (discussing pharmaceutical companies' various human rights responsibilities).

121. Hunt Rep. 2009, *supra* note 61, ¶ 17.

122. *Id.* ¶¶ 17, 24, 32.

123. *Id.* ¶¶ 34–35.

124. See Org. for Econ. Coop. & Dev. [OECD], Competition Comm., *Competition Issues in the Distribution of Pharmaceuticals*, Contribution from the United States, ¶ 4, OECD Doc. DAF/COMP/GF/WD(2014)43 (Feb. 10, 2014) [hereinafter OECD Competition Comm.], [https://www.ftc.gov/system/files/attachments/us-submissions-occd-other-international-competition-fora/pharmaceuticals\\_us\\_occd.pdf](https://www.ftc.gov/system/files/attachments/us-submissions-occd-other-international-competition-fora/pharmaceuticals_us_occd.pdf) (describing the complex structure of the pharmaceutical distribution system).

Among other things, the PBMs, in particular, play pivotal, extensive roles as intermediaries by vigorously intervening in nearly every stage of the process.<sup>125</sup>

PBMs reportedly administer prescription drug benefits for 266 million insured people in the U.S.<sup>126</sup> The market concentration in the PBM industry is so high that the three largest PBMs—Express Scripts, CVS Health, and OptumRx—administer prescriptions for over 180 million people, cover over 80 percent of the market share, and earn annual record revenues amounting to \$200 billion.<sup>127</sup> The key services and intermediary roles of PBMs are mainly described as negotiating drug prices with manufacturers, creating formularies where prescription drugs are listed by cost and quality, providing claims adjudication, controlling generic substitution and therapeutic interchange, providing mail-order pharmacy services, and establishing pharmacy networks.<sup>128</sup>

In more detailed description, PBMs are retained by health insurers and provide them with access to an established network of pharmacies, including mail-order pharmacies, and certain formulary services; all of which permit health insurers' members (customers) to obtain drugs at established prices.<sup>129</sup> Thus, PBMs represent multiple health insurers and “allow for collective reimbursement rate negotiations, avoiding the unworkable situation where each [insurer] would need to negotiate separately with each pharmacy.”<sup>130</sup> PBMs also contract with retail pharmacies for reimbursement when

125. See *Pharm. Care Mgmt. Ass'n v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005) (stating that PBMs serve as intermediaries between pharmaceutical manufacturers, pharmacies, and health benefit providers).

126. Visante, *Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers*, PHARMACEUTICAL CARE MGMT. ASS'N. 1, 3 (Feb. 2016), <https://www.pcmagnet.org/wp-content/uploads/2016/08/visante-pbm-savings-feb-2016.pdf>.

127. Complaint & Demand for Jury Trial ¶¶ 5–6, *Boss v. CVS Health Corp.*, No. 3:17-cv-01823-BRM-LHG (D.N.J. Mar. 17, 2017).

128. OECD Competition Comm., *supra* note 124, ¶ 7; KAISER FAMILY FOUND., FOLLOW THE PILL: UNDERSTANDING THE U.S. COMMERCIAL PHARMACEUTICAL SUPPLY CHAIN 14–15 (2005); U.S. FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, IMPROVING HEALTH CARE: A DOSE OF COMPETITION 11 (2004), <https://www.ftc.gov/sites/default/files/documents/reports/improving-health-care-dose-competition-report-federal-trade-commission-and-department-justice/040723healthcarerpt.pdf>.

129. *Pharm. Care Mgmt. Ass'n v. Rowe*, No. Civ. 03-153-B-H, 2005 WL 757608, at \*1 (D. Me. Feb. 2, 2005).

130. Memorandum at 4, *In re Pharmacy Benefit Managers Antitrust Litig.*, No. 2:06-md-01782-CDJ (E.D. Pa. Jan. 18, 2017).

prescriptions are filled for plan members.<sup>131</sup> This service is referred to as claim adjudication.<sup>132</sup> The dynamic process of pharmacy reimbursement is as follows:

All PBMs use a real-time, point-of-sale system linked to retail and mail-order pharmacies and distribution centers. This process provides verification of coverage, formulary restrictions, drug interactions, and individual co-pay information. This process also provides prescription drug information back at the PBM data warehouse, where it can be used for customized reporting and quality-focused clinical and intervention programs.<sup>133</sup>

When a consumer fills a prescription at a local pharmacy, complex computer processing interactions between the pharmacy and a PBM occur.<sup>134</sup> An FTC study describes these interactions as follows:

[T]he pharmacy transmits the insurance coverage information to a PBM, which verifies the insurance and determines if the consumer's insurance plan covers the prescribed drug. If so, the PBM determines three amounts: (a) the consumer's copayment; (b) how much the PBM will reimburse the pharmacy to dispense the drug; and (c) how much the PBM will bill the [health insurer] for the transaction. The PBM transmits the first two items (the consumer copayment and the pharmacy reimbursement amount) back to the pharmacy, logs the payment information on its computer system, and transmits the billing information to the [health insurer]. The [health insurer] then remits payment to the PBM, which then pays the local pharmacy. This process, known as

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131. See KAISER FAMILY FOUND., *supra* note 128, at 14 (outlining PBM services regarding pharmacy network and reduced reimbursement rates).

132. *Id.* at 15.

133. *Id.*

134. *Id.*

claims adjudication, is handled electronically through the PBMs' sophisticated networks of databases.<sup>135</sup>

Furthermore, PBMs negotiate deeper volume discounts and rebates with manufacturers by pooling the prescription drug purchasing power of a substantial number of health-benefit providers.<sup>136</sup> This pooling not only provides PBMs' customers with savings on prescription drugs and other pharmaceutical products, but also gives PBMs "tremendous market power to demand concessions from the manufacturers."<sup>137</sup> As such, a variety of services offered by PBMs are designed to work to achieve market efficiencies and savings for health insurers, pharmacies, and consumers.<sup>138</sup>

Problematically, structural shortcomings of the pharmaceutical sector arise mainly from the fact that while each market entity has different price information, PBMs enjoy exclusive accessibility to full price information.<sup>139</sup> This is particularly because other market entities, including pharmaceutical companies, are completely locked in the far-reaching roles of PBMs; therefore, they are strongly incentivized to contract with PBMs for their services, simply with a view to avoid falling behind in robust competition with other rivals in the same market.<sup>140</sup> This pattern of behavior eventually makes PBMs privy to all the price information that remains undisclosed to the public.<sup>141</sup> As the flow of price information converges on PBMs, they can have an overwhelming ascendancy over other entities in the

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135. FED. TRADE COMM'N, PHARMACY BENEFIT MANAGERS: OWNERSHIP OF MAIL-ORDER PHARMACIES 1–2 (2005) [hereinafter U.S. FED. TRADE COMM'N Rep. 2005], [https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitpt\\_0.pdf](https://www.ftc.gov/sites/default/files/documents/reports/pharmacy-benefit-managers-ownership-mail-order-pharmacies-federal-trade-commission-report/050906pharmbenefitpt_0.pdf); see also Complaint ¶ 28, Klein v. Prime Therapeutics, LLC, No. 0:17-cv-01884-PAM-HB (D. Minn. June 2, 2017) (describing the process, between a PBM and a pharmacy, that follows a plan member presenting a prescription).

136. Pharm. Care Mgmt. Ass'n v. Rowe, No. Civ. 03-153-B-H, 2005 WL 757608, at \*1 (D. Me. Feb. 2, 2005).

137. Pharm. Care Mgmt. Ass'n v. Rowe, 429 F.3d 294, 298 (1st Cir. 2005).

138. *In re Pharmacy Benefit Managers Antitrust Litig.*, 582 F.3d 432, 434 (3d Cir. 2009).

139. *Cf. Visante*, *supra* note 126, at 4 (explaining that PBMs negotiate drug prices with drug manufacturers and retail pharmacies, providing PBMs with full price information on drugs).

140. *Cf. id.* (demonstrating that PBMs create market incentives by providing specific drugs to health benefit providers by negotiating deals with drug manufacturers and pharmacies).

141. *See id.* (demonstrating that PBMs negotiate drug prices with every level of the pharmaceutical industry, providing PBMs with exclusive information on drug prices).

course of negotiation of rebates, discounts, and reimbursements.<sup>142</sup> Thus, the asymmetry of price information allows PBMs to hold significant bargaining power, which, in turn, incentivizes other market players to elect to buy PBMs off in order to exploit their market dominant position, and thereby outrival competitors or gain supra-competitive profits in the market.<sup>143</sup>

Consequently, this concentrated market structure gives PBMs market power whereby they can exert constant, substantial control over the price and business relations between market entities in the supply chain.<sup>144</sup> Therefore, PBMs have been in the cross-hairs of antitrust lawsuits alleging that their practices restrain competition in violation of federal antitrust law.<sup>145</sup> Those practices take various forms such as: unilateral conduct by a single PBM, horizontal collusion between multiple PBMs, or collusion between PBMs and other entities—especially pharmaceutical companies and health insurers.<sup>146</sup> However, as discussed below, given that the market power of PBMs is overreaching enough to influence retail pharmacies, the purview of the plausible antitrust allegations can be broadened to include a conspiracy between PBMs and pharmacies.<sup>147</sup> Indeed, in their roles as intermediaries, PBMs can have the opportunity and ability to engage in activities that may align their interest with those of other market players.<sup>148</sup>

In short, an increasingly concentrated market where pharmaceutical transactions and distribution processes center around PBMs and lack of transparency leading to the asymmetry of

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142. *See id.* at 13 (explaining that PBMs can negotiate significant discounts and rebates with drug manufacturers).

143. *Cf. Pharm. Care Mgmt. Ass'n. v. Rowe*, 429 F.3d 294, 298 (1st Cir. 2005) (describing methods whereby drug manufacturers buy PBMs off to substitute a more expensive brand drug for a cheaper generic drug or to withhold discounts given by drug manufacturers to the health benefit provider).

144. *See id.* at 298 (demonstrating that PBMs have the power to negotiate for the financial benefit of health care providers or drug manufacturers).

145. *See* OECD Competition Comm., *supra* note 124, ¶ 21 (demonstrating that the FTC regularly investigates PBMs for antitrust violations).

146. *See generally id.* ¶ 23 (demonstrating that the FTC investigates claims of horizontal collusion).

147. Steve Pociask, *Pharmacy Benefit Managers: Market Power and Lack of Transparency*, AM. CONSUMER INST. 1, 2 <http://www.theamericanconsumer.org/wp-content/uploads/2017/03/ACI-PBM-CG-Final.pdf> (last visited Nov. 25, 2018).

148. *See Rowe*, 429 F.3d at 298 (demonstrating how the intermediary role of PBMs includes aligning their interests with those of other market players by negotiating drug prices between drug manufacturers and health benefit providers).



information (*i.e.*, market failure) has allowed PBMs to become price-makers and hold market power.<sup>149</sup> Thus, PBMs privy to better price and cost information have leverage in dealing with other players and exercise substantial bargaining power.<sup>150</sup> In particular, it seems clear that a myriad of generic collusion alleged in ongoing, multistate generic-pricing litigation are likely furthered by the proactive functioning of PBMs.<sup>151</sup> Hence, it follows that but for PBMs engaging in overarching generic conspiracy, generic manufacturers cannot succeed in anticompetitive horizontal conspiracy schemes to fix prices and allocate markets for certain generic drugs or to thereby gain supra-competitive profits.<sup>152</sup>

While the functioning of PBMs in relation to generic collusion is overall far-reaching and determinative, the key driving force behind likely engagements of PBMs in anticompetitive practices is opaque manufacturer rebates and pharmacy reimbursement schemes.<sup>153</sup> PBMs can negotiate with generic manufacturers to extract steep rebates or various forms of kickbacks in return for providing better formulary placement or raising the market share of that manufacturer's drug to the negotiated level.<sup>154</sup> Manufacturer rebates are *typically* not available for generic drugs since pharmacies can dispense either a brand drug or generic when a generic version of the prescribed brand drug is available and therefore, manufacturer rebates passed by PBMs on to pharmacies cannot serve as an effective inducement to influence retail pharmacies to dispense generics.<sup>155</sup> This may be generally right, but cannot always be the

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149. Pociask, *supra* note 147, at 2, 5; David Dayen, *The Hidden Monopolies that Raise Drug Prices: How Pharmacy Benefit Managers Morphed from Processors to Predators*, AM. PROSPECT (Mar. 28, 2017), <http://prospect.org/article/hidden-monopolies-raise-drug-prices>.

150. Pociask, *supra* note 147, at 6.

151. *Id.* at 6–7.

152. See CONG. BUDGET OFFICE, PUB. NO. 4043, EFFECTS OF USING GENERIC DRUGS ON MEDICARE'S PRESCRIPTION DRUG SPENDING 7 (2010), <https://www.cbo.gov/sites/default/files/111th-congress-2009-2010/reports/09-15-prescriptiondrugs.pdf> (examining the market dynamics of generic drugs and the financial incentives for plans utilizing them).

153. See *id.* at 5–6 (examining the original design of PBM services, noting the negotiation of rebate pricing, price fixing, and user access to medicines).

154. See, e.g., *id.* at 6 (“Pharmacies may be willing to accept lower payments per prescription in exchange for the greater volume of sales that can result from being part of a plan’s pharmacy network.”).

155. A recent study of the U.S. Congressional Budget Office (CBO) states that rebates are generally not prone to be granted for multiple-source brand drugs and generic drugs. *Id.*; see also U.S. FED. TRADE COMM’N Rep. 2005, *supra* note 135, at 56 (noting that drug manufacturers paid PBMs to administer formularies including their drugs); HEALTH CARE FIN. ADMIN., STUDY OF PHARMACEUTICAL

case. In practice, pharmacies may still be incentivized to favor the particular generic drug in return for higher reimbursements for ingredient costs and dispensing fees, which results from rebates or purchase discounts offered by a generic manufacturer of that drug.<sup>156</sup>

In fact, the bona fide roles of PBMs have been generally understood as utilizing some of those rebates and reimbursements to reduce costs of health plan providers (health insurers), retail pharmacies, and consumers.<sup>157</sup> In 2017, the Pennsylvania District Court in *In re Pharmacy Benefit Managers Antitrust Litigation* confirmed the prior opinion of the Illinois District Court that proper “PBM administration of prescription drug benefit programs achieves a number of [market] efficiencies” and cost savings.<sup>158</sup> However, the exact amount of rebates and reimbursements is not publicly disclosed, but rather has been settled through under-the-table negotiations between PBMs and drug manufacturers.<sup>159</sup> Hence, recent antitrust concerns contend that anomalously large rebates and reimbursements paid by pharmaceutical companies serve as circumstantial or economic evidence that demonstrate the collusive ties between those companies and PBMs.

As such, the structural framework for the pharmaceutical supply process allows PBMs to abuse their market dominant positions and pharmaceutical companies to exploit the pivotal role of PBMs for anticompetitive purposes.<sup>160</sup> These structural shortcomings harm consumer welfare by hindering consumers from enjoying full access to essential medicines.<sup>161</sup> The regulatory mandate calling upon pharmaceutical companies and PBMs to abide by the baseline

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BENEFIT MANAGEMENT 9 (2001), [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/cms\\_2001\\_4.pdf](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/downloads/cms_2001_4.pdf); JACK HOADLEY, KAISER FAMILY FOUND., COST CONTAINMENT STRATEGIES FOR PRESCRIPTION DRUGS: ASSESSING THE EVIDENCE IN THE LITERATURE 84 (2005), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/cost-containment-strategies-for-prescription-drugs-assessing-the-evidence-in-the-literature-report.pdf>.

156. Cf. KAISER FAMILY FOUND., *supra* note 128, at 17 (listing types of discounts and rebates commonly used by generic pharmaceutical manufacturers).

157. *Id.* at 14 (emphasizing that PBMs work with public health programs to reduce “the amounts that the pharmacy will receive and the consumer must pay out-of-pocket. . .”).

158. Memorandum, *supra* note 130.

159. *Id.* at 6.

160. *Id.* at 7.

161. Hunt Rep. 2008, *supra* note 58, ¶¶ 23, 33.

corporate obligation to respect the right to access to medicines might contribute to the correction of market distortion.<sup>162</sup>

However, it should be noted that the source of monopoly power held by PBMs in the market is exclusive accessibility to price information, which results from structural imperfections such as lack of transparency, facilitating the asymmetry.<sup>163</sup> Hence, this case is out of line with the situation where corporate practices such as pay-for-delay settlements play an important role in the infringement of the right to access to medicines.<sup>164</sup> Seeking corporate responsibility may not be an effective remedy against structural shortcomings.<sup>165</sup> Rather, the structural remedy mandating the reduced role of PBMs or strengthening market transparency is likely to be more effective and have functional superiority over the behavioral remedy.<sup>166</sup>

#### CONCLUSION

The quintessence of Ruggie's *Protect, Respect and Remedy* framework connotes that non-state actors play a crucial, central role in facilitating humankind's access to fundamental human rights.<sup>167</sup> However, a close look at the relevant market signals that, in reality, business practices of for-profit corporations have often put the promotion of human rights at stake rather than mobilize support for universal principles.<sup>168</sup>

While access to medicines is crucial and imperative to the human enjoyment of sustainable health and life, corporate practices and structural shortcomings in the pharmaceutical industry increasingly drive derogation from this fundamental right.<sup>169</sup> Actual or potential concerns over pharmaceutical companies infringement of the right to access to medicines capture that profit-maximizing business activities often tend to fall short of their baseline corporate responsibility to

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162. Ruggie Rep. 2008, *supra* note 43, ¶¶ 2–3, 29–30, 55.

163. Complaint, *supra* note 135, ¶ 47.

164. See *supra* Part II.B.1 (discussing pharmaceutical behavioral shortcomings mainly resulting from pay-for-delay dispute settlements).

165. See, e.g., Complaint, *supra* note 135, ¶ 73 (noting the shortcomings of corporate decisions).

166. See *supra* Part II.B.2 (analyzing the structural shortcomings of the pharmaceutical industry and the benefits of increased market transparency).

167. DELAET, *supra* note 30, at 206.

168. *Id.* at 114.

169. See *supra* Part II.B.2 (discussing corporate practices and structural shortcomings in the pharmaceutical industry, which have impeded the fundamental right of sustainable health).

respect human rights as patently laid down in the Ruggie Principles.<sup>170</sup> For example, a pay-for-delay settlement that constitutes an antitrust violation indicates that parties to such a settlement, a brand-name drug manufacturer and a generic manufacturer, have fallen afoul of the fundamental human rights responsibility in relation to access to medicines in terms of availability, accessibility, acceptability, quality, transparency, and monitoring and accountability as set out in the Hunt Guidelines.<sup>171</sup> Additionally, the brand-name manufacturer holding the patent on an innovative medicine is subject to additional responsibilities as the manufacturer is deemed to have performed the public function of promoting the public health.<sup>172</sup> As such, reading the Hunt Guidelines in light of the Ruggie Principles provides significant insight into the human rights mandate to regulate corporate violations of the right to access to medicines through their business activities. Notably, a close look at cases where human rights law and competition law interact closely with each other in the pharmaceutical sector implies that corporate anticompetitive practices, like pay-for-delay settlements, incur concurrent, serious harm to the right to access to medicines and consumer welfare.<sup>173</sup> Hence, the human rights mandate to call upon pharmaceutical companies to live up to baseline and additional corporate obligations serves as an effective behavioral remedy conducive to the promotion of consumer welfare in the context of competition law.<sup>174</sup>

A coherent and coterminous policy suggestion arising from the interface between Ruggie Principles and Hunt Guidelines is that pharmaceutical companies have accountability to guarantee the public fair and full access to medicines. Recourse to voluntary or compulsory fulfillment of corporate responsibilities may clearly carry weight in global efforts to regulate corporate practices against the

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170. See *supra* notes 47–51 and accompanying text (emphasizing that corporations may have responsibilities beyond the baseline responsibility of respect).

171. Hunt Rep. 2008, *supra* note 58, annex.

172. Hunt Rep. 2009, *supra* note 61, ¶ 35.

173. See *supra* notes 105–07 and accompanying text (emphasizing that in the pharmaceutical sector where human rights and competition law intersect, there is an implication that corporate anticompetitive practices cause harm).

174. See *supra* notes 43–56 and accompanying text (discussing how John Ruggie's characterization of corporate baseline responsibilities to respect human rights has developed into a global standard).

right to access to medicines.<sup>175</sup> The preventive arm of the behavioral remedy aims to ensure sound compliance policies by setting parameters for corporate business judgments and decision making processes.<sup>176</sup> The corrective arm of the behavioral remedy ensures that corporate violations of human rights norms are adequately and timely sanctioned and that corporations adopt an appropriate policy response to correct such violations.<sup>177</sup>

However, corporate responsibility recourse as a behavioral remedy may have limited function where an impediment to access to medicines results from structural shortcomings of the pharmaceutical sector.<sup>178</sup> One of the main structural drawbacks is attributed to the pivotal and far-reaching role of PBMs, which is strongly vulnerable to arbitrary exploitation by pharmaceutical companies with support of PBMs for anticompetitive purposes.<sup>179</sup> PBMs are in a position to abuse their market dominance; therefore, pharmaceutical companies are strongly incentivized to buy off PBMs' market power for supra-competitive profits at the cost of consumers.<sup>180</sup> Hence, the pharmaceutical supply process concentrating on PBMs induces structural manipulation by market entities, which harms the right to access to medicines and consumer welfare.<sup>181</sup>

Where structural shortcomings serve as a determinative barrier to access to medicines and consumer welfare, corporate practices may carry less weight than where they play a critical role in impacting human rights and causing consumer harm.<sup>182</sup> An effective means in this case is likely to be the structural remedy that entails a complete overhaul of the regulatory and institutional frameworks of the

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175. *See supra* Part II.A (hypothesizing that corporate responsibilities may improve the right to access medicine).

176. *See supra* notes 53–56 and accompanying text (summarizing how the HRC's policies ensure companies will not engage in human rights abuses).

177. *See supra* notes 53–56 and accompanying text (noting that guiding principles redress corporate violations of human rights).

178. *See supra* notes 160–66 and accompanying text (discussing how corporate behavior and structural drawbacks can hinder one's access to health care).

179. *See supra* Part II.B.2 (positing that a main structural drawback is the role of PBMs who are vulnerable to pharmaceutical companies).

180. *See supra* Part II.B.2 (explaining that PBMs are able to abuse their position in the market because of the structural shortcomings of the lack of transparency regarding drug prices).

181. *See supra* Part II.B.2 (discussing how consumer welfare is impeded by pharmaceutical companies who are engaged in conspiracies and manipulation tactics).

182. *See supra* Part II.B (discussing corporate human rights responsibilities for protecting consumer welfare).

pharmaceutical sector.<sup>183</sup> Effective structural remedies for the establishment of the desirable pharmaceutical supply process may include structural reforms to secure market transparency. Thereby solving the problem of asymmetry of price information, curtailing the scope of the extensive intermediary role and function of PBMs, and establishing the due process and appropriate mechanisms to hold PBMs in check.

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183. See *supra* Part II.B (noting the benefits of a regulatory and institutional overhaul).