GENERIC DRUG SAVINGS IN THE U.S.

FIFTH ANNUAL EDITION: 2013
EXECUTIVE SUMMARY

Generic pharmaceuticals – now firmly positioned as a reliable lever to decrease healthcare costs – continued to deliver outstanding quality and value in 2013. The fifth annual GPhA/IMS report, Generic Drug Savings in the United States, quantifies the savings generated by more affordable generic medicines. For the first time, this year’s report spotlights retail savings from generics. All data in the 2013 report were supplied by the IMS Institute for Healthcare Informatics, a division of IMS Health.

Despite an unprecedented year of regulatory changes, the generic pharmaceutical industry’s strong record of savings for the U.S. health system continued. Total U.S. health care spending in 2011 reached $2.7 trillion in 2011, or $8,680 per person.\(^1\) Health spending grew 3.9 percent in 2011, the same rate of growth as in 2009 and 2010. Health spending continues to make up nearly 18 percent of the Gross Domestic Product (GDP).

Health spending continues to be a major investment by patients and taxpayers, federal and state governments, and payer organizations. National Health Expenditure Accounts data from the Centers for Medicare and Medicaid Services (CMS) also show that Medicare spending, which represented 21 percent of national health spending in 2011, grew 6.2 percent to $554.3 billion, an acceleration from growth of 4.3 percent in 2010. Total Medicaid spending grew 2.5 percent in 2011 to $407.7 billion, a deceleration from 5.9 percent growth in 2010. Federal Medicaid expenditures decreased 7.1 percent in 2011, while state Medicaid expenditures grew 22.2 percent. Consistent with previous years, generic use is vital to holding down health costs.

**Key findings from this year’s report:**

- Over the 10-year period 2003 through 2012, generic drug use has generated more than $1.2 trillion in savings to the health care system.

- In 2012, generics saved the U.S. health system $217 billion, up from $188 billion in 2011.

- Nervous system and cardiovascular treatments account for 60 percent of cost savings.

This year, a special section of the report is dedicated to retail pharmacy savings. Notably, generics have saved the retail market $931 billion over the last 10 years. And, over the recent decade, the federal government accounted for 31 percent of retail savings. Savings to Medicare Part D plans reached approximately $180 billion since the Part D program began in 2006, while Medicaid savings totaled more than $96 billion. During this same period, generics have saved out-of-pocket cash payers $78 billion, making a critical difference to these typically uninsured and poorer customers.

On the private payer side, generics in the last decade have saved commercial third-party payers $552 billion. Future savings are expected to accumulate at an increasing rate. As patients and customers look for more ways to save, generics continue to be one of the few areas where health savings can be counted – and counted on.

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Americans spent about $325.8 billion\(^2\) on prescription medicines in 2012, down about 3 percent from the prior year as the use of healthcare services overall continued a two-year decline. However, estimates from the IMS Institute for Healthcare Informatics show that drug spending is expected to grow between 3 and 4 percent annually over the next four years, reaching approximately $360 billion in 2017. This forecast assumes only a modest increase in drug demand as a result of expanded coverage under the Affordable Care Act (ACA) and some incremental pressure by payers and employers to limit drug price increases.

However, projected spending jumps dramatically—to as high as $450 billion\(^3\) by 2017—if enrollment in new ACA insurance exchanges reaches capacity and if brand prices continue to increase above the inflation rate. This level of spending would be unsustainable if not for the savings generated by the use of generic drugs. The use of generic versions of brand name drugs now saves the U.S. healthcare system more than $200 billion annually. In 2012, generic savings reached $217 billion, 15 percent more than the $188 billion saved in 2011. This equates to an average savings of $4 billion every week of the year.

Over the 10-year period 2003 through 2012, generic drug use has generated more than $1.2 trillion in savings to the health care system. The annual rate of increase in savings has averaged approximately 17 percent since 2007. These savings show conclusively that the use of lower cost generic medicines is vital to holding down the growth of health care spending.

**Federal Government Share of Retail Savings**

Generic medicines utilization is critical to the sustainability of federal health programs.

For the first time, this report breaks out the savings generics provide for each payer type (i.e., out-of-pocket, insurers, Medicaid, other third-party payers) at the retail level. Because retail sales represent close to 76 percent of the total savings, the break out by payer type offers added validation of the significant benefits available to consumers, patients and payers when choosing generics. For instance, Medicaid beneficiaries who get their prescriptions filled through retail outlets have saved more than $96 billion over the

\(^2\) The IMS Institute for Healthcare Informatics, *Declining Medicine Use and Costs: For Better or Worse?*, May 2013  
\(^3\) The IMS Health, *Global Use of Medicines: Outlook Through 2017*, Nov. 2013
past 10 years by using generic versions of more costly brand name drugs. Seniors enrolled in a Medicare Part D plan have
saved approximately $180 billion in prescription drug costs since the Part D benefit program began in 2006. Over the last
10 years, those enrolled in a Medicare Part D drug plan, Medicaid, or another federally sponsored drug benefit program
realized total retail savings of $301 billion, or approximately one-third of the total $931 billion in retail market savings
achieved through the use of generic medicines.

Outside of government, commercial third-party payers, such as insurance companies and employee health plans, have
saved $552 billion over the past 10 years. And those paying for drugs out-of-pocket, who typically are uninsured or
underinsured, have saved $78 billion in medicine costs over this period. Out-of-pocket payers represent about 11 percent
of all prescription drug users. In 2012 alone, savings in retail markets totaled $171 billion, with about $71 billion going to
payers in federal programs. With total U.S. health care costs approaching $3 trillion annually and growing, these critical
savings contribute significantly to holding down the spending growth rate.

Savings from Newer Generics Increasing Exponentially

Again in 2012, savings from newer generic medicines—defined as those entering the market in the past 10 years—
represent more than half of total savings. Of the $217 billion saved last year, $157 billion, or about 72 percent, came from
the newer generics. That compares to $123 billion of the total $188 billion, or 65 percent, in 2011. While there are large
cost savings associated with products whose patents expired before 2003, savings from new generic versions of reference
drug products have accumulated rapidly as generic versions of such big sellers as Zocor, Lipitor and Zoloft have come to
market. Over the past decade, savings from newer generics accounted for $639 billion of the $1.2 trillion saved, or 53
percent of the total savings.

Savings from newer generics will continue to grow over the coming years as patents expire on currently protected brand drug franchises. Between 2014 and 2016, brand drugs with $40 billion in annual sales will be exposed to generic competition. And this competition will spur even more development of newer and more advanced medicines. Today, there are some 2,000 drugs in clinical development with several hundred in Phase III or Phase II/III clinical trials.
**Savings Abound in Central Nervous System Drugs**

More than one-third (35 percent) of the total savings in 2012, or about $75 billion, came from generic versions of central nervous system drugs. Generic drugs used to treat cardiovascular conditions delivered an additional $53 billion in savings. These two therapeutic categories together provided patients, consumers and the U.S. health care system more than $130 billion in total savings last year. Generic metabolism drugs added another $30 billion in savings. Since 2003, savings generated by generic drugs in these three therapeutic classes alone have accounted for $949 billion dollars.

This savings analysis clearly demonstrates that efforts to reduce health care costs—whether on Capitol Hill or in the state legislatures—must recognize the billions of dollars in savings that can be achieved through the use of generic medicines.

While there are large cost savings associated with products whose patents expired before 2003 (blue area), savings from newly genericized products have accumulated rapidly.
METHODOLOGY

Data in this report were provided by the IMS Institute for Healthcare Informatics, a division of IMS Health. The analysis updates the fourth edition of the Generic Drugs Savings Study released in August 2012, and shows the cost savings that generic pharmaceuticals provided to the U.S. health care system over the 10-year period of 2003 through 2012. The fifth edition utilizes IMS data on sales and unit volumes of brand and generic products, estimating potential savings at the molecule level. To ensure consistency of the analysis, branded products are defined as originator molecules that no longer are patent protected; generic drugs are those that were introduced after expiry of patent protection on the reference product. The total savings was derived from a universe of 2,953 molecules, which are products that had both a brand and generic version available on the market.

Excluded from the analysis were drug products for which (1) there was no measurable generic competition, either because an exclusivity or patent still in effect or no generic version of the brand yet approved; and (2) only a generic drug was available for sale because the brand was no longer marketed. The overall methodology approach was to add 2012 generic volume to the 2011 study data for each molecule. The average brand price in the last year of patent protection (for expiries prior to 2003) was estimated using the formula [total sales of brand molecule] divided by [total standard units of brand]. For year 2012 brands with generic competition, the estimated value of the replaced brand product was calculated using the formula [average brand price] multiplied by [total standard units of generic]. Finally, the generic cost savings was computed using the formula [value of replaced brands with generics] minus [total sales of generic], with total savings equal to the sum of all cost savings across all therapeutic areas. To obtain the most accurate savings estimate, “standard units” are used throughout the study. The standard unit is the number of units divided by smallest common dose of a product form. Number of units is the number of tablets, capsules, ml or grams sold, times the number of packages multiplied by package size.

Note: IMS routinely updates its market audits, sometimes due to product categorization changes. This can result in changes to previously reported market sizes for certain drugs. For more information about this study, contact GPhA at 202-249-7100, or visit www.gphaonline.org. This IMS analysis was commissioned by the Generic Pharmaceutical Association; 777 6th Street, NW, Suite 510; Washington, DC 20001.

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<thead>
<tr>
<th>Types</th>
<th>% of Molecules</th>
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<tbody>
<tr>
<td>1. Brands without Generic Competition</td>
<td>27%</td>
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<tr>
<td>2. Loss of Exclusivity: after 2002</td>
<td>9%</td>
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<tr>
<td>3. Loss of Exclusivity: 2002 and before</td>
<td>5%</td>
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<tr>
<td>4. No brand volume in the data set</td>
<td>59%</td>
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<tr>
<td>Total Number</td>
<td>2,953</td>
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Source: IMS Health, Midas, Dec 2012
Data Source includes: US Clinics, Drugstores, Federal Facilities, Food Stores, HMOs, Home Healthcare, Long Term Care, Mail Service, Non-Fed Hospital and Misc.