

Specifically, when Turing acquired the rights to Daraprim, it maintained a restricted distribution system originally put in place by Impax, the previous owner.<sup>47</sup> In fact, Turing requested that a restricted distribution system be established before the sale occurred. As we will discuss later, restricted or controlled distribution systems are mandated by the FDA as part of safety protocols when a drug presents special concerns regarding safety, administration, or storage. Yet Impax (and later, Turing) instituted its restricted distribution system without the FDA and for no apparent safety reason at all, making the drug only available through Walgreen's Specialty Pharmacy.<sup>48</sup> Along with creating access problems for hospitals,<sup>49</sup> the move in part may have been designed to make it difficult for generics to gain access to the samples needed to gain approval for a generic version of the drug.<sup>50</sup>

Comments from Turing executives support this implication. In response to the Daraprim pricing controversy and the potential for generic competition, the director of patient access at Turing said the following: "Most likely I would block that purchase [by a generic]. We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make generics], no matter what. But I'm certainly not going to make it easier for them."<sup>51</sup> The comments suggest a concerted effort to block generic competition, and a failure to accept the intent of the generic drug system. Although Turing executives may have spoken more directly than others, actions in many corners of the pharmaceutical industry reflect a similar mind-set. Turing's actions, specifically the use of restricted distribution to block competition, are now under investigation by the New York attorney general, and U.S. lawmakers have also called on the FTC to look into the Turing business model.<sup>52</sup>

As other academics have detailed, the Daraprim system was not the first time a Shkreli-led company implemented a restricted distribution system.<sup>53</sup> Notably,

<sup>47</sup> Michael Carrier & Aaron Kesselheim, *The Daraprim Price Hike and a Role for Antitrust*, HEALTH AFF. BLOG (Oct. 21, 2015), <http://healthaffairs.org/blog/2015/10/21/the-daraprim-price-hike-and-a-role-for-antitrust/>.

<sup>48</sup> *Ibid.*

<sup>49</sup> Letter from Stephen B. Calderwood, President, Infectious Diseases Soc'y of Am., and Adaora Adimora, Chair, HIV Medicine Ass'n, to Tom Evegán, Head of Managed Markets, Turing Pharm., and Kevin Bernier, Nat'l Dir. of All. Dev. & Pub. Affairs, Turing Pharm. (Sept. 8, 2015), [www.hivma.org/uploadedFiles/HIVMA/HomePageContent/PyrimethamineLetterFINAL.pdf](http://www.hivma.org/uploadedFiles/HIVMA/HomePageContent/PyrimethamineLetterFINAL.pdf).

<sup>50</sup> Michael A. Carrier, Nicole L. Levidow, & Aaron S. Kesselheim, *Using Antitrust Law to Challenge Turing's Daraprim Price Increase*, 31 BERKELEY TECH. L.J. (2016), <http://ssrn.com/abstract=2724604>.

<sup>51</sup> Ed Silverman, *How Martin Shkreli Prevents Generic Versions of His Pricey Pill*, STAT (Oct. 5, 2015), <http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/>.

<sup>52</sup> Andrew Pollack, *New York Attorney General Examining Whether Turing Restricted Drug Access*, N.Y. TIMES (Oct. 12, 2015), [www.nytimes.com/2015/10/13/business/new-york-attorney-general-examining-if-turing-restricted-drug-access.html](http://www.nytimes.com/2015/10/13/business/new-york-attorney-general-examining-if-turing-restricted-drug-access.html).

<sup>53</sup> See Carrier, Levidow, & Kesselheim, *Using Antitrust Law*, *supra* note 50, at \*20–21.