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INCREASING GENERIC DRUG UTILIZATION: SAVING MONEY FOR PATIENTS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

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INCREASING GENERIC DRUG UTILIZATION: SAVING MONEY FOR PATIENTS

WEDNESDAY, MAY 18, 2005

HOUSE OF REPRESENTATIVES,
COMMITTEE ON ENERGY AND COMMERCE,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The subcommittee met, pursuant to notice, at 1:04 p.m., in room 2322 of the Rayburn House Office Building, Hon. Nathan Deal (chairman) presiding.

Members present: Representatives Deal, Bilirakis, Shimkus, Shadegg, Bono, Ferguson, Myrick, Burgess, Barton (ex officio), Brown, Waxman, Green, Strickland, Capps, Allen, and Baldwin.

Staff present: Chuck Clapton, chief health counsel; Ryan Long, professional staff; Bill O'Brien, legislative analyst; Eugenia Edwards, legislative clerk; Brandon Clark, health policy coordinator; John Ford, minority counsel; and Jessica McNiece, research assistant; and David Vogel, research assistant.

Mr. DEAL. I call the meeting to order. I am pleased to have this opportunity to have these distinguished members of the panel here, today.

And in my opening statement, I want to simply welcome you, and I will go ahead and introduce each of you as we go along the table: Ms. Kathleen Jaeger, who is President and CEO of the Generic Pharmaceutical Association. We are pleased to have you with us. Dr. Jan Berger, the Chief Clinical Officer of Caremark. Ms. Bonnie Kramer, Board of Directors Member of the American Association for Retired Persons. Dr. Bruce Perry, Medical Director for the Southeast Permanente Medical Group in Atlanta, Georgia, representing Kaiser Permanente. And Dr. Scott Gottlieb of the American Enterprise Institute. We are certainly pleased to have such a distinguished group before us today.

Given the increase in expenditures on healthcare costs in our country, I believe all of us would agree that it is appropriate that we are here today to explore the significant cost savings for American consumers and the American taxpayers if we could increase the rate of utilization of generic pharmaceuticals. Although the United States has one of the highest rates of generic utilization in the world, and generics available in our country are up to 50-percent cheaper than those available in other countries, we are still leaving significant savings on the table through under-utilization.

In fact, a recent HHS report conservatively estimates that in 2003, U.S. consumers could have saved an additional $17 billion if they would have fully utilized the generic drugs available on the

market today. And the FDA states that a typical patient could reduce their per-day cost by 14 to 16 percent by fully utilizing generic pharmaceuticals. Amazingly, for every 1-percent increase in generic drug utilization, it has been estimated that consumers and third-party payers could save between $1.3 and $4 billion every year. Clearly, generic pharmaceuticals could provide real savings for real people and could do so in a way that does not put patients' safety at risk.

That is why I am excited about the opportunity we have before us today to further explore ways to lower some of the obstacles to increased use of generic pharmaceuticals and to highlight some of the efforts already underway to achieve these important goals. Again, I welcome our distinguished members of the panel, and at this time, I will recognize my friend Mr. Brown from Ohio for his opening statement.

Mr. BROWN. Thank you, Mr. Chairman. I very much appreciate your having this hearing today on generic medicines as a vehicle for reducing healthcare costs. And thanks to the five witnesses who are with us today, too.

If the prescription drug market worked like other markets, a brand-name drug would enjoy a well-defined, immutable period of market exclusivity to reward and compensate innovation, and competition would drive the price down to more or less the cost of production plus a reasonable profit. The foundation for this free market structure is written into our Constitution. The Constitution requires the Federal Government to protect intellectual property, as we know; it also requires defining limits on that protection to prevent exploitation of consumers.

When it comes to prescription drugs, the public has a huge stake in the market working as it should. Unlike most innovations, new drugs and other healthcare innovations can have a direct bearing on human suffering and on human survival. That is why there is so much tension between innovation and access. That is why the public finances prescriptions drugs for millions of Americans who otherwise couldn't afford them. That is why anticompetitive behavior in the prescription drug market isn't just unethical; it is immoral.

I am sorry that pharma refused to participate in today's hearing. I don't particularly like leveling charges at brand-name drug makers when our friend and former colleague Billy Tauzin is not here to defend their actions.

We can't responsibly discuss generic utilization without discussing the tactics used to delay generic approvals. Utilization of approved generics may be less than 100 percent, but utilization of approvable but unapproved generics is zero. Brand-name drug manufacturers abuse the citizen-petition process to unjustifiably delay approval of generics. I am pleased the FDA is trying to tighten up the process to prevent such abuses. The agency can—and the agency should establish reasonable timeframes for review of these petitions and permit FTC to review them for anticompetitive intent.

Brand-name drug companies also compete against themselves to undermine the incentive for timely generic competition. They do this by producing authorized generics, which are no more than re-

packaged and re-priced versions of their brand products. Drug makers could simply reduce the price of their brand name products to the generic drug level, which would benefit consumers even more than generic competition, at least until the myths about generic inferiority are completely dispelled. They could price their generic product competitively, which would obviate the need for true generic competition; instead, they reduce the generic price by a token amount, knowing that their presence in the market curtails the profit potential for true generic competition. FTC analyzed a few authorized generics and decided they are not anticompetitive. Now, these pseudo-generics are proliferating, and the anticompetitive implications are clear.

Drug makers fight generic access at the State level. They attach irrelevant patents to their drugs to gum up the generic approval process. They play on fears about the quality of generics, fears that are 20 years old and should have evaporated when my colleague John Dingell helped to clean up the generic drug industry. When generic drug competition threatens one product, drug makers produce a slightly modified version and market it as new breakthrough product. We could name example after example.

They price it that way, too. I am all for incremental advances, but when second-generation products are oversold, overpriced, and the release is timed to thwart generic competition, consumers, simply put, are being robbed. Drug makers are currently pushing for a second Bioshield bill that provides the industry an array of patent extensions. Even I didn't expect the drug industry to sink so low as to exploit the threat of terrorism in pursuit of windfall profits.

Drugs makers use directed consumers ads to convince patients that the profitable drugs are the best ones. Like other major industries, drug companies use advertising to induce demand and develop brand loyalty. Except the drug industry isn't like other industries: drug companies knowingly involve themselves in life and death situations. Their products aren't expendable, and the resources that purchase them are indeed stretched thin. I appreciate the drug industry's efforts to set standards for directed consumer advertising, but drugs should be used because they are effective, not because they are effectively advertised. Drug makers should voluntarily refrain from DTC advertising and work with us to expand access to objective information like that provided on the NIH website.

The bottom line, Mr. Chairman, is this: competition brings drug prices down; generic drugs fuel competition. Misinformation, misperceptions, outmoded practice patterns and anticompetitive tactics frustrate competition. That, we cannot afford.

Mr. DEAL. I thank the gentleman. In fairness to pharma, I must tell you that they were not invited to this hearing, since we did not consider them to be a generic manufacturer.

Mr. BROWN. Mr. Chairman, my understanding from the minority staff is that we requested they be invited, and your staff told us that they were, and they declined.

Mr. DEAL. Well, I shall clear up to be sure, but I can assure you that you are going to have more than your share of opportunities

to talk to our former Chair, Mr. Tauzin—probably more than you want to.

Mr. BROWN. I noticed there are more than 2 or 3 pharma lobbyists roaming the Capitol from time to time, too, Mr. Chairman.

Mr. DEAL. Well, I am sure that you will have an opportunity to do that. This hearing today, of course, hopefully, is more focused on the generic issue. Mr. Bilirakis, the cochairman of overall committee.

Mr. BILIRAKIS. Thank you very much, Mr. Chairman. I, too, want to commend you on calling this hearing to examine the role of generic drugs in lowering healthcare costs. As you, I am sure, know, I have been a longtime proponent of generic drug industry.

Generic drugs contain the same active ingredients as brand-name drugs, for the most part; they meet the safety requirements as brand-name drugs. They are just as efficacious as brand-drugs—again, for the most part. They are held to the same manufacturing standards as brand-name drugs. Generic drugs are, in fact, just as safe and work just as well as their brand-name counterparts, except that they often cost much less.

Congress enacted the Hatch-Waxman Act a little more than 20 years ago to establish the framework that currently governs the entry of generic pharmaceutical products into the marketplace. The law—which has worked well—was designed to both to speed the entry of lower cost, generic drugs into the marketplace, while preserving an environment that encourages companies to develop innovative, new pharmaceuticals.

The Medicare Prescription Drug Law that we approved in 2003 built on the success of Hatch-Waxman by including provisions to further decrease the time that it takes to bring generic pharmaceuticals to the market. Consequently, more prescriptions are filled for generics today than ever before. In 1984, only about one-fifth of prescriptions were filled with generic alternatives, compared to more than half today. That is good, but I think not good enough.

We have not fully realized the potential that generic drugs hold for lowering healthcare costs. The Department of Health and Human Services recently reported that American consumers could have saved $17 billion in the year 2003 if they would have utilized generic drugs whenever they were available. There are several reasons why generics are not used more often. Certainly, one of those reasons is that many people, most people, simply refuse to believe that generics work as well as their brand-name counterparts. I have also heard that doctors and pharmacists sometimes lack adequate information about the safety, efficacy, and affordability of generics.

I want to make it clear that I strongly believe and support the pioneering work—and I think we should underline the words "pioneering work"—of America's pharmaceutical companies. These companies take tremendous risks by spending billions of dollars to bring new, lifesaving drugs to the markets. They rightly reap the rewards when those drugs make it through the rigorous approval process, and so do we. The work of the drug companies that some so deride does save lives. Their research and development allows others to bring generics to the market more quickly and more cheaply. I believe we must continue to ensure that we find an ap-

propriate balance—and there is that key word—between encouraging the use of lower cost, generic alternatives and protecting the incentives for innovator companies to continue their lifesaving and life-improving research.

I look forward to the testimony, as we all do, of our witnesses and am interested to hear their perspective on how we can save patients and taxpayers billions of dollars by encouraging the appropriate use of generic drugs. Thank you, Mr. Chairman.

Mr. DEAL. Thank the gentleman. Mr. Waxman?

Mr. WAXMAN. Thank you very much, and Mr. Chairman, it is a pleasure to be at a committee where both Democrats and Republicans agree that generic drugs are one of the more effective ways to lower costs of prescription drugs to consumers. That is certainly true, and FDA's rigorous regulatory framework assures us that generics are as safe and as effective as their brand-name counterparts. So I think that we should do all we can to ensure that generics are available and used widely.

The high cost of prescription drugs is one of the major challenges facing the American healthcare system today. I think we should be clear that the use of generics is only one part of the solution to the problem of the high cost of prescription drugs. We can do much more. First, we should remove the ban on the Secretary's ability to use the purchasing power of 40 million Medicare beneficiaries to negotiate lower prices for brand-name drugs. And second, the U.S. should not be paying prices for their drugs that are many times the prices in other countries. We need to change that.

Most drug expenditures, after all, are for drugs for which there is no approved generic version, so until we deal with the brand-name drug prices, we are not dealing with the problem. However, increasing the availability and use of generic drug products is of critical importance. Once generic products have entered the market, consumers can avail themselves of the drastic price advantages; but first, we must assure that generic drugs make it to the market as soon as possible.

Unfortunately, today there is an entire class of products known as biopharmaceuticals, widely known as biotech drugs, for which there are no available generic alternatives. These products account for billions of dollars in U.S. sales, and generic versions of these products could create enormous savings for consumers. We should do all we can to ensure that a generic-approval system for biopharmaceuticals is put in place as soon as possible. Every day delayed means American consumers pay a higher price.

The threats to rapid access of generics to the market are always with us. Incredibly, as we talk today, there is legislation in the Senate that Mr. Brown referred to, Bioshield, two proposals that would allow a brand-name company to get up to a 2-year extension on any drug or product the company markets, simply by developing a drug to deal with bioterrorism illness or emerging infectious disease. This is called a wildcard. It doesn't make sense. It is a gift of what could amount to billions of dollars to those companies without the consumers really getting what they need in exchange.

It is heartening to learn about practices of companies such as Kaiser Permanente and Caremark that help create wider use of generic products. We must continue to be vigilant in our efforts to

break down the barriers to rapid emergence of generic drugs on the market and at the same time, pursue equally vital options for lowering the cost of prescription drugs in this country.

I am pleased to welcome the witnesses to our hearing today and look forward to their testimony.

Mr. DEAL. I thank the gentleman. I recognize Dr. Burgess for an opening statement.

Mr. BURGESS. Thank you, Mr. Chairman, and again, thank you for holding this hearing on generic drug utilization.

There is no question that consumers should have access to lower cost, safe medications, and generic drugs do provide a vehicle to get here. Unfortunately, utilization of generic drugs has not been as widespread as it should be. Based on estimates in 2003, consumers could have saved $17 billion if they had used more generic drugs, where appropriate.

Because of the inequities of foreign regulation and regimes, the place of both prescription drug research and development goes on in America, and the American consumers bears the brunt of that. Generic drugs do provide consumers with a much lower cost alternative than branded medications, and we do need to consider remedying the inequities in the foreign market through a more aggressive use of trade tactics. Then, generic drugs can remain one of the few, safe low cost options to consumers.

Within the Medicare Modernization Act, this Congress provided much-needed reforms to the Hatch-Waxman drug-pricing law to speed more generics to the market. Reducing the amount of time that a brand-name manufacturer can reasonably maintain a patent on a drug will give the consumers greater access to lifesaving medications. I am interested to hear from the panel how effective these reforms have been and whether consumers are benefiting from the lower cost medications.

I am also hopeful that we can find ways to support more utilization of generic drugs. Consumers need to have pricing information available to them and differences between branded and generic medicines. Increased transparency of the marketplace, I believe, will benefit us all. The healthcare network, from doctors to pharmacists and health plans plays a vital role in helping patients realize substantial savings.

Finally, we need to ensure that medical decisions, including the prescribing of generics, remains in the hands of the physician. Substitute-therapeutics and placing other mediation in the hands of the patient when the doctor has prescribed something else really has no place in this debate, and I would encourage our body, our Congress, not to practice medicine by legislation because it is not appropriate for us to do so. But when it is clinically appropriate to prescribe generic drugs, we need to encourage their utilization.

Mr. Chairman, I look forward to hearing some information from our panel today about the cost of generics. While we are concerned about the cost of branded pharmaceuticals, sometimes of the cost of generics is many, many hundreds of a percent times the cost of their manufacture. Perhaps there are ways of even getting the costs even lower than what we see today.

In the arena of biopharmaceuticals, Mr. Chairman, that is a difference science, and that does bring a lot of different issues into

play. And we need to be very careful in this Congress about legislating that type of development.

With that, Mr. Chairman, I will yield back.

Mr. DEAL. I thank the gentleman. I recognize Ms. Capps for an opening statement.

Ms. CAPPS. Thank you, Mr. Chairman, for holding this hearing and to our witnesses for coming. The rising cost of prescription medications is critical issue for this committee, and that is because it is such a critical issue for our constituents.

Increasing medication prices are making healthcare and health insurance go through the roof—it is so expensive. And they are hurting the quality of healthcare that we pride ourselves on because they are putting needed therapies out of reach for so many Americans. New prescription drugs are great news for patients looking for new and better treatment, but what a tragic irony for a patient to realize there is treatment available, but not to that person because of the cost.

One part of the solution is clearly increased competition with generic drugs. Generics that are currently on the market give patients alternatives to expensive brand-name mediations. Certainly, it is worthwhile to encourage doctors and patients, where feasible, to use generics. But we also need to look at how to get more generics onto the market.

This committee has heard many accounts of how some brand-name prescription drug companies misuse the patent system to keep generics off the market. Some of my colleagues today have detailed some of these practices. And if we want to seriously address the cost of prescription medication, we need to address this problem squarely. But increasing generic access to market is only going to solve part of the problem.

For many brand-name drugs, no generic is available, and for some people—maybe few, but those people are important—like my friend who has Parkinson's. The generic brand is not able to be tolerated by her, so she needs to have the brand name.

We also need to find better ways to help Americans pay for the medications that they need. This has got to be part of the equation. For example, Medicare needs to be given the ability to negotiate a lower drug cost for seniors and those with disabilities. The fact that this was not permitted under the Medicare Bill last year is one of its great failings.

No one is saying the prescription drug companies should not make a profit. They have to make significant investments to bring us the wonderful medications that they produce, and they deserve some reward for the risks that they take. But their products do little good for the patients we represent if they are unavailable because they are so expensive. That is the issue that this committee needs to be examining. This hearing is a good start to that process, and I hope we will continue to examine this issue. And I look forward to the testimony that is about to begin. I yield back.

Mr. DEAL. I thank the gentlelady. I don't see anyone else here to make an opening statement. One thing about starting on time is that we are ahead of most of our members, so you will probably see some of them catch up as this hearing proceeds—I hope.

[Additional statements submitted for the record follow:]

PREPARED STATEMENT OF HON. PAUL E. GILLMOR, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OHIO

Thank you, Mr. Chairman for holding this important hearing.

While the new Medicare bill is just over the horizon, no matter how you cut it, our constituents are fed up with the high cost of health care, and in particular, the price of prescription drugs, whether it be brand or generic; and that's just it.

Patients many times put brand and generic drugs in the same category with regard to overall costs, even though they know generics are cheaper. All too often, due to perception and a general lack of education when it comes to generics, consumers ignore the fact that brands and generics share identical ingredients, dosage, effectiveness, quality, and safety. Even if a patient is well-aware of this equivalence, it is likely that he or she will be offered through a health plan, or prescribed by a physician, a more expensive brand drug simply because of an unawareness that a competing generic is already on the market.

I would also like to join my colleagues in drawing attention to the recent HHS report, quoting $17 billion in consumer savings where generics were available, but not utilized. I look forward to being educated by the well-balanced panel of witnesses, about their efforts to further educate physicians, pharmacists, health care providers, and patients alike to ensure market access to generic drugs, resulting in significant savings to patients' and taxpayers' pocketbooks.

Again, I thank the Chairman and yield back the remainder of my time.

PREPARED STATEMENT OF HON. CHARLIE NORWOOD, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF GEORGIA

Thank you, Mr. Chairman.

As Americans continue to struggle against the backdrop of high prescription drug costs, generic drug utilization is essential. Today, generics hold great hope for American consumers. There is at least one generic product available for most of the top therapeutic classes. Generics currently account for roughly 50 percent of all prescriptions filled in the United States. Employers—who can no longer afford unrestricted health benefits are seeking ways to stay competitive. Generics have proven an effective answer.

Generics are holding their own in the marketplace and encouraging their full potential is an admirable goal. But there is certainly room for expansion. While, a 2005 study found that 7 in 10 consumers would prefer a medicine that has been on the market for at least 10 years, only 46 percent were willing to use generics for serious health problems.

However, we should be encouraged that eighty-six percent of consumers report that they would be willing to use generics for common health problems. With 89% of seniors taking prescription drugs in the past year and nearly half of those taking at least five, generic drugs could save individuals and the federal government a lot of money. According to estimates prepared by the Congressional Budget Office, in 2003 U.S. consumers could have saved as much as an additional $17 billion by purchasing generics.

This is not a new idea. Generic drug utilization has already been the key to managing the growing cost of prescription drugs for private insurance plans and individuals alike. Incentives to use generics have enabled plan sponsors to continue providing coverage at a time when too many are dropping health coverage.

As this subcommittee looks towards ways of increasing generic utilization, we should focus our efforts on the relationship between patients and their doctors and their pharmacists.

Often patients want a name brand drug because it is more familiar to them. A good doctor—patient relationship can clarify that generics are identical to a brand name drugs. As healthcare professionals work to increase familiarity with, and knowledge of generics I believe that they will become even more accepted.

However, generic utilization will not solve all of our problems. There is a generic-utilization ceiling. Generics rely on the cycle of name-brand drugs and patent protections to encourage research and development into the next miracle pharmaceutical, which means future opportunities for generic companies.

Maximizing the use of generic drugs is a first step in U.S. efforts—to find better—market-driven—solutions to affordable prescription drugs. There is not a generic drug for every prescription, and patents rightfully protect name-brand drugs for their development costs. We—need to spread the word that management of prescription drug prices—through—market forces—is not an adversarial notion.

Our allies need to realize that market forces not government intervention is the answer regarding name brand drugs. To lower the price of name brand drugs we

should address our allies' monopolistic purchasing structures. But this is just another piece of the puzzle in addition to, not in place of increasing generic use.

In this light, I am looking forward to our witnesses' testimony and guidance. I yield back.

PREPARED STATEMENT OF HON. JOE BARTON, CHAIRMAN, COMMITTEE ON ENERGY AND COMMERCE

Thank you Chairman Deal for holding this hearing. I appreciate the opportunity to hear from today's panel of witnesses about how generic drugs can help lower the prices consumer pay for their medications.

I support lowering prescription drug costs. I also support free markets and competition. Generic drugs achieve both of those goals, in a way that is both safe and legal. In fact, generic drugs save consumers, health plans and the Medicare and Medicaid programs tens of billions of dollars every year.

Although you would never know it from the recent debates in Congress on drug pricing, we passed a law in 1984 that has been one of the most effective tools ever provided to consumers to lower their prescription drug costs.

This law, known as Hatch-Waxman (named for the senator from Utah and for our colleague from California), established a process for approving generic versions of brand-name drugs. These new generic versions are required to be identical to the originals, but are subject to expedited review and approval processes. As a result, these drugs are sold at a fraction of the cost of the original medications.

Since the mid-1980's we have seen a dramatic increase in generic availability. Currently, a little over 50% of all prescriptions in the United States are filled with generics, often at prices dramatically lower than those charged for comparable brand name drugs.

Because we have such a robust generic drug industry, American consumers actually paid $30 Billion LESS for generic drugs than European consumers paid for equivalent products. We also managed to achieve these savings without having to rely on the price controls that kill innovation and deny patients new medications.

I believe, however, that we can do an even better job in educating consumers about the advantages offered by generic drugs. According to a report by the Health and Human Services Report released in December U.S. consumers could have saved as much as $17 billion by purchasing available generic substitutes for brand name drugs.

I look forward from hearing from the witnesses today about what they are doing to promote cheaper, effective alternative medications. Their experiences can help us prepare for the implementation of the new Medicare prescription drug benefit in 2006 as well as assist our efforts to reform the Medicaid program. I also hope to hear any additional suggestions about how to further improve the current system to promote competition and ultimately lower drug prices for consumers.

Thank you again, Chairman Deal for holding today's hearing, and I yield back my time.

PREPARED STATEMENT OF HON. GENE GREEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Thank you, Mr. Chairman, for calling this hearing to examine the use of generic prescription drugs and the savings that generics offer to patients, health insurers and government programs.

For years, we have heard the reports about the soaring costs of prescription drugs.

It's no secret that the brand name drugs—not the generics—are behind this increase in drug costs.

In fact, in 2004 alone, brand name drug prices increased over 7 percent—more than twice the rate of inflation—while the price of generics increased only one half of one percent.

Whether it is due to the increasing cost of brand-name prescription drugs or increased patient and physician awareness, generic drugs are without doubt penetrating the market.

More than 50 percent of all prescriptions are filled with generic drugs, yet generics only account for 12 percent of prescription drug spending.

When you look at it that way, it's easy to believe that generics can be 70 to 80 percent cheaper than brand name prescription drugs.

These statistics suggest a tremendous opportunity for patients and insurers to save critical health care dollars.

And in a time of extreme budget crunches both at the federal level and in each of our states, we should take a long look at generic drugs and the increasing role they can play in health care financing.

Our challenge is to examine what role the government should play in increasing the availability of generic drugs and providing incentives for their use.

In my state of Texas, the Legislature effectively made generic prescriptions the default by mandating that physicians physically write out "brand necessary" or "brand medically necessary" on the prescription pad when no substitutions were appropriate.

The University of Texas's Center for Pharmaco-economic Studies estimated that this one policy could save patients and drug benefit programs in my state as much as $257 million each year.

One simple way to increase the utilization of generic drugs is to make them more readily-available.

To that end, we need to look at current statutes and regulations that have the effect of hindering the entry of generic drugs to the market, whether it is through an examination of patents, authorized generics or the approval process at the FDA.

I look forward to hearing from our witnesses on their experiences and recommendations on these issues, and I thank them for appearing before us today.

With that, Mr. Chairman, I yield back the balance of my time.

Mr. DEAL. Once again, we are pleased to have you here. We look forward to your testimony and the questions that will follow. And Ms. Jaeger, I will call on you first for 5 minutes.

STATEMENTS OF KATHLEEN D. JAEGER, PRESIDENT AND CEO, GENERIC PHARMACEUTICAL ASSOCIATION; JAN BERGER, CHIEF CLINICAL OFFICER, CAREMARK; BONNIE M. CRAMER, BOARD OF DIRECTORS, AMERICAN ASSOCIATION OF RETIRED PERSONS; BRUCE C. PERRY, MEDICAL DIRECTOR, THE SOUTHEAST PERMANENTE MEDICAL GROUP, KAISER PERMANENTE; AND SCOTT GOTTLIEB, AMERICAN ENTERPRISE INSTITUTE

Ms. JAEGER. Mr. Chairman and members of the committee, I am Kathleen Jaeger, President and CEO of the Generic Pharmaceutical Association. It is an honor to be here before you today to speak on behalf of an industry that helps to fill over 1 billion prescriptions a year, yielding annual savings of ten of billions of dollars to consumers, businesses, and government.

GPhA appreciates the opportunity to discuss current generic pharmaceutical use and ways to both increase access and effuse savings from these more affordable medicines. We will recognize—yes? Absolutely. Sure. Is this better?

We recognize the importance of this issue to the committee, given its broad jurisdiction over the nation's healthcare systems, including private insurers, Medicaid, and much of the Medicaid program.

Generic pharmaceuticals represent more than 53 percent of all prescription dispensed in the Unites States. They account for less than 12 cents of every dollar spent on prescription drugs. According to the National Association of Chain Drugstores, last year the average retail price for a brand drug was $96.01. The average retail price of generic was $28.74—a savings of nearly 70 percent per prescription.

It is important to note that while current generic utilization saves America tens of billions of dollars each year on the costs of medicines, a mere 1-percent increase in generic usage will yield almost $4 billion in additional savings. Now, let me repeat that fact. Moving 1 percent of the U.S. brand prescriptions to FDA approved generics will yield almost $4 billion in savings, savings that can be

used to help moderate prescription drugs spending at both the Federal and State levels and for individual customers as well.

Now, to see how this translates into real savings, we only need to look at the generic utilization rates of some State Medicaid programs. The States with the highest generic utilization rates are Hawaii at 56 percent, and Illinois, in a close second, at 55 percent. And dragging themselves into the world of cost-containment are New Jersey and Delaware, with both States having a meager 42-percent generic utilization rate. If all the Medicaid programs obtained a generic utilization rate in the high 50's, States and the Federal Government would save billions of dollars annually.

Now, what explains the wide variance in generic drug rates among the States? Well, easy. That is practices, practices that are currently employed in most private insurers in some States. And in fact, there are a number of initiatives that can be immediately adopted or encouraged by this committee that would rapidly increase the substitution of generic drugs.

Now, the easiest and most immediate place to start on savings on prescription drugs involves the overlooked prescription pad and physician-prescribing practices. At least 33 States require the physician to make a conscious decision and to handwrite "no substitution, dispensed as written" or a similar statement on the pad if only a brand drug can be dispensed. Other States have a check-off box or require the doctor to sign on a different line if they want the brand product. Encouraging States to simply redesign the prescription pad could form tremendous public savings for public and private healthcare providers and consumers. And in fact, Texas did just that in 2001 and saved $223 million a year.

The next best practice is the implementation of mandatory generic-substitution programs where they do not currently exist and strengthening such programs in States where loopholes may lower the overall substitution. As an example of strengthening a mandatory generic program, Massachusetts, recently took a series of steps over a 3-year period that they estimate shaved $150 million off the State's annual drug tab. A large part of the savings came from implementing a tougher dispensed-as-written program, requiring doctors to explain in writing the need and get permission from the State in order for the brand to be dispensed.

Another issue closely related to the mandatory-substitution and physician-prescribing practices involves the elimination of carve-outs for classes of drug products, including mental health, diabetic, and epileptic, and cancer drug products to name a few. Some States have, unfortunately, instituted this bad practice, which is supported by special interests that make it extremely easy for physicians to bypass generic-drug-substitution laws. This carve-out policy is based on the erroneous assumption that the use of generics will undermine the treatment outcomes. There is no scientific or medical basis for this assertion; and thus, it unnecessarily increases State Medicare program costs by millions of dollars. This bad practice must be stopped.

There also are several additional best practices relating pricing and incentives that will dramatically reduce drug expenditures. These involve implementing aggressive, maximum allowable cost—or MAC—formulations by capping the maximum price States will

pay for certain prescriptions and having pharmacists having the incentive to dispense the less expensive generic. While some States do adopt these, others do not, and slightly over half the States take advantage of their ability to set their own payment ceilings for multi-source drugs. And for that do, not all of these States have implemented an aggressive MAC system, leaving unrealized savings on the table.

And finally, an area of virtually untapped opportunity for generic utilization involves the investment in consumer education: an aggressive effort to educate providers and patients about the safety, sameness, and savings of generics. And of course, those who administer healthcare plans such as Kaiser and Caremark, here, know all too well that differential co-payments can also provide substantial savings.

The best practices that I have referenced can be implemented at the State level, with or without Federal legislation; however, to ensure a nationwide adherence and maximum savings, a Federal approach, which would ensure a more uniform and efficient policy course of action, should produce increased Federal savings. Please be assured that we would be happy to work with this committee toward passing and implementing successful policies in this area.

Nonetheless, is essential to note that tremendous savings from these vast practices can be dramatically curtailed with the passage of legislation and international trade agreements that will, if unchecked, disrupt the timely introduction of new, affordable generic drugs. One such threat is embodied within the certain provisions of a certain Bioshield II legislation. GPhA supports some aspects of the proposed legislation, such as the need for product-liability protections, expanded tax credits, and FDA review of drug applications, but GPhA remains opposed to unnecessarily extending brand product monopolies for already approved drugs which will do little to secure America and would allow brand pharma to profiteer off the fears of Americans.

Another threat to the U.S. generic savings involves attempts to use international trade agreements to limit the timely introduction of generics in the United States. GPhA has serious concerns about a number of provisions contained in free trade agreements that the United States has originally negotiated and is currently negotiating. It is GPhA's position that no free trade agreement should upset the U.S. of pharmaceutical innovation and access, nor should they block generic drugs from being exported abroad.

And Mr. Chairman, I would be remiss if I left this hearing without urging Congress to encourage the FDA to immediately clear a pathway for generic biologics and issue important industry guidelines. Generic biologics represents another opportunity for additional, untapped consumer savings. We also urge Congress to require sufficient FDA oversight and accountability to ensure the timely introduction of generic drugs. The return on investment from increased FDA oversight and accountability regarding the generic drug approval program would pay significantly in long-lasting dividends to all Americans.

And finally, GPhA encourages Congress to encourage CMS to complete its analysis on authorized generic drugs, products that are masquerading as generics, with respect to the best price cal-

culation for brand companies and issue a policy clarification on this matter.

And Mr. Chairman, I want to reiterate that the tools needed to capture millions of dollars in savings in consumers exists today. It is clear that generic pharmaceuticals already save billions of dollars a year in prescription drugs costs. More substantial drugs savings can be accompanying by adopting and tightening best practices and remaining vigilant to those special interests seeking on a national and international level to erect barrier to the timely introduction of generic drugs. But we can and we should do better so we can ensure that healthcare and prescription drugs remain affordable for all consumers. And with your help, I am confident we can, and we will. And I will be pleased to answer any questions you may have. Thank you.

[The prepared statement of Kathleen Jaeger follows:]

PREPARED STATEMENT OF KATHLEEN JAEGER, PRESIDENT AND CEO, GENERIC PHARMACEUTICAL ASSOCIATION

Mr. Chairman and Members of the Committee. I'm Kathleen Jaeger, President and CEO of the Generic Pharmaceutical Association. Today I am pleased to speak on behalf of nearly 130 member companies that manufacture and distribute generic pharmaceutical products, including bulk active pharmaceutical chemicals.

We appreciate the opportunity to discuss current generic pharmaceutical utilization and the opportunities available to tap a substantial reservoir of additional savings for consumers, as well as for State- and Federally-funded programs. Because your committee has such broad jurisdiction over our nation's health care programs, including private insurers, Medicaid, and much of the Medicare program, we well recognize your keen interest in and knowledge about the impact of growing pharmaceutical cost on all purchasers of health care. GPHA's recommendations for achieving substantial savings can be accomplished by adopting initiatives in two broad categories:

1) Adopting initiatives that would increase generic utilization and produce substantial savings; and
2) Preventing initiatives that would erect new barriers to generic competition and thus increase overall cost.

First, I would like to provide a brief overview of the safety and sameness of generic drugs as well as to discuss recent pharmaceutical cost trends. For more than two decades, FDA-approved generic medicines have been providing consumers with the same medicines, and offering the same clinical results as their brand name counterparts at a substantial savings for consumers.

The rigorous FDA-approval process for generics ensures that our products have the same active ingredients, are taken in the same way, provide the same dose, and produce the same clinical results. Repeatedly since the founding of our industry, the FDA has assured the general public, doctors and healthcare providers that the only difference between a generic drug and its brand name counterpart is the cost. Our products have been used to fill over tens of billion prescriptions, a track record for safety and sameness that stands on its own.

Generic pharmaceuticals represent more than 53 percent of all prescriptions dispensed in the United States, but they account for only 12 percent of all dollars spent on prescription drugs. According to various studies, generics can be as much as 80 percent less than brands. And, according to the National Association of Chain Drug Stores, last year the average retail price for a brand drug was $96.01 while the average retail price of a generic was $28.74, a savings of nearly 70 percent per prescription.

It is important to note that while current generic utilization saves America tens of billions of dollars each year on the cost of medicines, increasing utilization will introduce even more dramatic savings.

Recently, AARP released its annual Rx Watchdog Report, which tracks prices that drug manufacturers charged wholesalers during the past year for about 200 prescription drugs popular with older Americans. The brand pharmaceutical price hikes were the largest annual jump since AARP began sponsoring the study five years ago.

According to the report, the 7.1 percent hike continues a trend of increasing brand drug prices, despite the fact that inflation in 2004 was 2.7 percent.

The report also noted that in contrast, the price for 75 popular generic drugs hardly budged in 2004, rising 0.5 percent, 2.2 percent below the rate of inflation.

The value of generic medicines as the prescription for relief from high drug costs was further confirmed in a December 2004 study released by the Department of Health and Human Services. While we believe the number to be much higher, the HHS study found that in the United States, "if consumers were to buy generic products whenever possible . . . we estimate savings to be approximately $17 billion."

Clearly, greater use of generic pharmaceuticals could help arrest the escalation of drug spending at both the federal and state levels, and for individual consumers as well. Promoting the increased utilization of generic drugs is therefore, quite simply, good and affordable medicine for everyone.

Yet, as I indicated previously, there remain a number of opportunities and threats to substantially enhancing the savings potential that generic pharmaceuticals provide.

I. INITIATIVES THAT WOULD INCREASE GENERIC UTILIZATION AND PRODUCE SUBSTANTIAL SAVINGS

Adopting or encouraging the use of practices that immediately increase the use of FDA-approved generic pharmaceuticals in place of expensive brand name drugs is imperative. In fact, a one percent increase in generic utilization yields almost 4 billion dollars in savings!! [1]

One critical step that deserves immediate consideration by Congress is the adequate funding and oversight of FDA's generic approval division, the Office of Generic Drugs (OGD). Lack of sufficient oversight and accountability at the Commissioner and Center levels, allows generic applications to endure needlessly protracted legal and scientific consults—delaying generic approvals for several months to several years. Also, allocations for OGD have remained flat for the past couple of years, and the result of this constraint on resources is clear.

Today, when consumers need FDA-approved generic medicines more than ever before, more than 700 applications languish due to lack of resources at OGD. Cooperative efforts between our industry and the staff of the Office of Generic Drugs have resulted in a streamlining of the approval process and better generic pharmaceutical applications. Yet, due to the lack of sufficient agency accountability and OGD resource constraints, approvals significantly lag behind the increasingly strong applications of our member companies. Moreover, this problem will only worsen over the next few years as more generic drug applications are submitted for equivalents of blockbuster brand products that come off patent: $27 billion in 2007, $29 billion in 2008, $21 billion in 2009 and $44 billion in 2010.[2]

Congress can, and should, require accountability and increase funding to support more timely approvals. The return on investment from more accountability and increased funding will pay significant and long-lasting dividends for all Americans—individual consumers, employers and state governments and the federal government.

GPhA believes that there are a number of additional ways to immediately and effectively increase generic utilization rates on the national and state level, for Medicaid and other federal programs, for state funded programs, and for private insurers and individual consumers who must pay out of pocket.

While not all-inclusive, GPhA has identified several initiatives that alone, or in combination, would help increase the utilization of more affordable generic medicines. Four of these proposals involve changes related to the way generic medicines are prescribed and substituted. Three of our proposals address incentives and the value of efficient cost management. One initiative focuses on the value of education.

We also want to take the opportunity of this hearing to raise a flag on several issues currently looming on the legislative and international horizon that could derail America's leadership in safe and effective affordable pharmaceutical products.

Let's look first at prescribing practices and generic substitution. The easiest, and most immediate, place to start saving on prescription medicines involves the often overlooked prescription pad, and physician prescribing practices.

The format of a prescription pad varies from state to state. Yet, this format can have a profound impact on whether physicians are more or less likely to prescribe brands over generics. At least 33 states require the physician to make a conscious decision and handwrite "no substitution", "dispense as written" or a similar state-

[1] 2005 IMS Health: National Sales Perspective (2004 Data Analysis) & IMS Health NPA

[2] Bain & Company.

ment on the pad if only a brand drug can be prescribed. Other states may have a check-off box or require the doctor to sign on a different line if they want the brand product dispensed and not a generic.

Encouraging states to simply redesign the prescription pad form could provide tremendous savings to public and private healthcare providers and consumers.

For example, before 2001 the State of Texas had a two-line prescription pad where the physician could sign the "brand only" line and override the substitution of a generic for the brand. In 2001, Texas implemented a new pad that required a physician to handwrite "Brand medically necessary" in order to prohibit generic substitution. According to an analysis by the University of Texas, this simple change resulted in estimated savings of $223 million.[3] If states were to adopt this type of approach, which makes the dispensing of an expensive brand drug a proactive choice by the physician, states would unlock a vast, untapped opportunity for savings.

We also believe that there are several additional ways to increase usage of generic drugs, by strengthening the substitution process and prescribing practices in favor of generic medicines where they are available.

Next, we believe that the issues of requiring the substitution of generics offer an untapped opportunity for savings. GPhA urges that mandatory generic substitution policies be implemented where they do not currently exist, and strengthened in states where loopholes may lower overall substitution. As an example of savings, legislation expected to be approved by the Tennessee Legislature that requires substitution of generic drugs for more expensive brand drugs has been projected by state officials to save $32 million for that Medicaid program—$11.5 million in state funds and almost $21 million in federal funds.

While the federal government may not want to specifically mandate this at the state level, CMS could certainly assist in making a compelling argument for states that do not have mandatory substitution. While CMS has recently announced its support for mandatory generic substitution policies, and most private entities already have embraced this policy, more can be done to encourage adoption by the public sectors.

GPhA would propose policies be implemented to ensure that that the substitution of generic medicines, when available, cannot be overridden without a valid medical reason.

For example, in Massachusetts, Medicaid officials took a series of steps over the past three years that they estimate shaved $150 million off the annual tab for drugs. A large part of the savings came from a change in a policy within their mandatory generic substitution program related to "Dispense as Written."

Massachusetts doctors were routinely asking for brand name drugs by writing "Dispense as Written," and Medicaid was paying $10 million to $11 million a month for brand-name drugs that had generic equivalents. After reviewing the situation, a tougher policy was put into place that requires the doctor to explain why, in writing, and get permission from the Medicaid program in order to force dispensing of a brand drug instead of its equivalent lower-cost generic. Once the new policy went into effect, spending on brand-name drugs with generic equivalents dropped dramatically to $200,000 to $300,000 a month.[4]

Another issue closely related to mandatory substitution and physician-prescribing practices involves a new version of the old argument that generic drugs are not the same as brands. This argument is appearing in the form of "carve-outs" for mental health, epileptic, diabetic, arthritis, cancer and many other drug products.

Some states have instituted practices, supported by brand drug special interests that make it extremely easy for physicians to bypass generic drug substitution laws for mental health drugs. The rationale for carve-out provisions is based on the erroneous assumption that the use of generic drugs will undermine treatment outcomes of patients with mental illness. There is no scientific or medical basis for this assertion and it is inconsistent with FDA's determination of therapeutic equivalence.

In the mental health category alone, there are currently more than 60 major mental health drugs on the market including anti-depressants, anti-psychotics, anti-anxiety, and stimulants. Fifteen of the most prescribed mental health drugs accounted for more than $18 billion in brand name drug sales in 2001. Sales of anti-psychotics totaled $6.5 billion in 2003.

Simply stated, the "carve-out" policy is contrary to FDA's pronouncement of therapeutic equivalence, and increases state Medicaid program costs by millions of dollars without any credible, independent evidence-based studies that indicate that using a brand drug will result in a different outcome than using a generic.

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[3] May 2001, Center for Pharmacoeconomic Studies, University of Texas at Austin

[4] Tough Medicine is Paying of For State; Boston Globe; February 17, 2004

To understand the cost of "carve-outs" one needs only to look to the State of Florida. Two years after the state implemented a preferred drug list with a carve-out for mental health drugs, an analysis by state officials showed that the elimination of the carve-out could provide substantial savings. And, less than two weeks ago, Florida followed through by passing legislation to eliminate carve-outs "aimed at saving nearly $300 million a year."[5]

Other states that have rejected carve-outs have achieved substantial savings without any impact on health outcomes. One year after the state of Kentucky changed its policy to treat an anti-psychotic drug like all other medications for the purpose of substitution, "mental health advocates said they could trace no ill effects to the decision."[6]

GPhA strongly encourages the modernization and strengthening of the process by which substitution of a generic for a more expensive brand product is encouraged.[7]

There are also several additional issues related to pricing and incentives that GPhA believes can help dramatically increase generic utilization rates. These involve implementing aggressive maximum allowable cost—or MAC—formulations, and providing an incentive for pharmacists to dispense generics.

States have the flexibility to establish their own payment ceilings for multiple source drugs, so long as it does not exceed the federal payment ceiling for drugs. Slightly over half the states take advantage of this cost containment tool, which enables them to limit their liability with regards to drug pricing.

Many states have implemented MACs, or maximum allowable cost formulations, for a limited number of drugs. And, while establishing aggressive MACs is certainly a worthy objective, it is the rigorous application of MACs to both brands and generics that can yield substantial state savings. This is a common practice among private health insurers that has resulted in significant savings for them.

Another opportunity for increasing generic utilization involves incentive fees for pharmacists. Drug specific payment ceilings calculated at the Centers for Medicaid and Medicare Services allow for payment to pharmacists of a "reasonable" dispensing fee established by the state Medicaid agency.

CMS regulations do not define "reasonable" and there is great variation among states in the amount of the dispensing fee and the manner in which it is calculated.[8] Lots of states offer no differential at all between the dispensing fee paid for brand-name prescription drugs and generic drugs. Offering a higher dispensing fee for generic drugs than brand drugs would encourages greater dispensing of generic drugs at the pharmacy, thus saving scarce Medicaid dollars.

Finally, an area of virtually untapped opportunity for increasing generic utilization involves the investment in consumer education programs that address misinformation campaigns by brand companies as well as misperceptions about the sameness and effectiveness of generics. An aggressive effort to educate providers and patients can result in substantial savings.

For example, AARP and Consumers Union have separately produced extraordinarily useful and empowering information to consumers to help them make the right decisions about choosing affordable medications. There are other examples as well. The Generics First program initiated by Medco Health Services demonstrates the impact that a generics education program can have. In 2002, Medco sent pharmacists to hold face-to-face clinical discussions with 1,700 physicians in 10 states. In addition to the meetings, the pharmacists left patient education materials and generic samples that physicians could provide to patients. The effort focused on educating the physicians on the availability, clinical benefits and economic value of generics and encouraged their use as a first line treatment.[9]

In addition, Express Scripts has implemented a program called "GenericsWork" that encourages physicians to prescribe, and patients to ask for low-cost generics. It is supported by a communication and education strategy targeted to both audiences. Express Scripts projects savings of $25 million over 3 years per 100,000 lives.

According to published reports, at least six (6) states have experimented with similar "counter-detailing" efforts. The Wall Street Journal reported that in October 2000, a Florida "counter-detailer" visited 88 physicians who tended to prescribe brand-name anti-inflammatory drugs. An analysis of those physicians prescribing

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[5] Advocates Also Point Out Concerns of Public Safety; The Tampa Tribune (May 13, 2005). The law is due to go into effect, July 1st if signed by the Governor.

[6] States Try to Limit Drugs in Medicaid but Makers Resist; New York Times; December 18, 2003.

[7] May 2001, Center for Pharmacoeconomic Studies, University of Texas at Austin

[8] Ibid

[9] The Bergen County Record newspaper, November 5, 2002

habits three months later showed a change in prescribing that was expected to save Florida $196,000 a year.[10]

West Virginia launched a pilot "counter-detailing" program in 2002. The head of West Virginia's Public Employee Insurance Agency predicted at the outset that a 2 percent increase in generic utilization (from 43 percent to 45 percent) would save his state $1 million.[11]

GPhA has developed a consumer educational campaign designed to maximize awareness of generics. It focuses on the core message that generics are the same medicine, provide the same results, but at lower cost than brand name drugs. This educational program can be made available and distributed directly, or indirectly, and customized to suit any health care provider's needs. For example, a state could partner with GPhA or merely use the materials as they have been created to support generic product use and patient acceptance within their program—without the cost of developing such a campaign on their own.

GPhA stands ready to assist in implementing such educational programs in both the federal and state levels, as well as with employers, providers, insurers and physicians and pharmacists.

Another tremendous opportunity of untapped savings is in the area of biopharmaceuticals. Biologics are growing at almost twice the rate of total pharmaceuticals. There are more than 600 biotech drugs currently in phase II and III clinical trials. And marketed biologics are approximately $30 billion in U.S. Sales, 12% of total pharmaceuticals, and growing about 20% annually. They could reach $60 billion in sales by 2010.

Acting Commissioner Dr. Crawford addressed the issue of biogenerics. Dr. Crawford stated that "[w]e now have the science to fashion a generics biologics program," and the agency has "to put a system in place to deal with it." GPhA couldn't agree more. The opportunity of additional savings is only a few steps away. We urge Congress to demand that FDA: (1) issue guidance documents to provide further advice to industry participants; and (2) approve generic applications that have scientific sign off. And finally, we urge Congress to encourage FDA to immediately establish a clear, definitive flexible pathway for generic biopharmaceuticals.

II. PREVENTING INITIATIVES THAT WOULD ERECT NEW BARRIERS TO GENERIC COMPETITION AND THUS INCREASE OVERALL COST

Ensuring that federal and international legislation as well as trade agreements do not disrupt the level playing field is necessary for the continued, timely introduction of affordable life-saving generic drugs.

These threats to savings are contained in such initiatives as attempts to use bioterrorism preparedness as a vehicle for brand product monopoly extensions; and efforts to utilize international trade agreements to restrict the development and timely approval of generics in America

For the past year, Congress has been exploring ways to expand and improve BioShield I. Senators Joseph Lieberman, Orrin Hatch and Sam Brownback introduced the Project BioShield II Act of 2005 to further improve America's security. While this legislation includes several promising incentives, it also includes provisions that would dramatically increase health care costs for consumers and the federal government and deliver windfall profits to brand pharmaceutical companies.

While GPhA supports efforts to encourage the production of countermeasures, some aspects of this legislation threaten the economic viability of our health care system. Outrageous measures to extend brand monopolies like 'wild cards' and overly generous patent extensions will delay consumers' access to affordable medicines.

For nearly 20 years, such special interest measures have been soundly rejected by Congress as catering to special interests at the public's expense. Yet, they have now resurfaced in legislation intended to strengthen America's security.

The bill contains promising incentives, such as needed product liability protections, expanded tax incentives, and fast track FDA review of drug applications, which GPhA supports. But as the legislation currently stands, it rewards de minimis product modifications of already approved products and discourages "true" innovation. Simply put, it allows brand pharma to play off Americans' fears to extend their product monopolies and keep affordable medicines off the market. Accordingly, this legislation is little more than a blank check to the brand pharmaceutical industry.

GPhA remains opposed to:

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[10] The Wall Street Journal, August 22, 2001

[11] The Washington Post, August 5, 2002

- The overly broad definition of a countermeasure, which could be extended to already approved products. Because the legislation fails to limit the term to novel medicines—ones that are clinically superior and fill a security priority void—patent extensions could be applied to a wide range of already approved drugs.
- Extending data exclusivity up to 10 years.
- Unlimited and uncapped patent extensions on any countermeasure product. Under this bill, multiple patents claiming the brand product could be extended.
- "Wild card" provisions that could be applied to any product in a company's portfolio, thus providing a windfall to brand pharmaceutical companies for products wholly unrelated to bioterrorism.

Rather than providing the brand industry with enormous windfalls, GPhA urges Congress to strengthen BioShield by adding incentives for "true" research priorities and incentives that don't jeopardize the nation's healthcare system.

Another threat to U.S. generic savings involves attempts to use international free trade agreements to limit the timely introduction of generics in the United States.

GPhA remains active on the international level, to ensure that harmonization efforts and treaties do not raise new barriers to the introduction of affordable medicines in the U.S., or make it difficult for generic companies to compete in the international arena.

Specifically, GPhA has serious concerns about a number of provisions contained in Free Trade Agreements (FTAs) that the United States has recently negotiated with various trading partners, including Australia, Bahrain, Chile, Morocco and Singapore, and potentially may be negotiated with Andean, SACU, ASEAN and other countries.

Some FTA provisions regarding intellectual property and other measures involving pharmaceuticals appear to contradict, both explicitly and in spirit, commitments made by the United States in the World Trade Organization and several appear inconsistent with U.S. law. GPhA is concerned that such measures could block generic drug exports abroad, substantially delay the timely access of affordable pharmaceuticals in those territories, and create the means to delay generic competition here at home, such as through international harmonization measures.

It is GPhA's position that no Free Trade Agreement should be used as a means to facilitate the brand industry's strategic global objectives of unfairly extending drug market protections and destroying the U.S. balance between pharmaceutical innovation and access.

GPhA will continue to monitor these issues, while focusing efforts on those initiatives that will help boost generic utilization and lower costs to the federal and state governments, to employers, insurers and all consumers.

In summary, it is clear that generic pharmaceuticals already save tens of billions of dollars a year in prescription drug costs. It is also clear, that with substitution at approximately 53 percent, there is still much room to grow America's utilization of generic drugs.

Ensuring the long-term growth in generic drug savings will result from Congress requiring FDA accountability and providing OGD with the resources necessary to free the logjam of new generic product approvals, by increasing the appropriations necessary to adequately fund the Office of Generic Drugs.

Additional increases in drug savings will come from changes to prescribing practices. Some of this growth can be accomplished by tightening existing substitution mechanisms. Additional growth can be accomplished by providing incentives for the increased use of generics. Some of this growth can come from educating consumers about the safety and sameness of generic medicines.

And finally, ensuring affordable generic pharmaceuticals for American consumers in the future will require that we remain vigilant to those special interests seeking, on a national or international level, to erect barriers to generic competition by unfairly extending market protections under the guise of bioterrorism preparedness, or by using international treaties to delay competition from America's generic pharmaceutical industry in the name of international harmonization.

America's generic industry is working right now to lower prescription drug costs. Prescriptions are being filled right now, one out of every two, with lower cost generics. But we can, and should do better, so we can ensure that health care and prescription drugs remains affordable for all consumers.

Thank you.

Mr. DEAL. Thank you. Dr. Berger?

STATEMENT OF JAN BERGER

Ms. BERGER. Good afternoon. My name is Dr. Jan Berger, and I am the Chief Clinical Officer for Caremark RX, Incorporated. As you may know, Caremark is a leading pharmacy benefit-management company that provides comprehensive drug services to over 2,000 health plan sponsors throughout the United States. Our clients include employers, health plans, managed care organizations, insurance companies, unions, and government-employee programs, including the Federal Employees' Health Benefits Program. Caremark operates a national retail pharmacy network of over 59,000 participating pharmacies and seven mail service pharmacies. We process over 55 billion prescriptions each year on behalf of our beneficiaries.

I would like to thank the chairman for calling this hearing today on generic prescription drugs. Our company has been creating and implementing programs to promote generics as an effective alternative to expensive, brand-name prescriptions for years. The Congressional Budget Office estimated that in 2002, generic drugs enabled savings of almost $100 billion versus the cost of the equivalent brand name prescriptions. Promoting the use of generic drug alternatives is a key factor in helping to control the total prescription drug costs in the U.S. market. This is particularly relevant as the first outpatient drug benefit in the Medicare program is implemented in January.

As you know, the FDA ensures that generic medications maintain the same high standards of safety, strength, quality, and effectiveness as brand-name medications. Based on the FDA guidelines, the only difference between brand-name and generic drugs are their name, appearance, and price. You may wonder then, why doesn't everyone use generic drugs? There are many outside influences that work against the average consumer's choice to use generic drugs. The most obvious are the lack of awareness of safe and available generic options, the competing visibility of brand names, the stereotype that generics are inferior, and the lack of motivation by both patient and physician due to benefit-plan-design structure and physician sampling. However, we believe that one once beneficiaries understand that generics are safe and effective, they will be interested in the fact that generic drugs can save them money.

Caremark has developed and operates a wide range of programs that help patients take advantage of generic drugs. By increasing the dispensing of generic drugs, health plans typically realize a savings of 30 to 70 percent, compared to the use of the more expensive brand-name drugs. How do we do it? We work to educate patients, physicians, and pharmacists about safe and effective generic options, both concurrently and retrospectively, and we work to design health plan structures that encourage the choice of generics.

Many of our programs are patient-oriented so that patients themselves are encouraged to use the generics. These include educating the patient on availability, safety, and effectiveness; educating the patient about their own potential cost savings; and working within the plan design to motivate patients to consider generics. Numbers of studies have shown that lower out-of-pocket costs for a patient result in greater compliance with their prescription drug regimen, so because generics are less expensive to the

participant, typically, they are able to take them more continually—increased adherence—and have better health outcomes.

In addition to Caremark's programs to educate beneficiaries of our generics, Caremark also assists prescribers in choosing generic drugs because they have the power of the pen. Specific activities here include face-to-face physician consultation through our National Academic Physician Detailing program, and through drug utilization review or DUR letters, physician feedback and peer comparisons, and utilizing tools that help identify generic opportunities and help eliminate the hassles of generic prescribing such as difficult drug names and spellings. Our programs operate both at the retail and mail order level in order to encourage physicians to consider generic options when writing prescriptions.

Of course, the final decision of dispensing a brand-name drug or a generic always rests with the prescribing physician. We believe that widespread usage of electronic prescribing—or e-prescribing—could assist physicians in the dispensing of generics. We are working the commercial market in order to encourage our health plans and employers clients to employ e-prescribing programs with providing physicians with either handheld or web-based technologies. Provisions included in the Medicare Drug Benefit law will ensure that Medicare beneficiary physicians will have access to patient-specific formulary information and will be able to greater discuss generic drugs options at the point of care, rather than at the pharmacy counter. Greater use of e-prescribing program will not only increase generic utilization, but are likely to improve safety by reducing medication errors.

Pharmacists are the third group we work with in order to find opportunities to increase generic utilization. We do this through online communication at the point of sale to alert a pharmacist to potential generic dispensing opportunities; pharmacist feedback and peer comparisons; and in some cases, monetary incentives are provided, based at least partially on the efforts to improve generic drug substitution and dispensing rates.

Caremark understands the value of generics and will continue to promote their appropriate use. Our efforts with patients, prescribers, and pharmacists, as well as the efforts of others in the industry have paid off. Generic drug utilization has increased. In 2004, across Caremark's client base, the overall generic-substitution rate was 95.1 percent. This means that over 95 percent of the time that a prescription was dispensed for a prescription drug with a generic equivalent available, a generic option was actually dispensed.

I do, however, wish to bring to your attention a legislative issue that could prove counterproductive to all of the work that Caremark and others have been doing to increase the use of generics. We recognize that Congress is actively pursing Bioshield II legislation that would enhance manufacturers' ability to bring bioterrorism countermeasures to market. We commend these efforts, but are concerned that in doing Congress will unintentionally enact legislation that will inhibit the production of generic drugs. Specifically, we urge Congress to remove all of the patent-extension provisions for brand-drugs as they consider this important legislation. While we are supportive of tax incentives and limitations of

liability for manufacturers, we believe these protections should be sufficient incentives for companies to invest in the production of biomedical countermeasures.

Patent-restoration and wildcard extensions for brand-name pharmaceuticals are not in the best interest of healthcare, patients, State and local governments, or private payers. The end result will be higher prescription drug bills for all concern and potentially reduced access to necessary healthcare. A rough estimate of cost of the extending of patent life of the top ten selling drugs for 2 years was over $45 billion. We strongly urge the House, when considering Bioshield II, to eliminate all patent-extension provisions.

In conclusion, Caremark is committed to delivering high quality healthcare services, and we believe one of the more important, clinically safe and effective cost-containment techniques is the promotion of generic drugs. I thank the committee for asking me to speak about our business practices today and look forward to an ongoing dialog with you, Mr. Chairman, and the members of this committee.

[The prepared statement of Jan Berger follows:]

PREPARED STATEMENT OF JAN BERGER, CHIEF CLINICAL OFFICER, CAREMARK

INTRODUCTION

I would like to first thank the Committee for calling this hearing today on generic prescription drugs. Our company has been creating and implementing programs to promote generic as an effective alternative to expensive brand name prescription drugs for years. Caremark is pleased that the Congress is interested in the health care improvement and cost savings opportunities that are represented by generics.

I am a physician and the Chief Clinical Officer for Caremark. At Caremark I am responsible for the physician oversight of the Caremark corporate clinical strategy, support of sales and account management, governmental and lobbyist activities, Medicare Part D, product development, disease management and technology initiatives including: e-prescribing and Internet activities. I am a board certified pediatrician with clinical experience in private, managed care and academic medicine.

Caremark appreciates the opportunity to offer testimony on generic prescription drugs. Generic drugs represent a cost effective alternative to expensive brand name prescription drugs. By making this cost effective alternative available to patients, patient adherence to therapy increases, clinical outcomes are improved and healthcare costs are reduced. We commend the Energy and Commerce Subcommittee on Health for considering this very important issue. Based on its many years of experience in managing the pharmacy benefits for tens of millions of Americans, Caremark is pleased to be able to offer its comments and recommendations.

I will touch on three major points in my testimony to you today. First, I will explain how Caremark and the pharmacy benefit management (PBM) industry generally promotes generic drug utilization. Second, I will discuss some of the challenges we face in trying to increase generic utilization, and the efforts Caremark has made to increase consumer and provider awareness of generic drugs. Third, I will identify some of the more significant federal policy barriers we see to increased utilization of generic drugs.

CAREMARK RX INC. AND THE IMPACT OF GENERIC PRESCRIPTION DRUGS ON OUR MARKET

Caremark Rx, Inc. (Caremark or "the company") is a leading pharmacy benefit management (PBM) company, providing through its affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. Caremark's clients include employers, health plans, managed care organizations, insurance companies, unions, government agencies, including the Federal Employees Health Benefits Program (FEHBP), CalPERS, and other funded benefit plans. Caremark operates a national retail pharmacy network with over 59,000 participating pharmacies, seven mail-service pharmacies, the industry's only FDA-regulated repackaging plant, and 21 licensed specialty pharmacies for the

delivery of specialty medications to individuals with chronic or genetic diseases and disorders. Caremark processes over 550 million prescriptions annually.

THE PROMISE OF GENERIC DRUGS

The Congressional Budget Office (CBO) estimated that in 2002 the selection of generic drugs enabled savings of almost $100 billion vs. the costs for the equivalent brand name prescriptions. In addition, as blockbuster brands are losing their patent protection, more generic drugs are being introduced to the market every year. Every generic drug introduction is an opportunity to increase generic drug utilization.

Promoting the use of generic drug alternatives is a key factor in helping to control total prescription drug costs in the U.S.. Prescription drug spending grew at an annual rate of 10.7 percent from 2002 to 2003, reaching 11 percent of total national health spending in 2003.[1] If generic drug alternatives are introduced into the market, current brand name drug prices decline. A recent report indicated that "prices decrease 30 percent during the first 6-12 months after a generic drug enters the market, during which time only a single manufacturer may produce the generic, after which the price may decrease by as much as 70 percent when other generic drug competitors enter the market".[2]

In an environment where health care costs are on the rise, it is vital that the cost savings available from increase generic drug utilization be realized. This is particularly relevant as the first outpatient drug benefit in the Medicare program is implemented January 1, 2006. Policy makers and industry stakeholders will want to ensure that there is an appropriate balance between quality of care delivered and effective cost-containment strategies, such as generic drug utilization.

The FDA ensures that generic medications maintain the same high standards of safety, strength, quality, and effectiveness as brand name medications. Since generic drugs contain the same active ingredients in the same amounts as brand drugs, they're just as safe and just as effective. In fact, the two versions are equal in strength and perform the same way within the body. Through strict regulations and scrutiny, the FDA ensures these similarities. That means, beyond the name, generic drugs and brands are therapeutically equivalent and bioequivalent.[3]

Based on FDA guidelines, the only differences between brand name and generic drugs are their **name, appearance and price.** By law, generic drugs must look different from their brand name counterpart: what is sold as a blue pill from the brand manufacturer might be sold as a white pill from the generic manufacturer. And, because generic drugs can have multiple competitors and don't carry the high costs of research and advertising, they can be sold at a much lower cost. Prescription generic medication essentially is the same as the brand name drug in everything but name. That is why generic drugs are such a great value for patients and health plans, patients can receive the same medication, just as safe and just as effective as the brand, for a much better price. In short, the promise of generic drugs is equal effectiveness and lower costs.

Based on Caremark's experience in managing drug benefit programs in a wide variety of settings, we can say unequivocally that one of the simplest and most effective ways to control drug costs while maintaining high quality care is to increase the use of generic, as compared to brand, medications by patients. For example, generic drugs introduced over the last three years alone reduced total drug costs for Caremark's health plan clients in 2003 by 3.1 percent. By increasing generic drug substitution, health plans typically realize a savings of 30-70 percent compared to use of the more expensive brand-name drugs Caremark's programs to increase generic utilization have two main areas of focus:

- **Education—Empower and educate the physicians and patients about** the safety and effectiveness, as well as lower cost, of generic drugs through proactive, concurrent and retrospective programs.

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[1] Cynthia Smith et al. "Trends: Health Spending Slows in 2003". *Health Affairs,* Volume 24, Number 1. January/February 2005.

[2] Milne, Christopher-Paul and Catherine Cairns. "Generic Drug Regulation in the US Under the Hatch-Waxman Act". *Pharmaceutical Development Regulation* 2003; 1(1). Tufts Center for the Study of Drug Development, Tufts University.

[3] **Therapeutically Equivalent:** Two drugs are considered therapeutically equivalent if they can be expected to produce the same clinical effect with the safety profile.

Bioequivalent: Acting on the body with the same strength and similar bioavailability as the same dosage of a sample of a given substance. Use of differing formulations of a drug or chemical compound. Two drugs are considered bioequivalent if they contain the same active pharmaceutical ingredient and if there is no significant difference in the rate, and extent to which, the products are absorbed in the human body under similar experimental conditions, when administered at the same dose. See Food, Drug and Cosmetic Act, 21 U.S.C. § 505(j)(8)(B).

- **Plan Design—**Structuring the plans designs to encourage the use of generic drugs.

In addition to patients and physicians, the dispensing pharmacist is also an important decision-maker with regards to generic drug dispensing. Caremark recognizes this and works with our network pharmacies in a variety of ways to maximize the potential value for our clients and their members from generic drugs. These include on-line communications at the point of sale that alert a pharmacist to potential generic drug dispensing opportunities, financial incentives for pharmacies to dispense generic drugs rather than more costly brand alternatives, and extensive analytic and reporting tools to further help pharmacies recognize and maximize generic dispensing opportunities.

RAISING AWARENESS

Why doesn't everyone use generic drugs? There are many outside influences that work against the average consumer's choice to use generic drugs. The most obvious are:

- **Awareness:** Many patients are simply unaware that generic drugs are *just as safe* and *just as effective* as their brand name counterparts. They may also be unaware that a generic drug exists for the prescription they are filling. And they may not know they can ask their doctor or pharmacist for the generic version.
- **Visibility:** Blockbuster brands have a strong marketing presence through direct-to-consumer advertising, while prescription generics do not.
- **Mistaken Identity:** People often associate the term "generic" with lower quality (e.g., "Brand X" generic paper towels). In the case of generic drugs, "generic" simply means a non-branded prescription medication.
- **Motivation:** If patients pay nearly the same co-pay for a brand name drug and a generic drug, then there's little reason for them to choose the generic. Creating a pharmacy plan that clearly distinguishes the economic or financial benefits of using generic drugs will motivate patients to learn more about and use generic drugs.
- **Physician Focus:** It's often easier to prescribe, pronounce and spell a brand name drug name (e.g., Dyazide) than a generic one (hydrochlorothiazide/triamterene). The priority for physicians is the clinical care of their patients; drug costs are secondary. Studies have found that approximately 23 percent of physicians could correctly identify the price of common prescription medications. While, physicians aren't directly impacted by the actual cost of brand medications; they do, however, receive brand samples and substantial marketing and sales attention from brand name drug manufacturers.
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owerful Patents: The patents for many brand name drugs are vigorously defended even after the protection period is over. Brand manufacturers often try to extend their patents and exclusivity periods to protect their product from competition by generic drugs. Sometimes brand manufacturers create new formulations or "me-too" variations to the original brand to divert attention from the generic drug.

These issues affect patients in their homes, at the physician's office, and at the pharmacy. They can influence decisions about what drugs are dispensed. These are major forces that influence rising drug costs today.

Hence, Caremark's patient education programs focus first on safety and effectiveness. Perhaps the biggest obstacle to the use of generic drugs is the perception that generic drugs are inferior. Patients need to know that they aren't sacrificing anything—quality of care or safety or effectiveness—by using generic drugs. Only then will they be interested in the second message: generic drugs can save them money.

CAREMARK'S FOCUS ON INCREASED GENERIC DRUG UTILIZATION

Caremark promotes the use of generics through several different programs. These programs focus on three key audiences: patients, physicians and pharmacists.

- **Patient Programs—**Patients are encouraged to use generics through: (1) educational programs and (2) plan designs that create an economic incentive to use generics.

1. **Educational Programs—**These include general mailing that explain what generics are, and how patients can save money without compromising their care by choosing generics. They also include patient-specific mailings based on identifying retail brand name prescriptions dispensed when there was a generic drug available. In this case, Caremark will then a mailing to the patient in cases where the patient requested the prescription to be filled with a brand when a generic was available.

2. **Plan Design—**There are many ways to encourage generic drug utilization through plan design. Some of the ways to do this include:

- Adjusting co-pay differentials to be higher for more expensive brand name drugs
- Requiring patients to obtain explicit physician authorization in order to receive brand name dispensing when an approved generic product is available.
- Requiring that patients accept generic products or pay the difference in price between the brand name and generic drugs, in addition to the standard co-payment.
- Educational Mailings—Caremark will identify retail brand name prescriptions dispensed when there is a generic drug available, and will then send mailings to the patient in cases where the patient requested the prescription to be filled with a brand when a generic was available.

Prescriber Programs—In addition to Caremark's programs to educate patients about generic drugs, Caremark also assists prescribers to choose generic drugs.

Caremark's physician education programs focus on promoting appropriate and cost-effective prescription utilization. Specific program activities include physician education via retrospective DUR (drug utilization review) letters, physician profiling and report cards, and face-to-face physician consultation through our national academic physician detailing program. These activities provide physicians with current clinical and economic information on pharmaceutical products and treatment protocols within specific therapeutic classes, including utilization of generic drugs. Some of these programs are described in greater detail below:

- Under Caremark's physician profiling program, a report is sent to physicians identifying claim-specific examples of brand products that could be converted to a generic drugs. Physicians will then be given patient-specific opportunities to prescribe a generic product. Twice a year, Caremark also produces a report showing the physicians' generic substitution rate (GSR) compared with peers in their specialty and against other physicians in the Caremark book of business. The report also shows the top five multisource brands where substitutions did not occur. Physicians may request a list of their patients who have been prescribed the multisource brand.
- Under the Caremark CustomCare Mail program DAW (Dispense as Written) prescriptions for brand name drugs are identified at Caremark's mail service pharmacy. A Caremark clinician contacts the prescribing physician to ask the physician to consider converting the prescription to a generic drug substitute and to educate the physician on the value of generic drugs. The final decision to dispense a brand name drug or generic substitute always rests with the prescribing physician. Caremark is successful in 45 percent of cases when requesting that physicians convert DAW prescriptions to a generic product.
- Caremark clinicians analyze and identify certain therapeutic categories that may include clinically similar drugs. Through a clinical pharmacist review, physicians are contacted and educated around the Caremark pharmacist's clinical recommendations. Caremark will then ask the physician to prescribe the generic alternative if clinically appropriate. This is done prior to filling at Caremark's mail service.
- Retail DAW mailings: Caremark will identify retail brand name prescriptions dispensed when there is a generic drug available, and will then send mailings to the physician who requested the prescription to be filled with the brand-name version of the prescription drug. Mailings educate the recipient on the safety, efficacy, and value of generic drugs, and on the actions they can take to have the next prescription filled as a generic drug.
- Generic Therapeutic Interchange at retail: Caremark clinicians identify certain therapeutic categories that may include clinically similar drugs. If a drug does not have a generic drug alternative, Caremark will send communications to the physician to consider prescribing a generic drug within the same class for the next prescription.
- Lastly, one of the most vital programs that will assist in the dispensing of generics by physicians is the use of electronic prescribing (e-prescribing). E-prescribing will allow for a better dialogue between physicians and their patients about the range of prescription options available by providing physicians with instant access to patient-specific formulary information, and the medication histories of their patients.—This will allow physicians to discuss generic drug options at the point-of-prescribing rather than having these issues addressed only after the fact at the pharmacy counter or later. The requirement for Medicare drug benefit plans to implement an e-prescribing program will go a long way towards encouraging the widespread use of e-prescribing in the commercial market "by setting uniform federal standards that can be adopted by all partici-

pants in the health care system. This will, in turn, not only, encourage a better doctor-patient relationship, improve safety by reducing medication errors but also increase the utilization of generic drugs.

Pharmacy Programs—Clinical pharmacy management programs alert pharmacists to opportunities to substitute generic drugs. These programs are employed both before and after a prescription is dispensed. Some of these programs are described below:

- Caremark's claim adjudication systems automatically identify when a brand name drug has a generic drug equivalent. The pharmacist will dispense the generic drug alternative, provided the physician has not written "Dispense as Written" (DAW). Retail pharmacies are given monetary incentives based, in significant part, on their efforts to improve our clients' generic drug substitution and dispensing rates. They improve performance in these areas by their own dispensing decisions and by influencing patients and physicians to use the most cost-effective, clinically appropriate medications. Individual pharmacists are not paid fees tied to performance results.
- The MAC (maximum allowable cost) program is an effective tool to promote utilization of generic drugs. The MAC program encourages generic drug substitution at the pharmacy level by establishing a ceiling price on the amount reimbursed to pharmacies for specific multisource brand-name and generic drug products. Pharmacy reimbursement is limited to the MAC price for drug products on the MAC list, and so pharmacies will retain more of the reimbursement if they dispense the less costly generic product. This creates a strong incentive for the pharmacy to dispense a generic drug.

Caremark helps pharmacies contain costs for patients and health plans by providing pharmacies with reporting tools for evaluating and improving their own performance and that identify missed opportunities. Pharmacies can access their own data electronically via downloadable spreadsheets in weekly e-mails and through other electronic media. This reporting enables pharmacies to drill down to the store level and view important cost-containment data, including generic drug substitution and generic drug dispensing rates, as well as comparisons with other pharmacies within each state.

OPPORTUNITIES FOR INCREASED USE OF GENERIC DRUGS—CONGRESS AND THE FDA

Caremark understands the value of generics and will continue to promote their appropriate use. Our historical efforts with beneficiaries, physicians and pharmacies and in support of health plan sponsors that we have described, as well as the efforts of others in the industry have paid off. Generic drug utilization has increased. In fact in 2003, across Caremark's entire client base, the overall generic substitution rate (GSR) was 94.8 percent. This means that about 95 percent of the time that a prescription was dispensed for a prescription drug with a generic equivalent available, a generic option was actually dispensed.

While generic substitution rates are over 90 percent, the generic dispensing rate, that is the percentage of total prescriptions dispensed that are generic, is only between 40-50 percent. Therefore, the greatest opportunity today to increase the savings realized from generic drugs lies not in increasing the rate of dispensing a generic drug when a generic drug is available, but instead, in increasing the availability of generic drugs generally. The more generic drug products that are available, the greater the overall rate at which pharmacies and PBMs like Caremark can dispense generic drugs. Increasing the availability of generic drug alternatives is the key to increasing overall generic drug utilization.

There are many factors that create barriers to the availability of generic drug alternatives. Some of these barriers can be addressed by Congress, and we urge the Congress to take action to reduce or eliminate these barriers so that lower cost generic drugs can be brought to market more quickly thereby, lowering overall health care costs to the American consumer.

The following sections outline three areas where Caremark believes Congress' actions can and will significantly affect generic drug utilization in the future:

1. First, the Medicare Modernization Act of 2003 made changes to the Hatch-Waxman Act to close perceived loopholes that allowed brand manufacturers to extend their patents beyond the time originally intended and deemed appropriate by Congress. We encourage Congress to continue these efforts in order to ensure that generic manufacturers have a level competitive playing field with brand name manufacturers.
2. Second, we urge Congress and the FDA to move forward on a regulatory process that leads to the approval of generic biologics as an alternative to brand name biologic products. This is truly the next frontier generic drug products and

progress in this area should improve the affordability and accessibility of these very important, but expensive products.

3. Third, we ask that as Congress considers Bioshield II legislation that would enhance manufacturers' ability to bring bioterrorism countermeasures to market more quickly, it not unintentionally enact legislation that will inhibit the production of generic drug by. increasing the protections against market competition already enjoyed by brand manufacturers. This would serve as a major disincentives for generic drug manufacturers to make cost-saving generic products available to the American public.

THE HATCH-WAXMAN ACT: CHANGE IN THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003 (MMA)

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Act. Title I of the Act sought to reduce the time it took for generic drugs to enter the market through the creation of an abbreviated new drug application (ANDA) process. For the first time, generic manufacturers did not need to repeat the preclinical and clinical research and trials that must be conducted by brand manufacturers before obtaining FDA approval. Generic pharmaceutical manufacturers instead needed only to show that their product was bioequivalent to the brand name product.

Caremark supports the intent of the 1984 Hatch-Waxman Act to encourage greater consumer access to lower-priced generic alternatives. However, over time, brand name manufacturers have found loopholes in the Act that allow them to extend their patents beyond the initial period, thereby frustrating the purpose of the law and delaying the introduction of generic drugs to market.

In 2003 Congress took an important step towards the promotion of generic drug competition with the changes to Hatch-Waxman enacted by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Under the new law, a brand name manufacturer no longer can receive 30-month stays for patents that are submitted to the FDA after an ANDA has been submitted for that product. In addition, the MMA included a modification to the start date of the 180-day exclusivity period that ensures that it is not used up in patent disputes.

We believe that the changes to Hatch-Waxman Act under the MMA are steps in the right direction. However, there is still work to be done in order to ensure that the Hatch-Waxman Act removes *all* barriers that exist to increased competition and generic drug availability.

GENERIC BIOLOGICS

When the provisions of the Hatch-Waxman Act were drafted, the biotechnology market was in its infancy. Since then, biotechnology and patent approvals for biotechnology products have grown rapidly. The growth in this market has recently caused policymakers and industry leaders to consider making generic alternatives to the brand versions of these biologic products available to consumers. This is particularly relevant now, given that 18 biologic products worth $10 billion a year will lose patent protection over the next few years.[4]

Biologic drugs tend to be very expensive, and in a time of rapidly growing prescription drug costs, it is important that biogeneric alternatives be considered to help create a more competitive, lower cost market. Similar to conventional drugs, when a generic version of a biological product becomes available, the market can be expected to be more competitive, and Caremark anticipates that it will be better able to negotiate discounts and offer those products at a lower cost to consumers and payers.

Biotechnology and Specialty Pharmacy

Specialty pharmacy is a significant component to Caremark's overall service offering. Most of the specialty products that Caremark offers to consumers are biologic drugs. In contrast to conventional drugs, which are chemically synthesized from small molecules, many biologics are synthetic or recombinant versions of natural biologic substances such as proteins and enzymes that often require specific handling and storage techniques.

Caremark believes that the development of a streamlined FDA regulatory approval process for follow-on biologics would greatly increase generic product competition. We believe it is critical that the FDA use the administrative tools it has at

[4] Milne, Christopher-Paul and Catherine Cairns. "Generic Drug Regulation in the US Under the Hatch-Waxman Act". *Pharmaceutical Development Regulation 2003;* 1(1). Tufts Center for the Study of Drug Development, Tufts University.

its disposal to allow biogeneric alternatives to enter the market. In addition, we encourage Congress to create a legislative solution in areas where the FDA does not have administrative authority to do so, or is not using its current administrative authority due to concerns about legal interpretation.

Promote Regulatory Process to Approve Generic Biologics

To date, the FDA does not approve most therapeutic biologics through the new drug application (NDA) process, which is used to approve most drugs. There are however, several therapeutic biologics such as insulin and growth hormones that have, by exception, been approved via the NDA process.

Biologics are generally approved separately, under the biologics license application (BLA) process, which is authorized under the Public Health Service Act (PHSA), not the Food, Drug and Cosmetics Act (FDCA) (which governs the NDA and ANDA processes). The BLA does not contain a process similar to the ANDA, which would expedite the approval of generic biologics. To date, the FDA has not made any administrative changes to either the BLA or the NDA/ANDA process to approve generic biologics.

Caremark encourages the FDA or Congress to move forward with an administrative process which would speed the availability of generic biologics to American consumers. We believe this could be done in one of two ways: 1) the FDA or Congress could create one approval process for biologics and pharmaceuticals, thereby allowing generic biologics to enter the market through the ANDA process; or 2) create an expedited approval process within the PHSA for generic biologic, similar to what was created under the Hatch-Waxman Act.

We understand that the FDA has publicly stated that the Agency has limited administrative authority to create a process whereby generic biologics may be approved. If the FDA continues to take this position, we encourage Congress to take action in order to address the issue.

Bioequivalency

One of the most significant barriers to biogeneric approval is demonstrating the bioequivalence of these products. Progress is being made daily to better understand how to analyze and evaluate the clinical evidence that will prove bioequivalence. According to public comments from the FDA, significant progress is being made at the Agency to promote the development of bioequivalence evaluation tools, including molecular imaging techniques, in-vivo sampling methods, pharmacodynamic measures and mathematical models that test the performance of inhalation drugs.[5]

We believe that the science around bioequivalence testing has evolved to the point where the FDA should begin considering accelerated generic approvals of bioequivalent products. We believe the time is now ripe for the FDA and Congress to take action to ensure that this science and technology is harnessed to bring to market lower-cost biogeneric alternatives.

BIOSHIELD AND THE IMPACT ON GENERIC PHARMACEUTICALS

BioShield I shows commitment to bio-preparedness

The enactment of BioShield I (P.L. 108-276) in July of 2004 was a defining moment in the nation's commitment to bio-preparedness. Clearly there is a need to develop new countermeasures for protection against the bioterror pathogens, toxins, or infectious diseases that potentially could be targeted against the United States.

Since the passage of BioShield I, some policy makers have raised concerns about the limitations of BioShield I, especially in dealing with the reluctance of pharmaceutical manufacturers to engage in research and development of biomedical countermeasures. Without public demand or appropriate incentives to spur countermeasures production today, the market for these products may not develop quickly enough.

Several bills have been introduced, that aim to strengthen BioShield I by giving the federal government tools to collaborate with private companies in developing countermeasures, thereby ensuring that the nation is more adequately prepared for potential bioterrorism attacks. One such bill, BioShield II (S. 975) would allow the Secretary of the Department of Health and Human Services (HHS) to deploy a variety of additional incentives, including the "wild-card" patent extension.

The wild-card patent provision

In general, under a "wild-card" patent provision, a brand name manufacturer may receive an incentive of additional market exclusivity on any drug, including non-countermeasure drugs and blockbuster drugs, for which it holds an unexpired pat-

[5] http://www.fda.gov/oc/speeches/2005/GPhA0301.html

ent. Specifically, as contained in S. 975, the Secretary of HHS would have the discretion to grant a manufacturer, who has won a BioShield contract, a wild-card patent extension ranging from six months to two years, for any qualified product the company manufactures upon successful development of a biomedical countermeasure. If you consider the just ten top selling brand names drugs that could be certified, the cost of this provision for the US buyers of prescription drugs, including consumers, especially seniors and the disabled and health plan sponsors, such as the federal government, exceed $45 billion.

Wild-card incentives delay generic drug competition

While Caremark supports some of the other incentives, such as tax incentives and liability protections, to encourage more pharmaceutical companies to participate in bioterrorism countermeasure, we strongly urge that Congress not pass legislation that includes protectionist patent-related incentives such as the "wild-card" provision. Such incentives will delay or even prevent generic drug competition for brand drugs, thereby undermining the balance so carefully achieved under Hatch-Waxman. By delaying the entry of generic drugs to the marketplace, these incentives would unnecessarily restrict access to less expensive versions of safe, effective and much needed medications, thereby burdening consumers, government, and private insurers with higher prescription drug bills.

While S.975 would require that the Secretary consider, among other things, the impact of the patent extension on consumers and healthcare providers in deciding whether to grant the wild-card extension, we are concerned that in some cases the urgent need for countermeasure development may seemingly outweigh the potential harm of extending the patent rights on a non-countermeasure drug. However, attempting to promote one public policy goal (security) by sacrificing another (access to affordable health care) through anti-competitive protectionist measures is not in the nation's interest, and not an appropriate tradeoff.

BioShield II patent incentives would propagate uncertainty in the generic drug marketplace

Under S. 975, all manufacturers who successfully produce the contracted countermeasure, including those that are awarded the wild-card extension, have the option to instead elect for full-term patent restoration on the countermeasure to compensate for time lost during the regulatory review process. In fact, at any time a contracting manufacturer granted the wild-card extension may choose the countermeasure patent restoration option instead of the wild-card, but the manufacturer may only choose one option. It could take five years or more for a successful countermeasure to be delivered, due to the time needed for research and development, during which time the patent on the selected wild-card drug may expire. The ability of a manufacturer to name a wild-card drug but never invoke the provision would significantly impact generic manufacturers, who would be deterred from developing a generic version of the selected wild-card drug due to the threat of litigation and liability for treble damages. As a result, American consumers, health insurers, and the prescription drug plans soon to be offering the new Medicare Prescription Drug benefit would have potentially fewer generic drug alternatives from which to choose, thereby increasing healthcare costs and eliminating treatment options for Americans.

BioShield II proposes to waive Hatch-Waxman limits on patent term restoration

S. 975 goes beyond the patent term restoration options under existing law, which allow only a fraction of the patent term lost during the approval process to be restored. It would allow the entire delay associated with regulatory review to be restored. This provision could allow the firm with a winning countermeasure drug to choose to extend the life of the patent on the new product to its full 17 years. Extending the life of brand name patents for this period of time is an unnecessary boon to brand manufacturers that will come at the price of the American consumer, as it will seriously inhibit generic drug manufacturers from bringing new generic products to market, thereby reducing the availability of lower cost generic products to consumers.

Congress should encourage the countermeasure and generic drug markets

The ability of the Federal Government to offer sufficient incentives to large pharmaceutical companies to invest substantial amounts of private capital towards the development of biomedical countermeasures—a relatively underdeveloped marketplace for research and development—is clearly important to the safety and security of our nation, but should not come at the expense of reduced generic drug options and therefore, reduced access to necessary health care.

Caremark continues to support the acceleration of research, development and manufacturing of novel biomedical countermeasure agents. Tax incentives and limitations on liability should be sufficient incentives for companies to invest in the production of biomedical countermeasures. Patent restoration and wild-card extensions are not in the best interest of the American people, generic pharmaceutical manufacturers, pharmacy benefit management companies, and the country's healthcare system at large.

CONCLUSION

Caremark is committed to delivering high quality health care services to American consumers. We provide, through our affiliates comprehensive drug benefit services to over 2,000 health plan sponsors and their plan participants throughout the U.S. One of the most important, clinically safe and effective, cost containment techniques that we employ as a PBM is the promotion of generic drug utilization through educational offerings, pharmacy programs and plan benefit design strategies. By encouraging generic drug utilization, we are able to offer safe and effective drugs at lower prices to consumers.

I thank the Committee members for asking me to speak about our business practices to promote appropriate utilization of generic drugs today, and look forward to an ongoing dialogue to determine how to increase the promotion and utilization of generic products in the future. I also appreciate the opportunity to raise legislative and administrative policy issues that could affect the ability to efficiently and expeditiously bring generic prescription drugs to market. Again, I commend the Committee for considering this very important issue and look forward to further discussion and policy development in this critical area.

Mr. DEAL. Thank you, ma'am. Ms. Cramer?

STATEMENT OF BONNIE M. CRAMER

Ms. CRAMER. Mr. Chairman and member of the committee, I am Bonnie Cramer, a member of the all-volunteer AARP Board of Directors. Thank you for the opportunity to testify today.

Americans of all ages need access to affordable prescription mediations. Generic drugs have an important role in helping to control drug costs. Recent AARP studies reveal that generic drug prices, which are traditionally less expensive, are not rising as fast as their brand-name counterparts. Brand-name prescription drug prices to continue to rise much faster than the rate of inflation. The use of generic drugs is steadily increasing, but more needs to be done to ensure the availability of these lower-cost alternatives.

For instance, the patent life of innovator dugs should not be unnecessarily extended, and once the patent on the innovator drug has expired, generic drug manufacturers should not be hindered by unnecessary litigation and other efforts to extend patent protection beyond what true innovation deserves. In addition to generally being less expensive, generic drugs are also a safe alternative to brand-name drugs. For an overwhelming majority of individuals, generic drugs can be substituted for the brand-name equivalent drug. However, in a few cases, an individual may not react the same to a generic drug as they would to its brand-name counterpart. For example, some individuals may be allergic to inert ingredients included in the generic drug. AARP supports the use of generic drugs whenever possible, but we also believe that physicians must retain the ability to override generic substitution where medically appropriate. In addition, individuals should not be penalized financially when the generic drug is not medically appropriate. Any formulary override should be conducted with as little burden on a physician and patient as possible.

Americans are becoming increasing familiar with generic drugs, but we need to do more to educate consumers and physicians about the benefits of generic drugs. In 2002, AARP launched a nationwide Wise-Use campaign to promote the appropriate use of generics. This campaign included print and broadcasts ads and a brochure entitled "Before You Take Your Medicine, Take This Advice", which we developed with the American Pharmacist Association and distributed in pharmacies nationwide. This year, AARP is taking that campaign further by unveiling a drug-safety and effectiveness reference tool on AARP webpage.

Generic drugs offer most Americans the same therapeutic value as brand-name prescriptions drugs, but at a more affordable price. We urge Congress to do more to ensure that Americans have access to lower cost generic drugs as part of a broader agenda to bring down the rising cost of prescription drugs. Thank you, again, for inviting us here, and I am happy to answer any questions you may have.

[The prepared statement of Bonnie M. Cramer follows:]

PREPARED STATEMENT OF BONNIE M. CRAMER, AARP BOARD MEMBER

Mr. Chairman and members of the Committee, my name is Bonnie Cramer. I am a member of AARP's Board of Directors. On behalf of our over 35 million members, thank you for convening this hearing and for including AARP in your discussions about the use of generic prescription drugs.

In November, millions of older Americans and those with disabilities will have the opportunity to choose to enroll in a long-overdue Medicare prescription drug benefit. Medicare coverage of prescription drugs will ensure that beneficiaries can afford necessary medications. However, even with the addition of this new benefit, more needs to be done to keep overall drug costs down. Generic drugs have an important role to play in helping to control drug prices for beneficiaries, the Medicare program, and for the entire health care system.

RISING DRUG PRICES

High prescription drug prices are taking a toll on our health care system—both the public and private sectors. Employer-sponsored health care premiums are rising at double digit increases,[1] in large part due to increasing prescription drug costs. As a result of rising health care costs, more employers are dropping coverage, thus increasing the number of uninsured Americans. There are currently more than 45 million Americans who lack health care coverage and these individuals pay the highest prices for their prescription drug needs. Many choose not to fill prescriptions because they cannot afford to pay for them. A recent AARP survey showed that among Americans age 50 and older, one in four said they decided against filling a prescription; cost was reported to be the main deterrent.[2]

Rising prescription drug prices continue to squeeze public programs at both the state and federal level. In 2003, the federal government spent $25.2 billion on prescription drugs for public programs.[3] Prescription drug spending in the Medicaid program increased at an average annual rate of 17—percent between 2000 and 2003.[4]

GENERIC DRUGS CAN ACHIEVE SAVINGS

Brand name prescription drug prices continue to rise at rates that are increasingly unaffordable for the average American. A recent AARP study revealed that,

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[1] Kaiser Family Foundation and Health Insurance and Educational Trust, *Employer Health Benefits 2004 Summary of Findings.*

[2] *Prescription Drug Use Among Midlife and Older Americans,* AARP, January 2005.

[3] Centers for Medicare and Medicaid Services, *Expenditures for Health Services and Supplies Under Public Programs, by Type of Expenditure and Program: Calendar Year 2003,* available at http://www.cms.hhs.gov/statistics/nhe/historical/t10.asp (noting that of this amount $5.3—billion was non-Medicaid dollars and $19.9—billion represented Medicaid spending on prescription drugs).

[4] John Holohan and Arunabh Ghosh, "Understanding the Recent Growth in Medicaid Spending, 2000-2003," Health Affairs, Jan. 26, 2005 at W5-52.

on average, pharmaceutical manufacturer prices for the 195 brand name drugs most widely used by older Americans increased at more than double the rate of general inflation from 2000 through 2004.[5] The average annual increase in manufacturer prices charged to wholesalers and other direct purchasers for these drugs was 7.1 percent in 2004, up from 4.1 percent in 2000. For the 153 brand-name drugs that were in the market for the entire five year period, this translates into a cumulative average price increase of over 35 percent, over two-and-one-half times the general inflation rate of 13.5 percent over the same period.

In contrast, generic drug prices are lower than brand name prescription drugs, and more interestingly, manufacturers' prices on generic drugs are not rising as fast as their brand name counterparts. A recent AARP study revealed that, on average, manufacturer list prices for the top 75 generic drugs most widely used by older Americans rose 0.5 percent in 2004 compared to a 13.3 percent average increase in 2003.[6] This average annual increase was less than one-fifth the rate of general inflation for 2004.

GENERIC DRUGS CAN BE A SAFE ALTERNATIVE

In addition to generally being less expensive, generic drugs are also a safe alternative to brand name drugs. In order to gain Food and Drug Administration ("FDA") approval to market a generic drug, a manufacturer must demonstrate that the generic drug is bioequivalent to the comparable brand name prescription drug. To prove bioequivalence, the generic drug manufacturer must demonstrate two things. First, that the generic drug is pharmaceutically equivalent, in other words that it has the same active ingredients, strength, dosage, and method of administration as the brand name pharmaceutical. Second, the manufacturer must prove that the generic drug has comparable bioavailability, meaning that the generic drug must have the same rate and extent of absorption as the brand name pharmaceutical.

Nearly all generic drugs are expected to be bioequivalent to their brand name counterparts (e.g., "A"-rated generic drugs). For an overwhelming majority of individuals, these generic drugs can be safely substituted for the brand name equivalent drug. However, in a few limited cases, generic drugs may not meet the standards of therapeutic equivalency. These "B"-list drugs should not be substituted for the brand name drug.

There is documented evidence that suggests that for a small number of individuals, generic substitution may not be appropriate. For example, some individuals may be allergic to inert ingredients (e.g., coating) included in the generic drug. Therefore, AARP believes that prescribers must retain the ability to override generic substitution in cases when the prescribing physician has deemed such substitution to be medically appropriate (e.g., individual does not respond well to the generic drug treatment regimen).

Thus, a critical component of any drug formulary or preferred drug list that promotes use of generics is an efficient and effective exceptions process. Such a process should provide prompt access to a brand name or other appropriate drug whenever—based on sound clinical evidence provided by the prescribing physician—the generic is not medically appropriate for an individual patient. Equally important is ensuring that, whenever such exceptions are granted, the patient is not charged more for obtaining a medically appropriate drug. Furthermore, individuals who are granted such exceptions should not be required to go through the exceptions process again once it has been established that the generic is not medically appropriate for them.

ACCESS TO GENERIC DRUGS

Use of generic drugs is steadily increasing. In 2001, generic drugs accounted for nearly half of all retail prescription drugs dispensed in the United States, up from 18.6 percent in 1984.[7] In 2003, generic drug prescriptions represented 43 percent of all prescriptions written, and 47 percent of new (non-refill) prescriptions.[8]

In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, which helped speed generic drugs to market. Unfortunately, brand name pharmaceutical manufacturers

[5] *Trends in Manufacturer Prices of Brand Name Prescription Drugs Used by Older Americans, 2004 Year-End Update,* AARP Public Policy Institute Data Digest #DD112, April 2005.

[6] *Trends in Manufacturer Prices of Generic Prescription Drugs Used by Older Americans, 2004 Year-End Update,* AARP Public Policy Institute Data Digest #DD113, April 2005.

[7] *Generic Drugs Research Report,* AARP Public Policy Institute, publication IB61, May 2003.

[8] IMS Health, 2004.

have often tried to circumvent the Hatch-Waxman Act. Brand name pharmaceutical manufacturers facing loss of patent protection on blockbuster drugs began using litigation and other means to extend the life of patents. Courts and the Federal Trade Commission ("FTC") have determined that some brand name prescription drug manufacturers colluded with generic drug manufacturers to delay the marketing of competing generic products. The first generic version of a brand name drug to establish that it does not infringe on a valid patent receives a 180-day period of market exclusivity. Therefore, stopping or delaying market entry of the first generic drug prohibited all other generic drugs from competing, thus extending the brand name manufacturer's market exclusivity.

In another effort to extend the life of their patent protections, brand name manufacturers have also used the practice of "evergreening," the process of extending the patent protection of a brand name prescription drug as the term of the original patent nears expiration. One common method of evergreening is the "late-file patent", whereby brand name manufacturers change a small aspect of their drug (e.g., color, new dosage requirements, tablet shape) prior to the expiration of the patent and then obtain a new patent based on the "improvements" to the drug.

Evergreening blocks generic competition in at least two ways. First, after the slight change results in the granting of a new patent, the brand name manufacturer heavily promotes the "new" formulation as being much better than the old and creates enormous demand for the "new" product for which it can charge monopolistic prices. Thus, the market demand moves to the new expensive product even though there is little science-based evidence that the old product, for which generics may now be available, is inferior.

Second, brand name manufacturers used the late filed patents to manipulate the automatic 30-month stay of generic competition granted by Hatch-Waxman when the generic manufacturer notified the FDA that it would like approval to market a generic version of a brand name drug. The thirty months stay was designed to allow time for a court to resolve whether the generic infringes the brand name manufacturer's patent. But, after the first stay based on an older patent of a particular drug was resolved in favor of the generic, the brand name manufacturer then would file another suit against the generic based upon a later-filed patent on the same drug. This gave the brand name manufacturer another automatic 30-month stay preventing the generic manufacturer from bringing its drug to market until that patent issue was resolved. Brand name manufacturers were filing multiple challenges in order to extend their patent life. The Medicare Modernization Act of 2003 ("MMA"), bans this form of evergreening by limiting brand name pharmaceuticals to a single automatic 30-month stay.

Pharmaceutical innovation plays an important role in prolonging the life and improving the quality of life for individuals. Pharmaceutical manufacturers are rewarded for their innovations in the form of patents and FDA-granted market exclusivity on their products. However, the patent life of these innovator drugs should not be unnecessarily extended. Once the patent on the innovator drug has expired, generic drug manufacturers should not be hindered by unnecessary litigation and other efforts by the patent holder to extend patent protection beyond what true innovation deserves. There have been eleven successful challenges to patent laws brought by generic drug manufacturers; these challenges have provided over $27—billion in savings.[9]

Pharmaceutical companies that engage in actions to unnecessarily extend the life of their patent do so because holding the patent yields significant income for the company every year. However, this money is generated by individuals and health care payers. If generic drugs were brought to market in a timely manner, this could reap significant savings for the health care system in this country. AARP opposes patent extensions or extensions of market exclusivity.

In addition to bringing generics to market in a timely manner, the U.S. health care system can reap significant savings by investing heavily in the research of comparative clinical effectiveness of prescription drugs. Unlike in other countries, the U.S. does not require that drugs coming onto the market test better than drugs already available in the marketplace. Funding of comparative clinical effectiveness studies would provide scientifically based information on the relative clinical effectiveness of different prescription drugs. In some cases the newer drug may be the best treatment option, in other cases the best treatment option may be the generic drug already on the market. Armed with this information, individuals and their prescribers can make better treatment decisions.

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[9] Generic Pharmaceutical Association's testimony to the HHS Task Force on Drug Importation, April 5, 2004.

CONSUMER EDUCATION

Although Americans are becoming increasingly familiar with generics drugs—a recent AARP study showed that 97—percent of respondents say they have heard about generic prescription drugs [10]—some confusion about the benefits of generics still exits. Twenty-four—percent of respondents indicated that generic drugs were different from brand name drugs, and among those who thought there was a difference, only four in ten believed generic drugs to be less effective. Surprisingly, overall only 21—percent of respondents believed generic drugs to be less expensive than brand name prescription drugs.

More education is needed to help consumers and physicians understand the benefits of generic drugs. Physicians generally support generic substitution,[11] but they also report frequent visits by brand name pharmaceutical manufacturer representatives, which can influence their prescribing behavior. Consumers also need to be aware that direct-to-consumer ("DTC") advertising often steers them towards brand name prescription drugs when a less costly generic and/or a less costly brand name drug may be available. Some DTC advertising is beneficial—such as advertising that raises awareness about certain diseases and/or conditions. However, the pharmaceutical industry spends billions of DTC advertising dollars to promote "new" formulation of products, which may show little improvement over less costly alternatives already available in the marketplace.

In April 2002, AARP launched a nationwide "Wise Use" campaign to promote the appropriate use of generic medicines. The campaign urged consumers to inform their doctor or pharmacist about all other medicines they were taking; to follow their physician's advice about exactly how to use their medicine properly; and to resist being pressured by direct-to-consumer pharmaceutical advertising to request an inappropriate or possibly unnecessary medicine. The campaign included print and broadcast ads, and a brochure, "Before You Take Your Medicine, Take This Advice," developed with the American Pharmaceutical (now "Pharmacists") Association, distributed in pharmacies nationwide.

This year, AARP took its education campaign further by unveiling a drug safety and effectiveness reference tool at http://www.aarp.org/health/comparedrugs. Based on the Drug Effectiveness Review Project conducted at the Oregon Health and Science University, AARP helps consumers compare the clinical and economic benefits of various drugs within common therapeutic categories. We urge consumers to review this information and, if applicable to their medical condition, to discuss it with their physician or other health care professional.

CONCLUSION

Generic drugs offer most Americans the same therapeutic value as brand name prescription drugs, but at a more affordable price. We urge Congress to do more to ensure that Americans have access to lower cost generic drugs as part of a broader agenda to bring down the rising cost of prescription drugs. AARP appreciates the opportunity to testify and we look forward to working with this Committee and Congress to help our members—and all Americans—understand the wise and safe use of generic drugs.

Mr. DEAL. Thank you, ma'am. Dr. Perry?

STATEMENT OF BRUCE C. PERRY

Mr. PERRY. Chairman Deal, Congressman Brown, and distinguished subcommittee members, I am Bruce Perry, a family physician, geriatrician, and Medical Director of Kaiser Permanente, Georgia Region. I am here today on behalf of Kaiser Permanente.

Timely access to generic drugs is central to our effort to provide high quality and affordable prescription drug benefits. This year, Permanente physicians will prescribe nearly $3 billion worth of drugs. The very close partnership between our pharmacists and physicians allows us to use generic drugs very effectively. While

[10] *Prescription Drug Use Among Midlife and Older Americans,* AARP, Jan. 2005.

[11] *Physicians' Attitudes and Practices Regarding Generic Drugs,* AARP, March 2005 (reporting that 78—percent of respondents support generic substitution in most cases, 17—percent support generic substitution in all cases where the generic drug is available, and only 5—percent do not support generic substitution).

just over 50 percent of prescriptions in the U.S. are written for generics, we write about 70 percent. Last year, Americans spent more than $250 billion on prescription drugs. Improved generic providing could save billions of dollars, money that could be spent on other healthcare services such as prevention or simply saved.

Safety and effectiveness underlie all of Kaiser Permanente's pharmacy services. Let me offer you one example. Cox-2 inhibitors are used to treat pain and inflammation. Cox-2s were believed to reduce significant gastrointestinal side effects of other pain relievers, including bleeding. They have never been seen as superior pain relievers, compared to ibuprofen, for example—although heavy advertising may have led many patients to believe so. Stanford scientists showed the Cox-2s potential to improve safety was limited to patients at high risk of serious bleeding, less than 5 percent. They developed a scoring tool to determine which patients would benefit. Once Kaiser Permanente adopted this tool, our physicians prescribed Cox-2s about 5 percent of the time. Until the recent withdraws of Vioxx and Bextra, Cox-2s were prescribed by other physicians approximately 50 percent of the time. Aggressive promotion meant that patients were at increased risk for heart attacks and higher spending. If the use of Cox-2s in the U.S. had been the same as Permanente physicians, last year, Americans would have saved more than $4 million or almost 2 percent of all drug spending. Promoting greater use of generics can not only save money; it can be a lot safer for our patients.

Kaiser Permanente's programs do not deny access to brand-name drugs. Our goal is to prescribe those drugs to those patients who really need them. The result is better quality and lower costs. Our program works for four reasons. First, our physicians and pharmacists, themselves, develop and implement our pharmacy program. Second, our physicians have the latest information about alternative drug therapies. Third, Permanente physicians know they will not be penalized for prescribing non-formulary or expensive brand-name drugs. Indeed, they know that their patient can get them if they need them. Finally, Permanent physicians know that the savings from their efforts willower member premiums or enable them to provide other care.

Physicians are clamoring for better information about comparative clinical effectiveness of prescription drugs. Thanks to your work, AHRQ has begun comparative clinic-effectiveness studies. This year, Congress appropriated $15 million for this. While modest, it is an important first step, one that should be seen as an investment in better care and lower spending. I encourage you to strongly support increased funding for this vital research in this and future years.

Mr. Chairman, thank you for the invitation to testify. I will be glad to answer any questions.

[The prepared statement of Bruce C. Perry follows:]

PREPARED STATEMENT OF BRUCE C. PERRY, EXECUTIVE DIRECTOR, THE SOUTHEAST PERMANENTE MEDICAL GROUP ON BEHALF OF THE KAISER PERMANENTE MEDICAL CARE PROGRAM

Chairman Deal, Congressman Brown, and distinguished Sub-committee members, I am Dr. Bruce Perry, a family physician and geriatrician and Medical Director of The Southeast Permanente Medical Group, which together with Kaiser Foundation

Health Plan of Georgia make up Kaiser Permanente's Georgia Region. I also serve as Chairman of the Executive Committee of the Permanente Federation, the umbrella organization that coordinates national activities of the eight Permanente Medical Groups. I appreciate the opportunity to testify here today on the important subject of access to generic drug therapies. Timely access to high quality generic drugs is central to Kaiser Permanente's efforts to provide high quality and affordable prescription drug benefits.

I am testifying today on behalf of the national Kaiser Permanente Medical Care Program. Kaiser Permanente is the nation's largest integrated health care delivery system. We provide comprehensive health care services to more than 8.4 million members in our 8 regions, located in 9 states [1] and the District of Columbia. In each Region, the nonprofit Kaiser Foundation Health Plan enters into a mutually exclusive arrangement with an independent Permanente Medical Group to provide all medical services required by Health Plan members.

In our organization, virtually all pharmacy services are provided directly in Kaiser Permanente facilities by Health Plan employed pharmacists. This year, Permanente physicians will prescribe and Kaiser pharmacists will dispense more than $3 billion worth of prescription drugs. Our physicians and pharmacists make their best efforts to ensure that our members receive the highest possible quality and most cost-effective pharmaceutical care based on the best and most current available clinical evidence. This is supported by a strong culture of cooperation and collaboration between our medical groups and our pharmacy program.

It is this very close partnership between the pharmacy operations team of our Health Plan and the physicians of the Permanente Medical Groups that allows Kaiser Permanente to experience very high levels of use of generic drugs. While the Generic Pharmaceutical Association reports that 53 percent of prescriptions in the United States are written for generic drugs, approximately 70 percent of all prescriptions written by Permanente physicians nationally are for generic drugs. More than $250 billion was spent by or on behalf of US patients in 2004 for prescription drugs. There is no question that improved generic prescribing by US physicians has the potential to save many billions of dollars—money that can be spent on other health care services or newer drugs, or simply saved, slowing the growth of overall health care spending.

We expect that our pharmaceutical costs will increase annually in excess of the overall inflation rate. How much more than the inflation rate is the real question. We acknowledge that increased pharmaceutical utilization can in well-defined instances improve health and/or reduce spending on hospital and medical services that drugs make unnecessary. Overall, however, it is true that rising drug spending increases overall health care costs. Capturing the value of prescription drugs, and avoiding waste, is enhanced by the effective use of generic drugs.

DETERMINING THE PREFERRED DRUGS FOR KAISER PERMANENTE MEMBERS

At Kaiser Permanente, we take very seriously our obligation to deliver the highest quality care to our members. As with virtually all other health plans, each Kaiser Permanente region establishes a formulary that includes a list of drugs that are preferred as first-line therapies. The formulary is established by a regional pharmaceutics and therapeutics (P&T) committee.

Our P&T committees are comprised of Permanente physicians from a broad range of medical disciplines and the regional pharmacy services director. When a new drug becomes available to treat a particular condition, or when a review of existing drug therapies is undertaken, the P&T committee is commonly aided by physicians with expertise in the appropriate specialty.

When a new blood pressure medicine becomes available, for example, a panel of cardiologists and internists will make recommendations to the P&T committee. Their recommendations will reflect the latest information on all drugs in the therapeutic class as presented in a monograph prepared for the P& T committee by our pharmacist-staffed drug information service. The drugs included on the preferred drugs lists are those that, first and foremost, evidence indicates are clinically superior to the other drugs in the therapeutic class. If the preferred drug is available as a generic, the generic version will virtually always be the preferred drug on the formulary. Along with formulary-consistent prescribing by Permanente physicians, this explains in large part why Kaiser Permanente has been so successful in using generic drugs.

[1] California, Colorado, Georgia, Hawaii, Maryland, Ohio, Oregon, Virginia and Washington

Opportunities Presented by High Quality Generic Drugs

I would like to discuss three examples that illustrate how Kaiser Permanente uses generics to match clinical excellence with cost savings opportunities when they are available in a class that contains many drugs. While it is true that drugs that recently received FDA approval sometimes provide additional value for patients in terms of reduced side effects or greater efficacy, it is difficult to measure that value because only very rarely do brand name pharmaceutical manufacturers conduct head-to-head studies to assess whether newer drugs really are better than other available drugs. Independent head-to-head comparative research is also rare. However, one general observation can be made—many, if not most, patients can be successfully treated with available generic drugs. If these drugs fail to achieve the desired therapeutic outcome, a newer drug can be prescribed. This is particularly true when what was originally a breakthrough drug becomes available as a generic drug, and the follow-on alternatives are still under patent.

Antidepressants

A good example is Prozac and follow-on antidepressants known as selective serotonin reuptake inhibitors or SSRIs. When Prozac, now generically available as fluoxetine, first came to market in the late 1980s, it was generally accepted as a breakthrough over the older tricyclic antidepressants. While probably no more effective than the older, existing drugs, the much less onerous side effects of Prozac meant that patients were much better able to tolerate Prozac and continue therapy. As a result, this became the drug of choice for a proportionately large number of patients with clinically diagnosed moderate depression.

In the years that followed, competitors in the class of SSRIs, Paxil (paroxetine), Zoloft (sertraline), Celexa (citalopram), and line extensions and follow-on versions of all of these (weekly Prozac, extended release Paxil, Lexapro (escitalopram)) became available, providing a panoply of choices for clinicians in a pharmacological area where the first treatment, whatever is selected, may not be successful. It is important to note that, while SSRIs have somewhat different side effects profiles, none of these drugs appear to have meaningfully different performance as the first drug in the class prescribed to a patient. In other words, no one really knows whether a patient will succeed on the first choice, no matter what the first choice is.

Today, high quality generic versions for Prozac, Paxil and Celexa are available. As a result, it is possible to start virtually all patients (except for those with a known sensitivity to or a side effect from a particular drug) on any one of the generic alternatives before attempting therapy on drugs that are still under patent. An appropriate strategy like this, which is implemented in all Kaiser Permanente regions, enables Permanente physicians to offer our patients both high quality therapy and lower copayments (generic copayments are generally lower than those for brand name drugs). By reserving the patented alternatives for those patients who truly need them, we are able to keep drug costs, and employer and individual premiums that are directly related to those costs, down.

We estimate that our regional "Fluoxetine First" programs, which are approved by all of our Regional chiefs of psychiatry, save Kaiser Permanente members over $100 million annually in drug costs nationally, compared to broader U.S. prescribing patterns. If all U.S. prescribing of these drugs for new patients requiring antidepressants matched that of Permanente physicians, there would be savings of well into the billions of dollars annually with no reduction in clinical quality.

Cox-2 Inhibitors and other Nonsteroidal Anti-inflammatory Drugs

Cox-2 inhibitors (such as Celebrex, Vioxx and Bextra) represent a type of non-steroidal anti-inflammatory drug (NSAID) that have been used to treat the pain and inflammation that comes with various forms of arthritis. It was believed that Cox-2 inhibitors would provide an advantage over older NSAIDs (like ibuprofen and naproxen) because they were presumed to cause significant gastrointestinal side effects, which can include bleeding from gastrointestinal ulcers. They have never been considered superior pain relievers, although heavy promotion of these drugs may have led many patients to believe they are. We now know that high doses of these drugs represent a significant cardiovascular risk for patients and as of today, two of the three Cox-2s, Vioxx and Bextra, have been removed from the market. Caution dictates that physicians should reserve the remaining Cox-2 inhibitor, Celebrex, for those patients who fail on traditional NSAID therapy and do not have significant cardiovascular risk factors.

Even before the early hints of serious cardiovascular risk were confirmed and widely accepted by the medical community, work done by scientists at Stanford University showed that the potential gastrointestinal safety benefit of Cox-2 inhibitors was largely limited to patients who were at high risk of serious gastrointestinal

bleeding from traditional NSAIDs. This was important because they found that fewer than five percent of patients are actually at high risk of serious gastrointestinal side effects.

In a very practical response to these data, the same scientists developed a scoring tool to apply to patients who were candidates for NSAIDs to determine their risk levels. Kaiser Permanente, with the enthusiastic support of our Regional chiefs of rheumatology and internal medicine, adopted this scoring tool to provide physicians with simple, automated methods to know the risk levels of the patients they were seeing. Once this scoring tool was implemented, Permanente physicians prescribed Cox-2 inhibitors for Kaiser members less than five percent of the time when NSAID therapy was necessary. Until the recent withdrawal of the two Cox-2s, among the rest of the US population, these drugs were being prescribed approximately 50 percent of the time. The lack of good independent, credible information for physicians about the limited clinical role for these medicines combined with ubiquitous promotion to patients and physicians meant that millions more patients than necessary were prescribed them, and billions of dollars in needless drug expenditures resulted.

We estimate that in 2004 alone, if U.S. use of the three Cox-2s compared to traditional NSAIDs had matched that of Permanente physicians, U.S. consumers and businesses paying for prescription drugs would have saved over $4 billion dollars, or almost 2 percent of *all* U.S. drug spending. Here is a great example where promoting the use of high-quality generic drugs can be not only significantly less costly, but safer.

Cholesterol-lowering Statins

A few years ago, the Wall Street Journal reported on Kaiser Permanente's use of generic lovastatin (Mevacor) as the first line cholesterol lowering drug for our members. While lovastatin is not the most potent statin on the market, through appropriate dosing a majority of patients can readily achieve their target cholesterol levels. Members who have a clinical need for a more potent statin have easy access to them. An astonishing fact is that Kaiser Permanente physicians can treat six patients appropriately with lovastatin for the same cost as one patient on one of the still-patented alternatives. This program along with other steps taken by Kaiser Permanente to address cardiovascular disease has been so successful that in Northern California, for example, it was recently determined that heart disease is no longer the leading cause of death among Kaiser Permanente members (cancer is), even though it remains the leading cause for non-Kaiser Permanente members in the San Francisco area and throughout the nation.

How Appropriate Generic Prescribing is Achieved

The value of generic drugs is maximized when programs are designed in a way that does not deny access to necessary but more expensive brand name prescription drugs. Our goal, instead, is to target the more expensive drugs to those patients who stand to benefit from whatever additional value newer drugs might provide, rather than simply defaulting automatically to the newest drug for all patients. This result is equally high quality, but far more cost effective use.

These programs work within Kaiser Permanente for several reasons.

- First and foremost, our physician clinical experts are intimately involved in the development and implementation of good drug use management initiatives. Permanente physicians have the confidence that their most expert colleagues are in agreement with the recommendations for drug use initiatives.
- Second, the Health Plan's clinical pharmacists are available for consultation and provide the latest information about alternative drug therapies. Kaiser Permanente invests significant resources to make sure that physicians have ready access to the best objective drug information that exists.
- Third, physicians delivering care to patients know that they will not be penalized for prescribing nonformulary or more expensive brand name drugs—they know that those drugs are readily available when necessary. Indeed, they know that some patients will need the newer drugs and receive them when needed.
- Finally, Permanente physicians know that savings resulting from their efforts will either lower member premiums or enable spending in other areas, whether subsidizing other, more expensive drugs, building new facilities or buying necessary medical equipment.

THE BROADER CHALLENGE

If it is Kaiser Permanente's integrated nature, financial structure and close cooperation among physicians and pharmacists that leads to our high use of generic drugs, the question remains: what lessons learned in the group practice environment can be applied in less integrated settings?

It might not be possible for other types of health plans to achieve Kaiser Permanente's level of success in generic prescribing, but I believe that steps are already being taken that can help realize savings through increased use of generic drugs. Physicians are clamoring for better, objective information about the comparative clinical effectiveness of prescription drugs. Thanks to the work of this Committee, the Medicare Modernization Act included provisions authorizing the Agency for Healthcare Research and Quality to initiate a research agenda on the comparative effectiveness of alternative therapies, including drugs for the same condition. For fiscal year 2005, Congress appropriated $15 million to fund this activity. While modest, it is an important first step, and we encourage members to support increased funding in future years. We strongly believe that increased support for this important research will result in exponentially greater savings in the future, as physicians see clinical evidence that guides their practices. I am confident that the research will show that generic drugs can be used safely and effectively more frequently than they are now.

We also believe that physician organizations, such as medical associations and specialty societies, need to take the lead in defining best practices. Much that is learned from multispecialty group practices like the Permanente Medical Groups and our colleagues in academic medicine and medical foundations is not effectively translated to the larger medical community. We think our colleagues in organized medicine can play an important role in expanding good drug use practices.

The new Medicare drug benefit also provides an opportunity to expand appropriate use of generics. The new drug benefit will provide important value for Medicare beneficiaries, but other than for low income persons, many beneficiaries will experience gaps in coverage. In this context, high-quality, affordable generics are critical to ensure that beneficiaries have access to the therapies they need. Simply stated, Medicare beneficiaries can have many more of their prescriptions covered under the current benefit design if generic medicines are appropriately prescribed. We are confident that CMS can and will work with physicians caring for Medicare beneficiaries in ways that will provide information about the relative value and clinical appropriateness of generic drugs.

Mr. Chairman, thank you for the invitation to testify here today. I would be happy to answer any questions you may have.

Mr. DEAL. Thank you. Dr. Gottlieb?

STATEMENT OF SCOTT GOTTLIEB

Mr. GOTTLIEB. Thank you, Mr. Chairman, Congressman Brown, members of the committee. Thank you for inviting me to testify before you today. Allow me to briefly introduce myself and then tell you how my experience relates to what I am going to discuss today.

I am a practicing physician and a former Senior Advisor to the Commissioner of the Food and Drug Administration and the Administrator of the Centers for Medicare and Medicaid Services. At the FDA and then at CMS, I worked on many policies that were promulgated during my time at those two agencies that were aimed at increasing the availability of safe and effective generic drugs and providing a framework for people to make wider use of them. But it is as a physician that I have developed my deepest appreciation for the value that generic drugs offer.

Practicing in a mostly Medicaid clinic, I often had to approach my patients' prescriptions requirement, not on what they needed, but on what they could afford. They could only a fixed, and usually small, amount of money each month, out of pocket, on medicines. Generics made it possible for me to provide my patients with the lifesaving benefits of safe and effective medicine while staying within their tight budgets.

So the question becomes what steps can we take to encourage more widespread use of safe and effective, FDA-approved generic drugs, where these option make sense for patients, both therapeutically and economically, and without trampling the incentives for

brand-name drug makers to continue to come up with newer—and yes, better molecules by dismantling legitimate patent protections.

The good news is that each year patients are making wider use of generic drugs, recognizing the value that they bring. Drug insurance companies, which are exposing consumers to more of the costs of their incrementally more expensive medical choices are also driving this trend. Through aggressively tiers formularies of co-pays on more expensive, branded drugs, consumer who can afford to contribute to the incremental cost of expensive tastes when it comes to medicines are being asked to pay a portion of that decision. This is giving consumers reason to make wider use of low-cost, generic options and even over-the-counter drugs where these substitutions for branded drugs make therapeutic sense.

One recent study by Aetna of almost 14,000 beneficiaries found a 5.5-percent decrease in pharmacy costs and a 7-percent increase in overall generic utilization when consumers were exposed to more of the cost of their incremental drug decision. There is also some evidence from Medstat and elsewhere that Medicare beneficiaries who have been using their new Medicare drug cards are more likely than other seniors to use generic drugs, I think, precisely because the information they have available through the drug card keeps them informed and educated on how they can save money with generic drugs.

I believe these trends to expose consumers who can afford to pay some of the cost of the decisions will accelerate under the new Medicare prescription drug plan as the plan, themselves, become more aggressive and adept at managing a drug benefit and steering patients to lower-cost options where they exist and where they offer similar therapeutic benefits, but there are some things that we should all be mindful of.

First, the decision that plans make about which medicines to have a high co-pay on or prior authorization is often not linked directly to the cost of the medicine or its value to the patient relative to a generic alterative, but simply on whether the plan got a good deal from the drug company. So a far better way to expose consumers to the incremental cost of a more expensive drug decision is through health savings accounts or through coinsurance. Of course, patients have to want to participate in their own healthcare decisionmaking or be able to, and no everyone will, so we need to maintain a safety net for those who cannot.

Second, if we are going to truly take advantage of some of the opportunities to offer more patient-specific therapies in the future, using tools like genomics and proteomics, then it simply follows that patients will need to be more active participants in weighing the competing medical options that they will have that will all have benefits and tradeoffs, including economic tradeoffs.

So what can this committee do to help us prepare for this future of consumer-led healthcare? I think one of the big impediments to more active participation by consumers is a lack of information at the point of care about the economic impact of peoples' decisions. Far too often when I prescribe medicine to a patient, I get a phone call a few hours later. They are at the pharmacy and found out there is a $50 co-pay on the medicine I prescribed, and can I find something else that doesn't have a co-pay. Having information

about things such co-pays accessible right in my office and having them available outside of my office for my patients would give my patients and I the information tools we need to factor economics into our choices. I am confident that, armed with this information, we would opt for lower-cost generics where they made therapeutic sense more often than we do today.

That leads me to my last point. How can we make this information more widely available? Here, I encourage you to look at some recent steps that Aetna has taken. They have developed a sophisticated website that allows patients to mix and match similar drugs to see how they can lower their overall drug bill by changing their drug mix. This is also one area where I believe that CMS is taking the lead in setting a good example for the private market through efforts like their drug-compare website and pushing for incentives and standards to promote more widespread adoption of e-prescribing. I believe the government can play an appropriate role, following the lead set by CMS, to help patients have more information available to them so that they can weigh for themselves the value that generic drugs offer at the time that they need to make a decision about which drugs they want to use.

Finally, I would like to close on two cautionary thoughts for the committee to consider. First, especially in an age when decisions to take drugs that are in development today are going involve more personal preferences and involve criteria that allow doctors to more closely match medicines to patients, I do not believe policies that force patients into generic drugs will success in maximizing overall public health benefit. Strategies like Fail-First, especially when inappropriately applied to areas to medicine where compliance is such a big factor to success, like mental health, has already been shown to cost more in the end. If plans are going to steer patients to generic drugs through restrictions on access to branded alternatives, they need to provide easy ways to opt around these restrictions for patients for whom the branded drugs makes the most sense.

Second, and last, I believe we all need to recognize that no two molecules are the same. While two very similar drugs in the same drug class might provide largely equal benefits for the majority of patients, there are always patients for whom one seemingly similar drug will have very different effects than its close cousin. As doctors, we see this anecdotally every day, and literature supports our experience. In fact, we cannot have it both ways—recognizing, for example, that Vioxx might have certain risks that another similar drug does not, yet not recognizing that seemingly similar molecules also have different benefits.

In closing, we need to arm consumers who want to be more active participants in their health choices, and who have the economic means and wherewithal to do so, with information that could help them weigh economics as one more factor in their treatment decisions. With the right information available at the right time, I am confident more of my patients would make wider use of safe and effective generics when these therapeutic options make equal sense. Thank you.

[The prepared statement of Scott Gottlieb follows:]

PREPARED STATEMENT OF SCOTT GOTTLIEB, RESIDENT FELLOW, AMERICAN ENTERPRISE INSTITUTE

Mr. Chairman, members of the Committee: Thank you for inviting me to testify before you today.

Allow me to briefly introduce myself, and then tell you how my experience relates to what I am going to discuss today. I am a practicing physician and a former senior advisor to the Commissioner of the Food and Drug Administration and the Administrator of the Centers for Medicare and Medicaid Services.

At FDA and then at CMS, I worked on many policies that were promulgated during my time at those two agencies that were aimed at increasing the availability of safe and effective generic drugs, and providing a framework for people to make wider use of them.

But it is as a physician that I have developed my deepest appreciation for the value that generic drugs offer.

Practicing in a mostly Medicaid clinic, I often had to approach my patients' prescription requirements not on what they needed, but what they could afford. They could only spend a fixed and usually small amount of money each month—out of pocket—on medicines.

Generic drugs make it possible for me to provide my patients with the lifesaving benefits of safe and effective medicines, while staying within their tight budgets.

This is not a unique recognition, but one made also by policymaker across Washington, and especially on this committee. So the question becomes: what steps can we take to encourage more widespread use of safe and effective, FDA approved generic drugs where these options make sense for patients both a therapeutically and economically, without trampling the incentives for brand drug makers to continue to come up with newer and yes better molecules by dismantling legitimate patent protections.

The good news is that each year, patients are making wider use of generic drugs, recognizing the value that they bring. Drug insurance companies, which are exposing consumers to more of the cost of their incrementally more expensive medical choices, are also driving this trend. Through aggressively tiered formularies or co-pays on more expensive branded drugs, consumers who can afford to contribute to the incremental cost of expensive taste when it come to medicines, are being asked to pay a portion of that that decision.

This is giving consumers reason to make wider use of low cost generic options, and even over the counter drugs, where these substitutions for branded drugs make therapeutic sense.

One recent study by Aetna of almost 14,000 beneficiaries found a 5.5 percent decrease in pharmacy costs and a 7 percent increase in overall generic utilization when consumers were exposed to more of the cost of their incremental drug decision.

There is also some evidence from MEDSTAT and elsewhere that Medicare beneficiaries who have been using the new Medicare drug cards are more likely than other seniors to use generic drugs, I think precisely because the information they have available through the drug card keeps them informed and educated on how much they can save with generic drugs.

I believe these trends to expose consumers who can afford to pay to some of the cost of their decisions will accelerate under the new Medicare Prescription Drug Plan, as the plans themselves become more aggressive, and adept at managing a drug benefit and steering patients to lower cost options where they exist and where they offer similar therapeutic benefits.

But there are some things that we should all be mindful of.

First, the decision that plans make about which medicines to have high co-pay on, or to have prior authorization on, is often not linked directly to the cost of the medicine, or its value to the patient relative to the generic alternative, but simply on whether the plan got a good deal from the drug company.

So a far better way to expose consumers to the incremental cost of more expensive drug decisions is through Health Savings Accounts, or through co-insurance.

Of course, patients have to want to participate in their own health care decision-making, or be able to, and not everyone will. So we need to maintain a safety net for those who cannot.

Second, if we are going to truly take advantage of some of the opportunities to offer more patient-specific therapies in the future, using tools like genomics and proteomics, then it simply follows that the patient will need to be a more active participant in weighing competing medical options that will all have certain benefits and tradeoffs, including economic tradeoffs.

So what can this Committee do to help us prepare for this future of consumer led healthcare? I think one of the big impediments to more active participation by consumers is the lack of information—at the point of care—about the economic impact of peoples' decisions. Far too often, I prescribe a medicine to a patient only to get a phone call a few hours later. They are at the pharmacy and found out there is a $50 co-pay on the medicine I prescribed. Can I find something else for them that does not have a co-pay.

It is simply impossible for me to keep track of all of the different formularies from all of the different plans that all of my different patients are on. Having this information accessible right in my office, and having it available outside of my office for my patients, would give my patients and I the information tools we need to factor economics into our choices.

I am confident, that armed with that information, we would opt for lower cost generics—where they make therapeutic sense—more often than we do today.

That leads me to my last point: How can we make this information more widely available? Here I encourage you to look at some recent steps that Aetna has taken. They have developed a sophisticated web site that allows patients to mix and match similar drugs to see how they can lower their overall drug bill by changing their drug mix.

This is one area where I also believe that CMS is taking the lead and setting a good example for the private market, through efforts like their drug compare web site and pushing for incentives and standards to promote more widespread adoption of e-prescribing.

I believe government can play an appropriate role, following the lead set by CMS, to help patients have more information available to them so that they can weight for themselves the value generic drugs offer at the time that they need to make decisions about which drug they want to use.

Finally, I'd like to close on two cautionary thoughts for the Committee to consider:

First, especially in an age when decisions to take the drugs that are in development today are going to involve more personal preferences and involve criteria that allow doctors to more closely match medicines to patients, I do not believe policies that force patients into generic drugs will succeed in maximizing overall public health benefit.

Strategies like "Fail First"—especially when inappropriately applied to areas of medicine where compliance is such a big factor to success, like mental health—has already been shown to cost more in the end. If plans are going to steer patients to generic drugs through restrictions on access to branded alternatives, they need to provide easy ways to opt around these restrictions for patients for whom the branded drug makes the most sense.

Second and lastly, I believe we all need to recognize that no two molecules are the same. While two very similar drugs, in the same drug "class" might provide largely equal benefits for the majority of patients, there are always patients for whom one seemingly similar drug will have very different affects than its close cousin.

As doctors we see this anecdotally every day and the literature supports our experience. In fact, we cannot have it both ways—recognizing for example that Vioxx might have certain risks that another similar drug does not, yet not recognizing that seemingly similar molecules also have different benefits.

To end on my point about the direction of the technology and of drug development, we are heading toward more targeted treatments, better information about those treatments, and drugs more finely matched to individual patient needs.

We simply cannot adopt policies that force square pegs into round holes, forcing patients on to medicines when better options exist, simply because of cost. We cannot take that decision away from the doctor and the patient. Doing so bucks the tide of innovation and best practice.

What we can, and I think should do, is arm consumers who want to be more active participants in their health choices, and who have the economic means and wherewithal to do so, with information that can help them weigh economics as one more factor in their treatment decisions. Too often in my own medical practice I have been left in my office, scratching my head along with my patient, wondering what the drug bill will be when my patient arrives at their pharmacy.

With all of the valuable information tools we have at our fingertips, there is no reason we need to be left asking these questions. Armed with the right information at the right time, I am confident more of my patients will make wider use of safe and effective generic drugs when these therapeutic options make equal sense.

Mr. DEAL. I thank the gentleman. I recognize myself for questions. Ms. Jaeger, one of the things that I understand that is at

least a partial impediment to getting some generics on the market is the backlog at FDA for approval of applications. Is that correct?

Ms. JAEGER. That is correct, Chairman.

Mr. DEAL. Could you give us some of what that problem—the magnitude of it?

Ms. JAEGER. Certainly. Over the years, the OGD has limited resources, and if you look at the last 2 or 3 years, OGD, the Office of Generic Drugs within the FDA, has been flat-funded; yet every year they receive more and more applications for generic drugs, and they are not getting any resources. So as of December of 2002, there were over 7,000 applications pending before the agency for their review. And it turns out, of course, that they probably won't even picked up and looked at until probably sometimes late this Fall, if at all.

And so we are looking at a situation where applications are languishing there before FDA, and it is just a matter of time before they get picked up and reviewed. The review time for generics is much longer than, actually, and NDA product, a brand product, taking, on average, somewhere around 17 months. And we would hope that through some more accountability, some more oversights within the FDA, starting with the Commissioner's Office and going down to the Senator level, that perhaps we could move some of the applications through in a more timely fashion.

So it is an issue of yes, OGD needs more appropriations and needs more resources to deal with the backlog, but we also need to ensure that we provide the generic drug with the appropriate oversight and accountability because some applications are going on consults—legal consults going; scientific consults—and these consults, also, are taking a substantial amount of time—sometimes 7 months, sometimes 9 months, and sometimes years in the legal office of FDA.

Mr. DEAL. One of the things that has been suggested is that generics should be put in the same category as we place medical devices, applications for new drug products, even animal medicines, and that is in order to speed up the review time. They have agreed, and we put in place, a user fee for them. Would your association be willing to pay a user fee in order to have additional resources that would speed up the time for approval?

Ms. JAEGER. That is a good question, Mr. Chairman.

In the past, it didn't make much sense because there were so many loopholes in the Hatch-Waxman Law that even if our industry did actually pay a user fee, the applications were going to languish there because of all of the loopholes that the brand industry could utilize to delay the generic applications. So in the past it made no sense.

As we go forward, I think our industry could certainly consider that thought again; but again, it also creates a barrier for some of the smaller drug companies to bring their products to the market. The more competitors we have in the marketplace, the more it benefits consumers and brings down costs.

Mr. DEAL. Well, you know some of—I know in the medical device area, those fees are calculated based on the size of the company that is asking for help, and they have reduced fees if they are smaller companies.

So is that something we could look at, perhaps, down the road?

Ms. JAEGER. Certainly, we can have our industry look at that and get back to you, Mr. Chairman.

Mr. DEAL. Would you do that, please?

Ms. JAEGER. Yes.

Mr. DEAL. Ms. Cramer, I think we have all agreed here that part of the solution to this is better patient information, and you have pointed out what AARP is doing by way of trying to educate the public about consumers. Have you indicated or have you had any indication that this is taking hold? That it is having an effect?

Ms. CRAMER. Mr. Chairman, as you have indicated, AARP has a number of avenues for consumer education. I mentioned our Wise Use Program, where we try to promote the use of generic drugs.

We also have an online drug safety and effective tool that is available to members as well as nonmembers alike, and next month we will be launching a new tool on the web that will also be available to members and nonmembers, alike, called Medicines and You, which will do a number of things to educate individuals on drug interactions and number of other things. We have not, to date, evaluated the effectiveness of the Wise Use Program.

Mr. DEAL. Okay. My time is getting away from me, too, and I want to hit something really quickly.

Ms. Jaeger, you indicated that one way to speed this up was to have in place State statues that would require the "no substitution" to be handwritten on the pad where you prescribe it. Dr. Gottlieb has indicated that in one other area you talked about, about the carve-outs not being appropriate, that we have to be careful that we don't go to the Fail First approach on some of those areas.

As we are hopefully going to be looking at Medicaid reforms, are those kinds of things, like requiring doctors to go the little extra mile to make sure they get a brand name versus a generic—are those the kind of things that you are suggesting we incorporate in Medicare reform? Many of the States already have those in place, my State being one of them. What are you seeing in terms of—not necessarily you, but anybody else that wants to comment, what are you seeing in terms of movement in that direction to put the emphasis on the front end, rather than relying on consumer education?

Ms. JAEGER. Certainly, I would be happy to answer that. I think a lot of States are doing some positive initiatives in their State Medicaid program; however, at least the vast majority of the States—are not utilizing all of the tools that are out there to maximize generic substitution. Our concept is that if you take a mandatory substitution program, and you look and you see, well, there are some holes in that, well, then you plug the holes, such as adopting a rigorous DAW program, dispensed-as-written program, like Massachusetts did and Hawaii did.

At the same time, States also need to look at aggressive MACing, how they reimburse under that program. And a lot of States, while they may adopt MACing, they don't really have aggressive MACing.

Some States aren't looking at the products in the marketplace, the three generics in the marketplace, and taking that average and using that average to reimburse, where other States are perhaps

still using the brand plus two generics, so it think, really, it is a combination of all of those tool that would actually substantially increase generic utilization and saving.

Mr. DEAL. Thank you. My time has run out. Mr. Brown?

Mr. BROWN. Thank you, Mr. Chairman. Ms. Jaeger, you have raise several concerns about a number of provisions contained in recently negotiate free trade agreements, and I appreciate your comments about that. As you likely know, Congress is likely to vote, and Majority Leader DeLay said with would be voting on CAFTA, the Central American Free Trade Agreement, before the end of May. It is my understanding that CAFTA enables brand-name drug companies to deny Central American consumers the same benefits of generic competition for even longer period than U.S. Law, and I want to explore that and have you explain that.

Under U.S. law, patent extension for brand-name manufacturers are limited—because of some reforms recently, are limited to the active ingredient of the new drug and to the extension of a single patent. My understanding is that CAFTA allows multiple extensions for any and all patents covering a drug without any time limits at all. If that is the case, CAFTA, then, would give drug makers significant, more powerful patent-extension tools to delay competition from generic medications, more in these Central American countries and the Dominican Republic, than they have in the U.S. Is that correct?

Ms. JAEGER. Yes. Let me actually take your first issue first, having to do with the 5-year date of registration period. In the CAFTA agreement, there is a 5-year registration period for a brand company to file an application in a CAFTA country. They need to file that application within 5 years of receiving FDA approval. So as you can imagine, most likely, the brands aren't going into a CAFTA country until the eve of their exclusivity here in the United States has expired or is about to expire. And that actually would delay, of course, the entry of that lifesaving medicine to the CAFTA country, but it also will delay a generic going into a CAFTA country for at least 13 years because you have to add up the 5-year date of registration period plus 1 to 2 or 3 years, depending on the country, for their review of that application. And of course, once that product is approved, then, they would get an additional 5 years in that CAFTA country. So we are concerned about that particular provision from, not only, international harmonization concept, but also about exporting out products into the CAFTA countries.

The second issue, on patent extension: in CAFTA, there is a provision on patent extensions, and the language is very, very murky. We would like it to be interpreted that it be consistent with the U.S. law, which is that only a new chemical entity can get a patent extension. Unfortunately, the way it is written, it is murky to us, and it looks like that any product could receive a patent extension for a regulatory review period. So as you can imagine, if you had a product that had a modest labeling change or went to a once-a-week-dosage form, those products, too, could obtain additional market protection, and we think some interpretations could roll that back and get it to be consistent with the U.S. law. And we, really, again, are very concerned about international harmonization meas-

ures with respect to the free trade agreements, not only CAFTA, but others as well.

Mr. BROWN. Okay. So if that is the case, as you claim, the name-brand drug makers will have more powerful patent extension tools in the five Central American countries and the Dominican Republic—will have more powerful tools to do this than they have in the United States. Take this out to the next step, if you would. The name-brand drug industry clearly has used its political muscle, not just in this Congress, but around the world. And during the CAFTA negotiations, one country, Guatemala, actually had passed a generic drug law that the U.S. trade rep, representing the United States government—and as you know, the U.S. trade rep has an arm—I don't recall the exact name and office of prescriptions drugs, whatever—that they pretty much said to the Guatemalan government that if you want to be included in the Central American Free Trade Agreement, that generic drug law needs to be repealed, which it was. Understanding that political muscle or that lobbying muscle that the drug industry had, are you concerned that the drug industry will use CAFTA as leverage to force the U.S. to conform to the Central American laws and be able to use political muscle in that direction to, in a sense, lobby Central America for stronger patent protection laws, therefore less access to generics, and then turn around and use those laws to weaken generic competition opportunities in the U.S.

Ms. JAEGER. We are concerned that if the free trade agreements, as they are being negotiated right now and as they are interpreted—to the ones that actually have been passed—if they are not pulled back to be consistent with the U.S. law, there could be some damage to the U.S. healthcare system in years to come.

To give you an example: in most free trade agreements, the best-mode requirement having to do with patentability has been omitted. Now, that is an issue here for the United States. That is very critical with respect to patentability and having a company downstream trying to make a product. As you can imagine, there must be 45 or 50 different ways to make a biopharmaceutical. In the United States, we require the brand company to put forth the best mode of making the product in their patent. And unfortunately, that particular requirement is being deleted. And now, we are also seeing here—there is a House patent-reform bill that is actually throwing that concept up—that thorough international harmonization, perhaps the U.S. should delete best-mode.

Now, we are hopeful that Congress in their wisdom will see pharma's backdoor maneuvers for what they are and reject that and again maintain the U.S. patent law, as is. And also, hopefully, with respect to market exclusivity around the world, you know, pharma has been very good and very diligent about going and getting other countries to increase their market exclusivity up to 10 years in some situations, six in others. They have got reform packages in Canada and in other country, so the generic industry is concerned about international harmonization measures. There are two provisions in two bills in the Senate that are asking for international harmonization with respect to market exclusivity.

So we are concerned, again, that these issues are out there, but to date, at least the Congress in their wisdom, again, has flatly re-

jected these concepts, and hopefully, we, as a Congress, can urge USTR to cleanup the free trade agreement base document and provide a fair interpretation.

Mr. BILIRAKIS [presiding]. The gentleman's time has expired. Chairman Barton to inquire.

Chairman BARTON. Well, thank you, Mr. Chairman. I am just going to ask one question because I am supposed to be on the floor right now on our amendment to the Homeland Security Bill. Mr. Brown and I are pretty close on agreement on most things. We always come to it on a different point of view. I am a supporter of the CAFTA agreement. I would list him as undecided. I don't think we have convinced him yet. But we share a similar concern about generic drugs in the marketplace being hamstrung by slightly modifying a patent or modifying something so that you have to go through the review process again. I am with him on that.

Is that something that this committee should look at this year? Do we need to, perhaps, modify Hatch-Waxman to make sure that the drug manufactures don't game the system to re-extend their patents and not let the generic version come into the marketplace as soon as it could? Is that something we need to look at?

Ms. JAEGER. Well, let me just be clear for the record. GPhA actually supports CAFTA. What we are looking for is interpretation with respect to CAFTA, and we would also like USTR to change their base document going forward. I mean that is what we think is really the problem with the issue, is that the USTR has this base document, and every free trade agreement they kind of go up to the next notch, and they are continuing to increase this base document. We even think it needs to be brought back to current U.S. law, and we think it needs to be clarified so that no gaming can occur, because right now, the way it is drafted, gaming could potential occur in other countries, and you could have a situation where products cannot get into a CAFTA country or an Andean country going forward.

Chairman BARTON. Mine is not a CAFTA question. I am glad that you and I agree that we support CAFTA. Okay. What I am asking is, in the United States market, whether there was a CAFTA agreement on the table or not—generics that are approved do save money. Should we modify—and I am not advocating; I am asking an honest question. Should we modify, do anything, so that patents that are about to expire that have a generic equivalent that could come into the marketplace don't get slowed down because the patent holder modifies something or maybe perhaps filed, I have heard, in some cases as many as 50 patents when they got the original patent, and then they come in and say, we have changed it, and therefore it is this now, and you really can't do a generic. That is my question.

Ms. JAEGER. And to answer you question is that, through MMA, we did have some hatchback reforms that actually did close some of the unintended loopholes, and so we have made some progress on that front, and we are starting to start to see some of the results. However, having said that, we are seeing that brand pharma has found new games in the system and that we are just starting to see these new games being played out.

So yes, I would agree with you that we need to consider and identify the new loopholes and actually take the appropriate corrective action.

Chairman BARTON. Great. Thank you. Thank you, Mr. Chairman.

Mr. BILIRAKIS. The Chair thanks the gentleman. Mr. Waxman to inquire.

Mr. WAXMAN. Thank you very much, Mr. Chairman. I want to ask Ms. Jaeger.

We all recognize that we need to encourage doctors to prescribe generic drugs; however, there has been a longstanding disinformation campaign, presumably by brand-name companies, leading doctors to believe that generic drugs can be only 80 percent as effective as the brand-name version. My understanding is that this statement is a serious misrepresentation of FDA's statistical tests for determining the equivalence of generic versions. According to FDA's official listing of all approved generic drugs, the agency has twice conducted surveys to quantify the average difference between the innovator and the generic products, and in both cases, in both studies the agency found that the average difference was 3.5 percent or less. The agency has also stated that the existing bioequivalent standards are, in fact, so tight that, if FDA were to require more stringent tests, it would even be possible that if the innovator form reformulated its own product, they would not be able to demonstrate bioequivalence to itself. Is FDA correct in this regard?

Ms. JAEGER. Yes, we believe that FDA is correct. There has been numerous misinformation campaigns out there by various brand companies, one having to do—I think that most people would probably know, having to do with the narrow therapeutic index products. DuPont Mark, back in the late 80's, going into the early 90's, went around the country trying to convince policymakers at the State level that generic drugs that fell into the category of NTI products were not as safe and were not as effective as their brand-name counterparts; and therefore, they had to have carve-out rules with respect to these NTIs. The FDA did come into the issue and actually did testify in a number of States on behalf of the generic industry, and did write a number of letters to medical professionals and policymakers at the State level. But unfortunately, more needs to be done because now we see a new wave of this misinformation campaign, having to do with mental health drug, epilepsy, cancer—all sorts of drug products. And so a strong campaign from the Food and Drug Administration about the safety and sameness of generics, I think, would be very, very helpful.

Mr. WAXMAN. And this story that is circulating about only 80 percent as effective, you don't buy that? FDA doesn't buy it?

Ms. JAEGER. No. What the brand company representatives will always say is that the generics only have about 80 percent of the active ingredient, and they will say that is FDA's rule. Well, the rule is 80 to 125, and that has to do with a statistical parameter. It has nothing to do with potency of the product. The potency of the generic has to match, by Federal law, that of the brand. It has to be 100-percent potent, so this concept that generics have less than 100—80, 75, whatever it may be—is really just plain wrong.

Mr. WAXMAN. I just want to ask you two more questions, and I guess very quickly because the time is expiring. You described the threat to generic access in this Bioshield II legislation. It would provide excessive incentives to drug companies with no relationship to the value of the benefits we might expect. I am concerned about this wildcard exclusivity provision and want to understand it in more detail, how it would work. As I understand it, a manufacturer could gain an outrageous windfall in exchange for only a minor addition to our arsenal of countermeasures. Say, for example, Pfizer wants to develop a treatment for a minor side effect of an anthrax vaccine. Is it true that Pfizer could, then, turn around and get 2 additional years of exclusivity on its best-selling drug Lipitor? And how much would that cost the American people?

Ms. JAEGER. Well, if Pfizer just even did a minor study on animals having to do with one of the antibiotics in their portfolio, never mind an anthrax vaccine, but just a small antibiotic, a small study, they would be able to reap a 2-year wildcard extension. And that wildcard extension can be put onto any product of their choice. The product does not have to do with anything with respect to bioterrorism. So if Pfizer was to put that wildcard on the product Lipitor, that would be a windfall to Pfizer of $14 billion and lost savings to the healthcare system of about $10 billion. And when we have looked at it, we took the top 20 most profitable drugs in the United States. We extended each product for about one wildcard, just one, and it turned to be about $100 billion in windfall to brand pharma.

Mr. WAXMAN. And quickly, the few seconds I have left, if we had a pathway for biological products, can you give examples of some of these products that are off-patent or will come off patent soon and what kind of savings we could anticipate from generic biological products if Congress creates an approval system for them?

Ms. JAEGER. Absolutely. There are a number of products, right now, that companies have applications in that are pending before the agency having to do with insulin and human growth hormone. Others have to do with companies looking at Epo. All of these products would provide substantial savings to the American consumers if we had generics.

Now, to give you sort of an example, right now, the biologic market is about $30 billion in pharmaceutical costs. By 2010, it is supposed to be up to $60 billion. So if we just take a modest competition concept and say that generics come in about 20 percent of that of the brand product, that is savings of substantial billions of dollars. And so even if it is a 10-percent differential—which we think it is going to be much, much more than that—again, it is going to provide substantial savings to the healthcare system, especially Medicaid and Medicare.

Mr. WAXMAN. Thank you very much. Thank you.

Mr. BILIRAKIS. Thank you, Mr. Waxman. The Chair recognizes himself.

I was glad to see Ms. Capps come back in because she told us about the situation where a generic resulted in an allergy, so sort of continuing on with Mr. Waxman's point on the equivalency, if you will, and efficacy and whatnot—and maybe this is better-asked of Dr. Gottlieb.

The situation Ms. Capps referred to, where there is an allergic reaction to the generic drug, and therefore that patient had to go back to the brand-name drug, if we have an equivalency here of ingredients, et cetera, et cetera, why would that be, Doctor?

Mr. GOTTLIEB. I was struck by the comments as well, and I am mostly struck by the comments of my patients in my office every time they come in and tell me that they had a different reaction to the generic drug than the branded drug, and they request the branded drug only. Sometimes, there are different ingredients used in the generic drugs to help formulate the pill, and sometimes that could get to how the pill is ultimately dissolved in the stomach and perhaps absorbed. But by and large, the experience that the patient receives from a generic drug and a branded drug should be absolutely the same. They should be bioequivalent in the patient's blood and have the same therapeutic effects. So I think these anecdotal experience is notwithstanding, and it probably is for certainly isolated patients situations where the different things used to formulate the pill might have a specific effect on a patient. I think, by and large, it is more of a perception problem with patients, and in that respect, you know, quite frankly, the branded drug makers have a perception of quality, and sometimes the generic drug makers don't. I have patients who come in and say I don't want a drug from India; I don't want a drug from China. And so there is a perception in peoples' minds of a difference in the quality. I think that plays into how they experience their drugs.

I am glad to see that GPhA has done some of its own advertising efforts to try to support the quality of generic drugs. FDA has done a lot, and the government's played a role there. I think the generic drug industry is highly profitable and can probably, hopefully, do more in the future to help substantiate in peoples' mind that they are getting a similar quality medicine that should have the same effect as the brand alternative.

Mr. BILIRAKIS. Well, you know, Dr. Tom Colburn, who is now in the Senate, was on this committee a few years ago, and I know that he mentioned to me a number of times that there were exceptions, that there wasn't the same efficacy and whatnot; and therefore, doctors had to be careful in terms of prescribing—it was to that effect. I am not trying to put words in his mouth, but that is basically the way I interpreted his comments.

And I asked Dr. Burgess, after I made my opening statement, and he sort of, in a sense, said the same thing—you know, very rare situations. So I mean that does happen. I mean it is not just a perception—I shall use the word perception. It is not just a perception?

Mr. GOTTLIEB. I think it is largely a perception issue. I think there is isolated cases in medicine where there have been drugs that have been formulated the follow-up version have been formulated differently and had certain different reactions for some patients. I am thinking of a couple in my mind, but that is the real minority of experience with patients. And I think in the majority of cases where you hear patients coming in and complaining of a different response to the drug, it usually ahs to do with a different taste that the drug had or a different composition that it had in their mouth as they swallowed it or it dissolved because of the way

its formulated and not really related to the active ingredients in the drug.

Mr. BILIRAKIS. I did want to ask you about the information available to physicians, a point that you made in your statement, but first—and I shall probably run out of time, and if I do, possibly you can furnish that to us in writing. I think that would be a very interesting point there.

But let me ask Ms. Jaeger, how many drugs are there out there? Your testimony referred to 195 most used drugs——

Ms. JAEGER. Right.

Mr. BILIRAKIS. [continuing] that sort of thing?

Ms. JAEGER. I would have to defer to FDA, but I think there are like over 700——

Mr. BILIRAKIS. Over 700?

Ms. JAEGER. [continuing] various drug products, some being very, very old, and their newest are probably in the part of the list.

Mr. BILIRAKIS. Now, of the 53 percent of all prescriptions dispensed that generics represent, what percentage is just for drugs that have a generic alternative? Do you know the answer to that?

Ms. JAEGER. Are you talking about the generic efficacy rate, sir?

Mr. BILIRAKIS. Yeah, I am talking about the—I guess the question is what percentage of brand-name approved drugs have a generic alternative.

Ms. JAEGER. I don't have exactly that number. The ones, of course, that are solid dosage forms than others and those that have gone off patent, most all likely have a generic equivalent to them.

Mr. BILIRAKIS. They all have——

Ms. JAEGER. However, there are areas which we do not have generic alternative, such as like topical corticosteroid situations, other inhalation products, such as Flonase, a major blockbuster. And that is because there is no bioequivalence technology to date that can actually support the approval of those products. Research is ongoing in those areas, but more research needs to be done before a generic can come into the marketplace.

Mr. BILIRAKIS. So in the areas where it can be done, you say that generics exist or at least are in the process of being approved or disapproved or whatever. Is that correct? Very, very quickly because I——

Ms. JAEGER. Sure. I think that there are a number of research projects that FDA could take and NIH could take to actually move along so that we could ensure that all of those brand products that should have generic competition do.

Mr. BILIRAKIS. I thank you. Let us see. Ms. Bono to inquire. We have going to wait awhile. I guess I got to go to the other side. Ms. Capps.

Ms. CAPPS. Thank you, Mr. Bilirakis. It is nice to see you back in this chair.

And Ms. Jaeger, I am tempted to follow-up because it was very interesting, the conversation about protecting from over-use of generics, if in fact—and we could have that argument—or not argument—conversation, because I think we basically agree. We just want to make sure that we are doing the right thing. But I just want to not let us forget the major piece of information that you brought to us, the fact for every 1-percent increase of generic utili-

zation, there would be nearly $4 billion—I think I heard you say that.

Ms. JAEGER. Four billion.

Ms. CAPPS. In additional savings in through the various policies that you discussed in your opening testimony. Now, I serve on the Budget Committee, and I understand the task that is going to be given to this committee, which is going to be challenging for me, onerous, and we need all of the help we can get. If you could, spell out a little more in detail what this would mean for Medicaid.

Ms. JAEGER. With respect to Medicaid, I think the question really deserves to go to CMS, and they could probably best answer that question. But however, from the information we have provided today, I think you can sort of extrapolate, being that Medicaid is roughly about 17 to 18 percent of the total pharmaceutical prescriptions in the United States, and so, roughly, the savings are going be in the average of about $500 to $600 million per year.

Ms. CAPPS. For Medicaid?

Ms. JAEGER. For Medicaid.

Ms. CAPPS. I see. So this would mean that the incentive would be that the more Medicaid recipients are using generic prescriptions, then the greater the savings will be to the overall policy, meaning that more Medicaid recipients would be able to—and so forth that follows.

And you spoke about some best practices, which I am also impressed with, but also, again, want to make sure there are safeguards there and hope that we could work with you to, not enforce these, but to make them available. Sometimes, as you have said, there are small, minute techniques on the prescription pad or in patient information and education that we could help disseminate so that this could be possible, and I encourage you to continue to do that and hope that we can work with you.

I am going to turn now to the other major health topic, Medicare population. Ms. Cramer, I would be interested in finding out what kind of patient protections you feel should be build in to guard against patient harm in the population you are representing, the seniors and those with disabilities, but particularly seniors with the AARP, and how formularies can be used in the most appropriate ways.

Particularly—if I could spell this out a little bit more, I am particularly concerned about the impact that formularies may have on the Medicare population, Medicare folks who are the disproportionately high users of prescriptions, and the dangers that some plans have so that they can increase their profits, and they do so at the expense of access to drugs under their plan.

In fact, my friend who we were talking about earlier with Mr. Bilirakis, asked if she could use the brand-name, and her Medicaid-Plus Choice provider, the HMO, denied her. So we want to make comment on steps that Medicare should take to ensure that beneficiaries are not harmed by restrictive formularies.

Ms. CRAMER. Congresswoman, with respect to your question about patient safeguards that should be available, AARP reports that when formularies offer preferred drug brands to their patients for generic drugs that there should be a very well-defined—overly priced—AARP believes that the final decision about—however, that

physicians—there need to be a clear—AARP believes that patients should be protected by—the appropriate medications—the brand name instead of the generic. The AARP also believe that patients should have quick access to the brand-name drugs; there should be no delays.

Ms. CAPPS. It is easier said than done, and sometimes it feels to consumers that the person practicing medicine is the person in green eyeshade, and if you are ever in contact, sometimes, with your insurer or the HMO-person, you think is this person anywhere connected to—and we don't want to undermine the skill and also the responsibility that the provider, most often the physician, has with respect to the patient. And I want to turn to Mr. Carey. Mr. Carey——

Mr. BILIRAKIS. Well, your time has expired.

Ms. CAPPS. Oh, I have already gone—oh, all right. If I could, I would ask you how your formulary, Mr. Carey.

Mr. BILIRAKIS. Furnish it in writing, as Dr. Gottlieb——

Ms. CAPPS. Thank you. I would like to note——

Mr. BILIRAKIS. Ms. Bono to inquire.

Ms. BONO. Thank you, Mr. Chairman. I want to thank all of the panelists for being here and say that Dr. Gottlieb has done a good job of answering my questions already, so I am going to read some prepared questions for Dr. Berger. Can you explain some of the incentives you give to pharmacies to encourage greater dispensing of generics?

Ms. BERGER. This is generally—sorry. I will tell you I have very little information and can get back to you further information on this, because the financial arrangements that are made with the pharmacies are really done outside of my purview. They are not done across the board. They are done individually, through relationships with our clients. So that is really all I can share with you at this point in time, due to my lack of knowledge on that specific issue.

Ms. BONO. Can you explain what the process would be for a physician who wanted to prescribe a brand-name drug to a Caremark patient when a generic was available?

Ms. BERGER. Absolutely. At the end of the day, it is the physician's decision as to what drug is prescribed, so if there is a generic available and the physician either chooses or feels it is necessary for a participant—which is what we call patients. I am a little schizophrenic at times, because I am a practicing physician as well—but if the participant needs the medication, they have every right to write it.

Ms. BONO. Is there going to be a follow-up from Caremark to that physician to talk about the next time a name brand is requested? Is there follow up to make sure that that doesn't happen again?

Ms. BERGER. We will communicate with the physician. We communicate with all physicians around educating them on generics. But if there is a generic available, and we have not had a specific conversation on that patient on that drug, we will have a conversation with them, get their feedback, and then document that so that there is a period of time that we will not go back to them on that specific prescription for that specific patient again.

Ms. BONO. Okay. Thank you. And Dr. Gottlieb, can you explain what Fail First policies are? I think we understand the idea, but can you explain why you feel they are a bad idea.

Mr. GOTTLIEB. Well, Fail First policies, as you know, are policies where patients are steered toward a certain drug or a certain class of drugs because of the economic savings, by in large, because there is a generic alternative. I think in many areas of medicine, our problem is that we are really under-medicating a lot of chronic disease, mental health being one of them, certainly, thing like hypertension, diabetics. And if there is a reason why a doctor wants to prescribe a certain drug for a certain patient that might not, on the face of it, make economic sense, but the doctor feels it is going to make that patient comply with the medicine or achieve a certain goal more quickly, that is a very important public health benefit that I wouldn't want to take away from the physician. You know? For example, if I have a patient that I don't think is going to come back and visit me many times, I want to get it right the first time. I want to give them the most efficacious drug and the most tolerable drug. Well, in some cases, that might be an expensive, branded calcium channel blocker, even though guidelines might say use the generic diuretic first or a beta blocker or some older medicine. But there is a conscious reason why I opted for a different drug, even though it might not have met formulary guidelines or the economic considerations of my health plan.

The other thing that concerns me as a physician, just as sort of a follow-up point, is not only the generic substitutions that can be made that don't take into considerations these kinds of individual concerns that a doctor might have for a specific patient, but also the way formularies lump drugs and lump classes of drugs—for example: saying that all lipid-lowering statins are the same. Well, doctors know they are not the same, and there might be a reason why you want to start with a more expensive statin, because it might be a higher potency—or lumping together categories of drugs called ASE inhibitor with ARBs, which some formularies do. For a certain percentage of patients, they have very real differences, and you might be making a very important therapeutic decision, putting a patient on one drug over another. And so that concerns me as well when you look at formularies.

Ms. BONO. Thank you very much. Mr. Chairman, I think my time is about up. I shall yield back.

Mr. BILIRAKIS. The Chair thanks the gentlelady. Mr. Allen to inquire.

Mr. ALLEN. Thank you, Mr. Chairman. I also want to thank Ms. Baldwin for allowing me to go a little bit out of order.

I want to thank all of the panelists. I did want to say to Ms. Jaeger, thank you very much for your comments about CAFTA and about trade-agreements in general. This has been the hidden story of our trade negotiations. And I believe that what the USTR tried to do in Australia was really unconscionable—that is another whole story—and that you need to look at CAFTA and what we did in Guatemala, successfully getting the Guatemalan legislature to reverse itself and give five to more years of exclusivity in that law, there, which will simply prolong the ability to bring generics to the Guatemalan market.

I did want to turn, however, this whole question of comparative effectiveness and make a couple of comments and then ask Dr. Perry a little bit about how it is working for Kaiser Permanente. One of the problems we have is that there is so little information that is not pharma-funded about the effectiveness of the drugs. And we see the ads just flood our television airways, and that is what some people are using to make their decisions. And so we now have, in the last Congress, we got $15 million.

I will turn to that right now, since it is there. I will divert for a moment to this. One point I wanted to make in the course of this hearing was to say that when we talk about generic substitutions, they are of great usefulness. But remember: of the top 50 best-selling drug—the top 50 drugs by sales in the United States—three have generic substitutes. Three. So we have a long way to go to manage the healthcare costs of our pharmaceuticals, but generics can help. Thank you. That is very good. Generics can help.

You know, the Department of Defense just earlier this month announced that it will stop paying for Nexium, which we all know as the healing purple pill from the TV ads. It was the most heavily advertised drug in 2004, and the Pentagon, like others, need to steer people and physicians away from these very expensive me-too drugs that frankly have no significant medical advantage but cost much more than available generics.

So Joanne Emerson and I, last year, had a bill for $75 million to go to ARC and the National Institutes of Health for comparative-effectiveness and cost-effectiveness research. Before all of my time is gone, I do want to ask Dr. Perry, because you mentioned the importance of those kinds of competitive-effectiveness studies, from your experience, can you give us some guidance? One, is $15 million going to be enough to do the job? And two, is there any light you could shed on your own experience with doing comparative-effectiveness undertakings? I gather you have got regional committees to review drugs that treat the same condition.

Mr. PERRY. In Kaiser Permanente, the pharmacists and the physicians use as much evidence as is out there to determine formularies and information for physicians and information for members and patients, and we heavily use the comparative-efficacy studies. Where they exist, we really use them, but they don't exist in enough areas.

I shall give you an example. As I was flying up from Atlanta, I was reading my medical magazine, my literature, and there is an ongoing controversy with the very drugs that Dr. Gottlieb was saying. The more expensive drugs in the United States studies reduce heart attacks. Now, there is a British study that says it increases heart attacks. We need to know that information because it is very important for us, but also, we need to know that, or just think of the impact on Medicare Part D and the impact of both the cost of drugs and what is the long-term outcome.

So we have these controversies, these areas where we don't know, in major areas like cardiovascular disease and diabetes, and we need to know that because it has such a profound impact. And we do, very rightfully, spend, I think it is over $35 billion in NIH and some of it on primary research, and it is going to have, hopefully, more therapies evolve, but until we know which one is the

right one, there are going to be tremendous impacts, so I think that $15 is very small, given the magnitude of the impact on us, and on Medicare, and on the patients and members we serve.

Mr. ALLEN. Thank you. I would just—in conclusion, Mr. Chairman, would just say, you know, this can be a completely bipartisan effort going forward, and I look forward to working with you.

Mr. BILIRAKIS. It would seem that way, wouldn't it, because of all of the opening statements here, and we all seem to be in agreement in general.

I would ask: you made the comment that of the top 50 sellers, only three have generics?

Mr. ALLEN. That is right.

Mr. BILIRAKIS. But I asked Ms. Jaeger, basically, regarding the top sellers, and you indicated that virtually all of them have generics or at least they are in the pipeline or something of that nature. Did I——

Ms. JAEGER. They have applications pending before the administration.

Mr. BILIRAKIS. All right. That is my point.

Ms. JAEGER. The application will be pending, yes.

Mr. BILIRAKIS. Yes.

Ms. JAEGER. And so at some point in time, when the patents expire and the market exclusivity expire for those particular products——

Mr. BILIRAKIS. Okay.

Ms. JAEGER. [continuing] for those particular products, then the generics will come onto the market.

Mr. BILIRAKIS. So generics have been concocted, have been manufactured and what not, and they are in the pipeline.

Ms. JAEGER. Right. And those are the applications pending before FDA on a number of those products.

Mr. BILIRAKIS. All right. Thank you. Thank you. Let us see. Mr. Shimkus?

Mr. SHIMKUS. Thank you, Mr. Chairman. I will be brief. There are three things I want to mention. Obviously, I want to get into the CAFTA debate a little bit just because, one, what this debate on this trade agreement is to lower tariffs, in fact, get our tariffs down to zero. I mean the tariffs into our country by what we import is zero. And what we are trying to do is lower tariff so we can get our agricultural products, and our manufactured goods, and our hi-tech and all that other stuff into these other countries.

And the debate, how this ties to this, is the patent-protection issues because the patent protections are very, very important in our hi-tech communities. I mean when we have trade agreements, we don't want our foreign countries being able to make bootleg copies of our intellectual music or all of that hi-tech equipment, so that is where there is a convergence of this. And so I just throw that out to make sure that we have that part of the record.

Dr. Perry, in terms of generic utilization rates, how important of a factor is it that virtually all pharmacy services are provided in Kaiser facilities by pharmacists that work for your health plan?

Mr. PERRY. I think it is very important in that we have the clinic experts, the pharmacists and the physicians, working together, communicating together on both the high-level policy and on the

care of individual members. So the reason we get higher formulary adherence and higher rates of generic prescribing is the physicians know that they were involved or their representatives were involved in developing the pharmacy initiates. They know that they had expert pharmacy knowledge involved. We use feedback, but it is really a team working together.

Mr. SHIMKUS. Sort of like faith and confidence in the process?

Mr. PERRY. Yes.

Mr. SHIMKUS. And it allows them to be more involved and active in this issue, then.

Mr. PERRY. Yes.

Mr. SHIMKUS. And I would concur with my colleague from Maine. This subject is just very, very frustrating to the average consumer and person in this country. And I was trying to sketch out—I am not going to put it in the record because it is kind of ugly—how this process works. And I have got like six steps: you have an idea; you kind of go to the market; FDA approval; patent; patent extension; generics. Where I think most of us understand that if you are going to do research and development and capital investment, you have got to get a return on that, otherwise you are not going to add new drugs to the market. But I think it is also—we would like for that to end sometimes so that there is a return on the investment, but then you don't game the system.

And Mr. Chairman, even in the last Congress, we were talking about how there was gaming of the system by filing multitude of patents and extensions and long-lasting—and it is my understanding that if you have a patent on a formula, a basic chemical formula for a drug, then that get patented and the clock should start running. And then, for that formula, that basic formula, then the generic should go after that time runs out. Am I misguided in that?

Ms. JAEGER. No, I mean the way this Hatch-Waxman system is setup is that it actually protects innovation, and it balances access, and GPhA supports the balance of innovation and access. So we believe that whether it be free trade agreements or here at home that we need to incentivize the brand industry to do the necessary research—true research—to bring novel products into the marketplace. Where the generic industry sees problems is when pharma companies game the system. On average, blockbuster products have about 10 patents covering their drug product that are listed in what we call the FDA orange book. Well, our system for generic approvals is a linkage concept, which it links the generals approvals with the patent extension.

Mr. SHIMKUS. Can I stop you? I want to ask a question on that because that is really the heart of the—premise of—we all took basic chemistry, and we know there is a basic formula. How can file a multitude of patents on a basic chemical formula? If there is one formula? Now, I know there is going to be long-lasting and encapsulated, that you want to take one pill a week instead of one pill a day, but that would be a different formula. So why don't you file a patent on that single formula? Or how can we allow multitude of filings of patents on a simple, chemical formula?

Ms. JAEGER. Well, in the United States, the patentability requirements are quite broad. We actually have the broadest patent-

ability requirements in the world, and brand pharma will actually patent every attribute of that product as well as sort of——

Mr. SHIMKUS. Define every attribute. I guess that is the issue. If there is a basic chemical formula——

Ms. JAEGER. Um-hum.

Mr. SHIMKUS. So they are also patenting whether it is a round pill or encapsulated or——

Ms. JAEGER. Whether it is a round pill——

Mr. SHIMKUS. [continuing] or it is liquid or——

Ms. JAEGER. Where they will basically patent the process of the product. They will patent how it metabolizes at certain times. They will patent various polymorphs, isomorphs. They will patent their formula, itself, what it is for.

Mr. SHIMKUS. And if they find a difference usage, then they will patent it for the different usage.

Ms. JAEGER. They will patent it for that as well.

Mr. SHIMKUS. Mr. Chairman, I would just suggest that we look at—and it is actually a different committee's jurisdiction. But if you want to patent a chemical a chemical formula, we ought patent the chemical formula and work with the judiciary and not allow all of this gaming of the system through the patent system. And I yield back my time.

Mr. DEAL. I thank the gentleman. Ms. Baldwin?

Ms. BALDWIN. Thank you, Mr. Chairman. This question is for Dr. Perry, but if others want to comment, they should feel free.

Regarding the role of physicians in encouraging the use of generics: one of the major healthcare systems in the district that I represent, Dean Healthcare, has really severe restrictions in place, regarding interaction between physicians and the pharmaceutical representatives. Dean physicians are not permitted to have contact with the pharmaceutical reps or to be given anything—you know, pens, calendars, the knick-knacks, et cetera—other than free drug samples. The interaction is permitted on specific occasions where all pharmaceutical reps are invited to come at a specific place and time, and the doctors can then approach those representatives at that point in time if they choose to do so.

Among other things, this policy has the effect of reducing the numbers of items, like knick-knacks, in a doctor's office that might advertise brand-name drugs, and hopefully it makes doctors and patients more likely to consider generics. I ask what you think about such a policy, whether Kaiser Permanente has any sort of similar policy or is grappling with it, and what sort of impact you think widespread adoption of this sort of policy might have.

Mr. PERRY. Partially, we don't want the distraction of pharmaceutical reps, and the—really should be interacting with the doctor and not with patient. And so we have restricted access to the pharmaceutical representatives in the facilities. All of the medical groups, I know, are moving toward a similar policy about the restriction of the acceptance of gifts and knick-knacks and to have various restrictions on the amount of any type of support for educational activities. So whereas I would have to look directly at the Dean policy and where we are evolving, but I think there are similarities.

Ms. BALDWIN. Any other comments—Dr. Gottlieb?

Mr. GOTTLIEB. I was checking my pockets to make sure I didn't have a drug pen before I answered.

I will say, first of all, I certainly don't see a lot of it where I practice. I practice in a community hospital where there aren't thought leaders, and you know if a pharmaceutical rep comes around with a drug pen, that is about it. There might be other stuff going on with some of the thought leaders in the industry, but I think the industry's own code of conducts have really cut back on a lot of what you might feel would be more egregious kind of handouts.

Where I am a little bit concerned about the idea of putting restrictions on the ability of physicians to access pharmaceutical reps or other scientific resources from the pharmaceutical companies is that it is part of what I am seeing as a general trend in the government to regulate the practice of medicine more broadly. And certainly, the restriction on access to pharmaceutical reps is really a restriction on access to information from the people who have the biggest incentive to try to provide you with that information, and in a lot of cases the information is valuable, and in a lot cases, the information just won't get in the hands of the physician because there is no other party incentivized as strongly to hand out copies of journal articles or copies of treatment guidelines or whatever it might be, which is usually the kind of information that I get passed to me.

I would also point you in the direction of looking at FDA, at the risk-management policies that the FDA has promulgated, where they really put significant restrictions on not only the kind of doctor who can prescribe certain drugs, but when the doctor can prescribe. And this is really a Federal policy to restrict access to medicines based on restricting the physician's access to medicine.

And I think some of the reimbursement policies that are coming forward that tie reimbursement to certain activities on the part of the physician are another intrusion in to the practice of medicine. And so taken as a whole, that alarms me as a physician, and I think the thought of restricting information to a physician and doing away with he presumption that the physician is a learned intermediary and can integrate the information and won't succumb to clever marketing pitches, but use the information in a valuable way, I think that is a of a piece with a broader direction.

Ms. BALDWIN. I should stress that I wasn't suggesting this become a part of law.

Mr. GOTTLIEB. Okay.

Ms. BALDWIN. But you know it is certainly a trend in the industry for policy.

Mr. PERRY. I think it is—in terms of the Permanente Medical Group, we are ensured that physicians have access to the best medical knowledge that is not driven by commercial concerns. And so we will find various mechanisms to do that. And we are also going to make sure that there is nothing from outside entities to interfere with out physicians interacting in an effective manner with our members.

Ms. BERGER. We have actually taken a page from the pharmaceutical manufacturers' books, and we actually have pharmacists who go in and talk about generics with physicians and education them around the generics. So you know, they were successful in

what they did, and we have taken it in a little different route, and that is one of the methodologies. We have between 125 and 150 pharmacists, who go in; educate the physicians around generics, the use of generics, and actually give them specific tools they can use in remembering how to prescribe generics in their practice.

Mr. DEAL. The gentlelady's time has expired. Mr. Ferguson?

Mr. FERGUSON. Thank you, Mr. Chairman. A couple of quick observations—and I don't think my colleagues are here who raised these before.

Mr. Allen was talking about the chart about the top 50 drugs and how so few of them actually have generics. I don't think there is any mystery there. If a drug gets a generic, it is going to fall off the top-selling list. So I don't know what is so illustrative about the chart.

And my friend Mr. Shimkus, before, was talking about gaming the system and the patent business. Obviously, nobody thinks—I think very few of us would say there ought to gaming of the system, but I what is not frequently talked about is half or more of patent life is eaten up before that firm makes dollar-one on that drug. So I think, obviously, no one thinks we should be gaming the patent system, but we should also recognize the fact that the enormous resources, the hundreds of billions of dollars that go into finding these new drugs—that patent clock is ticking as soon as the patent is approved, not when that drug goes on the market. I think that is an important point that ought to be made.

Another point that I don't think has been talked about today is the difference between generic substitution and therapeutic substitution. And I think this is very important to some of the things that we are talking about today. And when we are talking about generic substitution, as we are today, we are not talking about therapeutic substitution.

Substituting a generic copy of a brand-name medicine, which is generic substitution, is wholly different than therapeutic substitution, which is substituting one medicine—whether it is a brand or generic—for another different medicine. Generic copies of brand-name drugs are not equivalent to all brand-name medicines in the same class. Even within a class of drugs that work in the same fundamental way, drugs can have different indications and side effects for patients, even patients who are suffering from the same condition.

Because of the differences between medicines within in a class, encouraging patients or forcing patients or coercing patients to change medication, particularly to one that has not shown an effectiveness in treatment of that patient's condition, could result in a harm to that patient's health.

And that is where I want to ask Dr. Gottlieb: we have heard that characteristics of a patient may affect how a given medicine works and that use of a different medicine may have bad effects—in fact, can disastrous effects. Can you give us an example or two, or do you have any experience in this regard, of instances where two medicines cause a different reaction? And maybe tell us a little bit about how severe those reactions could be.

Mr. GOTTLIEB. Absolutely. And I touched briefly on this point before, when I was talking about that—not just generic substitutions,

but the way plans design their formularies by lumping different classes of drugs together for the purposes of lumping a new class of drugs, perhaps, with a class that has some older, generic alternatives that you could then opt the patient onto.

A good example of this is the ASE inhibitors and the ARBs, two classes of antihypertensive medication that for most patients probably have similar benefits if you are prescribing it just for blood pressure lowering. But for certain patients, those drugs have quite different profiles. There are reasons why you might want to prescribe one to a diabetic patient with certain kidney problems.

But even when you look in the existing classes of drugs, like statins, for example, lipid lowering statins, you see high-dose statins and low-dose statins. You see statins that work in different ways and are co-formulated with different molecules. And there are very good reasons why, as a physician, you would opt to put a patient one drug versus another, and the decision is being made at the formulary level, and the designs of a lot of formularies at lot of plans really are taking away that kind of decisionmaking.

So it is not just a question of whether or not the plan is going to put you on the new calcium-channel blocker versus the old calcium-channel blocker, that are largely equivalent molecules—or in fact, the same molecule because it is just a generic version of the branded drug—but the decisions that are being made are the decisions that you pointed to, which are decisions to substitute drugs that are either in another class or within the same, broad class, but in fact, have much different profiles. And the examples in medicine are just as countless where for a certain percent of patients, the different drug will make a difference. You know, we always say for 95 percent of patients or 90 percent of patients, it might not matter; but the 5 or 10 percent of patients who it does, that is where you want to have very easy ways to opt around the kinds of restrictions that the plans sometimes put in place.

Mr. FERGUSON. Dr. Berger, how does this work in practice? How does therapeutic substitution work in practice? Are there incentives that you offer to either doctors who are prescribing the drugs or to pharmacists who are filling the prescriptions with regard to therapeutic substitution?

Ms. BERGER. No, there are no incentives. We do, in some classes and in some cases, do therapeutic substitution, where we call the physician and ask them would this be a clinically appropriate consideration for them. But as I said earlier, at the end of the day, it is always the physician's decision because they do know the patient best.

Mr. FERGUSON. Is there a tone of voice in that call?

Ms. BERGER. What? What was that?

Mr. FERGUSON. I said is there a tone of voice in that call?

Ms. BERGER. No, and actually we have team that oversees to make sure there is no tone of voice. The other thing, I want to take a step back——

Mr. FERGUSON. So there is an accent, but no tone of voice?

Ms. BERGER. There you go. The one thing I do want to say and take this a little further is any of the activities that we do, including requests for therapeutic substitution, go through our P&T Committees, our Pharmacy and Therapeutics Committee, which is a

100-percent external committee to anybody within Caremark. It is physicians across specialty, across the country. It is pharmacists. It is a dean of a pharmacy school. And they make the decision that this is a reasonable question to ask. Then, that goes forward in those cases to the physician to say is this reasonable, and the physician makes the decision. The physician is not incentivized, nor is a pharmacist, into doing anything different than what they feel is appropriate.

Mr. FERGUSON. And is this your policy in your practice because you recognize the risks of therapeutic substitution and the problems that that can cause?

Ms. BERGER. We feel it is the clinically correct way to go.

Mr. FERGUSON. Thank you, Mr. Chairman. My time is just about up, but I just wanted to, again, stress that as I understand it, this is not wise. It is in many cases, as we have heard, a dangerous practice. And certainly, we should be making sure that folks who are in the business, as you are—a crucial position of being a part of that decisionmaking chain about what medicines patients end up getting, that we make sure that we really draw this distinction on a policy level and a practice level, the difference between generic substitution and therapeutics.

I thank you, and I yield back.

Mr. DEAL. Thank the gentleman. Mr. Strickland.

Mr. STRICKLAND. Thank you, Mr. Chairman. I think the reason that so many of us love this committee is the fact that what we discuss here effects, directly, the lives of our constituents.

Dr. Gottlieb, you said a few moments ago that—you made reference to the fact that you may be concerned that government is starting to interfere with the practice of medicine. And some years ago, we had a TV ad where a sweet lady with white hair said, "I don't want the government in my medicine cabinet." But I think we don't want the pharmaceutical companies determining what is in our medicine cabinet or the insurance companies determining what is in our medicine cabinet either. We want our physicians making that decision.

Which leads me to my experience with my 79-year-old sister last weekend, who had a blood pressure problem, and she gets her medicine through the mail, and it didn't show up as it was scheduled to show up, and so when she puts through a call she was told that, we no longer pay for that medicine. We asked your doctor if he would agree to a substitute; he said no. And then, they asked her—they said, do you want it, because you will have to pay for all of it. And she said, well, of course, if my doctor wants me to take it, I want it. So I think there is problem out of the hands, away from the judgment, of those who are capable of making the decisions.

In my own case, with the statin medication—I took a statin medication for cholesterol for over a year, and it did nothing to lower my cholesterol level. And then I was changed to another one, and immediately, it was dramatically lowered, with no change in my behavior or my eating habits. I don't know how to explain that. Maybe you can as a physician.

But having said those things, I have one particular question, and I think this has been answered to some extent, but I want to make it as crystal clear as I can. Name-brand companies can diminish

generic drug companies incentive to challenge patents or to develop the generics by marketing virtually identically versions at a lower cost, thereby directly competing with a company that has developed the generic by using the so-called authorized generic drugs. Now this, obviously, would have a disincentive for companies to pursue the development of a generic drug.

In your opinion—and any of you can answer this. But in your opinion, do authorized generics impact the incentives to develop what I would call true generic drugs? And if that is the case, what can we do about this? And if we do nothing, what will be the result?

Ms. JAEGER. I shall take that question.

Authorized generics are basically brands masquerading as generics, and they do come in and they are tying to compete with the generic. And what they are doing is devaluing the 180 days of generic exclusivity, and that is the exclusivity that is rewarded to the generic company for challenging those patents and being successfully in going to the marketplace.

But if a generic company is not guaranteed that 180 days, they are going to have to look long and hard about how many challenges they bring in the future. Now, there may be a short-term gain, and the opposition will say, you are getting some competition; but it is the long-term consequences to our healthcare system that are at stake here. And so we believe that authorized generics, the whole process, should be stopped, and 180 days exclusivity should be just that, excusive, exclusive for the generic manufacturer.

Mr. STRICKLAND. Do the others agree with that answer, or do you take exception?

Ms. GOTTLIEB. Well, I am by no means an expert in this area. But you know it should be noted, just generally, that a lot of the recent court cases have gone in favor of the branded companies on their policy here. I understand Ms. Jaeger's position and have heard some of the criticisms of the FDA's own posture in this area, but the court cases have spoken pretty clearly about whether or not the branded companies have the ability to do this as a commercial activity.

Mr. STRICKLAND. Anyone else? If not, I would just like to say, Mr. Chairman, that this may be something that we need to address because I think it gets to the very heart of whether or no generics are going to be incentivized. And if they aren't, they are not likely to be developed. And if the courts are making certain decisions, perhaps it is appropriate for us to consider legislation——

Mr. DEAL. Would the gentleman yield on that?

Mr. STRICKLAND. I would yield.

Mr. DEAL. I think there is an amplification of that issue that Ms. Jaeger touched on in her opening statement. It might deincentivize that.

As I understand it, you are advocating that these alternative generics be included in the computation of the best price, which would significantly change the rebate formulations that are used. Is that correct?

Ms. JAEGER. That is correct.

Mr. DEAL. That is a complicated question. If you would like her to explain what it meant, I shall be glad for her to do it on your time. I think we have got a little bit left.

Mr. STRICKLAND. You want her to tell you what you asked.

Mr. DEAL. Tell what I just said; that is right. But you would agree with that?

Ms. JAEGER. And Mr. Chairman, we also just wanted to correct the record. Our industry does challenge patents, and for the most part—the FTC put out a report a couple of years ago and said that the generic industry did prevail in about 75 percent of the cases they actually brought into court. Now, we certainly don't win on every patent, but the vast majority we do actually win on. And so a lot of these patents are not the basic compound patent; they are not the formulation patent; they are not the indication of use patent. There are actually peripheral patents out there that are actually just needless barriers to generic entry. And so it is imperative that the generic industry be able to challenge those patents and be rewarded. Otherwise, the companies decide not to take on those challenges; they sit on the sideline; and we have just given the brand company de facto patent extension. So again, that would be very, very harmful to the healthcare industry.

Mr. DEAL. Thank you. Ms. Myrick?

Ms. MYRICK. Thank you, Mr. Chairman. And thank you all for being here. I am sorry I missed your testimony, but we have got the written one.

And I have got a question on something that Dr. Gottlieb had said, and really if Dr. Berger or Dr. Perry or both of you want to answer—and it is related to brain disease drugs—or some people call them mental disorder drugs. But Dr. Gottlieb, I understand that in your testimony you stated that, in general, generic use among people with a brain disease has been relatively low. Is the low generic-substitution rate due to the physical differences between the brand-name and generic drugs, or would you say there are other factors that make brand names more prominent for mental health-type prescriptions?

Mr. GOTTLIEB. I am actually not sure that the mix between generic and brand drugs in the different—at least in depression, I would imagine that it is exactly as you state, that the overwhelming use is in branded drugs. I think there are certain areas of medicine where the prescriptions choices of physicians are more finely tuned to the patients, and mental health happens to be, perhaps, at the top of the list or near the top, maybe with the exception of cancer and some very specific diseases, because the drugs, by and large, within the classes have subtly different profiles that become very important in trying to match the drug to a patient's particular tolerance. So for example, Prozac might have more sexual side effects than a newer drug, and you might not want to give it to a young patient if you are worried about compliance. Some of the typical antipsychotics might have a greater propensity for patients to gain weight. You might not want to give one to a patient who is worried about weight gain. One of the typical antipsychotics that is used to treat schizophrenia is more sedating, so you might want to give it to a patient who is more agitated. One of them, I

know, makes you more agitated, so might want to give it to a patient who is sedated.

And so these become very subtle choices that the doctor needs to make, and by and large, since you don't have a lot of generic drugs in these classes, if you are going to make very specific prescription choices, closely matched to the patient, you are not going to just push everyone toward the generic drug, just for economic reason in this kind of a therapeutic category, where you are really considering the patient's characteristics in how you are prescribing.

Ms. MYRICK. Is it possible to make nearly exact generic copies of some of these drugs?

Mr. GOTTLIEB. Well, most of—I am thinking of the typical antipsychotics. They are all on patent. The older antipsychotics are off-patent, a drug like Haldol, but has a very different safety profile than the newer ones, the ones that are called atypical, so most physicians wouldn't want to use it as a first-line agent, except in specific circumstances.

And with the SSRIs, selective serotonin reuptake inhibitors, for example, there are—there is a drug off patent. There is more coming off patent. But again, the drugs have very specific characteristics, so there might be a reason that you might opt, in that kind of a therapeutic class, for some of the branded drugs, even though the generic exists, because the branded drug might have a slightly different profile.

So when the patents are up on the entire class, certainly, but right now, a lot of those drugs are still under patent protection.

Ms. MYRICK. For the other doctors: is this, when you have to deal with this type of thing, with a brain disease type of a problem, do most doctors take this into consideration when they are prescribing, and do most insurance companies literally accept that? Or is there a challenge with the insurance companies saying, well, I shall pay for Zoloft, but I won't pay for Prozac or something like that—because I know exactly what Dr. Gottlieb said. There really is a difference in how they affect, and there is so much trial and error in this field anyway, and if you find one that works, it is really a challenge, so——

Mr. PERRY. Let me speak to the most common mental health issue, and that is depression. And we do, in depression, have, I believe, three of the drugs that are now generic, and we also have brand drugs to treat depression.

In a large review of multiple studies that was done recently, the conclusion was that you did need to have a range, but there was no one magic bullet; that it is perfectly permissible to start with one of the generics; and some people will respond to that; and about 20 percent of people will not. And then you can try another generic, and some will respond and some will not. You can go to a more expensive brand drug, and about the same percent will respond and the same percentage will not.

Ms. MYRICK. Really?

Mr. PERRY. And so what we have done with our formulary is have a range of options. We do encourage the generics, but we have a range of options, knowing that people respond differently. And so I thin it is perfectly permissible, if you know your patient, to start

with a generic, but there are some people that you ay not. But again, I think a generic strategy is a ration way to go.

Ms. MYRICK. Would you agree?

Ms. BERGER. Absolutely. It is the same way that Caremark looks, especially at the antidepressant area. And we have found that as we educate physicians that there are generics in that class and to begin with them, we are seeing a greater uptake on the use of generics as a first line——

Ms. MYRICK. Right.

Ms. BERGER. [continuing] with the knowledge and great success. But we also don't tend to intervene once somebody is stable on an antidepressant, asking them to go to a different generic.

Ms. MYRICK. Thank you very much. I yield back, if I have time.

Mr. DEAL. I believe you had another response. Would you indulge his response on that? Dr. Gottlieb, if you wanted to make a comment?

Mr. GOTTLIEB. I was just going to make the observation that in some areas of medicine, you only get a limited opportunity to get the patient feeling better or else they fall out of your care. And this is one of those areas of medicine where you have a very—and with a lot of patients, you have a very narrow window to get it right because if they don't feel like they are getting better, they just won't—they will fall out of treatment. So if you think that you are making a decision where you are matching a drug closely to the patient, you would want that to come into play right away and not have to be forced into a certain treatment paradigm, just on economic considerations.

Mr. DEAL. That is where you said you do not think the Fail First approach is not appropriate here?

Mr. GOTTLIEB. No, not here. I think that the overwhelming evidence that I have looked at is that Fail First in this realm could, in fact, end up increasing cost instead of saving it, and not maximize overall public health benefit.

Mr. DEAL. Thank you. Mr. Shadegg?

Mr. SHADEGG. Thank you very much, Mr. Chairman. I want to begin by saying thank you to the panel. This is phenomenally complex. I am sorry I wasn't able to be here at the beginning for your testimony.

It is difficult, sitting here, to know how to proceed and how to do what is right for the consumer. I personally feel that the No. 1 consideration ought to be the recommendation of the physician; but that ought not to be influenced improperly by a formulary. Yet I think a formulary that guides both physicians and patient to the least expensive, effective drug is the right thing to do. And so it seems to me that it is very difficult to find that precise balance. I also would want to encourage the use of generics where they can be used effectively.

Dr. Perry, Dr. Berger described the process by which her company goes through making a decision to allow someone to use something that is not on a formulary and trying to make sure that that decision is ultimately made by the physician. Do you agree with—does your company operate in the same fashion?

Mr. PERRY. Let me describe how we operate.

Mr. SHADEGG. Okay.

Mr. PERRY. And I think that would be the best. We do have a large formulary; there is one formulary. So the advantage of being a Permanente physician is that there is only one formulary that we have to deal with. And I do hear my colleagues out in the general medical community when they have six or seven or eight they have to deal with. But there is one formulary, and it is a large formulary.

But when the physician wants to prescribe a non-formulary drug, our process is that he or she writes that medication out—I am talking about our process in my medical group—and a 30-day supply is given, no questions asked. And then, the physician is asked to submit some documentation on the reasons why that prescription was written, and again, very high approval rate on this exception process because our physicians already bought into the formulary. They know their representatives developed it. It was evidence-based; it was based on the literature. And so when they write that prescription, there is usually a very good and rational reason, and so we have this exception process that is not a pre-approval process.

Mr. SHADEGG. Ms. Berger, does that parallel what you do, then?

Ms. BERGER. No. Because of our formulary being what we would call an open formulary, every drug is available. If it is FDA approved, it is available to the participant. What their out-of-pocket cost is is what is the alternatives of drugs——

Mr. SHADEGG. It is a variant?

Ms. BERGER. [continuing] on the formulary—so it is a varied—you know, whether you want to call it tiered or varied methodology of out-of-pocket cost, and that is determined by our clients, by the health plans or the employers who chose to utilize Caremark.

Mr. SHADEGG. Two things concern me. One is doctors who want to keep the plan happy so they never write a script out of the formulary because they just want to keep the plan happy because they figure keeping the plan happy is the way to stay employed. And sometimes, there is a danger that the patients' health becomes secondary to that factor. That is one that concerns me.

The second one that concerns me is demand-pull advertising. And you know I am a First Amendment guy, but I have some real problems with demand-pull advertising, and I guess I am interested in how you see that affecting what you do each day and how you get the doctors—the doctors I know tell me that they have to fight demand-pull advertising with patients who come in and say, well, I need this drug. And then they have to get into an argument with the patient about whether or not, in fact, they need that drug. Do you have a comment?

Ms. BERGER. It is a challenge. We do—again, getting back to those 150 pharmacists that we utilize to sit with the physicians and educate them. We use that as an alternative way of educating physicians and supporting them when the patient does come in and say, I saw X on TV, and I want that. And so it is a big issue.

I think the one other thing that is a hard challenge—at the end of the day, generics are very patient-friendly because the No. 1 reason we hear people don't take their medicine is it costs them too much. And so if we can find the methodology where it costs them less—and you know, Dr. Gottlieb talked about people staying ad-

herent or compliant to medicine. If we can find ways to get the medicines that they can afford to stay on—you know. And that is the thing we try to work with the physicians on because most of us as physicians, including myself, don't have a clue how much the drugs cost or how much each of our patients are paying for each drug that we are writing for. And so that is a challenge.

Mr. SHADEGG. Dr. Perry, what impact do you see form demand-pull advertising?

Mr. PERRY. Let me speak as a physician first. I understand what your friends are saying. It really is when you are trying to deal with somebody's diabetes, what they want to talk about is the ad they have torn out of the paper, and you are talking about getting them to have better diabetes control. So it is a significant issue. And we try to interact by having great patient-education material, helping our Permanente physicians with those difficult conversations, so they can take what is the desire of the member to get better and focus it away from the ad and focus in on how do I improve my own care? So we have course; we have classes. We have ways to try to build that skill, but it does have a significant impact when I am sitting in front of a patient.

Mr. SHADEGG. Dr. Gottlieb did you—it looked like you were jumping to make a comment.

Mr. GOTTLIEB. Well, I have certainly heard the concern that you are expressing when I was at FDA, and we undertook studies during that time, before that, and since to look at what impact advertising was having on the doctor-patient relationship and the predilection to use certain drugs, and the overwhelming evidence that FDA was able to accumulate in its own survey data was that most physicians didn't really feel it was an intrusion into their relationship with the patient or a significant burden on their time. And that was offset by significant evidence that advertising drove patients into the physician's office and prompted them to seek treatment for things that might not have otherwise been aware of, and that was a significant, overall, public health benefit.

Now, that said, there are probably things that we can do to try to create a regulatory environment that allows for, if not encourages, the creation of more ads that are diseased-focuses, that are help-seeking, that encourage patients to be aware of specific conditions and away from advertising that just might be more promotion in nature for a specific product and doesn't have an educational component, but that is a function of the way in which advertising is regulated, I think, to be looked at.

But to certainly think of limiting the adverting, I think the public health argument there would be that it would probably do more harm than good.

Mr. SHADEGG. I thank all of you. I am way beyond my time. Thank you, Mr. Chairman.

Mr. DEAL. Thank you. And once again, thanks to all of the panel members for your patience with us. And we have had fairly good attendance. We just come and go like the weather sometimes.

With Mr. Brown's indulgence, I would like to raise one issue—and I don't expect it to be answered here, but I feel sure your association might want to provide us with a written response to it.

My concern is the TEVA case—I guess it is—that, as I understand it, is not appealed to the Supreme Court. As I understand that case, it says that the fact that a drug is in the orange book list, and somebody has come in with a generic application in the 45-day window period and no suit has been file, that the fact that there is a patented drug out there, that that in and of itself does not create sufficient controversy for a declaratory judgment action.

I think our intention was that it would be a situation where declaratory judgment would be proper. Otherwise, the generics operate under the cloud of a trouble/damages lawsuit down the road.

Would you be so kind—and any of you who else might have some involvement in that—would you be so kind as to provide us some insight as to what the impact of that might be and what solutions, if any, might be appropriate?

Ms. JAEGER. We'd be absolutely thrilled to do that, sir.

Mr. DEAL. And also, in conclusion, I want to thank Mr. Brown for his being here for the hearing. He was here longer than I was today. I had to go to the floor. I apologize for that.

There are certainly things that we did not cover that are very closely related to your testimony today, and biogenerics being one of those. And with Mr. Brown's cooperation and assistance, I would look forward, maybe, to having a hearing that would focus on that particular issue. It is very different. It is more complex, and solutions might be more difficult to arrive at. But I do think it is a timely issue, and perhaps, we can work together to have a future hearing on that, and some of you may be invited back for that one.

But for this, for today, thank you very much for our attendance in our hearing.

Ms. JAEGER. Thank you.

Mr. DEAL. The committee is adjourned.

[Whereupon, at 3:24 p.m., the subcommittee was adjourned.]

[Additional material submitted for the record follows:]

PREPARED STATEMENT OF NATIONAL ASSOCIATION OF CHAIN DRUG STORES

Chairman Deal and members of the House Energy and Commerce Committee Health Subcommittee, the National Association of Chain Drug Stores (NACDS) is pleased today to offer our perspective on the value of generic pharmaceuticals, their potential to achieve significant cost savings in the U.S. healthcare system, and the role of community pharmacists and chain pharmacies in helping to address the rising cost of prescription drugs by encouraging use of generics.

The National Association of Chain Drug Stores (NACDS) represents the nation's leading retail chain pharmacies and suppliers, helping them better meet the changing needs of their patients and customers. NACDS members operate more than 35,000 pharmacies, employ 108,000 pharmacists, fill more than 2.3 billion prescriptions yearly, and have annual sales of over $700 billion. Other members include—almost—1000 suppliers of products and services to the chain drug industry.

THE VALUE OF GENERIC PHARMACEUTICALS

The United States health care system values the contributions made by brand name pharmaceutical companies in providing the innovative therapies that many of us rely on to maintain life and health. Brand name pharmaceuticals are priced at a premium, in part, to help brand name manufacturers pay for their research and development costs. Alternatively, prices for generic drugs are typically much lower because generic drug makers do not face the same developmental costs as do brand name drug makers.

In contrast to the brand name drug market, where there may be a single source of supply, and pharmacies are "price takers", in the generic market, retail pharmacies are "price makers." As more and more versions of generic drugs are approved, retail pharmacies create the competitive pressures that force generic manu-

facturers to compete on price, lowering the overall generic prescription prices for cash paying individuals, as well as public and private payers.

In 2004, the average price of a brand name drug was $96.01, while the average price of a generic drug was $28.74—roughly 30 percent of the average brand name price.[1] Generics in the United States are also competitively priced relative to drugs in other countries. An FDA analysis compared the seven most often used generic prescription drugs for common chronic conditions in the United States. For six of the seven drugs, the generics were priced lower in the United States than the brand name versions in Canada. Five of the seven U.S. generic drugs were also less expensive than the Canadian generics.[2]

GENERIC PHARMACEUTICALS OFFER DRAMATIC SAVINGS

Simply based on the average prices, use of generic pharmaceuticals instead of their brand name equivalents clearly is a cost-effective way of achieving savings in both private and public health care programs. Seventy-three percent of drugs listed in the FDA's Orange Book have generic counterparts.[3] In recent years, generic versions of a number of leading prescription drugs have been introduced. Today, roughly half of all prescriptions are filled with generic drugs. However, in 2004, brand pharmaceutical sales in the United States totaled $235 billion while generics accounted for just $18.1 billion in sales.[4]

Given the volume of generic drugs on the market today, it might be assumed that the percentage of all prescriptions being dispensed with generic equivalents—as well as spending for generics—might have increased. However, both percentages have remained relatively flat over the last few years.

Prescription growth for generics remained at 10 percent in 2004 for the third straight year and sales of generics constituted only 8 percent of U.S. prescription drug sales.[5]

Similarly, although many state Medicaid programs have passed laws mandating the prescribing of generics,[6] data from the Centers for Medicare and Medicaid Services reveal the average state Medicaid generic dispensing rate was still only about 51 percent for the 12-month period ending September 2004. Generics accounted for less than 17 percent of all Medicaid expenditures for prescription drugs over that period. States can increase their use of generics by implementing step therapy programs in the appropriate cases where a lower-cost generic might be tried first instead of a higher-priced brand name drug. We believe that there are significant savings to Medicaid from adopting step therapy approaches used by the private sector, and we will be discussing these ideas with policymakers during the upcoming Medicaid debate.

A 2001 study by the Center for Pharmacoeconomic Studies at the University of Texas estimated that a 10 percent decrease in the rate of brand name dispensing would save $16.6 million across Texas each year.[7] Given continued growth in drug prices and utilization, even greater dollar savings could be achieved today. The FDA estimates that drug costs per day for "typical" patients can fall by 14 to 16 percent if patients use generics instead of branded drugs, depending on their medical needs, while patients whose needs can be fully satisfied with generics could experience reductions of 52 percent in the daily costs of their medications.[8]

Generic drugs can also help slow the annual increase in drug spending. A recent GAO study found that average usual and customary prices for brand drugs increased about three times faster than for generic drugs. Between January 2000 and June 2004, average prices for 52 frequently used brand drugs increased by 26.4 percent, a 5.5 percent average annual rate of increase, while prices for 47 frequently

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[1] NACDS, Industry Facts-at-a-Glance, on the Web at http://www.nacds.org/wmspage.cfm?parm1=507. Last accessed May 16, 2005.

[2] FDA Consumer Magazine, July-August 2004.

[3] Generic Pharmaceutical Association (GPhA), "Generic Pharmaceutical Facts at a Glance." On the Web at http://www.gphaonline.org/aboutgenerics/factsabout.html. Last accessed May 16, 2005.

[4] IMS Health

[5] *2004 Year-End U.S. Prescription and Sales Information and Commentary,* IMS National Sales Perspectives, February, IMS Health, 2005.

[6] *Medicaid Outpatient Prescription Drug Benefits: Findings from a National Survey, 2003,* J.S. Crowley, D. Ashner, and L. Elam, Kaiser Commission, 2003.

[7] *Estimating the Economic Impact of Increasing Generic Substitution of Multi-Source Brand Name Prescription Products in Texas: Policy Report,* Center for Pharmacoeconomic Studies, The University of Texas at Austin, May 2001.

[8] FDA Center for Drug Evaluation and Research, "Savings From Generic Drugs Purchased at Retail Pharmacies' On the Web at http://www.fda.gov/cder/consumerinfo/savingsfromgenericdrugs.htm. Last accessed May 16, 2005.

used generic drugs increased 8.3 percent, a 1.8 percent average annual rate of increase.[9]

Potential savings from generic substitution should significantly increase when several high-volume brand name drugs come off patent between now and the end of 2007. For instance, top-selling brand name drugs Nexium (GERD/ulcer), Pravachol, Zocor (cholesterol), and Zoloft (antidepressant) are all expected to come off patent. The experience with Prozac coming off patent in 2001 indicates that the first generics arriving on the market can be expected to cost at minimum 30 percent less than their brand name equivalents. Once additional generics enter the market, the market price for the generic versions of these drugs will likely be about 60 percent less than the price of the brand name drugs.

Scheduled Patent Expirations with Significant Generic Substitution Opportunity

Brand Name	Generic	Manufacturer	Approximate $ Sales	Scheduled Patent Expiration	Purpose/indication
Zofran	ondansetron	GlaxoSmithKline	$800,000,000	2005	Prevents nausea in chemotherapy
Prevacid	lansoprazole	Tap Pharma	$4,000,000,000	2005	Gastrointestinal distress
Zithromax	azithromycin	Pfizer	$1,506,000,000	2005	Macrolide antibiotic
Pravachol	pravastatin	Bristol-Myers-Squibb	$2,000,000,000	2006	High cholesterol
Zoloft	sertraline	Pfizer	$2,250,000,000	2006	Antidepressant
Lamisil	terbinafine	Novartis	$646,000,000	2006	Nail fungus
Risperdal	risperidone	Johnson & Johnson	$2,200,000,000	2007	Anti-psychotic
Norvasc	amlodipine	Pfizer	$2,000,000,000	2007	Hypertension and angina

SOURCE: NFM Research, 2004, published in Drug Store Management, August 2004.

THE ROLE OF PHARMACISTS, PHARMACIES IN ENCOURAGING GENERIC USE

The FDA and many insurance plans provide consumers with materials encouraging them to contact their physician or pharmacist for information on generic drugs. Given their expertise, pharmacists can be valuable resources for physicians and health plans in determining appropriate treatment and encouraging generic utilization. Pharmacists work with patients and insurers in many different ways to encourage generic use.

We believe that the economic incentives for pharmacists to dispense lower-cost generics must be aligned with the interests of health plans, patients, and payers. For example, many plans encourage the use of generics by requiring lower cost sharing on generic drugs as compared to brand name drugs. Some are waiving the copays for generics. Some plans provide an increase in the dispensing fee for pharmacies to dispense a generic drug rather than a brand. Other plans have created contests to encourage pharmacists to dispense generics. Some plans are providing generic samples to physicians so that patients start on generics rather than brand name drugs. All these initiatives help increase generic drug use and help lower the rate of growth of prescription drug spending.

Obstacles to Increased Generic Use

While pharmacists in community-based practice settings work with patients and physicians to maximize the use of lower-cost generics when they are available on the market, there are many factors that affect the ability of pharmacists to dispense generic equivalent drugs. Efforts to encourage greater use of generics may be limited by several factors. Despite holding generally favorable views concerning generics, physicians may be less likely to prescribe them due to familiarity and trust in brands. Some consumers express a reluctance to use them because of misunderstandings about safety and efficacy. Patients may not be aware that a generic may be available to treat their condition, particularly when the generic is a different chemical entity (a therapeutic alternative) from the medication prescribed.

Extensive direct-to-consumer advertising and physician-centered marketing by brand name pharmaceutical manufacturers likely influence prescribing patterns. Surveys have shown direct-to-consumer advertising to be a substantial driver of consumer preference, with over 50 percent of patients asking their health care pro-

[9] GAO, "Prescription Drugs: Trends in Usual and Customary Prices for Drugs Frequently Used by Medicare and Non-Medicare Enrollees" GAO-05-104R (October 6, 2004).

viders to prescribe drugs seen on television.[10] Sales forces and marketing efforts targeted at physicians also tend to be much bigger for brand drugs.

The rebates paid by the manufacturers of the more expensive sole source, brand name drugs to PBMs and third-party payors may create incentives for those payors to switch consumers from inexpensive generic equivalents—for which the payor does not receive a rebate—to sole source, brand name drugs for which a high rebate is paid. The purchaser may perceive greater savings from use of brand name drugs because of rebates.

Pharmacy benefit managers (PBMs), which manage the drug benefit for most people with private health insurance, also may have disincentives to promote the use of generic drugs if they make more money from the rebates from brand name drug manufacturers. Because PBMs draw a significant portion of their income from rebates, this switching could result in a significant over-utilization of sole source, brand name drugs and under-utilization of generic drugs. Similar incentives may apply to mail order pharmacies, some of which are owned by PBMs. Many consumers using mail have chronic conditions and are more likely to fill the same prescription again and again and may not be informed if a generic becomes available. Retail pharmacies tend to switch patients to generics as soon as they become available.

This clearly lowers health care costs for those that are uninsured, as well as those who are insured because the insured usually pay lower copays for generic drugs as compared to brand drugs. As a result, community pharmacies dispense generic drugs in about 50 percent of all prescriptions filled, while the generic prescription rate for mail order prescriptions is only about 37 percent.[11]

We are also concerned, as public news reports have suggested, that some PBMs may not pass along all the savings from generics because they charge the plan a higher price for dispensing a generic than they would pay the pharmacist for dispensing the generic. The plan keeps the spread, which should have been passed through to the payer and the patient. This is an issue that Congress should closely monitor as the new Medicare Part D prescription drug program is implemented.

Summary

With expenditures on health care costs increasing, it becomes ever more crucial to maximize the substitution of generic drugs.

Emphasizing the broad use of generics should yield significant cost savings to the prescription drug plans participating under Medicare Part D, and in turn to the federal government, particularly over the next three years as a number of top-selling brand name drugs lose their patents.

We appreciate the opportunity to submit a statement for the record, and look forward to working with the Committee on policies that make generic drugs more available and affordable for patients.

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[10] *Influence of Patients' Requests for Direct-to-Consumer Advertised Antidepressants,* Richard L. Kravitz, M.D., MSPH et al., *Journal of the American Medical Association,* April 27, 2005, Vol. 293, No. 16.

[11] IMS Health Data, January 2003.

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