



July 14, 2015

The Honorable Edith Ramirez  
Federal Trade Commission  
600 Pennsylvania Avenue, NW  
Washington, DC 20580

Re: Generic Drug Manufacturer Consolidation is Problematic for Consumers

Dear Chairwoman Ramirez:

The undersigned consumer and public interest organizations, Consumers Union, Consumer Federation of America, U.S. PIRG, Public Citizen, Consumer Action, Consumer Watchdog, Community Catalyst, and National Center for Health Research, have watched with growing concern in recent years as the generic drug industry has become increasingly concentrated. The latest announced merger—the hostile bid by Teva Pharmaceuticals (“Teva”) to acquire Mylan—would combine the two largest generic drug manufacturers in the United States. We are concerned that this merger would: (1) increase prices for generic as well as specialty drugs; (2) exacerbate drug shortages; and (3) reduce the development of new generic drugs. We urge the Federal Trade Commission to investigate this merger thoroughly, and to take action to block it.

We hope this investigation will be part of a reinvigorated look at generic drug markets. We urge the Commission to carefully investigate all such mergers, along with other business arrangements in this concentrated industry, to ensure that the remaining competition is protected and that new competition has a chance to develop.

## I. Background

Access to lower-cost generic drugs has been of vital importance to consumers in helping control health care costs. Generic drugs are pharmaceutical substitutes for brand-name drugs that offer the same therapeutic benefits as their brand-name equivalents. The only real difference between brand-name and generic drugs is the price. On average, a generic drug can cost 80 to 85 percent less than its brand-name counterpart.<sup>1</sup> Given the substantial cost-savings, both payors and consumers are readily relying on generic drugs. Millions of Americans take generic drugs. Today, nearly eight in every ten prescriptions filled in the United States is for a generic.<sup>2</sup> As a result of increased generic usage, from 2004 through 2013, Americans saved nearly \$1.5 trillion.<sup>3</sup>

However, we are concerned that access to and cost-savings associated with generic drugs will not be sustained. We are aware that there are several pending acquisitions within the industry including Mylan's proposed acquisition of Perrigo. In the last decade, there has been significant consolidation among generic drug manufacturers.<sup>4</sup> This increased consolidation has already led to higher prices and to generic drug shortages.<sup>5</sup> Given the importance of generic drugs to controlling healthcare costs, we are greatly concerned about this consolidation.<sup>6</sup>

In past generics mergers, the Commission has attempted to preserve competition by requiring the merging generic drug manufacturers to divest specific generic drugs that competed with each other, so those drugs would continue to be available independently.<sup>7</sup> Whether those divestitures have actually worked to effectively preserve competition is open to dispute.

But this merger is far bigger and more far-reaching. A merged Teva/Mylan would have a 25 percent market share over all generic drugs,<sup>8</sup> and would combine the largest number of overlapping, currently competing drugs of any generic drug company merger ever. The merged company would have a virtual lock on a number of key generics. The merger would also reduce competitive incentives within the industry to develop new generics. We do not see how divestitures can possibly remedy the substantial loss of competition that would result from this merger. There is increasing evidence that divestitures often fail to live up to their promise for preserving competition for the divested products,<sup>9</sup> including divestitures in generic drug merger remedies. Moreover, product divestitures would not alleviate the loss of rivalry among major

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<sup>1</sup> See Food and Drug Administration, *Facts About Generic Drugs* at 2, available at <http://goo.gl/9I0zJg>.

<sup>2</sup> *Id.* at 1.

<sup>3</sup> Generic Pharmaceutical Ass'n, *Generic Drug Savings in the U.S.* at 1 (6th ed. 2014), available at <http://goo.gl/wwXvOz>.

<sup>4</sup> Laura Cooper, *Teva, Actavis, Other Generic Drugmakers May Be On Acquisition Trail*, THE STREET (Apr. 16, 2015, 10:04 AM), <http://goo.gl/1XomnE>.

<sup>5</sup> *Why Are Generic Drug Prices Shooting Up?*, FORBES (Feb. 27, 2015, 8:38 AM), <http://goo.gl/wMBL3w>.

<sup>6</sup> See generally Stephen W. Schondelmeyer and Leigh Purvis, *Trends in Retail Prices of Generic Prescription Drugs Widely Used by Older Americans, 2006 to 2013* (2015), available at <http://goo.gl/eXEyUR>.

<sup>7</sup> See FTC, *Overview of FTC Antitrust Actions in Pharmaceutical Services and Products* at 26-55 (2013), available at <https://goo.gl/MZVYED>.

<sup>8</sup> Caroline Humer and Ransdell Pierson, *Drug overlaps, shortages may complicate Teva bid for Mylan*, REUTERS (Apr. 24, 2015, 4:58 PM), <http://goo.gl/iUSD4D>.

<sup>9</sup> John Kwoka, *MERGERS, MERGER CONTROL, AND REMEDIES: A RETROSPECTIVE ANALYSIS OF U.S. POLICY 156* (2015) (discussing divestiture remedies in product markets associated with price increases).

generic drug manufacturers, and would not protect innovation and the growth of generics. We are concerned that we would see higher prices on generic and specialty drugs, a worsening of drug shortages, and fewer generic drugs becoming available.

## **II. A Combined Teva and Mylan Would Further Increase Generic and Specialty Drug Prices**

In recent years, generic drug prices have increased at a dramatic rate. Just over the period of July 2013 to July 2014, more than half of all retail generic drugs experienced price increases.<sup>10</sup> In fact, over the same time frame, 18 percent of generic drugs saw at least a 25 percent increase in price—with nine percent of all generic drugs more than doubling in price.<sup>11</sup>

Generic drug manufacturer consolidation has played a significant role in these generic drug price increases.<sup>12</sup> As a result of consolidation to date, today there are only four major generic drug manufacturers—Teva, Mylan, Actavis, and Novartis/Sandoz.<sup>13</sup> Both Teva and Mylan have massive drug portfolios and research and development budgets. Teva's takeover of Mylan would effectively be a four-to-three merger, creating a single entity with more than double the market share of the next-largest generic drug manufacturer.<sup>14</sup> An even more highly concentrated generic drug market would likely result in both unilateral and coordinated anticompetitive effects, including further price increases and a diminished competitive drive within the industry to develop new generic drugs.<sup>15</sup>

We are also concerned about the combination of Teva's and Mylan's vast generic drug portfolios. Not even including any potential "pipeline" drugs, Mylan currently makes 360 generic products, while Teva makes 375.<sup>16</sup> We understand there to be significant overlap between a large number of these drugs. In resisting the takeover, Mylan has stated that there could be an overlap of "thousands" of products globally.<sup>17</sup> As stated by Mylan's Executive Chairman, Robert J. Coury, "[o]ur massive overlapping position would create significant antitrust concerns."<sup>18</sup> In our view, the significant anticompetitive harm that would result from this merger cannot be alleviated through simply divesting specific drugs that now compete with each other, as the Commission has done in past generics mergers. Because of the significant overlapping drug portfolios of the two companies, coupled with the loss of Mylan's substantial

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<sup>10</sup> Adam J. Fein, *Retail Generic Drug Inflation Reaches New Heights*, DRUG CHANNELS (Aug. 12, 2014), <http://goo.gl/KR4fPZ>.

<sup>11</sup> *Id.*

<sup>12</sup> See Mari Edlin, *The Rising Cost of Generic Drugs: Shortages, Industry Mergers are Major Causes*, MANAGED HEALTHCARE EXECUTIVE (Dec. 9, 2014), <http://goo.gl/zvCm6N>.

<sup>13</sup> *The Industry*, GENERIC PHARMACEUTICAL ASSOC., <http://goo.gl/EHXnIm> (last visited July 10, 2015).

<sup>14</sup> Humer and Pierson, *supra* note 8.

<sup>15</sup> See generally U.S. Dep't of Justice and FTC, *Horizontal Merger Guidelines* (2010), available at <http://goo.gl/uiIiRD>.

<sup>16</sup> Humer and Pierson, *supra* note 8.

<sup>17</sup> *Mylan Board Unanimously Rejects Unsolicited Expression of Interest from Teva*, FIERCEPHARMA (Apr. 27, 2015), <http://goo.gl/VELYVL>.

<sup>18</sup> *Id.*; see also *Teva/Mylan: Consolidation in the Generic Drug Market Gets Hostile; Significant Divestitures Likely*, THE CAPITAL FORUM at 4 (2015) (noting that combined drug portfolio could lead to increased bargaining power with payors to increase prices on all generic drugs).

separate research and development activities in generic drugs, no divestiture of specific drugs would be sufficient to replace the loss of competition.

Specialty drugs, which are an increasing amount of overall drug spending, are an additional area of concern. Specialty drugs are complex, often expensive medications made by a limited number of brand and generic manufacturers and used to treat serious and life-threatening diseases. In the words of Teva's President and CEO, Erez Vigodman, a combination of Teva and Mylan would allow the company to "leverage on its significant assets and capabilities in generics and specialty."<sup>19</sup>

Promoting lower prices on generic and specialty drugs is of critical importance to consumers throughout America. Many Americans are finding that they simply cannot afford generic medications, or must forgo other necessities to pay for their supposedly cheaper generic drugs.<sup>20</sup> Where consumers are faced with increasing drug costs, they often skip medication doses, with failure in medication adherence leading to worsening health problems<sup>21</sup> and substantial costs to the American health care system. Due to a lack of medication adherence, an estimated \$100 to \$289 billion per year is spent on re-hospitalizations and physician visits that would have otherwise been avoided.<sup>22</sup>

### **III. A Combined Teva and Mylan Would Worsen Drug Shortages**

Recent generic manufacturer consolidation has weakened the drug manufacturing system helping to lead to increased drug shortages. For a greater part of the past decade, America has been experiencing an increased incidence of drug shortages.<sup>23</sup> Currently, the Food and Drug Administration ("FDA") lists over 70 different medications that are in short supply.<sup>24</sup> A leading factor in drug shortages throughout the United States is consolidation within the generic drug manufacturing industry.<sup>25</sup> Consolidation leads to fewer production facilities and manufacturing lines to produce needed drugs.<sup>26</sup> According to one expert, industry consolidation has directly led to "sixteen out of thirty-one cancer drugs [being] in current short supply."<sup>27</sup>

Teva's acquisition of Mylan will likely worsen drug shortages in the United States. As the Commission has recognized, it must evaluate "whether the proposed transaction [will]

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<sup>19</sup> See Letter from Erez Vigodman, President and CEO of Teva, to Robert J. Coury, Executive Chairman of the Board of Directors of Mylan N.V. (Apr. 29, 2015), available at <http://goo.gl/ah6Emx>.

<sup>20</sup> See Gloria Riviera, Katie Yu, and Lauren Effron, *With Generic Prescription Drug Prices Surging, Families Are Feeling the Squeeze*, ABC NEWS (May 28, 2015 6:43 PM), <http://goo.gl/SkDrzA>.

<sup>21</sup> See Virgil Dickson, *Reform Update: Generic drugs' high prices spur fears of failed drug adherence*, MODERN HEALTHCARE (Oct. 9, 2014), <http://goo.gl/Mcm6to>.

<sup>22</sup> Centers for Disease Control and Prevention, *Medication Adherence* (2013), available at <http://goo.gl/PJFqkw>.

<sup>23</sup> C. Lee Ventola, *The Drug Shortage Crisis in the United States: Causes, Impact, and Management Strategies*, 36 PHARMACY & THERAPEUTICS 740, 740 (2011), available at <http://goo.gl/u1C1fF>.

<sup>24</sup> See *FDA Drug Shortages*, FDA.GOV, <http://goo.gl/AJ06dK> (last visited July 10, 2015).

<sup>25</sup> See Ventola, *supra* note 23 at 742.

<sup>26</sup> See *Examining the Increase In Drug Shortages Before the Comm. on Energy and Com.*, 112th Cong. 4 (2011) (statement of Dr. Howard K. Koh, Assistant Secretary of Health U.S. Dep't of Health and Human Servs.), available at <http://goo.gl/Jtegg2>.

<sup>27</sup> *Drug Shortages: Why They Happen and What They Mean Before Sen. Comm. on Finance*, 112th Cong. 2 (2011) (statement of Dr. Rena M. Conti, Assistant Professor University of Chicago), available at <http://goo.gl/I25h8Y>.

exacerbate” drug shortages.<sup>28</sup> Of the 70 drugs that are currently in short supply, three are made by both Mylan and Teva, while five other drugs are produced solely by Teva and four additional drugs are produced solely by Mylan.<sup>29</sup> Along with exacerbating the current drug shortages of these medications, a merger between the two largest generic manufacturers would likely eliminate more manufacturing facilities, leading to reduced production and creating other shortages of generic and specialty drugs.

A remedy relying on divestitures of specific drugs will not alleviate this drug shortage problem. In the consent decree involving Teva’s 2008 acquisition of Barr Pharmaceuticals (“Barr”), the Commission required Teva and Barr to sell assets for 29 different products, including generic drugs.<sup>30</sup> A number of those drugs have appeared since then on the FDA’s drug shortage list, including carboplatin, a chemotherapy drug; deferoxamine, a critical medication used to remove excess iron; and tamoxifen citrate, a breast cancer treatment – and some are still on the shortage list.<sup>31</sup> A divestiture remedy in this merger would involve far more drugs, risking far more critical shortages.

A drug shortage can severely compromise a patient’s care, and can be fatal if the patient does not have access to a vital drug.<sup>32</sup> With limited access to medications, physicians often have to turn to alternative treatments that are not as effective. Secondary options can often lead to higher rates of medical errors and long-term costs to the American healthcare system.<sup>33</sup>

By eliminating the second largest generic drug manufacturer, this merger would make the generic market even more susceptible to drug shortages, harming consumers and public health.

#### **IV. Divestitures Will be Inadequate to Protect Competition**

As we have noted, requiring divestitures of specific generic drugs would not be an adequate solution, for two reasons. First, specific targeted divestitures will not protect the overall competition that leads to innovation and new generics development.<sup>34</sup> And second, there is evidence that these types of product divestitures do not succeed, and the fact that some products from past mergers are now on drug shortage lists demonstrates the weakness of this approach.

If this merger is permitted to go forward with product divestitures, even a large number of them, consumers will lose out. Three firms will dominate the generic market. These firms

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<sup>28</sup> Press Release, FTC, FTC places Conditions on Watson Pharmaceutical’s Proposed Acquisition of Actavis (Oct. 15, 2012), *available at* <https://goo.gl/ri7ael>.

<sup>29</sup> Humer and Pierson, *supra* note 8.

<sup>30</sup> Press Release, FTC, FTC Intervenes in Teva Pharmaceutical Industries’ Proposed \$8.9 Billion Acquisition of Barr Pharmaceuticals (Dec. 19, 2008), *available at* <https://goo.gl/25CTSP>.

<sup>31</sup> See Current Drug Shortage Bulletins, ASHP, <http://goo.gl/oFuI3o> (last visited July 10, 2015).

<sup>32</sup> See Mark Koba, *Drug Shortage in the U.S. May Pose Deadly Problem for Patients*, TIME (Jan. 6, 2015), <http://goo.gl/fyYSy1>.

<sup>33</sup> See Ventola, *supra* note 23 at 742.

<sup>34</sup> See Kwoka, *supra* note 9 at 159 (noting that “agency challenges are often resolved in way that do not preserve or restore competition.”).

will have reduced incentives to develop and maintain affordable generic alternatives. Product divestitures simply cannot solve the crucial problems raised by this merger.

## **V. Conclusion**

For the forgoing reasons, the undersigned urge the Commission to undertake a thorough investigation of Teva's proposed takeover of Mylan. We believe you will conclude that the merger would substantially lessen competition in violation of the antitrust laws, and should be blocked.

Thank you for your consideration.

Respectfully,

Consumers Union  
Consumer Federation of America  
U.S. PIRG  
Public Citizen  
Consumer Action  
Consumer Watchdog  
Community Catalyst  
National Center for Health Research

Cc: Commissioner Julie Brill  
Commissioner Maureen K. Ohlhausen  
Commissioner Joshua D. Wright  
Commissioner Terrell McSweeney  
Deborah L. Feinstein, Director, FTC Bureau of Competition