



SAVINGS ACHIEVED THROUGH THE USE OF
GENERIC PHARMACEUTICALS
2000 - 2009

JULY 2010

GPhA

GENERIC PHARMACEUTICAL ASSOCIATION

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EXECUTIVE SUMMARY

This report builds on the historic study released in May 2009 showing that the use of generic drugs saved the U.S. health care system nearly three-quarters of a *trillion* dollars over the decade 1999-2008. Again this year, the Generic Pharmaceutical Association (GPhA) commissioned IMS Health, the world's leading provider of market intelligence to the pharmaceutical and health care industries, to conduct a 10-year supplemental savings analysis (2000-2009) that included brand and generic drug utilization data for 2009, the most recent full-year reporting period.

The results of the IMS analysis are astounding. For the decade 2000 through 2009, the use of generic prescription drugs in place of their brand-name counterparts saved the nation's health care system more than \$824 billion dollars. In 2009 alone the use of FDA-approved generics saved \$139.6 billion—a 15% growth over the prior year's savings—or about \$382 million every day. From the IMS analysis, GPhA makes the following observations:

- ❖ the exponential growth in savings since 2006 has been driven by the launch of generic versions of several blockbuster brand drugs;
- ❖ from 2008 to 2009, savings generated by the use of generic central nervous system drugs soared 20%;
- ❖ savings generated by new generics will continue to increase as \$89 billion in branded drug sales will lose patent protection over the next five years;
- ❖ every 2% increase in generic utilization in Medicaid programs saves taxpayers an additional \$1 billion annually; and
- ❖ over the past 10 years, patent settlements have resulted in billions of dollars in savings as dozens of first-time generics have come to market prior to patents expiring on the counterpart brand drugs.

GPhA maintains that similar savings could be achieved in the biopharmaceutical marketplace if FDA implements a workable approval pathway for biogenerics and biosimilars. Such a system must prevent innovators from forestalling generic competition by “evergreening” their patents in order to receive multiple market exclusivity periods. Biogeneric and biosimilar products would inject the competition needed in the biologic market to lower costs and provide measurable savings.

HIGHLIGHTS AND TRENDS

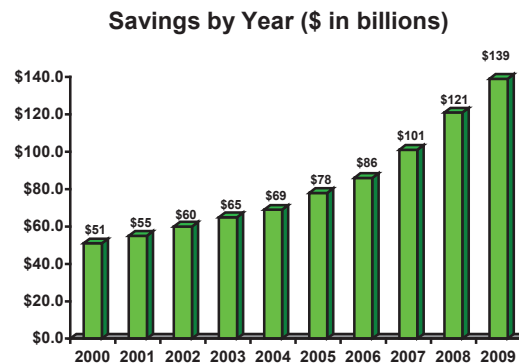
Substituting generic medicines for their brand-name counterparts saved our health care system more than \$824 billion dollars over the decade 2000 to 2009. In 2009 alone the use of FDA-approved generic pharmaceuticals saved the U.S. health care system \$139.6 billion. That equates to a savings of \$382 million per day—or **more than \$1 billion every three days**.

This remarkable level of savings dwarfs initial savings estimates that were made in 1984, when the Hatch-Waxman Act established the modern-day generic industry. At that time, it was projected that generics might save a billion dollars over the first 10 years. The Congressional Budget Office (CBO) reported in 1998 that savings realized from the substitution of generic for brand-name drugs saved consumers between \$8 billion and \$10 billion in 1994, the 10th year after Hatch-Waxman was enacted. Since then, annual savings have grown exponentially.

Generic Versions of Blockbuster Drugs Have Driven Surge in Savings

This new analysis from IMS Health, based on brand and generic prescription drug sales and pricing data, including 2009, the most recent year, shows that annual savings have exceeded \$100 billion in each of the last three years. During the first six years of the study period, savings increased steadily with an annual growth rate of between 3% and 10%, from \$51 billion in 2000 to \$78 billion in 2005.

Since 2005, savings have grown at an annual rate of more than 15%, from \$86 billion in 2006 to nearly \$140 billion in 2009. This phenomenal four-year growth period was driven both by the launch of generic versions of several blockbuster brand drugs, including Zocor[®], Norvasc[®] and Zolof[®], and greater nationwide use of affordable generic medicines.

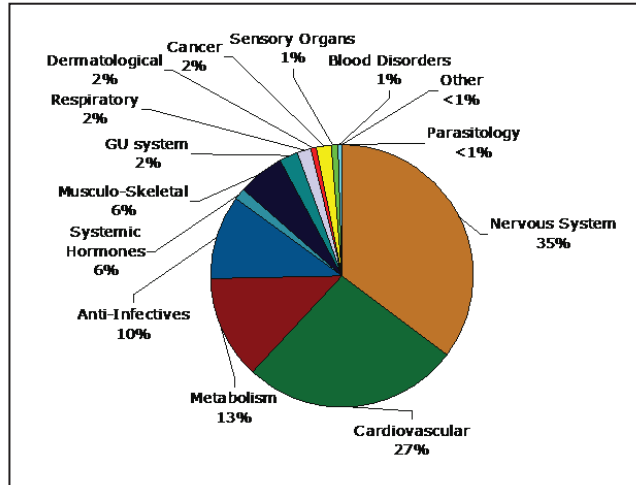


Over the 10-year period of this study, more than 20 billion prescriptions were dispensed in the U.S. using generic pharmaceuticals. In 2009 alone, 3 billion of the 4 billion prescriptions dispensed in the U.S. were filled with generic equivalents to the

brand drug. GPhA contends that without the availability of lower-cost generics, millions of Americans would not be able to afford the medicines they need.

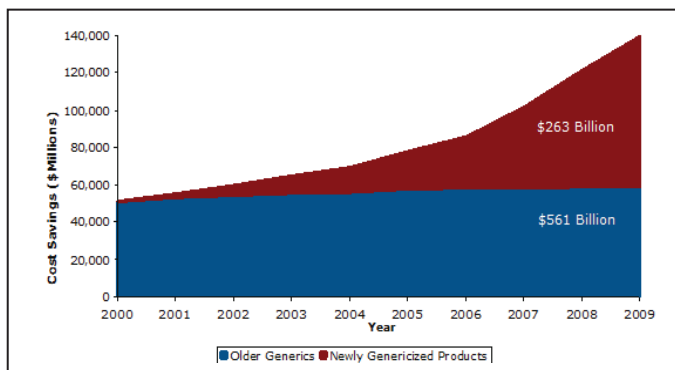
Cardiovascular Drugs Account for Highest Growth in Savings

Of note in 2009 was the measurable increase in savings generated by generic central nervous system (CNS) drugs. From 2008 to 2009, savings generated by generic use in this therapeutic area soared 20%, from \$41 billion in '08 to \$49 billion in '09. Generic cardiovascular drugs also experienced a significant growth in savings, up 14% to \$37.3 billion in 2009 from \$32.7 billion the prior year. In 2009, generic utilization in the three therapeutic categories of CNS, cardiovascular and metabolism accounted for nearly three-fourths of the total \$139 billion in savings. Over the 10-year period of the study, the use of generic CNS, cardiovascular and metabolism drugs have saved the U.S. health care system more than \$565 billion dollars.



Newer Generics Have Created Exponential Growth

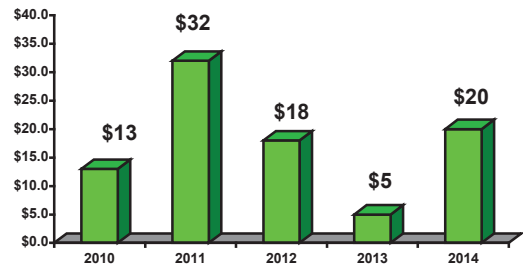
The analysis also found that savings from generics introduced over the past nine years are accumulating rapidly. In 2009, 64% of the savings, or approximately \$90 billion of the \$139 billion saved, was generated by these newer generic drugs. Over



the 10-year study period, nearly one-third of the \$824 billion in savings came from generic drugs approved since 2000. Equally significant is the fact that older generics, those approved prior to 2000, continue to provide a foundation of savings that has remained constant at the \$50 billion mark for more than a decade.

The savings generated by newer generics is expected to continue to increase exponentially as \$89 billion in name brand drug

sales will lose patent protection over the next five years. Six of the 10 current largest-selling drug products are expected to encounter generic competition, including the top two: Pfizer's \$14 billion cholesterol fighter Lipitor® and the blood clot preventer Plavix® by Bristol-Myers Squibb. Among the other name brand blockbusters that will lose patent protection between now and 2014 are Zyprexa®, Singulair® and Aricept®. As more affordable generics continue dominating chronic care classes such as antipsychotics, cholesterol control and antiulcerants, the savings these generic products achieve will play a significant role in reigning in health care costs.



Brand Sales with Expiring Patents (\$ in billions)

Generic Savings Are Critical as States Implement Health Care Reform

GPhA strongly believes that increasing the use of generic medicines represents a particularly important component in expanding access and controlling costs as states

CMS data show that for every 2% increase in generic utilization, Medicaid saves an additional \$1 billion annually.

implement the expansion of Medicaid mandated by health care reform signed into law in 2010. The government estimates that an additional 16 million new beneficiaries will be brought under the Medicaid program over the next three years, resulting in hefty cost increases.

One way states can control the growing costs is through a greater reliance on the use of generic drugs. Data from the federal Centers for Medicare and Medicaid Services (CMS) show that in 2009 about 290 million prescriptions were purchased through the Medicaid program at a total cost of \$23 billion. The availability of generics enabled Medicaid to purchase 64% of these prescriptions (186 million) by using just \$3.9 billion of the \$23 billion spent for drugs. In other words, Medicaid met nearly two-thirds of its prescription drug need with less than one-fifth of its prescription dollars.

CMS data show that for every 2% increase in generic utilization, Medicaid saves an additional \$1 billion annually. With the Medicaid generic use rate running a full 10 percentage points lower than the 75% national rate, states have considerable opportunities to achieve added savings.

Prices Continue to Fall for Generic Prescriptions

Access to approved, more affordable generic drugs has proven to be a primary driver of health care savings. A May 2010 report from AARP showed that while brand name drug prices increased 9.7% over the 12 months ending in March 2010, generic prices dropped nearly 10% during that same period. AARP concluded that the increase in brand prices was the largest one year spike since the group began tracking drug prices in 2002. It noted that over the period of the study, inflation remained nearly flat at 0.3%. AARP determined that the average annual cost of prescriptions for a person taking three brand medicines *increased* \$706 during the one-year period, while the cost of generic versions of those same three medicines *decreased* by \$51.

Against this background, it is critical that new FDA-approved generics be introduced into the market sooner rather than later. American consumers and payors, including the federal government and the states, lose billions of dollars each week that generic access is delayed. Inadequate funding of FDA's Office of Generic Drugs (OGD) in past years has resulted in a backlog of more than 2,000 unapproved generic applications and a median approval time of more than 27 months. GPhA has long advocated for more robust funding for OGD and last year succeeded in getting a boost of nearly 20% in the Office's fiscal year 2010 budget. With data showing that each one percent increase in the nationwide generic utilization rate yields \$4 billion in added savings, there is an enormous return on investment for adequately funding OGD to ensure near-term availability of new generic drugs.

Patent Litigation Settlements Provide Even Greater Savings

Access to the new cost-saving generics also is facilitated through pro-consumer settlements of drug patent litigation. Over the past 10 years, patent settlements have enabled dozens of first-time generics to come to market many months before patents on the counterpart brand drugs expired. For instance, settlement of the patent suit involving the anti-epileptic medication Lamictal® allowed the generic to come to market three months prior to brand patent expiration, saving patients more than \$190 million during the early launch period. And settlement of the Nexium® patent suit will allow a generic of this popular antiulcerant to be introduced nearly one year before patent expiry, saving consumers an estimated \$1.5 billion in prescription costs.

While the settlement issue has engendered opposition from some who contend such generic-brand agreements are anticompetitive, the federal courts repeatedly have

recognized that settlements can be desirable options in patent litigation. The record is clear: settlements allow generic drugs to come to market long before patents on the counterpart brands expire, resulting in billions of dollars in annual savings. Year after year, settlements have proven to be pro-consumer and pro-competitive.

Similar Savings Can Be Achieved in the Biologic Marketplace

It is GPhA's position that the success of generics in achieving savings for consumers using traditional chemical drugs can be duplicated in the biopharmaceutical market. Biogenerics and biosimilars would inject the competition needed in the biologic market to lower costs and provide significant savings for patients in need of these lifesaving treatments. To maximize this opportunity, it is essential that the FDA implement regulations that do not permit innovators to "evergreen" patents and thereby stall generic competition for years to come. The new health care reform laws authorizes FDA to approve biogeneric and biosimilar products that meet the Agency's rigid standards for safety, purity and effectiveness. But without safeguards against evergreening patents, innovators could manipulate the system to get repeated monopolies, effectively delaying competition indefinitely.

Current biologic medicine costs are staggering, putting these treatments out of reach for many patients. In some cases, insurance companies deny coverage for biologics because of their costs. Even when coverage is available, the co-pays can be thousands of dollars each year. Today, government spending for biologics is increasing at a faster pace than any other health care-related expense with the exception of diagnostic imaging tests. By the end of this year, spending for biologics is expected to reach \$100 billion, accounting for more than a quarter of the country's total drug spending. This escalation in spending is unsustainable. The proven means of reigning in costs is market competition. Competition from biogenerics would provide a market-based mechanism to help reduce expenditures and generate sizeable savings. Without competition, patients will continue to experience ever-increasing prices, which ultimately will impact the care they receive.

For complete information on any of the topics discussed in this study, including Medicaid and Medicare generic utilization, funding for the Office of Generic Drugs, patent settlements and the cost trends for brand and generic prescription drugs, please contact the Generic Pharmaceutical Association at 202-249-7100, or visit gphaonline.org. This IMS analysis was commissioned by the Generic Pharmaceutical Association; 777 6th Street, NW, Suite 501; Washington, DC 20001.

METHODOLOGY

This analysis conducted by IMS Health updates the previous analysis released in May 2009 on the total cost savings generic pharmaceuticals have provided to the U.S. health care system over the 10-year period of 2000 through 2009.

The analysis utilized 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, brand products are defined as originator molecules that no longer are patent protected; generic drugs are those that were launched after the patent protection had expired on the original reference product. The total savings was derived from a universe of 4,318 drugs, which are those products for which both brands and generics were available.

As shown in the chart at right, excluded from the savings analysis were drug products for which: (1) there was no measurable generic competition, either because of an exclusivity or patents still in effect or because there was no generic version of the brand yet approved; and (2) only a generic drug was available for sale because the brand drug was no longer available on the market.

Types	% of Molecules
1. No generic competition	45%
2. Lost exclusivity after 1999	8%
3. Lost exclusivity 1999 and before	15%
4. No brand volume in the data set	32%
Total Number of Molecules	4,318

Source: IMS Midas Data

Data Source includes: US Clinic, Drugstores, Fed Facilities, Food Stores, HMO, Home Healthcare, Long Term Health Care, Mail Service, Non-Fed Hospital and Misc.

Note: Because analysis was conducted across multiple TAs, some molecules can exist across multiple TAs.

The overall methodology approach was to add 2009 generic volume to the 2008 Cost Savings Study data for each molecule. The average brand price in the last year of patent protection (for patent expirations before 2000) was estimated using the formula (Total sales of brand molecule) divided by (Total standard units of brand). For year 2009 brands under generic competition, the estimated value of the replaced brand product with generics 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 the (Total sales of generic), with total savings equal to the sum total 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 refers to the number of tablets or capsules, ml or grams sold, multiplied by the number of packages sold, then multiplied by package size.

