Testimony of

Ms. Kathleen Jaeger

President and CEO
Generic Pharmaceutical Association
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Testimony to the
Senate Judiciary Committee
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EXAMINING THE IMPLICATIONS OF DRUG
IMPORTATION
Kathleen D. Jaeger
President & CEO
2300 Clarendon Boulevard Arlington, VA 22201
Ph. 703-647-2480 f. 703-647-2481
www.gphaonline.org
GPhA Testimony: Senate Judiciary Committee Hearing on Drug Importation
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Mr. Chairman, I am Kathleen Jaeger and I serve as President and CEO of the Generic Pharmaceutical Association. On behalf of GPHA and its members, I thank you for the opportunity to testify on the issue of drug importation.
GPHA represents manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. Our products are used to fill more than one billion prescriptions every year, producing countless billions of dollars in savings for consumers, businesses, and government. Patients rely on generics to improve their lives, and the nation relies on generics to help keep U.S. healthcare affordable.
I. INTRODUCTION
For more than two decades, FDA-approved generic pharmaceuticals have played a critical role in the effort to contain rising prescription drug costs. In the early 1980's, when you and Congressman Waxman wrote the Hatch-Waxman reforms, the nation faced a health care cost crisis similar to the one it faces today. Since that time, with your help, the generic pharmaceutical industry has matured and has provided tens of billions of dollars in savings each year, while improving the health of millions of Americans.
Mr. Chairman, GPhA and all of our members are proud of our commitment to--and our success at--helping Americans access less expensive, high quality medications. Today, FDA-approved generics account for more than 51 percent of all prescriptions filled in the United States. Yet, generics represent less than eight cents of every dollar consumers spend on prescription drugs. Clearly, the existence of a healthy generic drug industry has enhanced access to affordable medications - something all purchasers should want to continue to encourage.

Nonetheless, we well understand the frustration that consumers, businesses, and health plans have with ever-increasing drug costs. As Members of Congress struggle to respond to this frustration, it is critical to make certain that any policy option considered does not inadvertently undermine incentives for generic competition OR sacrifice safety or quality of our medicines. Unfortunately, as currently drafted, we believe that the legislation before Congress on reimportation has the potential for these unintended consequences.

Many of the Members of Congress we have worked most closely with in assuring greater access to more affordable generics are now seeking to develop a workable approach to import less expensive prescription drugs from abroad. We have great respect for this bipartisan effort - whether it be initiatives drafted by Senators Dorgan, Snowe, Kennedy and McCain, by Chairman Gregg of the HELP Committee, or by Chairman Grassley of the Finance Committee.

II. RECOMMENDATIONS

However, as I will describe in my testimony, GPhA has concerns about safety, and the impact of drug importation on maintaining and assuring the continuation of: a safe and secure drug supply system; a healthy generic drug industry; and the availability of affordable generics. Because of these concerns that have not yet been addressed, GPhA has taken a position opposing reimportation. However, if Congress believes it is necessary to pursue legislation in this area, we believe the following issues need to be addressed to limit unintended and negative impacts the proposals would have on cost and quality:

First and foremost, the Food and Drug Administration (FDA) must be provided with adequate resources to ensure the safety of this nation's drug supply. GPhA would recommend that oversight of safety issues related to importing drugs should be the responsibility of the FDA, and that Congress should ensure that any importation bill is accompanied by the necessary agency funding to do this effectively. Without adequate resources and the time to train the requisite number of specialists to oversee such a critical program, the agency will be hard pressed to implement the necessary safeguards, provide the requisite oversight, and take appropriate enforcement actions to ensure that this nation's drug supply system remains secure. Consumers should be confident that the same strict standards that the regulators require for domestic brand and generic drugs will be in place for imported drugs as well. We believe that FDA must have sufficient oversight over all drug importations in order to prevent this nation's drug supply chain being vulnerable to an influx of inferior and/or potentially dangerous medicines. Adequate patient safeguards therefore must first be in place to assure that unregulated imported products meet all applicable U.S. standards as a prerequisite of importation.

In testimony before the HHS Task Force on Drug Importation earlier this year, several panelists reviewed the severity of the prescription drug counterfeit issue facing multinational brand manufacturers. Counterfeiting is not a problem found only in developing countries; it has become a growing problem all over the world. Counterfeit prescription drugs have been repackaged and reformulated in foreign countries and then introduced into legitimate distribution channels. Counterfeiting activities are well-orchestrated business enterprises, with the intention of diverting products for robust markets, such as the United States and Australia.1 Given the gravity and breadth of the worldwide counterfeiting epidemic that plagues the pharmaceutical industry even under the current system, adequate safeguards must at, a minimum, remain intact.

Secondly, GPhA would recommend that the importation program should be limited to those drugs that will actually provide cost savings to health care consumers--brand drugs with no

1 John Theriault, Testimony before the HHS Task Force on Drug Importation, April 5, 2004.
generic competition. Permitting the importation of generic drugs has great potential to be counter-productive. U.S. generic drugs are not only cheaper than potential imported brand drugs, but as several reports suggest, U.S. generic drugs are generally more affordable than generics in Canada and other industrialized countries.2 Thus, it seems counterintuitive to permit entry of branded and generic imports if there is a less expensive generic already available to consumers here at home. Accordingly, any proposal to loosen the restrictions on imports should take into consideration the cost savings already available through U.S. generic drugs. Additionally, the resources given to the FDA to inspect and regulate imported drugs would better utilized on a limited sample of the drug market to minimize safety concerns and administrative burdens. If we permit the importation of generic drugs and their brand counterparts, we will in effect, be encouraging the use of prescription drugs which may be more costly than the generic drugs available in this country while substantially adding to the burden placed on FDA by importation.

Thirdly, while we would prefer that the imported drugs be required to be therapeutically equivalent, we strongly recommend that if an imported drug is therapeutically inequivalent to the FDA-approved domestic brand drug, consumers should be made aware of the difference through product labeling. To be therapeutically equivalent, the drug must not only have the same active ingredient or ingredients, route of administration, dosage form, and strength as its counterpart, it must also be bioequivalent. Generic drugs are required to be therapeutically equivalent to the referenced brand drug before they can be considered by FDA to be interchangeable for their FDA-approved domestic brand counterparts. Being therapeutically equivalent allows the generic to be substituted with the brand without any adverse effects to the patient. Thus, if an imported brand is not considered to be therapeutically equivalent to its domestic alternative, FDA should be provided the authority to label drug products accordingly to ensure that health care professionals and consumers are empowered to make well-informed decision before switching between medication products.

Lastly, any importation program should protect the important balance between innovation and access to generics by prohibiting importation during the 180-day exclusivity period for generic companies. By allowing importation during this vital period, current importation proposals could undermine the well-crafted compromise that provides the critical incentive for generic companies to challenge invalid patents and bring affordable medicines to the market years ahead of the expiration date of the invalid patent. The 180-day period has been an extremely important reason why the generic industry has thrived over the past 20 years by bringing consumers accelerated access to affordable medicines. Changes enacted under last year's Medicare Modernization Act were designed to restore its original value and effectiveness. Through patent challenges, generic drugs have bought billions of dollars of savings to consumers. For example, in just one case, Prozac, a challenge brought generic competition to the market three years early, saving $2.5 billion on that drug alone. However, if the importation of foreign drugs (which may not be therapeutically equivalent) is permitted during the 180-day

2 Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002

John R. Graham and Beverly A. Robson, The Fraser Institute, "Prescription Drug Prices in Canada and the United

States - Part I: A Comparative Survey," Public Policy Sources, No. 42 (2000) pp. 3-5
period, it will undo the carefully crafted balance between innovation and access that Congress has worked so hard to achieve.

III. IMMEDIATE AND AVAILABLE SOLUTIONS FOR LOWERING PRESCRIPTION DRUG COSTS

Although the debate about importation continues, there are steps that can be taken now to immediately reduce prescription drug costs. Generic pharmaceuticals are a safe, reliable solution to the problem of increased costs of prescription drugs. Increasing access to and utilization of generic drugs would benefit all consumers, businesses, and government purchasers, through lower out-of-pocket and insurance costs.

The tools to immediately increase generic drug utilization and the savings it provides include, but are not limited to: (1) solidifying a definitive, efficient pathway for affordable biopharmaceuticals; (2) mandating the use of therapeutically equivalent generics in all federal and state programs; (3) removing all needless generic substitution carve outs in federal and state programs; (4) having generic approvals be an Administration priority, which provide for agency consults, legal and scientific issues resolved in a timely fashion; (5) conducting scientific research to support the approval of nonsystematic generic medicines; (6) substantially improve the funding for and staffing of the FDA's office of generic drugs; and (7) educating consumers of the value of generic medicines.

FDA plays an important role in ensuring that American consumers have access to generics through its generic drug review and approval process. Yet, the Office of Generic Drugs, which is responsible for the approval of generic medicines, does not receive adequate funding. This is significant given that the number of generic drug applications continues to rise significantly, while the number of new drug applications is declining. Equally important is the fact that the review and approval of generic applications currently takes longer, on average, than the approval of new drugs, potentially delaying consumer access and savings. We urge the Senate to include a similar increase in funding for the OGD that was included by Representative Emerson in the House Agriculture appropriations bill. Congress and the Administration need to address the issues of increasing the resources necessary to approve generic drugs more efficiently, and of making generic approvals a priority, rather than creating an expensive new regulatory mechanism to monitor the importation of unregulated drugs.

Additionally, as Senator Hatch and the Senate Judiciary Committee recognized last month when discussing generic biopharmaceuticals, Congress and the Administration must focus attention on establishing a definitive process pursuant to which generic versions of expensive biopharmaceuticals can receive FDA approval. Last year, biopharmaceuticals cost payers more than $21 billion. Generic versions of these important, but expensive drugs would contribute additional billions of dollars a year in prescription drug savings.

Lastly, the Administration and states also could work together to ensure that aggressive generic substitution tools are employed in state Medicaid programs. States could garner additional savings by implementing aggressive generic substitution tools to other state senior supplemental programs and employee health programs.

IV. AUTHORIZED GENERICS

Finally, Congress and the Administration need to address the issue of "authorized generics" because they undermine the 180-day generic exclusivity period which encourages generic manufacturers to challenge weak and questionable patents. Successful patent challenges

significantly accelerate consumer access to affordable medicines. The practice of "authorized generics" involves brand companies licensing the distribution rights of their product, which has been the subject of a patent challenge, to generic companies that then can market the product during a 180-day generic exclusivity period that has been won by the first generic company challenging the patent. This could effectively remove the economic incentive for the company undertaking the patent challenge. GPhA urges Congress to explore and consider this issue.

V. INTERNATIONAL TRADE AGREEMENTS

GPhA is committed to a balance between innovation and access. To that end, we are committed to innovation in medicines and the preservation of intellectual property protections both in the United States and abroad. With this fragile balance as our main concern, we strongly believe that it is essential that new trade agreements take into consideration existing U.S. measures relating to the accessibility of affordable pharmaceuticals. New trade agreements, such as the one currently being considered with Australia, could potentially affect American consumers' access to affordable drugs as well as the business interests of the U.S. generic pharmaceutical industry. As evidence to support our concern, we need only look at the fall-out of the harmonization efforts relating to TRIPS. A study conducted by University of Minnesota Professor Stephen Schondelmeyer concluded that the cost of the TRIPS harmonization efforts would "exceed six billion over the next two decades." The study also suggested that "[t]he annual generic savings lost by American consumers due to delayed generic entry [as a result of TRIPS] will range from $200 million in some years to over $500 million in other years."3 Accordingly, if trade agreements contain certain provisions that promote innovation, yet are devoid of other essential provisions that foster access to generics, or contain export prohibitions that restrict access to bulk pharmaceuticals and other materials used to manufacture U.S. generic pharmaceutical products, American's access to affordable medicines could be severely harmed as a result of future harmonization measures.

VI. SUMMARY

In summary, GPhA believes that the debate around reimportation legislation is the logical conclusion of a continued frustration with rising brand name drug prices and utilization in this

3 S. Schondelmeyer, "Economic Impact of GATT Patent Extension on Currently Marketed Drugs," PRIME Institute,
University of Minnesota, March 1995.

country. We question whether pursuing such a policy would most effectively address the underlying problems the nation faces in this area. We believe there are a number of policies worthy of Congressional and Administration consideration, including policies that incentivize generic utilization, which would make a substantial contribution to our shared goal of assuring affordable quality medications for the American consumer. If Congress is to pursue reimportation legislation, however, we strongly believe that it must address some of the flaws of the current pending bills. We look forward to working with you and all interested Members from both parties in this regard.