

TESTIMONY OF THE

BLUE CROSS AND BLUE SHIELD ASSOCIATION

Before the

**COMMITTEE ON COMMERCE
U.S. SENATE**

ON

**GENERIC PHARMACEUTICALS: MARKETPLACE ACCESS AND
CONSUMER ISSUES**

Presented by:

**STEVEN S. MARTIN
PRESIDENT AND CHIEF EXECUTIVE OFFICER
BLUE CROSS AND BLUE SHIELD OF NEBRASKA**

APRIL 23, 2002

Mr. Chairman and members of the committee, I am Steve Martin, President and Chief Executive Officer of Blue Cross and Blue Shield of Nebraska. BCBS Nebraska provides health care coverage to more than 640,000 (one in three) Nebraskans.

Prior to joining Blue Cross and Blue Shield of Nebraska last month, I was President, and CEO for Prime Therapeutics, Inc. of Eagan, Minnesota. Prime Therapeutics, Inc. is a pharmacy benefits management company (PBM) owned by five Midwestern Blue Cross Blue Shield plans.

Today, I am testifying on behalf of the Blue Cross and Blue Shield Association (BCBSA). BCBSA represents the 43 independent Blue Cross and Blue Shield Plans throughout the nation that together provide health coverage to 83 million — one in four — Americans. I appreciate the opportunity to testify on the important issue of consumer access to generic drugs.

Blue Cross and Blue Shield Plans have extensive experience in providing prescription drug coverage to both working and retired Americans.

- BCBS Plans offer health coverage to working and retired Americans through a variety of managed care and indemnity products, including health maintenance organizations (HMOs), preferred provider organizations (PPOs) and point of service (POS) plans. Nearly all of these plans provide prescription drug benefits to their members.
- Collectively, BCBS Plans provide Medicare HMO options to more than one million Medicare beneficiaries, making them collectively the largest Medicare+Choice (M+C) contractor in the country. Most of BCBS M+C plans provide some coverage for outpatient prescription drug to their M+C members, although continuation of this coverage is a challenge given overall problems with continued funding of this program.
- Blue Cross and Blue Shield Plans underwrite and deliver the government-wide Service Benefit Plan under the Federal Employee Health Benefits Program (FEHBP). It covers over two million contracts and more than four million lives. The Service Benefit Plan provides

outpatient prescription drug benefits to its members, many of whom are retired.

Our constant challenge is to provide a meaningful level of coverage for prescription drugs while keeping premiums as affordable as possible.

In my testimony today, I will address three areas:

- Background on the skyrocketing costs of prescription drugs;
- The critical role of generic drugs in keeping health care coverage available and affordable and how BCBS Plans promote appropriate generic drug usage; and
- Legislative changes needed to promote vigorous competition in the prescription drug market.

I. BACKGROUND ON PRESCRIPTION DRUG COST TRENDS

Prescription drugs have significantly increased Americans' life span and contributed to their improved health status in the 20th century. Because pharmaceuticals are a key component in preventing and treating disease, BCBS Plans offer pharmacy benefits to their members. However, the cost of drug benefits is high and accounts for a growing share of BCBS Plans' total medical costs and our members' premium dollars. Our Plans are experiencing up to 20 percent increases in prescription drug costs each year. BCBSA expects these costs to continue to grow rapidly.

Factors Contributing to Increased Prescription Drug Spending:

While BCBS Plans use a range of strategies to manage growing prescription drug costs on behalf of their subscribers, spending is being propelled by a number of market and structural forces over which private insurers have little control. Some of the most significant forces are the following:

Demographic Trends

As the U.S. population ages, the number of people at risk for chronic and disabling diseases is rising dramatically. The single largest market for prescription drugs is the aging baby boom generation. According to U.S. Census data, the 54-to-64 age group will expand by 59 percent between 1998 and 2010. The drugs used by the middle aged and elderly tend to be expensive and often treat chronic conditions, such as hypertension, high cholesterol, diabetes and arthritis, which require a steady regimen throughout the patient's remaining life.

Rapid Flow of New Drugs to Market

Over the past decade, many new prescription drugs have come to market. One of the most robust measures of the flow of pharmaceutical technology is the annual number of new molecular entities (NMEs) approved by the FDA. NMEs are compounds that have never before been marketed in this country. Over the course of a generation -- from the early 1960s to the mid 1990s -- the annual number of new molecular entities (NMEs) receiving FDA approval nearly doubled. From an average of 13.7 in the 1960s, annual NME approvals rose to 25.6 in the first half of the 1990s and to 36.8 by the end of the decade.

Some of these new drugs are "breakthrough" products, which treat diseases and conditions that previously lacked effective therapies. Others are differentiated from older drugs only by having slightly less prevalent side effects, or different dosing forms. Physicians tend to adopt such new drugs rapidly, and direct-to-consumer advertising also increases their rate of market penetration. While these new products often provide important clinical benefits, they also increase health insurance premiums. Blues Plans have a longstanding commitment to provide coverage for clinically sound, effective services while finding ways to keep premiums affordable.

The National Institute for Health Care Management (NIHCM) recently released a report on trends in pharmacy spending for 2001. This report — subtitled “Another Year of Escalating Costs” — examines the growth of retail prescription drug sales. The report found that:

- Spending on outpatient prescription drugs dispensed through U.S. retail stores and pharmacies grew 17.1 percent from 2000 to 2001, from \$131.9 billion to \$154.5 billion. This represents the fourth straight year that spending on prescription medicines escalated 17 percent or more.
- Price increases were a more substantial component of the rise in drug spending in 2001 than in the previous year, accounting for 37 percent of the spending. The average price of a prescription bought at a retail pharmacy rose 10 percent from 2000 to 2001, to \$49.84 from \$45.27.
- A shift to prescribing more expensive medicines was responsible for 24 percent of the rise in drug spending in 2001.

We expect the flow of new drug technology to continue. Over the past two decades, the pharmaceutical industry and the federal government, through the National Institutes of Health, have made massive investments in research and development. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA) has estimated that the pharmaceutical industry spent \$30.3 billion in R&D in 2001. This represents more than three times the amount, \$8.4 billion, that private industry invested in pharmaceutical R&D in 1990, and is a 16.6 percent increase over the 2000 level.

Therefore, we want to assure that health plans and employers have enough resources to pay for all of the new breakthroughs in drugs and medical technology expected over the next several years.

Direct-to-Consumer Advertising of Prescription Drugs

Over the past decade, direct-to-consumer (DTC) advertising has revolutionized the marketing of prescription drugs. Traditionally, such advertising was limited to medical journals and trade publications aimed at physicians. Since 1985, when the FDA lifted its moratorium on promotion directed to consumers, this form of advertising has exploded, and since the agency relaxed its regulation of broadcast advertising in 1997, TV ads for prescription drugs have proliferated. In 1991, pharmaceutical companies spent \$55.3 million to promote prescription products directly to consumers. According to NIHCM, outlays on DTC advertising in 2000 were \$2.5 billion, more than double what was spent in 1997.

DTC advertising can promote the public health by encouraging patients with undiagnosed and untreated conditions to see their doctor. However, this consumer demand also contributes to health benefits costs. Surveys of both consumers and physicians show that DTC ads for prescription drugs are effective in stimulating demand for branded products.

For example, preliminary results of a new survey by the FDA indicate that patients who ask their physicians for a specific brand-name drug usually get a prescription for that medication. The survey found that nearly 25 percent of survey respondents asked their doctor for a specific brand-name drug, and 69 percent of those patients ultimately received a prescription for that drug. By comparison, 41 percent of respondents who asked their doctors about any drug were given medication by their doctor. The full FDA survey is expected to be released later this month.

II. GENERIC DRUGS PLAY A CRITICAL ROLE IN KEEPING HEALTH CARE COVERAGE AVAILABLE AND AFFORDABLE

Generic drugs are subject to rigorous review by the FDA to ensure that they are as safe and effective as their brand-name counterparts. Once approved for marketing, generic drugs offer consumers, employers and insurers significant savings compared to brand drugs. Generic drugs

play a critical role in keeping health care coverage available and affordable.

Generic Drug Safety

The first phase of new drug development -- preclinical research -- involves laboratory and animal testing of the compound and is primarily aimed at establishing safety. If successful, the brand manufacturer can then file an Investigational New Drug Application with the FDA. At the successful completion of lengthy human clinical trials, the brand manufacturer files a New Drug Application submission with the FDA seeking to bring the new compound to market. This rigorous process also is the basis for the generic drug application.

The generic manufacturer relies on the underlying safety and efficacy data supplied by the brand manufacturer when it submits its application to the FDA for approval. The generic manufacturer must demonstrate in its application that the generic drug is equivalent to the branded product based on bioavailability and/or bioequivalence studies. When compared to brand-name drugs, FDA-approved generic drugs must have the:

- *same* active ingredients,
- *same* dosage form,
- *same* standards for purity and quality,
- *same* standards for manufacturing,
- *same* amount of drug absorbed over the same time, and
- *same* clinical effect.

The only significant difference between generic drugs and their brand name counterparts is price.

Generic Drugs Create Billions of Dollars in Savings

Every day, the choice of generic products creates substantial savings for consumers. Typically, a generic drug enters the market priced 30 percent less than its brand counterpart. Within two

years, as more generics enter the market, the average price of the generic version of a drug drops until it is 75 percent less than the brand. According to the Congressional Budget Office estimates, the use of generics in place of brand names could save consumers between \$8 billion and \$10 billion each year.

As the Administration and Congress continues to work to develop a new Medicare prescription drug benefit, a new study finds that if such a program is enacted, it potentially would save \$14 billion in 2003 and \$250 billion during the next 10 years by increasing the rate of generic drug usage. The study, "Greater Use of Generics: A Prescription for Drug Cost Savings," was sponsored by the Generic Pharmaceutical Association and conducted by researchers from Brandeis University. It concludes that Medicare could achieve these savings by using generic pharmaceutical incentive techniques currently used in the private sector.

Generic Drug Market Penetration

Although generic drugs have the same safety and effectiveness profile as their brand counterparts and can produce significant cost savings for consumers, they have a low rate of market penetration.

According to NIHCM, only five generic drugs were among the 50 best-selling drugs in 2001. Data from the Generic Pharmaceuticals Association indicate that generic drugs made up approximately 42 percent of all prescriptions dispensed at the retail level but accounted for only approximately 8 percent of the \$141 billion spent on prescription drugs in 2000. Stated another way, brand name drugs, representing 58 percent of all prescriptions, accounted for 92 percent of the total retail cost of prescription drugs in 2000.

Using Benefit Design to Encourage Appropriate Use of Generic Drugs:

BCBS Plans have experienced a rapid acceleration in prescription drug costs over the past few years. BCBSA expects pharmacy costs to continue to rise, propelled by the medical needs of an aging population, the flow of new technology, and strong consumer demand. As this occurs, health insurers will need to manage prescription drug benefits as effectively as possible in order to keep premiums affordable. Some of pharmaceutical benefit management tools our Plans use to promote the use of generics and control costs include:

Tiered Copayment Plans

Blue Cross and Blue Shield Plans design their pharmacy benefits to ensure consumers have access to appropriate medications. One approach to achieving this objective is the tiered copayment plan. Now popular among nearly all health plans, tiered benefit designs provide financial incentives to encourage members to make cost effective drug purchases. Under these programs, plan members have more choices available to them than they would under more traditional benefit designs, but they pay a higher share of the cost of expensive drugs that have safe and effective, but less costly, alternatives. The intent is to encourage members to use drugs that are both clinically efficacious and cost effective.

Three-tiered structures, which classify drugs into three categories with differing levels of copayment (or coinsurance), are often structured as follows: Tier 1 consists of generic drugs, and has the lowest copayment/coinsurance. Tier 2 contains branded drugs that are clinically effective, cost effective, and meet the needs of most patients; these drugs require a moderate copayment/coinsurance. Tier 3 drugs, with the highest copayment/coinsurance, generally include branded drugs with a generic equivalent or branded therapeutic equivalent in Tier 2.

Step Therapy Programs

Another approach to ensuring cost-effective appropriate drug coverage is the use of step

therapy programs. Thanks to continued innovation on the part of the pharmaceutical industry, multiple drug therapies now exist to treat many health conditions. Step therapy is a type of protocol that specifies a sequence of different therapies, including prescription drugs, for a given medical condition. Hypertension, for example, can be treated with dozens of different drugs, some of which have generic counterparts, some of which do not. Under step therapy, a patient with hypertension would be treated first with medications (generics, where available) known to be safe and effective for this condition. The patient would remain on those medications if they prove effective in managing the hypertension. If not, more innovative treatments would be tried.

Physician Education

Health plans must work hand-in-hand with physicians to make these programs a success. For example, to support step therapy programs, a number of health plans share data with their participating physicians that compare their prescribing patterns to those of their peers. In regular meetings with network physicians, health plans can review these data and encourage physicians to adopt a step therapy approach where appropriate.

BCBS Plans' experiences confirm the savings derived from improved generic access. One Plan reported that just a one percent increase in generic drug utilization for the 760,000 people covered results in a \$3 million savings in drug costs per year.

As such, BCBS Plans strive to promote appropriate generic utilization through innovative programs. For example, Blue Cross Blue Shield of Michigan is launching a \$1 million public awareness marketing campaign using the slogan "generic drugs: the unadvertised brand," to increase consumer awareness of the quality and value of generic drugs.

As a result of this campaign and other initiatives to support appropriate use of generic drugs, Michigan Plan members saved about \$13 million on an annualized basis. In addition, the

initiative is believed to have generated annualized savings of as much as \$25 million statewide.

Despite the implementation of a range of benefit management tools and innovative consumer education campaigns about the safety and value of generic drugs, BCBS Plans continue to experience unsustainable prescription drug costs. In fact, I just returned from touring the state of Nebraska and every major employer, group and association has been re-examining their coverage. Employers are having to increase out-of-pocket costs for drugs and employees will be expected to pay more. This reality, and its impact on health care coverage availability and affordability, is exactly why today's hearing is so important.

III. LEGISLATIVE CHANGES ARE NEEDED TO PROMOTE VIGOROUS COMPETITION IN THE PRESCRIPTION DRUG MARKET

BCBS Plans believe the best way to lower prescription drug costs is to encourage vigorous competition in the marketplace by improving access to generics. BCBSA urges Congress to pass the Greater Access to Affordable Pharmaceuticals Act (GAAP). This legislation, sponsored by Senators John McCain and Charles Schumer and in the House by Representatives Sherrod Brown and Jo Ann Emerson, would:

- Improve access to generic drugs by eliminating barriers to market entry, including the automatic 30-month stay of FDA review of a generic application which is triggered as soon as a brand manufacturer files suit;
- Accelerate generic drug competition by transferring the market exclusivity granted to the first eligible generic applicant to other applicants if the former does not go to market; and
- Strengthen the citizen petition process by curbing abuses that delay competition in the marketplace.

Eliminate Barriers to Generic Drugs: 30-Month Stay

Several provisions of current law have the unintended consequence of delaying market entry of generic drugs. First, consumer access to generics is often delayed for 30 months because the law requires the FDA to automatically defer approval of a generic application if the brand manufacturer sues for patent infringement, costing consumers billions. The GAAP bill would eliminate the automatic 30-month stay, and brand manufacturers would retain the ability to seek a preliminary injunction from the courts to protect their interests.

A second barrier to generic market entry is created when brand manufacturers list patents with the FDA as late as a year or more after a generic application has been filed - which triggers a 45-day window during which a lawsuit to resolve the patent status can be filed. Brand manufacturers can and do use this strategy to delay generic competition because they currently are not required to list all patents with the FDA. The GAAP bill would remove this barrier by requiring brand manufacturers to list all patents for which an infringement claim could reasonably be asserted and to certify to the FDA that the listing is complete and accurate, to prevent unforeseen infringement suits.

A third barrier to market entry for generic drugs is the aforementioned 45-day period allowed for a brand manufacturer prior to suing a generic company for patent infringement. During the waiting period, a generic company's right to market its product is unprotected, discouraging market entry. The GAAP bill would allow generic manufacturers to seek a declaratory judgment that their product will not violate any patent listed with the FDA, expediting consumer access to affordable medicines if the challenge is successful.

In addition, under the GAAP legislation, if a patent is listed a year or more after a generic application is submitted, generic manufacturers could bypass the 45-day waiting period and

immediately seek a declaratory judgment of invalidity or noninfringement for any patent listed with the FDA.

Accelerate Generic Drug Competition: 180-Day Exclusivity

Current law grants a 180-day period of market exclusivity to the first generic applicant who certifies that the patents on the brand product it intends to copy are either invalid or will not be infringed by the manufacturing and marketing of a generic version of the drug. However, the 180-day period does not begin until the first applicant goes to market or litigation surrounding the certification is resolved. In the interim, all other generic applicants are kept out of the market. For this reason, brand name drug manufacturers have an incentive to pay the first generic applicant to stay out of the market, preventing competition among generic companies and delaying consumer access to generics for an extended period.

The GAAP bill allows the 180-day market exclusivity rights to become available to the next-to-file generic applicant if the previous applicant meets one of several conditions, including reaching a financial settlement with the brand name drug manufacturer to stay out of the market until the patents have expired.

Strengthen the Citizen Petitions Process

The citizen petition process is an important vehicle for public concerns regarding a drug's approval, but it is subject to abuse by those seeking to delay competition in the marketplace.

The GAAP bill would require the FDA to instruct the Federal Trade Commission to investigate any citizen petitions submitted to the FDA that are suspected of being filed for anticompetitive purposes. The bill also would require petitioners to notify the FDA whether the petitioner has

received, or will receive, consideration for filing the petition and to identify the party furnishing consideration.

BCBSA Strongly Supports the GAAP Bill

BCBS Plans strongly support the GAAP bill because its provisions would encourage vigorous competition in the prescription drug marketplace. BCBSA has endorsed the bill and has organized a Coalition to focus solely on moving this bill forward. The Coalition includes representatives from large businesses, unions, consumer groups, the insurance industry, and generic drug manufacturers.

In addition, BCBSA is sponsoring research to highlight the costs to consumers of delayed access to generic drugs.

IV. CONCLUSION

Health plans have developed a number of strategies for addressing the rising cost of prescription drugs, with some success. However, as drug costs continue to skyrocket, Congress must re-examine current laws that contribute to rising costs. Legislation such as GAAP that promotes vigorous competition in the prescription drug market by improving access to generic drugs will assure that health care coverage remains available and affordable for consumers.

Thank you again for the opportunity to testify today.

\\WRODATA\deptdata\POL&REP\W01\20W\Christine\McCain-Schumer\Commerce CmmteeTestimony04-22final.doc