September 2011

SAVINGS

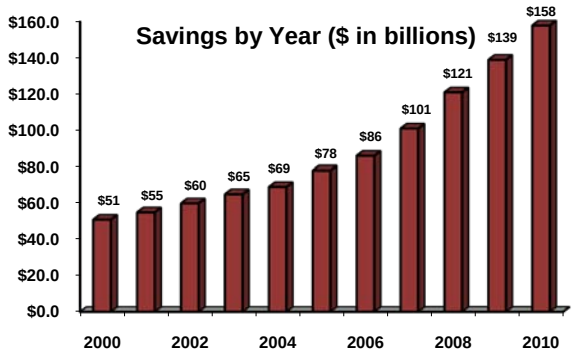
An Economic Analysis of Generic Drug Usage in the U.S.

EXECUTIVE SUMMARY

As government leaders in Washington and across the country look for ways to cut health care costs, this new analysis details the remarkable savings achieved through the use of generic medications. Over the past 12 years (January 1999 through December 2010), the use of FDA-approved generic prescription drugs has saved the U.S. health care system an astounding $1.031 trillion. And at the current generic utilization rate, more than $3 billion is being saved every week as American consumers and patients rely on generic medicines to provide the quality care they need.

This independent analysis, conducted for GPhA by the IMS Institute for Healthcare Informatics and IMS Health, shows that:

- The use of generic prescription drugs in place of their brand name counterparts saved the U.S. health care system more than $931 billion over the past decade (2001 through 2010).
- In 2010 alone, generic use generated more than $157 billion in savings.
- Savings from newer generic medicines—those that have entered the market since 2001—continue to increase exponentially and account for more than one-third of the total savings.



With government leaders being forced every day to make difficult choices pertaining to spending and deficits, it is imperative that the savings available through generic use be recognized. Policies that encourage generic dispensing and steer clear of unwarranted restrictions on generic use can bring even greater savings as new requirements under the 2010 health care reform law are put in place. For instance:

- Data from the Centers for Medicare and Medicaid Services (CMS) show that increasing generic use in Medicaid by just two percentage points would save the program more than $1.3 billion annually. These savings are critical to sustaining the viability of Medicaid, as studies have concluded that the program needlessly spends billions of dollars each year by reimbursing pharmacies for costly brand products when generics

with identical active ingredients, strengths, dosage forms and therapeutic benefits are available at lower costs.

- With more than a third of annual savings generated by generic medications coming from products that have entered the market since 2001, it would be misguided to enforce a ban on patent litigation settlements since most new generics get to market as the result of a settlement. In fact, of the 22 new, first-time generics launched this year, 16 will be launched prior to expiration of the brand drugs thanks to a patent settlement.

- Increasing funding to the FDA's Office of Generic Drugs (OGD) is also an essential component in ensuring the savings potential from generic medications is fully realized. Currently, more than 2,000 generic drug applications are awaiting OGD action, with as many as 365 of those for first-time generic drugs, according to the FDA. Savings are being left on the table each day this backlog continues to grow, as consumers and the government are forced to pay brand drug prices for prescriptions that could be available in affordable generic versions. With generic manufacturers on the verge of a historic agreement to provide the FDA with hundreds of millions of dollars in new user fee funding, it is critical that members of Congress follow suit to ensure that the savings generated by the use of generic medications will continue to grow.

- The forthcoming introduction of an approval pathway for biosimilars offers an additional opportunity to provide consumers and the government with enormous savings. Just as the introduction of generic versions of chemical drugs some quarter century ago ushered in a new era of access to safe and affordable medicines, biosimilars now hold the promise of providing consumers with the same benefit. In order for these benefits to be realized, however, it is critical that the FDA maintains its commitment to funding the biosimilars program, and ensures that a workable approval pathway is created that is free from obstacles that would serve only to delay the availability of these FDA-approved, safe, effective and lower-cost medications.

The analysis that follows clearly demonstrates that any effort to reduce health care costs — whether on Capitol Hill or in state legislatures — must recognize the billions of dollars in savings that can be achieved through the use of generic medicines. For more than 25 years, generic prescription drugs have allowed millions of Americans to get the medicine they need at an affordable cost. As new health care reform policies are implemented, the savings generated by generics will help make it possible to improve lives for less.

HIGHLIGHTS AND TRENDS

The IMS analysis shows that substituting generic prescription drugs in place of their brand-name counterparts saved the nation's health care system more than $931 billion dollars from 2001 through 2010. In 2010 alone, the use of FDA-approved generics saved more than $157 billion. That amounts to more than $3 billion in savings every week.

In addition, the IMS analysis also shows that:

- Savings from generic medications that have entered the market since 2001 have continued to grow at an exponential rate, reaching more than $360 billion by the end of 2010;
- Generic products for nervous system and cardiovascular treatments alone account for 62 percent of the cost savings;
- Despite having nearly seven times as many products on the market, generic medications still accounted for less drug spending than branded products with generic competition; 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.

This remarkable level of savings continues to dwarf the initial savings estimates that were made in 1984, when the Hatch-Waxman Act established the modern-day generic industry, and when it was projected that generics might save $1 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 Continued to Provide Big Savings

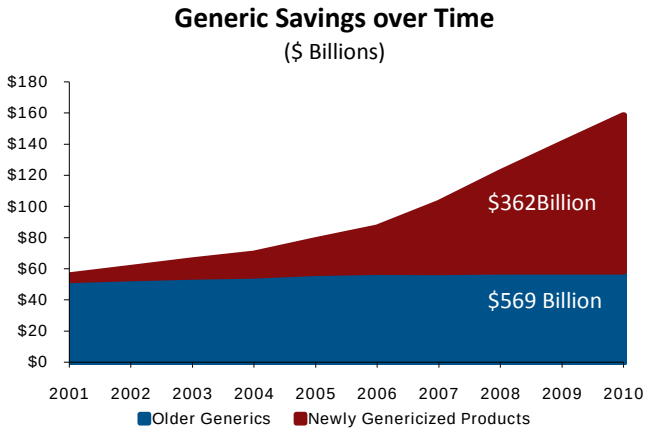
This new analysis from IMS Health, based on brand and generic prescription drug sales and pricing data, shows that, in 2010, annual savings from the use of generic medications continued to be driven by the introduction of generic versions of well-known brand drugs. Generic versions of Flomax® and Aricept®, among several other big selling drugs, helped to continue the double-digit percentage growth in savings from 2009.

When combined with the phenomenal four-year growth in savings between 2005 and 2009 that was spurred by the launch of generic versions of several

blockbuster brand drugs, including Zocor®, Norvasc® and Zoloft®, generic medications are now saving the U.S. health care system more than $3 billion every week. And with more than 20 new generic versions of blockbuster brand drugs entering the market this year—16 of which were made possible due to a pro-consumer patent settlement—2011 looks set to continue that trend.

Newer Generics Maintained Exponential Growth

The IMS analysis also found that the savings from generics introduced in the past 10 years has now reached approximately $362 billion and accounts for more than 40 percent of the overall generic savings. In 2010 alone, the U.S. health care system saved nearly $100 billion from these recently genericized products, or 63 percent of the savings for the entire year. Older generic medications, those approved prior to 2000, continued to provide a steady foundation of cost reduction as well, producing nearly $60 billion in savings in 2010.



The savings generated by newer generics is expected to continue increasing over the next several years as many of the world's largest-selling brand drugs lose patent protection and face generic competition for the first time. That includes the two biggest-selling drugs: Pfizer's $8 billion cholesterol fighter Lipitor® and the blood clot preventer Plavix® by Bristol-Myers Squibb, both of which will lose patent protection in November 2011 thanks to the use of pro-consumer patent settlements.

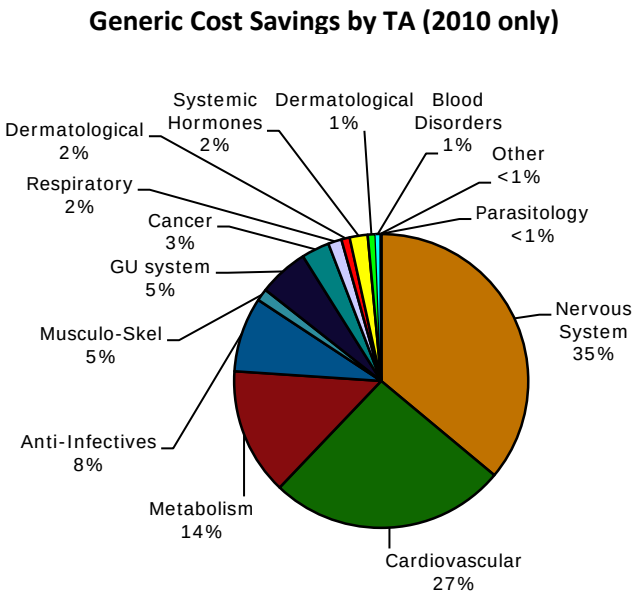
Among the other name-brand blockbusters that will lose patent protection between now and 2014 are Zyprexa®, Singulair® and Aricept®. Meanwhile, new reports continue to highlight the impact of generic medications for those suffering from chronic disease. These factors make it crystal clear that generic drugs are an integral part of the solution in reigning in U.S. health care costs.

Central Nervous System and Cardiovascular Drugs Lead the Way

Generic central nervous system (CNS) and cardiovascular drugs once again delivered the bulk of the savings generated by the generic industry in 2010. Combined, these two therapeutic areas alone provided the U.S. health care system more than $100 billion in savings. Generic CNS medications also

continued their significant yearly growth in savings, growing 10 percent over the savings generated in 2009.

Generic metabolism drugs also continued to be a major source of health care savings in 2010, reducing costs by more than $22 billion. Since 2001, the savings generated by these drugs has grown an astounding 500 percent from their initial level of more than $4 billion. When added to the savings provided by generic nervous system and cardiovascular medicines, these three therapeutic categories account for nearly three-fourths of all savings generated by generic drugs in 2010.



Generic Savings Are an Integral Component in Reducing Health Care Costs

GPhA has long maintained that reducing government overspending in Medicare and Medicaid is an integral part of the solution to reducing U.S. health care costs. And one way states can control these growing costs is through a greater reliance on the use of generic drugs. Because the federal government pays states a portion of the cost of prescription drugs they purchase through Medicaid, the government can save hundreds of millions of dollars each year as the use of less costly generic drugs increases.

According to data from the Centers for Medicare and Medicaid Services, in 2010 Medicaid paid, on average, approximately $200 for each monthly brand prescription, compared to just $20 for a month's prescription in the generic version. By increasing generic utilization in Medicaid by just one percentage point, the government and taxpayers would save more than $500 million. With Medicaid's generic utilization rate running nearly 10 percentage points lower than the 78 percent national rate, states have considerable opportunities to achieve added savings.

Generic Prescriptions Bring Patients Savings at the Pharmacy Counter

An additional IMS analysis has shown that generics are also bringing savings directly to patients at the pharmacy counter. In 2010 the average copayment for a generic drug was $6.06 per prescription, compared to $23.65 and $34.77 for preferred and non-preferred brand drugs, respectively, according to the IMS Institute for Healthcare Informatics study entitled "The Use of Medicines in the United States: Review of 2010."

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 — as many as 365 of which are for first-time generic drugs — and a median approval time of nearly 30 months. As a result, consumers and the government are forced to pay brand drug prices for prescriptions that could be available in affordable generic versions if the FDA is adequately funded.

Pro-Consumer Patent Settlements Continued to be a Major Boost to Savings

Access to 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. Of the 22 new generic drug launches expected in 2011, settlements made 16 of these possible where the generic will launch prior to patent expiry.

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Outside experts have also realized the savings pro-consumer settlements provide. An independent study by RBC Capital Markets, *Analyzing Litigation Success Rates*, found that generic companies are successful, thus able to market the generic product before patent expiration, in just 48 percent of cases, and that when factoring in settlements, generics are successful in bringing the generic product to market before patent expiration in 76 percent of cases.

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

Congress have repeatedly 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.

Generic Versions of Biologics Can Provide Comparable Savings

It is GPhA's position that the success of generics in achieving savings for consumers using traditional 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.

Estimates from various economic impact studies pin the projected savings from $42 billion on the low end to as high as $108 billion over the first 10 years of biogeneric market formation. Even stakeholders on the brand side of this issue —namely BIO and PhRMA—recognize that competition from biogenerics and biosimilars will significantly reduce health care costs.

In addition, the Congressional Budget Office (CBO) has estimated that the resulting increase in competition from biogenerics will yield substantially lower prices for certain drugs. CBO estimates that biogenerics will initially have prices about 25 percent below their brand-name counterparts and, after several years of competition, would have prices about 40 percent below those counterparts.

As the FDA continues to work toward implementing regulations on biogenerics, it is essential that the agency creates an approval process that is workable and free from obstacles that would serve only to delay the availability of FDA-approved, safe, effective and lower-cost biogeneric drugs.

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 510; Washington, DC 20001. www.gphaonline.org

METHODOLOGY

This analysis conducted by IMS Health updates the previous analysis released in July 2010 on the total cost savings generic pharmaceuticals have provided to the U.S. health care system over the 10-year period of 2001 through 2010.

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, branded products are defined as originator molecules that no longer are patent protected; generic drugs are those that were introduced after the patent protection had expired on the original reference product. The total savings was derived from a universe of 4,521 drugs, which are those products for which both brands and generics were available on the market.

Types	% of Molecules
1. Brands without Generic Competition	28%
2. Lost exclusivity after 2000	9%
3. Lost exclusivity 2000 and before	14%
4. No brand volume in the data set	49%
Total Number	4,521

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.

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.

The overall methodology approach was to add 2010 generic volume to the 2009 Cost Savings Study data for each molecule. The average brand price in the last year of patent protection (for patent expirations before 2001) was estimated using the formula (Total sales of brand molecule) divided by (Total standard units of brand).

For year 2010 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.

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