



*Economic Analysis*  
*Generic Pharmaceuticals 1999-2008*  
**\$734 Billion in Health Care Savings**  
*May 2009*

# ***Economic Analysis of Generic Pharmaceuticals 1999-2008***

## **\$734 Billion in Health Care Savings**

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### **EXECUTIVE SUMMARY**

The use of generic pharmaceuticals has resulted in a remarkable \$734 billion in savings to the U.S. health care system over the past decade, with \$121 billion of this savings achieved in 2008 alone. These findings and other statistical results are detailed in this report, which is based on an extensive analysis by IMS Health, the leading provider of global market intelligence to the pharmaceutical and healthcare industries.

While the IMS Health analysis covers only the 10-year period 1999 through 2008, it is evident that initial estimates that the 1984 Hatch-Waxman Act would “save \$1 billion over the next decade”<sup>1</sup> have been greatly exceeded. More important, the study is predictive of greater savings that could be realized in future years through the implementation of initiatives to:

- o *increase funding for FDA’s Office of Generic Drugs (OGD)* to ensure the timely review and approval of new generic pharmaceuticals;
- o *establish a science-based biogeneric approval pathway* that promotes innovation while providing patients access to more affordable versions of lifesaving biologic medicines; and
- o *encourage greater use of FDA-approved generic medicines* in publicly-funded prescription drug benefit plans, such as Medicaid, Medicare and other federal/state programs. For example, a 1% increase in the generic utilization rate in the Medicaid program could yield approximately \$490 million in added annual savings.<sup>2</sup>

The Hatch-Waxman Act, formally known as the Drug Price Competition and Patent Term Restoration Act of 1984, is perhaps the most important piece of pro-consumer legislation enacted over the past 25 years. It established a balance between protecting intellectual property, that provides the incentives to innovate new medicines, and encouraging the development of safe, effective and more affordable generic versions of existing drugs. Among the flawed arguments during the debate over Hatch-Waxman was the claim that generic competition would harm innovation. In fact, since the enactment of Hatch-Waxman, generic competition has helped unleash unprecedented investment in new drug research and development, which in turn has led to a period of unparalleled pharmaceutical innovation. This report, commissioned by the Generic Pharmaceutical Association as part of a year-long celebration of the 25th Anniversary of the Hatch-Waxman Act, validates the foresight of the sponsors of that landmark legislation.

To conduct this analysis, IMS utilized data for sales and unit volumes of brand and generic products. As detailed later in this paper, the total savings was derived using a data set encompassing only those products for which both brand and generic versions of the molecule were available to consumers and health care providers. Savings were calculated based on average prices as offered by manufacturers for brand and generic drugs, and the percent of generic utilization for each drug.

<sup>1</sup> *The Washington Post*. September 13, 1984.

<sup>2</sup> *Analysis of publicly available CMS data by industry experts with LECCG*



*GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry. Generic pharmaceuticals filled 69% of prescriptions dispensed last year in the U.S. but consumed just 16% of the total drug spending.*

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## OVERVIEW

Each year for the past quarter century, the generic pharmaceutical industry has delivered billions of dollars in savings on the purchase of prescription drugs. While there is little disagreement that generics result in savings, only one previous independent analysis has been conducted to quantify the annual savings achieved by the use of lower-cost generics. This is the second.

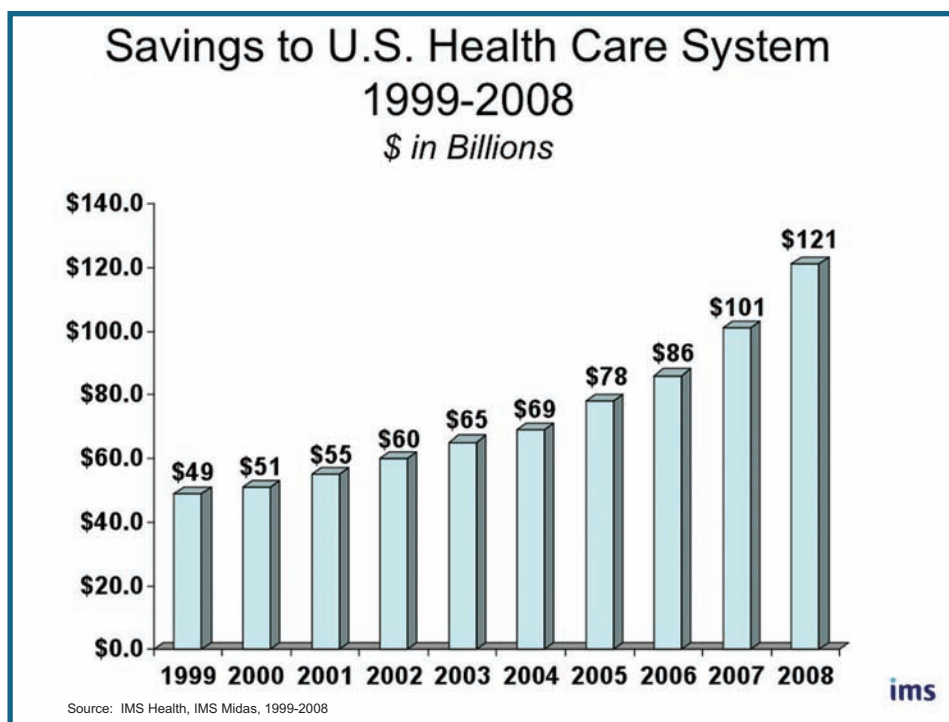
In 1998, the Congressional Budget Office (CBO) conducted and released an analysis of the savings generated by generics during the first 10 years of generic competition following the 1984 Hatch-Waxman Act. The CBO report, entitled “How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry,” utilized 1994 pricing data from approximately 70% of prescription sales through U.S. retail pharmacies. At the retail pharmacy transaction point, CBO estimated that by substituting generics for brand-name drugs, purchasers saved approximately \$8 billion to \$10 billion in 1994.<sup>3</sup>

In 2009, the Generic Pharmaceutical Association (GPhA) commissioned IMS Health to conduct an analysis of savings generated by generic pharmaceuticals to the overall health care system for the most recent 10-year period, 1999 through 2008.

This analysis shows that generic utilization has saved the American health care system more than \$734 billion over the 10-year period. The analysis calculated savings only when both brand and generic versions of a molecule were marketed and available to consumers and payers. Excluded from the analysis were molecules for which no generic had yet been launched, and also products that were available only in generic form. Savings were calculated using data at the product molecule level.

Total savings for the 10-year period were derived by adding values across all therapeutic areas (TAs) and for all years covered by the study.

<sup>3</sup> <http://www.cbo.gov/ftpdocs/6xx/doc655/pharm.pdf>



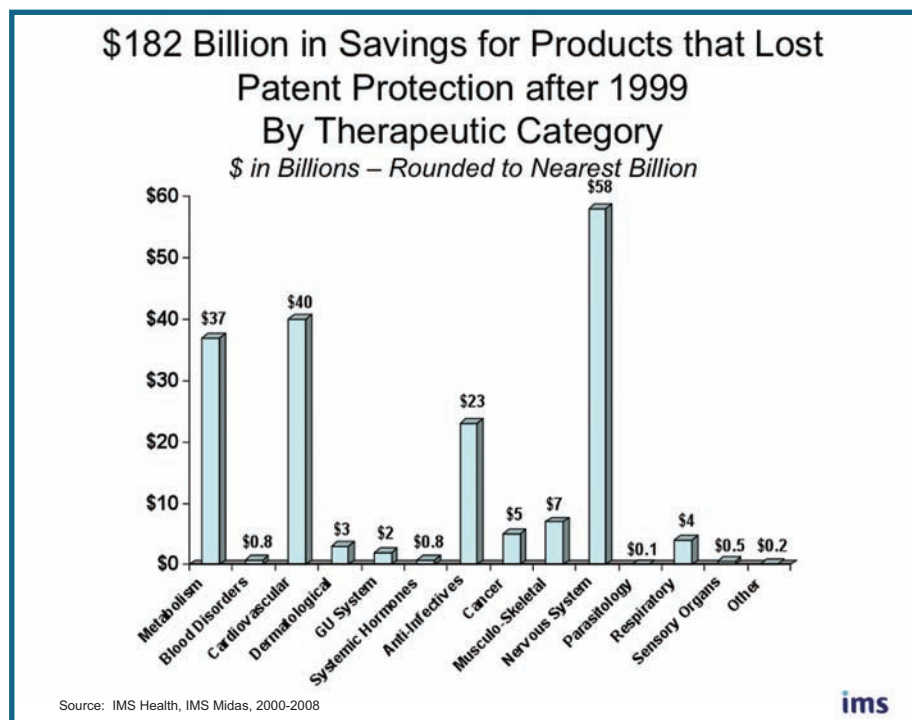
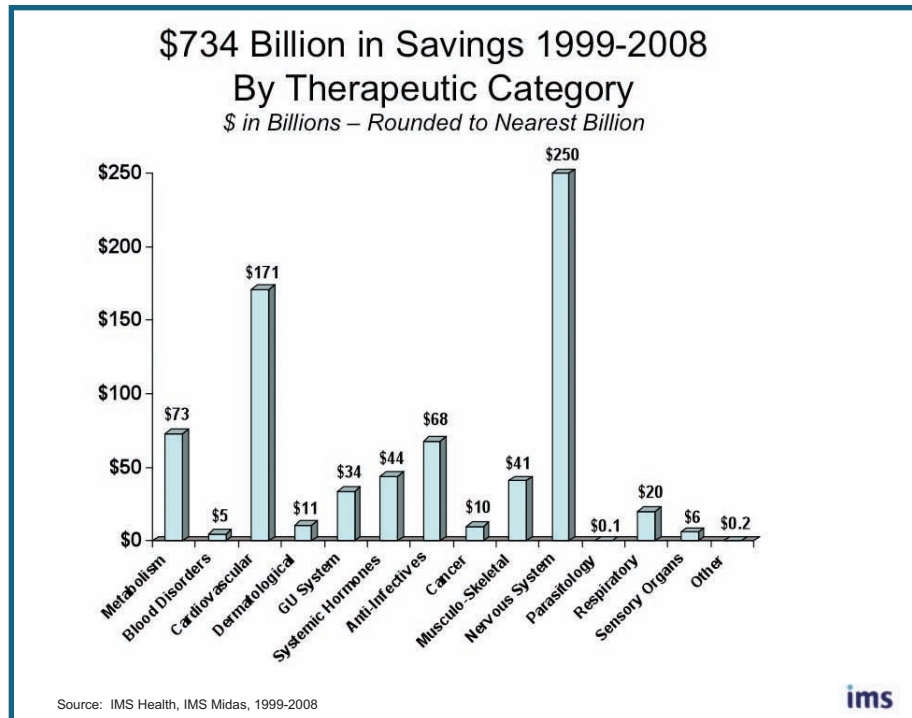
## HIGHLIGHTS

The use of generic pharmaceuticals over counterpart brand-name drugs saved the U.S. healthcare system approximately \$734 billion during the 10-year period, 1999 through 2008, according to an analysis by IMS Health. During the first six years of the study period, savings increased steadily at an annual rate of between 3% and 10%, with savings growing from \$49 billion in 1999 to \$69 billion in 2004.

Beginning in 2005 and continuing through 2008, the savings generated by generics grew at a double-digit annual pace, with the highest growth rate coming in 2008 when the savings topped \$121 billion, a full 20% ahead of the prior year.

The higher growth rates seen during the most recent years of the study were driven by two factors: an increase in the overall percentage of generic utilization, from 61% entering 2006 to 69% by the close of 2008; and the loss of patent protection by several brand-name blockbuster drugs, including Pravachol®, Ambien®, Fosamax®, Zolofit® and Zocor®.

The analysis also found that approximately \$552 billion of the total 10-year savings came from generics that were introduced prior to 1999, attesting to the ongoing safety and popularity of these affordable products. Newer generics, those introduced during the years covered by the study, generated an additional \$182 billion in savings, a portion of which can also be attributed to the success of the 2003 Medicare Modernization Act (MMA). Because many of the newer generics have been on the market for five years or less, savings achieved by these products will continue to escalate over the next decade.

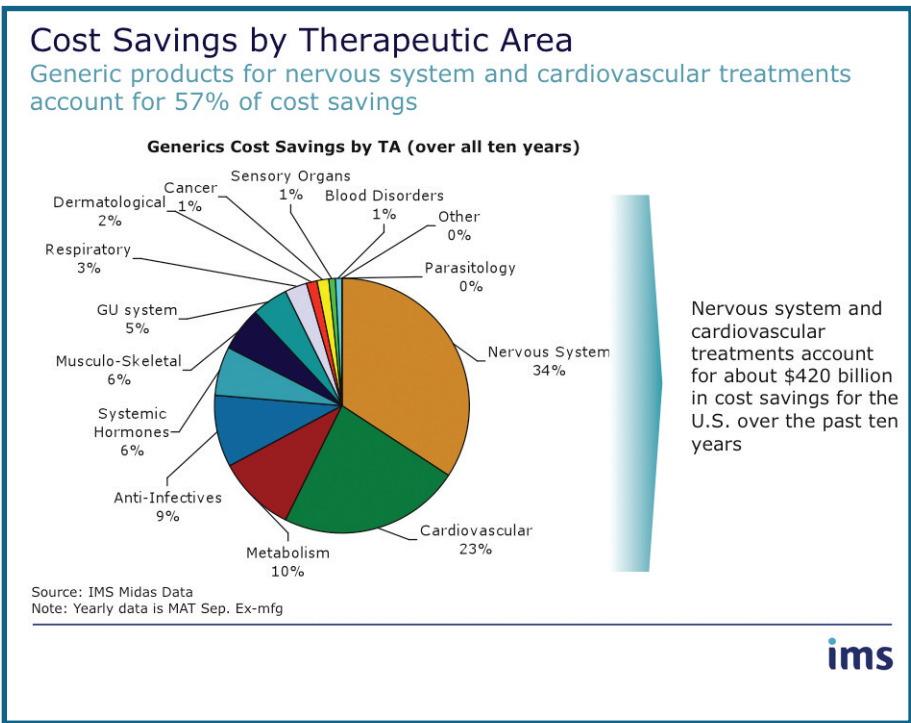
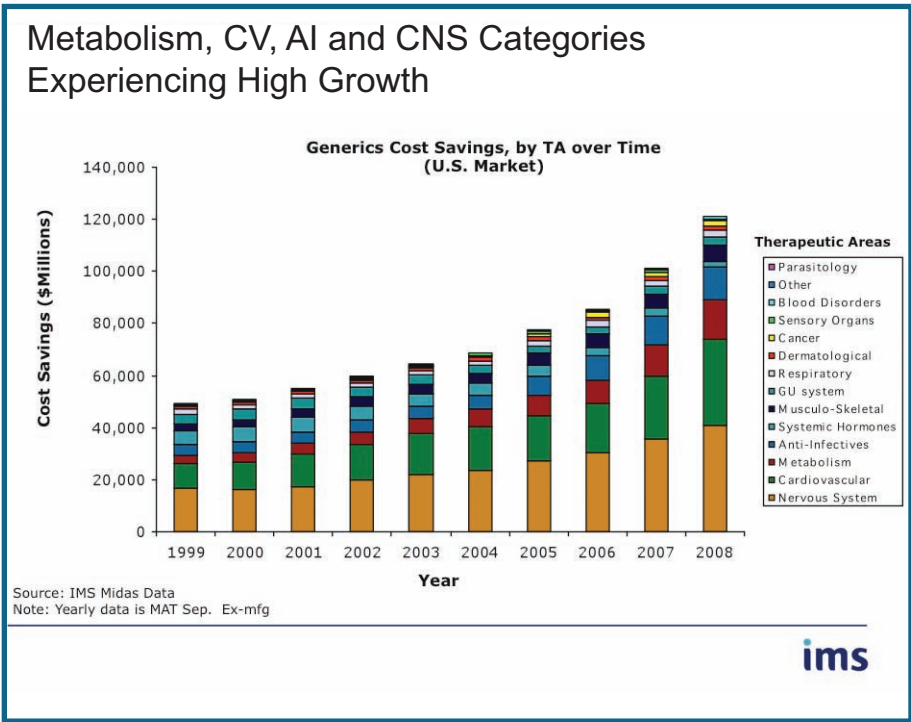


In fact, approximately 60% of the \$121 billion in savings achieved in 2008 came from generics approved over the past 10 years. Treatments in the therapeutic categories of metabolism, cardiovascular, anti-infectives, and central nervous system (CNS) have experienced the highest growth in savings as a result of generic utilization.

More than 57% of the total savings between 1999 and 2008, totaling some \$420 billion, came from the cardiovascular and CNS categories. Generic metabolism and anti-infective drugs combined to account for an additional 19% of the savings. In total, these four therapeutic categories resulted in overall savings of approximately \$561 billion, or 76% of total savings.

Other notable facts related to generic pharmaceuticals during the study period include:

- o In 2007, the average retail price for a generic prescription was \$34.34; the average retail price for a brand-name prescription was \$119.51. [Source: *The National Association of Chain Drug Stores, 2007*].
- o In 2008, the top 10 most dispensed generic prescription drugs by company in the U.S. were HYCD/APAP, levothyroxine, amoxicillin, lisinopril, simvastatin, HCTZ, amlodipine, azithromycin, warfarin sodium, and furosemide. [Source: *IMS Health, National Prescription Audit, Dec. 2008*]
- o Over the five-year period 2004-2008, brand-name products with combined annual sales of approximately \$71 billion lost market exclusivity and became open to generic competition; some of the major products were Allegra®, Ambien®, Effexor®, Flonase®, Pravachol®, Zolofit®, Zocor® and Zofran®.



## METHODOLOGY

The analysis conducted by IMS Health is a conservative estimate of the total savings generic pharmaceutical provided to the overall U.S. health care system for the 10-year period 1999 through 2008. The analysis utilized IMS data on sales and unit volumes of brand and generic products, estimating potential savings at the molecule level.

The total savings was derived using a data set universe of 3,834 molecules pruned to only include those molecules for which both brand and generic versions were available.

The analysis used to estimate savings excluded two significant categories of products:

- o products where there was no generic competition either because of patent protection or the lack of an approved generic product for the brand name drug; and
- o products where only a generic was available because the reference brand product was no longer on the market.

To ensure the consistency of this analysis, the following definitions were applied:

- o Brand products are defined as originator molecules that no longer are patent protected.
- o Generic products are those that were launched after the protection expired on the original reference product.

### Methodology: Molecule Segmentation

Cost savings were computed for types 2 and 3 only

Types	% of Molecules
1. No generic competition	48%
2. Lost of Exclusivity: after 1999	7%
3. Lost of Exclusivity: 1999 and before	12%
4. No brand volume in the data set	33%
Total Number	3834

Source: IMS Health, IMS Midas, 1999-2008

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### Methodology: Overall Approach

1. Define data set of genericized products

For each molecule:

2. Estimate average brand price in last year of patent protection\*  
= (Total sales of brand molecule) / (Total standard units of brand)

For each year under generic competition:

3. Estimate value of replaced brand products with generics  
= (Average brand price) \* (Total standard units of generic)
4. Estimate cost savings from generics  
= (Value of replaced brands with generics) – (Total sales of generic)
5. Sum total cost savings by therapeutic area, and overall

\*For patent expirations before 2000, brand price was calculated using first year available data (1999)

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- o The “standard unit” was defined as number of units divided by the “smallest common dose of a product form,” where the number of units equated to the number of capsules or tablets for an oral solid dosage form, or ml for a liquid, multiplied by the number of packages sold, multiplied by the package size.

The IMS analysis represents overall savings to the U.S. health care system resulting from generic utilization. Estimated savings were based on the price differences of the brand and generic products as they entered the supply chain.

Complexities associated with gathering pricing data at all locations within the pharmaceutical distribution chain make it exceptionally difficult to access direct savings to consumers. However, it can be assumed that a significant percentage of the \$734 billion in savings was reflected in the overall cost of prescription drugs in the U.S. health care system.

## Methodology: Price Estimate

Average brand price was calculated for products that had both generic and brand sales during the 10 year study period

Type	Price Estimate	Savings Calc.
2. Generic launched after 1999	$= \frac{\text{Total brand sales (one year before generic entry)}}{\text{Total brand standard units (one year before generic entry)}}$	Cost savings were calculated starting from year of generic entry
3. Generic launched on or before 1999	$= \frac{\text{Total brand sales (1999)}}{\text{Total brand standard units (1999)}}$	Cost savings were calculated for all ten years (1999-2008)



## ADDITIONAL NOTES

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman) had two overarching goals: to ensure the protection of intellectual property of the brand pharmaceutical industry while encouraging competition from lower-cost generic medicines. Guided by Senator Orrin Hatch and Representative Henry Waxman, Congress delivered a bill that offered a balance between innovation and access to affordable generics, and put in place a new regulatory pathway to bring safe and effective generic medicines to market. Noting the importance of this balance in the ceremony commemorating the signing of the Hatch-Waxman Act, President Ronald Reagan said, “This legislation will speed up the process of Federal approval of inexpensive generic versions of many brand name drugs, make the generic versions more widely available to consumers, and grant pharmaceutical firms added incentives to develop new drugs.”

### **GENERIC COMPETITION AND THE INNOVATION OF NEW MEDICINES**

Generic pharmaceutical companies rely on a vibrant and growing brand industry, and therefore, support intellectual property protections that incentivize robust innovation of new and improved drugs. Contrary to predictions from many early critics of the Hatch-Waxman Act, the creation of a regulatory approval pathway for generic drugs has not had a dampening effect on new drug research and development.

In fact, in the 25 years following Hatch-Waxman implementation, generic competition in the pharmaceutical marketplace has unleashed unprecedented investment in R&D, which has led to a period of unparalleled drug innovation. Entire new classes of drugs, such as statins like Lipitor® for treating high cholesterol and proton pump inhibitors like Nexium® for treating ulcers, have been introduced by brand companies seeking to stay ahead of the competition.

The interaction of competition and innovation has produced the same beneficial market dynamic in the pharmaceutical sector that is evident every day in other industries, such as electronics, communications and transportation. In crafting the Hatch-Waxman Act, Congress wisely recognized the critical need for ensuring a balance between innovation and competition. This balance has proven to be a successful model for maintaining the incentive to invent new drugs while at the same time encouraging the development of lower-cost generic versions of existing medicines.

### **GROWING CONSUMER ACCEPTANCE OF GENERIC MEDICINES**

The generic substitution rate in the U.S. in 2008, according to IMS statistics, was approximately 69%, with generic medicines accounting for more than 2.6 billion of the approximately 3.8 billion prescriptions dispensed. In terms of health care dollars, generics consumed just 16 cents of every dollar spent on prescription drugs. The increase in the utilization of generic medicines evident during the decade studied resulted from the dual effect of the introduction of new generic versions of brand products, as well as growing public acceptance of generics during the period.

Brand product patent expirations will continue to drive growth in the generic sector over the next several years. Industry analysts estimate that brand products with approximately \$90 billion in annual sales will lose market protection between 2009 and 2012, including such mega-sellers as Lipitor®, Plavix®, Singulair® and Viagra®.

In addition to the entrance of new generic products into the marketplace, recent reports have further quantified the impact of generic savings, as well as increased public acceptance of generic medicines as a mechanism to reduce costs.

The recent National Health Spending Report, published in January 2009 by the Centers for Medicare and Medicaid Services (CMS), found that growth in U.S. health care spending was at its slowest rate since 1998, while the 4.9% increase in retail prescription drug spending represented the slowest growth rate since 1963.

According to the National Health Spending Report, the deceleration of spending on prescription drugs was in part the result of “a further increase in generic dispensing rate.” In addition, the Report found that overall prescription drug prices grew at only 1.4% in 2007, driven by increased use of generics and the introduction of generic drug discount programs by large retail chain stores.

More recently, in April 2009, the AARP “Rx Watchdog Report” found that manufacturer prices for widely used brand name prescription drugs jumped by nearly nine percent in 2008, marking the largest average annual increase in six years and far exceeding the general inflation rate of just 3.8%. In contrast, the study by AARP’s Public Policy Institute found that the manufacturer prices of widely used generic drugs continued to decrease in 2008, falling by an average of 10.6%. The vast majority of generics (83 percent) did not change in price in 2008, despite an increase in general inflation. The AARP report concluded that switching to generic drugs whenever possible is one of the quickest and easiest ways to drastically reduce health care bills.

Also boding well for the generic sector is the finding of a Harris Poll released January 2009 on consumer attitudes toward generic pharmaceuticals. Harris reported, “In a period of just over two years, between October 2006 and December 2008, the proportion of adults who would choose generic drugs in preference to brand name prescription drugs has increased from 68% to 81%; and the number who would more often choose branded drugs has almost halved, down from 32% to only 19%.” The poll further revealed that 40% of those surveyed said they would “always chose to buy generic drugs over brand name,” a 17% increase over that group in 2006. Conversely, only 4% of respondents said they “would always choose to buy brand name prescription drugs over generics,” less than half of the response tallied in 2006. The Harris Poll concluded that the size of the trend toward low-cost generics, while predictable, was striking.

Consumer confidence in generics has been driven, in part, by strong support from FDA through frequent public statements confirming the safety and efficacy of generic products. FDA has worked through formal communication to health care providers and communications initiatives to consumers to assure patients that, “if one therapeutically equivalent drug is substituted for another, the physician, pharmacist, and patient have FDA’s assurance that the physician should see the same clinical results and safety profile.”

#### **OPPORTUNITIES TO INCREASE HEALTH CARE SAVINGS**

As Congress and the Administration work to reform America’s health care system, reducing health care costs while ensuring the delivery of quality care is goal number one. While this analysis does not attempt to quantify future savings, the data on the tremendous savings generated by generic competition support the conclusion that increasing the availability and utilization of generic medicines represent immediate steps that could be implemented to further increase health care savings. Based on the current generic utilization rate and the average costs per brand and generic prescriptions, a 3% increase in generic use nationally would generate approximately \$9 billion in added savings annually.

There are three significant opportunities that exist to provide additional savings while simultaneously expanding access to medicines: increase in generic drug use in Medicaid; a biogeneric approval pathway; and increased investments in FDA.

### GENERIC DRUGS AND MEDICAID

The benefits of increased generic utilization are acutely clear in the Medicaid program. The national average for Medicaid Generic Drug Utilization in the states is approximately 64%, varying from a low of 55% in one state to more than 70% in 9 states.

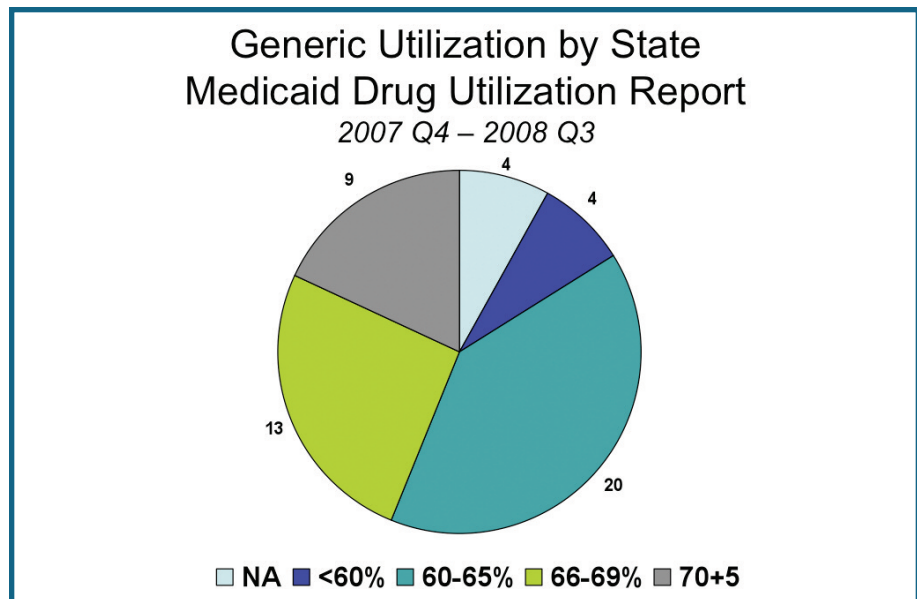
The Centers for Medicare and Medicaid Services (CMS) report for the fiscal year 2008 (Q4 2007 through Q3 2008) showed total prescription drug spending for the year at \$22.8 billion. Only 17% of this, or \$3.9 billion, was spent for prescriptions filled with generics. Nationally, the average cost to Medicaid for a generic prescription was \$21, compared to \$191 for the average brand version of the same drug. Interestingly, an increase in the Medicaid generic drug utilization rate of just 3% would result in an additional \$1.4 billion in savings each year. These savings are particularly critical to states during these challenging economic times.

Over the past two years, a number of state legislatures have considered initiatives that would “carve-out” certain therapeutic classes of drugs from Medicaid generic substitution laws. These unnecessary efforts not only would diminish generic utilization, but also add administrative costs for state drug benefit programs, pharmacists and prescribers. The result would be higher costs to state Medicaid agencies. Generic substitution, as now required in more than 40 states, is a well-established practice that generates billions of dollars in savings for consumers, employers and Medicaid programs.

### SAVINGS FROM BIOGENERIC

The success of the 1984 Hatch-Waxman model for traditional chemical drugs is an indication of the value that generic competition for expensive biopharmaceutical products would provide to the health care system.

Current biologic treatment costs are staggering, putting these lifesaving medicines out of reach for many patients. In some cases, insurance companies deny coverage for needed biologics because of their costs. Even when coverage is avail-



### Spending on Biologics in the U.S. Marketplace

- U.S. biologics spending will exceed \$100 billion by 2011
- Spending expected to increase 18%-21% annually
- By 2012, nearly half of all newly approved prescription drug products will be biologics
- Government spending for biologics is increasing at a faster pace than any other healthcare-related expense except diagnostic imaging tests
- By 2010, patents will expire on brand biologics with \$15 billion in annual sales

Sources: DataMonitor, Scrip Executive Briefing, October 31, 2008

able, the co-pays can be thousands of dollars each year. Furthermore, not only are the prices for these medicines increasing annually, but the use of biologics is growing as well.

Spending on biologics in the U.S. increased 21% in 2006 to reach \$54 billion, more than triple the \$17 billion spent on biologics just five years earlier. 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 2010, spending for biologics is expected to reach \$100 billion, accounting for more than a quarter of the country's total drug spend. The dual effect of escalating prices and increasing use is yielding unsustainable growth in spending.

### Savings Estimates of Biogeneric Competition

- **Shapiro Study (Clinton Under Sec. of Commerce)**  
Biogeneric versions of top 12 biologic categories with patents expiring would save \$67-\$108 billion over 10 years; up to \$378 billion over 20 years
- **Pharmaceutical Care Management Association**  
Generic versions of 32 leading biologics would save Medicare Part B \$14 billion over first 10 years
- **Citizens Against Government Waste**  
Total savings for all payers would be \$43 billion in the 2011-2020 period

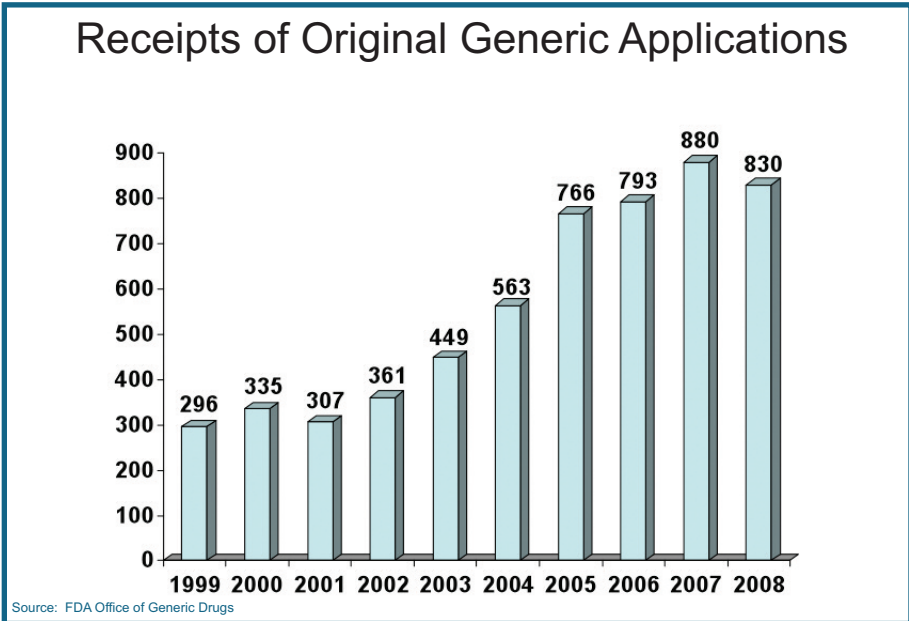
The proven means of reigning in escalating costs is market competition. Competition from biogenics would provide a market-based mechanism to help reduce private and federal expenditures and achieve significant savings.

Biogenics are expected to be priced initially at least 25-30% below the reference branded drug, with steeper discounts coming as additional generics enter the market. These lower prices are projected to produce savings to health care providers and patients of billions of dollars annually. Without competition, consumers will continue to experience ever-increasing prices, which could ultimately have a negative impact on the care they receive.

**INCREASING INVESTMENTS  
IN FDA**

Given the critical mission of the FDA to protect the public health, it is imperative that the Agency receive adequate funding to fulfill its obligations.

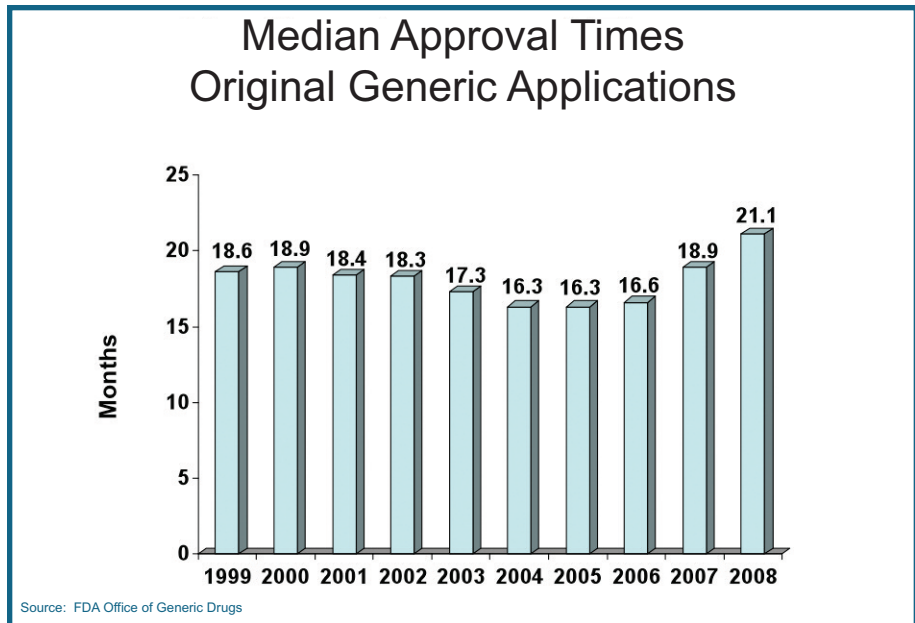
Providing the Office of Generic Drugs (OGD) with increased funding for the specific purpose of reviewing and approving generic drug applications is needed. Despite congressional intent and statutory language specifying a six-month review



cycle, the median review and approval time for generic applications has swelled to 21 months—more than a year longer than the statutory six months allowed for review and approval of such filings. Without additional funding for OGD, this unacceptable situation will get worse as patents covering brand drugs expire over the coming years and the number of generic drug applications increases.

A relatively modest increase in OGD’s current budget of

approximately \$42 million would enable the agency to hire additional scientists to perform timely reviews and approvals of generic applications. The return on investment from increased OGD funding will be long-lasting dividends for all Americans—individual consumers, employers, state governments and the federal government. The savings generated by new generics would allow the government to reach more Americans through its priority health care initiatives, such as Medicare, Medicaid and SCHIP.



## 2009: CELEBRATING 25 YEARS OF ACCESS TO AFFORDABLE MEDICINE

Twenty-five years ago, Senator Orrin Hatch and Representative Henry Waxman led an effort to pass what has become one of the most successful pro-consumer pieces of legislation of the past century—the 1984 Hatch-Waxman Act.

While some critics predicted the Hatch-Waxman Act would slow the innovation of new medicines, just the opposite has happened. Not only did the legislation launch what is now a robust and vibrant generic pharmaceutical industry, it helped unleash remarkable innovation of new and better medicines. Today, the generic industry contributes significant savings to federal and state governments, payers and employers and makes a real difference in the availability and cost of health care for Americans.





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