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# FDA Approves More Generic Drugs, but Competition Still Lags

FY 2012-17 program achieves mixed results

## Overview

The Generic Drug User Fee Amendments (GDUFA), passed by Congress in 2012, were intended to speed U.S. Food and Drug Administration approval of new generic drugs, which create competition for brand drugs and reduce drug prices for consumers. GDUFA created a five-year program to provide FDA with industry user fees to support regulatory review of new prescription generic drugs and to address a growing backlog of applications for new generic drugs. The legislation was reauthorized for another five years in 2017 as GDUFA II.

Generics—lower-cost versions of brand drugs that compete both with the original drug and with subsequent generic versions as they come to market—can significantly reduce prices. For example, a generic equivalent of a statin used to lower cholesterol levels in the blood typically costs many times less than the brand version of the same drug.

This brief examines how FDA's review of generic drug applications changed during the first GDUFA period, including review times and GDUFA's potential impact on competition. It also discusses the implications for FDA as it implements GDUFA II. Among the findings:

- Over the five years of the first GDUFA program, from fiscal years 2013 through 2017, FDA approved 2,700 new generic drugs, compared with 2,309 from fiscal 2008 through 2012, an increase of 16.9 percent. However, the median approval time did not significantly decline.
- The increase in approved drugs was largely driven by approvals of the fourth, fifth, sixth and even later versions of generics. Costs generally decline most significantly once second and third generics enter the market,<sup>1</sup> but versions after the third generic usually reduce prices less effectively.<sup>2</sup>
- Approval times are slowed when drug applications go through multiple review cycles, which are triggered when FDA finds deficiencies in the drug application.
- Despite the increased approvals of generics overall, more than 500 brand drugs still lack competition, even though there are no patent protections or periods of exclusivity that would prevent the approval of competing generic versions.<sup>3</sup> These "sole source" products are most at risk for price spikes.

GDUFA II is designed to build on the successes and shortcomings of the first five years of the program and includes a range of provisions intended to reduce multiple review cycles and prioritize FDA review of generic applications for drugs that have little competition. However, a number of factors outside the GDUFA program can affect the generic marketplace, and it is unclear whether the current regulatory framework can ensure adequate competition in the prescription drug marketplace. Policymakers seeking to reduce drug spending may want to consider approaches beyond FDA review to increase competition.

## Impact of generic competition on prices

The Drug Price Competition and Patent Term Restoration Act of 1984,<sup>4</sup> also known as the Hatch-Waxman Act, created an abbreviated pathway to bring generic drugs to market. While new brand drugs must undergo lengthy clinical human trials, the legislation allowed approval of generic drugs after a period of brand exclusivity that typically spans five or more years—once the manufacturers of generic equivalents produce scientific evidence that the generic drug is "bioequivalent" (meaning that it acts in the same way when administered in the same form and dosage as the brand drug). Since then, FDA has approved more than 16,000 generic applications, and the use of generic drugs has risen sharply.<sup>5</sup> Generics comprise a large majority of prescriptions dispensed in the U.S. and account for a relatively small share of spending compared with brand drugs. In 1984, less than 20 percent of prescriptions were for generic drugs;<sup>6</sup> today, generics account for approximately 90 percent of prescriptions, yet only a quarter of drug spending.<sup>7</sup>

This competition from generic drugs significantly reduces overall spending on prescription drugs.<sup>8</sup> Once competing generics are approved, they are sold at lower prices than the brand drug; prices generally decline further as more generic equivalents for the same drug enter the market.

While the relationship between a drug's price and the number of generic competitors, as well as between the price and the timing of generic availability, may vary among different drugs, an FDA analysis of retail prescription drug sales between 1999 and 2004 found that, on average, the first generic version of a drug produces limited cost savings, while the second generic competitor sells for about half the price of the brand drug.<sup>9</sup> Additional

generic competitors can lead to even lower prices: By the sixth entrant, generic prices are a quarter of the brand's price.<sup>10</sup> Another analysis found that within a year of the loss of brand exclusivity, generic drugs cost less than half as much as the brand drug; within three years, generics are a third of the brand's price.<sup>11</sup>

In general, competition and lower prices lead most patients to switch to generic versions of prescription drugs soon after they become available, which lowers overall spending on drugs. The Association for Accessible Medicines, the trade association for generic manufacturers, estimates that generics generated \$1.7 trillion in savings over the past 10 years.<sup>12</sup> However, recent research has shown that significant competition still does not exist in many cases. In 2016, research that categorized each prescription drug into a drug market (defined as including all drugs that have the same molecule and dosage form) found that such markets with at least one generic available had a median of two generic manufacturers, and nearly 40 percent had just one generic manufacturer.<sup>13</sup>

Additionally, FDA listed nearly 550 brand drugs<sup>14</sup> in 2018 that had no exclusivities or blocking patents—those held by the manufacturer of a brand drug that prevent generic versions from coming to market—but that are nonetheless produced by only one manufacturer and are therefore at risk for price spikes.<sup>15</sup> In some cases, incentives to create and market a generic may be limited by the small number of people who need the drug, as is the case with medicines that treat rare diseases. In other cases, potential competitors may have difficulty developing generic versions of a drug due to the complexity of the product or may lack access to samples of the brand drug needed to conduct FDA-required testing.<sup>16</sup> Manufacturers also face challenges in demonstrating the bioequivalence of complex products, which can require additional technical guidance from FDA.<sup>17</sup>

## Generic Drug User Fee Amendments of 2012

In the early 2000s, FDA's review of generic drug applications, known as abbreviated new drug applications (ANDAs), was not keeping pace with submissions.<sup>18</sup> A growing backlog awaited agency review,<sup>19</sup> reaching nearly 3,000 applications by October 2012.<sup>20</sup>

In response, the generic industry and FDA worked to develop a user fee program to address the growing backlog, improve application review times, and increase inspections of foreign manufacturing facilities.<sup>21</sup> (The legislation was preceded by the 1992 Prescription Drug User Fee Act, which set fees for drug manufacturers to support the more complicated review and approval of new brand drugs.) Congress authorized GDUFA from October 2012 to September 2017 and reauthorized it as GDUFA II for an additional five years starting in October 2017. FDA anticipated receiving 750 new generic applications each year over the initial GDUFA time frame.<sup>22</sup>

Under GDUFA, the review time depends on when FDA takes regulatory action on each application.<sup>23</sup> Upon review and completion of manufacturer facility inspections, if necessary,<sup>24</sup> FDA can issue an approval; a tentative approval, when brand patent or exclusivity periods have not yet expired and the manufacturer must wait to market the generic equivalent;<sup>25</sup> or a "complete response letter," which outlines the deficiencies manufacturers must address before the agency can approve the application. A complete response letter requires a response from the application sponsor, which initiates a new review cycle.<sup>26</sup> These multiple reviews can add significant time to the process.

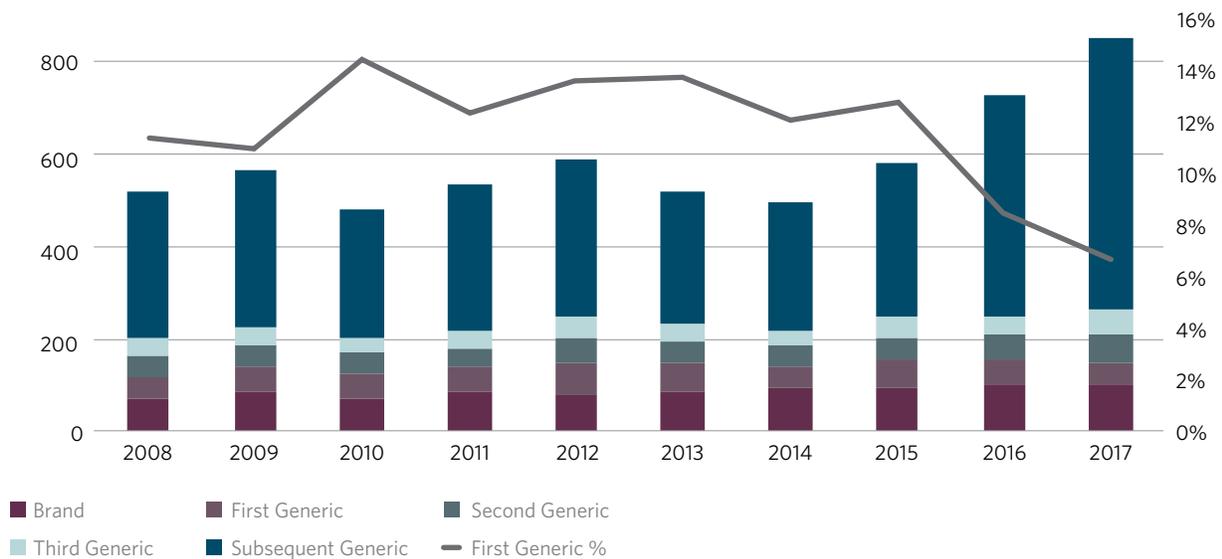
GDUFA set separate goals for the review both of backlogged applications and of new generic applications received by FDA from fiscal 2015 through 2017,<sup>27</sup> requiring the agency to complete its reviews of a progressively larger share of applications within a specified time frame for each of the three years. FDA achieved its GDUFA

goals for review of backlogged applications and new generic applications (see the appendix below). By the end of the five-year program, the agency had succeeded in reviewing at least 90 percent of the backlog of applications that it had received before Oct. 1, 2012, and had met its goal of reviewing 90 percent of new generic applications within 10 months of submission in fiscal 2017.<sup>28</sup>

## Subsequent generics comprised a larger share of FDA approvals

FDA’s “Approved Drug Products With Therapeutic Equivalence Evaluations” (also known as the “Orange Book” database) identifies generic approvals for each unique drug market—which it defines as all drugs with the same active ingredient and route of administration, regardless of dosage size. The August 2018 version of the “Orange Book” revealed that, compared with 2,309 applications approved from fiscal 2008 through 2012, FDA approved 2,700 ANDAs from fiscal 2013 through 2017 (the period of GDUFA I)—an increase of 16.9 percent. The number of ANDAs receiving FDA approval—those eligible for immediate marketing—was relatively stable in each year before GDUFA implementation, ranging from a low of 413 in fiscal 2010 to a high of 511 in 2012. Approvals were relatively stable in the first two years of GDUFA (fiscal 2013, 433 approvals; and 2014, 401 approvals), but increased markedly in fiscal 2015 (483 approvals), 2016 (629 approvals), and 2017 (754 approvals), as shown in Figure 1. In 2017, FDA reported that 25 percent of all ANDAs ever approved were approved during the GDUFA period.<sup>29</sup>

Figure 1  
Drug Approvals by Fiscal Year, 2008-17



Source: Analysis by The Pew Charitable Trusts

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To assess what share of generic applications approved under GDUFA were early generics (which usually result in greater price reductions than subsequent versions), this analysis relied on approval dates in the “Orange Book” database to determine the number of first, second, third, and subsequent generics approved in a unique drug market each fiscal year of GDUFA. When multiple applications were approved in a market on the same day, each was randomly assigned as the first, second, or third generic (submission dates for applications are not publicly available, so the order of submission could not be used). Any application approved after the third ANDA in a unique drug market was classified as a subsequent generic. No tentative approvals were included.

The analysis found that the increase in generic approvals in the latter two years of GDUFA was almost entirely due to subsequent generics rather than early entrants. Subsequent generics were responsible for 92.3 percent of the increase in FDA approvals during the GDUFA period (Figure 1), potentially limiting the price impact of the increase in approvals during this period—since subsequent generics are less effective in driving down average prices in a drug market.<sup>30</sup> Compared with the fiscal years 2008 to 2012, FDA approved a total of 30 more first, second, and third generics during the GDUFA period—an increase of 4.2 percent. During the same period, 361 more subsequent generics were approved—an increase of 22.6 percent. By fiscal 2017, subsequent generics made up 78 percent of all ANDA approvals, a substantial increase over the 67 to 71 percent of approvals made from fiscal 2008 to 2012.

At the same time, FDA prioritized first generic application reviews during GDUFA<sup>31</sup> and updated its policy in 2017 to also prioritize the review of second and third generics.<sup>32</sup> It is unclear whether any other agency considerations influenced prioritization of applications, and information on individual application submission dates is not publicly available. However, the volume of early ANDA applications (i.e., first, second, and third generics) is probably driven largely by factors unrelated to FDA’s review of these applications, such as the number of branded products that become eligible for competition through successful patent challenges, the market size of those products, the complexity of determining bioequivalence, the end of patent terms, and the expiration of FDA-granted exclusivities.

However, FDA approval times and prioritization of early generic drug equivalents alone may not be sufficient to spur adequate competition. The list of nearly 550 drugs eligible for additional competition may help developers understand market opportunities, but policymakers should examine other options to encourage robust generic development. These could include new incentives to submit generic applications to FDA and addressing barriers that may inhibit generic drug development, such as lack of access to samples of the brand drug.<sup>33</sup>

A limitation of this analysis is that it does not include information on which drugs are actively marketed, which in turn can affect competition and pricing; not all approved generics are actively marketed and available to purchasers. For example, ongoing patent litigation<sup>34</sup> can delay the market introduction of approved generic drugs.

## Application approval times were longer under GDUFA but trended down in program’s final years

While FDA met its review and other performance goals and increased the number of approvals under GDUFA, overall generic application approval times did not decline. Median approval times for all ANDAs, including backlogged applications from before October 2012, increased each year until fiscal 2014 and then declined slightly in both 2016 and 2017 (Table 1). Before GDUFA (see fiscal 2012), the median approval time was 31.75 months, but median approval time was 36 months in fiscal 2013. Median approval time increased to 42 months in fiscal 2014 and 2015 before declining to 39.42 months in 2016 and 37.26 months in 2017.

Table 1

## Median Review Times From ANDA Receipt to Approval Reported annually to Congress in budget justification reports

	2010 <sup>*</sup>	2011 <sup>*</sup>	2012 <sup>*</sup>	2013 <sup>†</sup>	2014 <sup>‡</sup>	2015 <sup>§</sup>	2016 <sup>  </sup>	2017 <sup>#</sup>
<b>Median review time from ANDA receipt to approval (months)</b>	27.85	29.52	31.75	36	42	42	39.42	37.26

Note: Includes all approved applications (backlog and Generic Drug User Fee Amendments cohort abbreviated new drug applications).

\* Food and Drug Administration, "FDA Budget Summary," <https://wayback.archive-it.org/3920/20150326110431/http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm388251.htm>.

† Department of Health and Human Services, "Fiscal Year 2015 Food and Drug Administration Justification of Estimates for Appropriations Committees."

‡ Department of Health and Human Services, "Fiscal Year 2016 Food and Drug Administration Justification of Estimates for Appropriations Committees," <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM432322.pdf>.

§ Department of Health and Human Services, "Fiscal Year 2017: Food and Drug Administration Justification of Estimates for Appropriations Committees," <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm559364.htm>.

|| Department of Health and Human Services, "Fiscal Year 2018 Food and Drug Administration Justification of Estimates for Appropriations Committees," <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/ucm603309.htm>.

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An FDA analysis comparing the first 5 percent and 10 percent of applications approved from fiscal 2010 through 2016 found that approval times were faster for applications received in 2015 and 2016 compared with previous years.<sup>35</sup> Exact figures are not available,<sup>36</sup> but the median approval time for the first 5 percent and 10 percent of approvals in both fiscal 2015 and 2016 was approximately 15 months, down from a 2013 median approval time of approximately 25 months for the first 5 percent of approvals and nearly 30 months for the first 10 percent of approvals.<sup>37</sup> While this includes only a portion of applications and is not representative of all applications received each year, the analysis suggests that approval times for applications received in fiscal 2015 and later may be growing shorter.

While FDA reports the share of applications it reviews within GDUFA goal time frames, as well as the median time to approval for all applications approved in a given fiscal year, it does not publish complete data on time to approval by year of application submission. There is no public information on what share of approvals each year was backlogged applications and what share was ANDAs submitted after GDUFA implementation. Similarly, there are no public data on average approval times by year for backlogged applications. Thus, it is not possible to determine precisely the impact backlogged applications had on approval times reported during GDUFA, nor is it possible to determine how the impact of backlogged applications changed throughout the GDUFA period.

However, backlogged applications comprised the large majority of ANDA approvals overall during the full five years of GDUFA. As of Oct. 1, 2016, four years into the five-year program, less than 20 percent of ANDAs approved during GDUFA had been submitted since the beginning of the program; the large majority of approvals were received before October 2012.<sup>38</sup> Their inclusion in metrics on median approval times resulted in higher overall approval times reported by the agency. Because submission dates are not public, it is not possible to determine whether a larger share of backlogged applications comprised subsequent generics compared with applications submitted during the GDUFA program.

## FDA approval times for second generics were steady

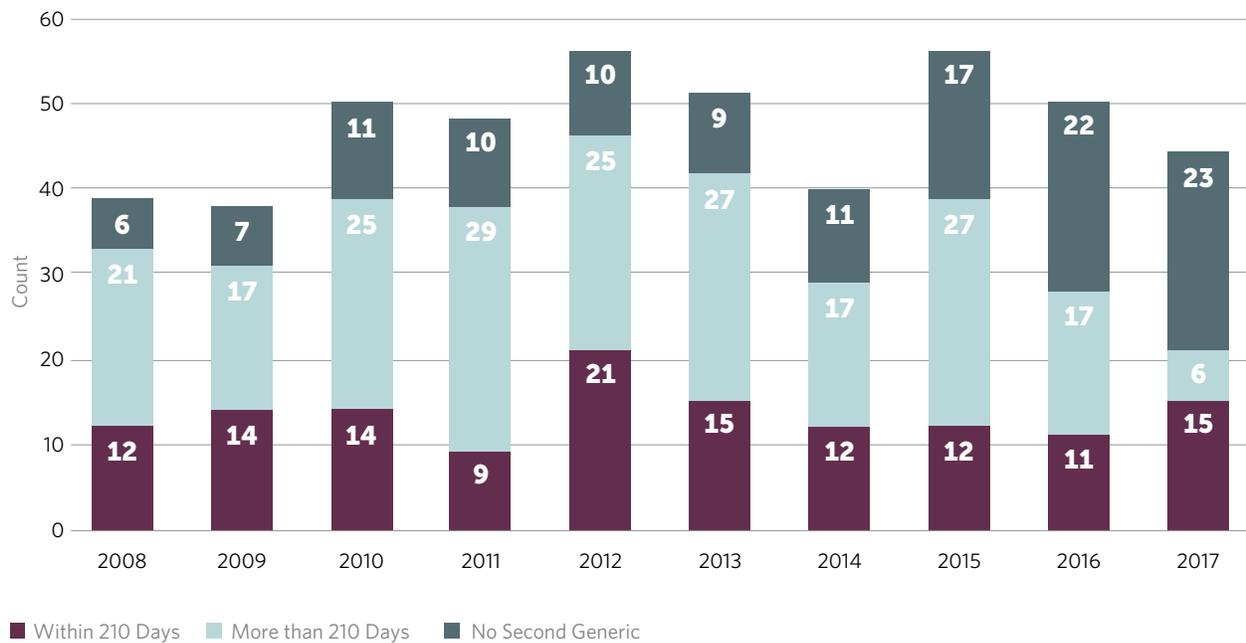
The most substantial reductions in average generic prices typically occur when a second generic manufacturer begins to produce a drug, which reduces the average generic price to nearly half the brand price.<sup>39</sup> This analysis estimates the time to approval of second generics both before and during GDUFA, with the caveat that while FDA approval is an indicator of likely market availability, other factors may prevent a generic drug from coming to market. The analysis does not take into account whether a drug was actually made available for sale by the manufacturer after approval, which would affect price competition.

The analysis again used approval dates from FDA's "Orange Book" database to identify all unique drug markets that had an exclusive first generic approved (i.e., drug markets for which the first generic approved was not accompanied by another generic approval on the same date)<sup>40</sup> during pre-GDUFA, from fiscal 2008 to 2012, and during GDUFA, from fiscal 2013 to 2017. The date of approval for any second generic was then determined, along with the number of days between approval of the first and second generic applications. If the second generic was approved during a different fiscal year than the first, both were grouped into the earlier year.

The analysis estimates how often second generics were approved by FDA and able to compete with a first generic as soon as possible. Because first generics often receive 180-day exclusivity, blocking approval of subsequent generics for six months, the analysis determined the share of second generic applications that were approved within 210 days of the first generic—composed of the 180-day exclusivity period and an additional 30 days, an arbitrary period used to account for any holiday, weekend, or other administrative delays that might prevent FDA from issuing the second generic approval on the 181st day.

The total number of exclusive first generics was relatively stable between fiscal 2008 and 2017 (Figure 2), ranging from 38 ANDAs in 2009 to 56 ANDAs in 2012 and 2015. During the pre-GDUFA period, 30.3 percent of exclusive first generics had a second generic approved within 210 days. During GDUFA, 27 percent had a second generic approved within 210 days (Figure 2). The number of exclusive first generics for which no second generic was approved increased during the latter three years of GDUFA, from 11 in fiscal 2014 to 23 in 2017, likely driven in part by the fact that less time had passed since the first generic was approved in the latter years of GDUFA. Manufacturers may still submit additional generic applications, ultimately reducing the number of drug markets with only one generic.

Figure 2  
 Time to Second Generic by Fiscal Year, 2008-17



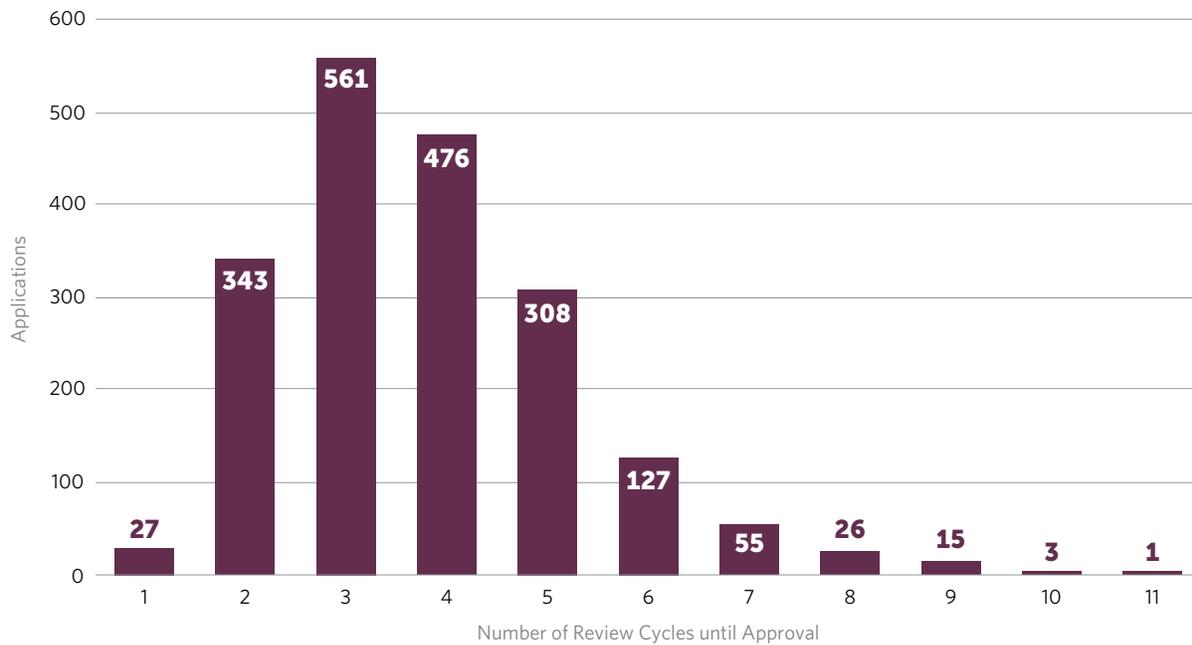
Source: Analysis by The Pew Charitable Trusts

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### Approval times delayed by multiple review cycles

Applications often undergo several review cycles before approval. In March 2017, FDA reported that an application historically goes through nearly four review cycles, on average, before it is approved (Figure 3).<sup>41</sup> Before GDUFA, the first-cycle approval rate was less than 1 percent. That had increased to 9 percent by March 2017,<sup>42</sup> but multiple review cycles continue to pose challenges to reducing approval timelines.

Figure 3  
 Number of Review Cycles to ANDA Approval, 2009–July 2014



Note: The average number of review cycles before abbreviated new drug application approval is 3.8.

Source: Reauthorization of the Prescription Drug User Fee Act, Medical Device User Fee Act, Generic Drug User Fee Amendments, and Biosimilar User Fee Act, before the Senate Committee on Health, Education, Labor, and Pensions (March 21, 2017) (statement of Janet Woodcock, director, Center for Drug Evaluation and Research, Food and Drug Administration), <https://www.help.senate.gov/download/testimony/woodcocktestimony34>

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When FDA takes any regulatory action other than approval or tentative approval, such as issuing a complete response letter or refusing to receive the application,<sup>43</sup> a new review cycle is triggered—requiring the sponsor to act. Although new generics are determined to be bioequivalent to the original product about 70 percent of the time,<sup>44</sup> FDA may find other deficiencies in the application that require a response from the sponsor. Most frequent deficiencies are for inadequate “chemistry, manufacturing, and controls” and “inadequate facilities.”<sup>45</sup> In calendar year 2017, about 12 percent of complete response letters were issued solely because of a facility deficiency.<sup>46</sup>

FDA also received more applications than anticipated during GDUFA, which may have contributed to longer review times.<sup>47</sup> GDUFA included an assumption that the agency would receive approximately 750 ANDAs a year, but sponsors submitted more than 2,500 applications in fiscal 2013 and 2014 alone. Fiscal 2015 was the only year in which the number of applications did not exceed 750.<sup>48</sup>

## Effects on drug costs

Additional generic approvals can increase competition and reduce prices, but it is not possible to determine exactly what role GDUFA played in drug pricing, since many other factors can affect it. One study found a slight inflation-adjusted increase in generic prices during GDUFA compared with previous major policy changes with the potential to affect drug markets—including implementation of the Medicare Modernization Act and the Affordable Care Act.<sup>49</sup> FDA examined the impact of 2017 approvals in the U.S. market and found that by the end of February 2018, approvals in 2017 had resulted in \$11.8 billion in savings to U.S. drug purchasers, without accounting for any off-invoice discounts or rebates.<sup>50</sup>

## New goals and program changes under GDUFA II

Congress passed GDUFA II as part of the FDA Reauthorization Act of 2017, which took effect in fiscal 2018.<sup>51</sup> GDUFA II includes a range of goals agreed to by FDA and industry for the agency's review of applications for generic drugs.<sup>52</sup>

Under GDUFA II, FDA has 10 months to review 90 percent of standard applications and eight months to review 90 percent of priority applications.<sup>53</sup> Applications for drugs with three or fewer competitors are eligible for priority review, if certain requirements are met;<sup>54</sup> prioritized products include sole source drugs as well as drugs with a single manufacturer at risk for drug shortages or price spikes.<sup>55</sup> GDUFA II also created a competitive generic designation program, which extends priority review and pre-application support to applications for drugs with a single manufacturer.<sup>56</sup> In some cases, a drug designated as a competitive generic may also be eligible for six months of market exclusivity.<sup>57</sup>

Despite GDUFA II's review timeline goals, several factors that can affect the time-to-approval rates remain beyond FDA's control. For example, if a complete response letter identifies major deficiencies in manufacturing facilities, it could be several months before the sponsor is able to take corrective action.<sup>58</sup> Additionally, exclusivities or blocking patents may inhibit FDA from granting approval after an application has been tentatively approved.<sup>59</sup>

GDUFA II also includes provisions intended to avoid multiple review cycles and improve the number of first-cycle approvals—one of the primary ways to shorten review times. To receive an eight-month priority review timeline, sponsors must provide FDA with information about manufacturing facilities at least 60 days before submitting the ANDA application.<sup>60</sup> FDA can use this information to determine whether a facility inspection is necessary, which may lead to a faster review.<sup>61</sup> As of July 2018, which is still early in GDUFA II, FDA had approved or tentatively approved 153 applications on the first cycle, representing 18 percent of approvals or tentative approvals in the GDUFA II period.<sup>62</sup>

FDA is conducting additional meetings with sponsors of complex products under GDUFA II, including pre-application and midreview-cycle meetings.<sup>63</sup> These meetings are intended to help clarify regulatory expectations for sponsors even before development begins.<sup>64</sup> FDA also is publishing product-specific guidance for complex products at least two years before the earliest lawful ANDA filing date, giving sponsors clarity on FDA's approach to determining bioequivalence.<sup>65</sup>

At a March 2, 2017, congressional hearing, Dr. Janet Woodcock, director of FDA's Center for Drug Evaluation and Research, stated that while GDUFA II's new initiatives will be labor-intensive for the agency, additional communications and outreach activities will enable more first-cycle approvals.<sup>66</sup>

GDUFA II also requires FDA to publicly report information related to generic application review, including the volume and status of priority applications, approval times, and number of review cycles before approval.<sup>67</sup> Additionally, FDA will publish a list of drugs with limited competition twice yearly, and collect and publish information on drugs withdrawn from the market monthly.<sup>68</sup> These reporting enhancements may enable developers to better understand FDA review activities and adjust to evolving market needs.

## Conclusion

Generic drugs generate competition and reduce overall drug spending. FDA review time for generic applications is an important indicator of how long it takes new generic drugs to reach the market and how quickly payers and patients may realize savings.

During GDUFA, FDA met its application review time and other programmatic goals. The number of generic applications approved increased significantly during the GDUFA period. FDA also completed review of a substantial backlog of pre-GDUFA applications. The total time from generic application submission to FDA approval initially increased under the program but started to decline in the latter years. While public data do not allow for a quantitative analysis of the impact of backlogged applications on approval times, these older applications represented a significant share of FDA workload during GDUFA, which increased median approval times.

While the number of generic products approved for marketing is important, the distribution of these products across drug markets and whether they lack significant competition is most relevant for assessing the likely impact on competition and drug spending. The increase in ANDA approvals during GDUFA was driven almost entirely by subsequent generics, which have less of an effect in driving down prices than second and third generics, approvals of which did not significantly increase during GDUFA. GDUFA II includes a range of provisions intended to prioritize FDA review of generic applications where there is little competition and thus the most potential to bring down prices.

Multiple review cycles for applications is a main driver of overall application review timelines. Predictable review processes and policies can help minimize risk to generic developers, increase the share of applications approved in the first cycle of review, and encourage market entry. GDUFA II places increased emphasis on improved communications and guidance, and includes a range of provisions intended to reduce multiple rounds of review and improve the rate of first-cycle approvals.

While GDUFA II seeks to build on lessons learned from the first GDUFA program to increase competition in drug markets, a number of factors can affect the generic marketplace—including purchaser consolidation, market size, the complexity of determining bioequivalence, and patents on brand-name drugs. In particular, small market size may be a significant barrier to additional manufacturer entry. Policymakers seeking to reduce drug costs should consider approaches beyond FDA review to stimulate competition.<sup>69</sup> They should also consider policies that have the potential to address drug spending through other means, such as changes in coverage and reimbursement policy, particularly in markets where generic or biosimilar competition is blocked by patents or exclusivities.

## Appendix: FDA met GDUFA goals

FDA met its GDUFA goals (Table A1). The agency reviewed and acted on 90 percent of backlogged applications by June 2016—15 months ahead of its goal.<sup>70</sup> The agency had not published final information by May 2018 on whether it met its performance goals for cohorts fiscal 2016 and 2017, and the 2017 applications did not mature until July 31, 2018, but the 2017 performance report suggested that it was on track to achieve them. As of the end of September 2017, the agency had taken first action on 82 percent of fiscal 2016 applications and 25 percent of 2017 applications.<sup>71</sup>

Table A1  
Cohort Review Goals and Outcomes

Cohort	Review goal	Outcome
<b>Backlog (before Oct. 1, 2012)</b>	Review and act on 90% of backlogged applications by end of GDUFA program (fiscal 2017)	As of Oct. 1, 2017, FDA had taken action on 98% of backlogged applications <sup>*</sup>
<b>Fiscal 2013</b>	No formal review goal	None reported
<b>Fiscal 2014</b>	No formal review goal	None reported
<b>Fiscal 2015</b>	Review and act on 60% of ANDA submissions within 15 months of submission	Reviewed and acted on 97% of ANDAs within 10 months of receipt <sup>†</sup>
<b>Fiscal 2016</b>	Review and act on 75% of ANDA submissions within 15 months of submission	Though all fiscal 2016 submissions did not mature until Dec. 31, 2017, for those actions that FDA had taken as of Oct. 1, 2017, 100% were taken within 15 months of submission <sup>‡</sup>
<b>Fiscal 2017</b>	Review and act on 90% of ANDA submissions within 10 months of submission	Though all fiscal 2017 submissions did not mature until July 31, 2018, for those actions that FDA had taken as of Oct. 1, 2017, 99% were taken within 10 months of submission <sup>§</sup>

\* Food and Drug Administration, “FY 2017 Performance Report to Congress for the Generic Drug User Fee Amendments,” <https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/UCM607654.pdf>.

† Ibid.

‡ Kathleen Uhl, director, Center for Drug Evaluation and Research, Food and Drug Administration, “State of OGD: Pivoting to GDUFA II” (presentation, Association for Accessible Medicines 2017 Fall Technical Conference, North Bethesda, Maryland, Nov. 6, 2017), <https://www.accessiblemeds.org/sites/default/files/2017-11/Kathleen%20Uhl.pdf>.

§ Ibid.

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In addition to review timeline goals, GDUFA included other programmatic goals achieved by FDA. The agency anticipated hiring about 1,000 people for the generic drug program but had hired over 1,500 through fiscal 2016.<sup>72</sup> The agency created more guidance documents and commissioned research to develop guidance for complex generics, products that are not easily demonstrable as bioequivalent and require additional FDA technical guidance.<sup>73</sup> The agency created or revised nearly 200 guidance documents in fiscal 2017.<sup>74</sup>

## Endnotes

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