Federal Spending on Off-Patent Drugs That Lack Generic Competition

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In recent years, several older, off-patent drugs have not attracted generic competition, allowing their manufacturers to implement substantial price increases.[1, 2] Since 2017, the Food and Drug Administration (FDA) has taken steps to encourage generic competition for these "single-source" drugs. Policymakers and politicians have proposed more aggressive solutions, such as allowing importation from manufacturers supplying other countries or instructing the federal government to manufacture these drugs itself.[2, 3] We estimated federal spending on off-patent drugs that lack generic competition and potential savings available from policies targeting this cohort of drugs.

METHODS

Using the FDA's published List of Off-Patent, Off-Exclusivity Drugs Without an Approved Generic (June 2019 version),[4] we excluded duplicates, drugs not listed in the Medicare or Medicaid Drug Spending Dashboards, and drugs with direct generic competition or competition from near-identical products (i.e., same formulation and ingredient) by October 2019. Because Spending Dashboard data aggregate costs for drugs with multiple formulations, we excluded drugs if only one of several formulations lacked generic competition.

We obtained 2018 annual drug spending from the Medicaid and Medicare Parts B and D Spending Dashboards. We estimated average Medicare Part D (41%) and Medicaid (60%) rebates from federal reports. In sensitivity analyses, we widely varied rebate estimates (Medicare Part D 20–60%, Medicaid 30–100%). Rebates for older, brand-name drugs may reach 100% in Medicaid due to annual supplemental rebates accounting for price increases over inflation. Drugs paid through Medicare Part B are not subject to manufacturer rebates.

We calculated total and median spending for all drugs in the cohort and the 20 drugs with the highest federal spending in 2018. We estimated potential savings from policies to increase competition or reduce prices by assuming spending reductions of 20–80%, based on previous estimates.[5]

RESULTS

Among 330 drugs on the FDA list that lacked generic competition, our final cohort consisted of 137 (42%) single-source drugs with available Medicare or Medicaid spending data in 2018. Fifty-seven (42%) were orally administered, 35 (26%) were injected, and 45 (33%) had another route of administration (e.g., topical, inhaled).

The median post-rebate federal spending per drug was $0.6 million (interquartile range $0.09–4.7 million), for a total of $1.6 billion for all drugs in the cohort (Table 1). Varying rebate estimates led to a total spending range of $1.0–2.2 billion. The top 20 drugs—15 of which were not orally administered—accounted for 89% of total spending (Table 2). Assuming policies to increase competition or reduce prices would have reduced spending on these drugs by 20–80%, federal savings would have ranged from $328 million to $1.3 billion in 2018.

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Table 1 Federal Spending and Estimated Savings for Policies Addressing Off-Patent Drugs Lacking Generic Competition

	Total spending, 2018; USD, millions	Estimated post-rebate spending, 2018; USD, millions	Estimated savings from reduced spending; USD, millions
Medicare Part D	1410	836	167–669
Medicare Part B	474	474	95–380
Medicaid	819	332	66–265
Total	2703	1642	328–1314

The first column represents the total spending from the Medicare and Medicaid Drug Dashboards associated with 137 off-patent drugs lacking generic competition. The second column adjusts spending for average rebates (41% for Medicare Part D, 60% for Medicaid). The third column represents the potential savings from policies that reduce (post-rebate) spending on these drugs between 20 and 80%

DISCUSSION

Policies to improve competition or reduce prices for off-patent drugs lacking generic competition would save the federal government around $1–2 billion annually. Price spikes among this cohort of drugs have attracted significant attention from policymakers and politicians over the last several years. However, because most of these drugs target a small number of patients, spending on them represents a small minority of the more than $100 billion in annual drug spending by Medicare and Medicaid.

Many of these single-source drugs are essential medicines, and price hikes resulting from lack of generic competition have been burdensome for patients who depend on them. There may be strong public health incentives to reduce cost and improve access for these drugs. However, such policies are unlikely to curb overall federal prescription drug spending.

Our cohort includes just under half of all "single-source" drugs reported by the FDA. However, most drugs were excluded for unavailable spending data, likely due to small utilization, and in our cohort, the top 20 drugs accounted for 89% of spending.

We did not account for spending by private payers, which would benefit from competition on these drugs and add to societal savings. Additionally, many drugs have at least one generic competitor but fewer than the 3 or more needed to generate major price reductions.[5] Policies to address limited generic competition could possibly extend to drugs with 3 or fewer competitors as well. Conversely, some drugs in our cohort may lack competition because they are technically challenging to replicate in generic form, such as inhalers and topical formulations. In these cases, enhanced government negotiating power may be needed to reduce prices, as has recently been proposed in Congress.

Table 2 Top 20 Off-Patent Drugs Lacking Generic Competition with Highest Federal Spending

Drug information			Post-rebate federal spending, 2018; USD, millions			
Generic name (brand name)	Route of administration	Approval date	Medicare Part D	Medicare Part B	Medicaid	Total
Octreotide acetate (Sandostatin LAR)	Injection	Nov 1998	32	414	0	446
Estrogens, conjugated (Premarin)[a]	Oral	May 1942	176	0	32	208
Brinzolamide (Azopt)	Ophthalmic	Apr 1998	110	0	4	114
Leuprolide acetate (Lupron Depot)	Injection	Jan 1989	41	5	26	72
Pentosan polysulfate sodium (Elmiron)	Oral	Sep 1996	58	0	12	70
Mesalamine (Pentasa)	Oral	May 1993	57	0	12	68
Iron sucrose (Venofer)	Injection	Nov 2000	0	4	61	65
Apomorphine hydrochloride (Apokyn)	Injection	Apr 2004	54	0	0	54
Ethinyl estradiol; etonogestrel (Nuvaring)	Vaginal	Oct 2001	2	0	48	50
Salmeterol xinafoate (Serevent Diskus)	Inhaled	Sep 1997	37	0	8	45
Budesonide (Pulmicort Flexhaler)	Inhaled	Jul 2006	33	0	9	41
Mometasone furoate (Asmanex Twisthaler)	Inhaled	Mar 2005	18	0	15	33
Pyrimethamine (Daraprim)	Oral	Jan 1953	20	0	12	32
Fluticasone propionate (Flovent Diskus)	Inhaled	Sep 2000	25	0	6	32
Leuprolide acetate (Lupron Depot-Ped)	Injection	Apr 1993	0	0	30	30
Triptorelin pamoate (Trelstar)	Injection	Jun 2000	6	17	1	24
Amino acids (Prosol)	Injection	Aug 1998	22	0	0	22
Iloprost (Ventavis)	Inhaled	Dec 2004	0	18	3	21
Tiopronin (Thiola)	Oral	Aug 1988	12	0	4	16
Testosterone (Androderm)	Transdermal	Sep 1995	12	0	2	14
Total			716	458	282	1456

[a]*Because Premarin is manufactured from natural animal estrogens, the exact ingredients have not been identified and the FDA has stated that it will not approve a generic alternative under current rules (Source: Ingersoll M. FDA Says It Won't Approve Generic Forms of Premarin. Wall Street Journal, 1997)*

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Compliance with Ethical Standards:

Conflict of Interest: *The authors declare that they do not have a conflict of interest.*

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