U.S. Department of Commerce
International Trade administration

Public Hearing on The U.S. Department of Commerce's Study on International Drug Pricing as Required by Section 1123 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003

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INTRODUCTION

The Generic Pharmaceutical Association (GPhA) appreciates the opportunity to provide input to the U.S. Department of Commerce's International Trade Administration on international drug pricing. 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. More than half of all prescriptions dispensed in the United States last year were filled with generics, yet generic drugs represent less than 8 percent of total pharmaceutical expenditures. No other industry has made, nor continues to make, a greater contribution to affordable health care in this country than the generic pharmaceutical industry.

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. Accordingly, if trade agreements contain certain provisions that promote innovation, yet are devoid of other essential provisions that foster access to generics (such as the Bolar, generic exclusivity and declaratory judgment provisions), American's access to affordable medicines could be severely harmed as a result of future harmonization measures.

The generic pharmaceutical sector is uniquely impacted by harmonization of agreements on intellectual property protections for pharmaceuticals — particularly insofar as they increase market exclusivity periods, fail to include essential access provisions, or contain provisions that impede access to affordable medicines. New trade agreements 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 the Agreement on Trade Related Aspects of Intellectual Property Rights (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."[1] Given that harmonization

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

efforts have such significant repercussions on the U.S. market for generic pharmaceuticals, it is important for the U.S. to focus attention on ensuring that access and innovation issues are appropriately balanced abroad. As the TRIPS study has demonstrated, a failure to do so can harm access and innovation here in the U.S. Accordingly, the important role that generic drugs play in providing American consumers with affordable medicines can, and should be expanded into other nations; yet, we also must be diligent in our efforts to preserve U.S. provisions that ensure access to affordable medicines here at home.

DISCUSSION

As the ITC responds to the Medicare Prescription Drug Improvement and Modernization Act of 2003's mandate to study and report on the drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development (OECD), GPhA urges it to consider the impact of such practices on the balance between innovation and access.

QUESTIONS

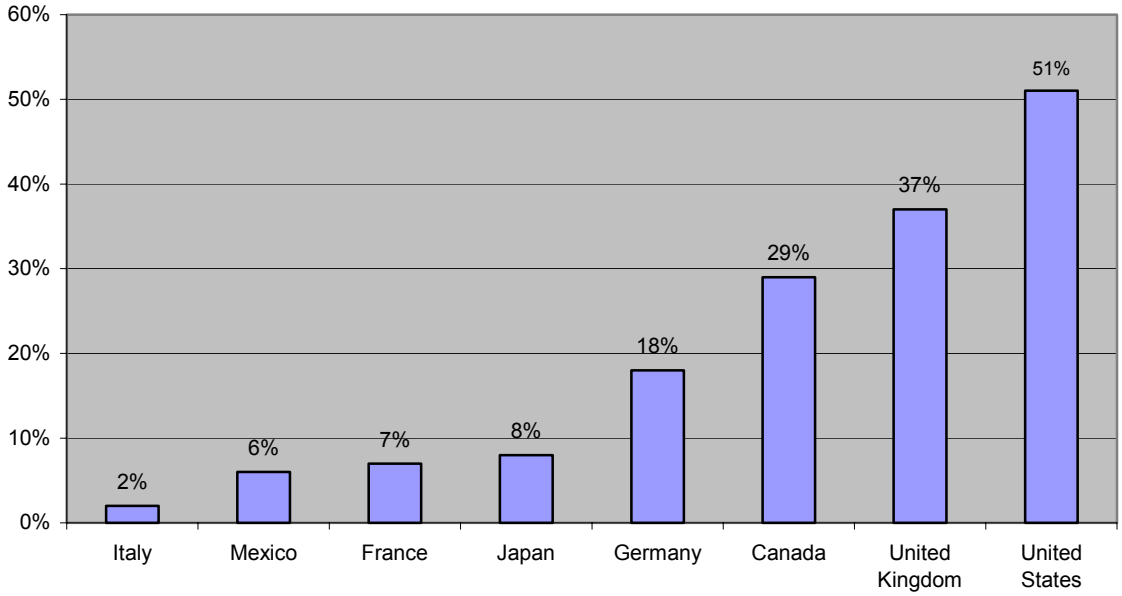
1. How do OECD countries set pharmaceutical prices? Within OECD countries, what mechanisms do governments use to control pharmaceutical expenditures?

The pharmaceutical pricing policies of OECD countries vary significantly and, thus, there is not one global policy that dictates how pharmaceutical prices are set. Countries generally fall into one of two categories: (1) highly regulated countries, such as Japan, Canada, and Italy; and (2) less regulated countries, like the U.K., Germany and the U.S. Consequently, some highly regulated countries use complex and aggressive price control schemes, whereas other countries in this category model their pharmaceutical prices after neighboring countries.

Of significance is the fact that in countries where prices of pharmaceuticals are heavily regulated, the generic utilization rate is low.[2] For example, in Italy the unbranded generic[3] utilization rate is 2 percent. Likewise, in France and Japan, the unbranded generic utilization rate is 7 percent and 8 percent, respectively. In contrast, countries with less regulation (Germany, U.K., U.S.), the generic utilization rates are much higher.[4] While Canada is a highly regulated country with price controls, Canada also has other significant governmental policies that encourage generic utilization.[5]

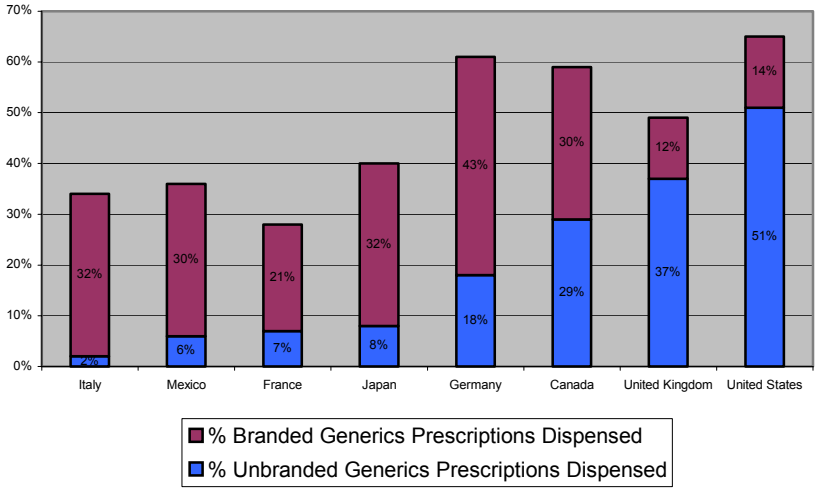
[2] See Foreign countries data based on P.M. Danzon and L.W. Chao, "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries," October, 2003.
[3] "Unbranded generics" compete on price and, thus, are generally not marketed to physicians. In contrast, "branded" generics are products that compete partly on brand image and are marketed to the health care community.
[4] Id.
[5] In Canada, the generic drug price is about 80% of the brand price. Canada has had policies to encourage compulsory licensing and for pharmacists to dispense generics. Id.

Unbranded Generics as a Percentage of Presciptions Dispensed by Country



Foreign countries data based on P.M. Danzon and L.W. Chao, "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries," October, 2003; U.S. data from IMS Health, 2003; Reugers News, Generic Drugs Sales Soaring to $80Bln by 2008, citing Graham Lewis of IMS Health discussing international generic growth, which confirmed the 2003 generic utilization rates of France (6%) and Italy (2%).

Branded & Unbranded Generic Drugs as a Percentage of Prescriptions Dispensed



Foreign countries data based on P.M. Danzon and L.W. Chao, "Prices and Availability of Pharmaceuticals: Evidence From Nine Countries," October, 2003; U.S. data from IMS Health, 2003.

Another essential fact is that in the United States, the vast majority of generics are "unbranded" generic products. Thus, in the United States unbranded generics compete on price and not on the "marketing image" of the product. Competing on price within a free market system allows the United States to encourage strong generic substitution (51 percent), while also benefiting from a low percentage of total drug costs for these products (generics account for about 8 percent of the total U.S. pharmaceutical expenditures). In contrast, in Germany, most of the generic products are "branded generics" (they compete on market image of the product) and the country has a total utilization rate of branded generics and unbranded generics of 61 percent. Yet, Germany's overall cost for these products is much higher, equaling 34 percent of total sales.[6]

2. If price controls and other government cost mechanisms were eliminated in OECD countries, how and to what degree would pharmaceutical prices and expenditures change in those countries and in the United States? What effects would these changes have on the sales and profits of pharmaceutical manufacturers?

If price controls and other cost mechanisms were eliminated in other countries, and no efforts were taken to expand access to generic drugs, pharmaceutical prices in OECD countries would rise and consumers would likely be harmed – since the benefits to consumers from more innovation and higher quality drugs would be more than outweighed by the high prices that they would have to pay. The win-win scenario is for OECD countries to eliminate price regulations while promoting access to generic drugs at the same time. In such a scenario, consumers benefit from both high-quality innovative drugs and from price competition. It would be particularly important to focus on access in those OECD countries where generic utilization rates are much lower than in the United States. For example, in Spain, Japan, France, and Australia, 10% or less of prescriptions are filled with generics.

When prices of brand pharmaceuticals are heavily regulated by foreign governments, and in some cases the price of the generic artificially inflated, there is less incentive for consumers to switch to generics. For example, both France and Italy maintain low brand prices through rigid regulation. As a result, the price differential between brands and generics is reduced, consumers are not price-sensitive to generics and the generic sector of the industry is small.[7] Lower utilization rates decrease the market for generic manufacturers and result in reduced competition. By removing the price regulation from the brand drugs, the need and the market for generics will expand, leading to more manufacturers, greater competition, increased innovation, lower generic drug prices, and ultimately greater overall cost savings than currently realized through price controls.

In addition to price controls, the absence of a single pharmaceutical market in the European Union has stifled generic competition in EU OECD countries. The EU has

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[6] Id.

[7] P. Danzon, "Making Sense of Drug Prices," *Regulation* Vol. 23, No. 1, 58.

developed a mechanism to ease regulatory barriers between European countries known as the Mutual Recognition Procedure, but because individual markets retain unique characteristics, generic manufacturers are finding it difficult to obtain a high rate of MRP application approvals.[8]

In the United States, governments, insurers, employers, and individuals still have the opportunity to pay less for their prescriptions because of the robust generic drug market. In Canada, for instance, some generic drug prices are six to 10 times more expensive than the U.S. generic equivalent.[9] If Canadians had access to generic drugs at the price that they are in America, it would save their system $400 million annually.[10] Most other countries could save similar amounts or more by allowing the generic industry to flourish in their countries, by removing price controls, allowing true competition, and providing incentives for consumers to switch to generics when they are available.

One critical mechanism that must be in place for a robust generic market is the Bolar provision that allows generic firms to develop drugs prior to patent expiry. The purpose of this provision is to ensure that generic medicines enter the market immediately after patent expiry to improve access and encourage competition. This provision has been upheld by the World Trade Organization (WTO) as conforming to TRIPS in a WTO dispute ruling. However, many OECD countries have not explicitly adopted Bolar-type provisions in their legislation. This results in significant delays in the marketing of generic drugs by creating de facto patent extensions. OECD countries that do not have Bolar provisions should seek to incorporate them.

In addition to government barriers to competition, non-governmental barriers exist in many OECD countries. For example, in Japan, there is a significant cultural bias in favor of "brand" items of all types, and doctors in Japan do not customarily prescribe by chemical name.[11] In Germany, the customary practice of prescribing a drug by chemical name followed by a manufacturers' name creates stock and supply issues for the pharmacist.[12] Several OECD countries lack incentives for pharmacists to prescribe generics.

If price controls are removed, but there are non-governmental barriers to vibrant competition, consumers may be harmed. The reason is that branded drug companies will be able to sustain higher prices without fears of competition from generic drug companies. The goal should be to remove price regulations, while at the same time taking steps to lower non-governmental barriers to competition. If a country were to do that, they would benefit from both the balance of innovation and access that has served the United States so well.

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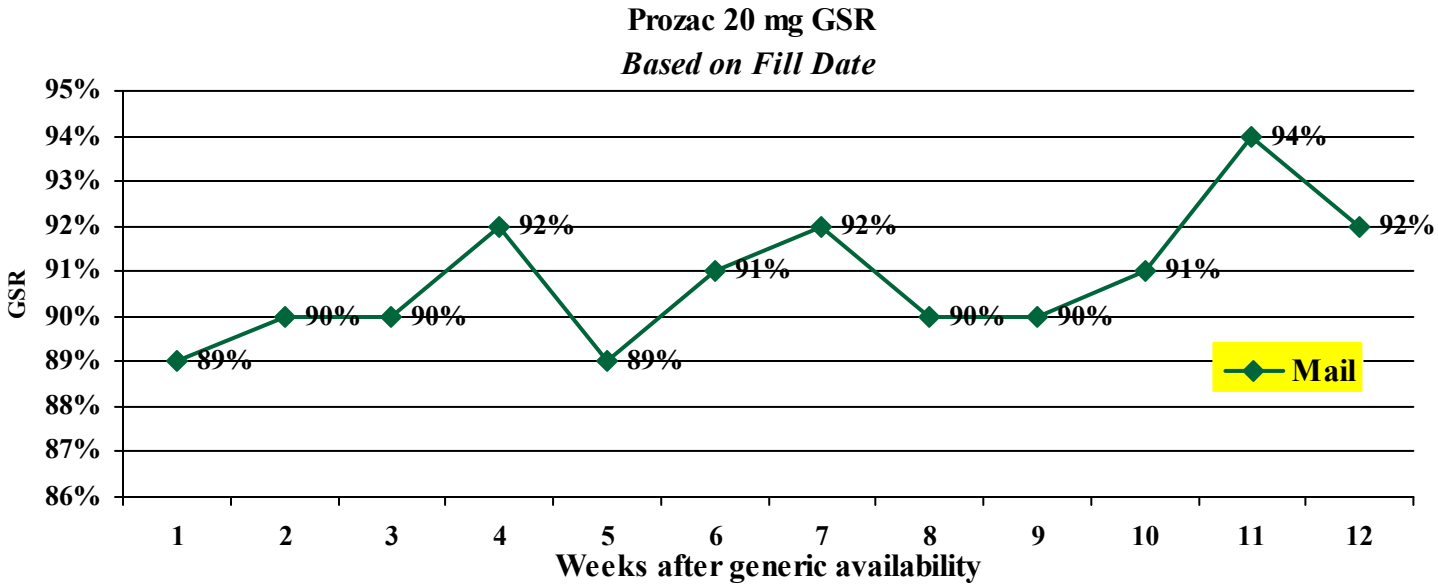
[8] P. Wittner, "The European Generics Outlook," 2003, 24-25.
[9] Palmer D'Angelo Consulting Inc. Report Series, "Generic Drug Prices: A Canada-US Comparison," August 2002
[10] Id.
[11] Remarks of Juichi Riku, Sawai Pharmaceutical Co., June 29, 2004, Seventh Annual International Generic Pharmaceutical Alliance Conference, Prague, Czech Republic.
[12] P. Wittner, "The European Generics Outlook," 2003, 67.

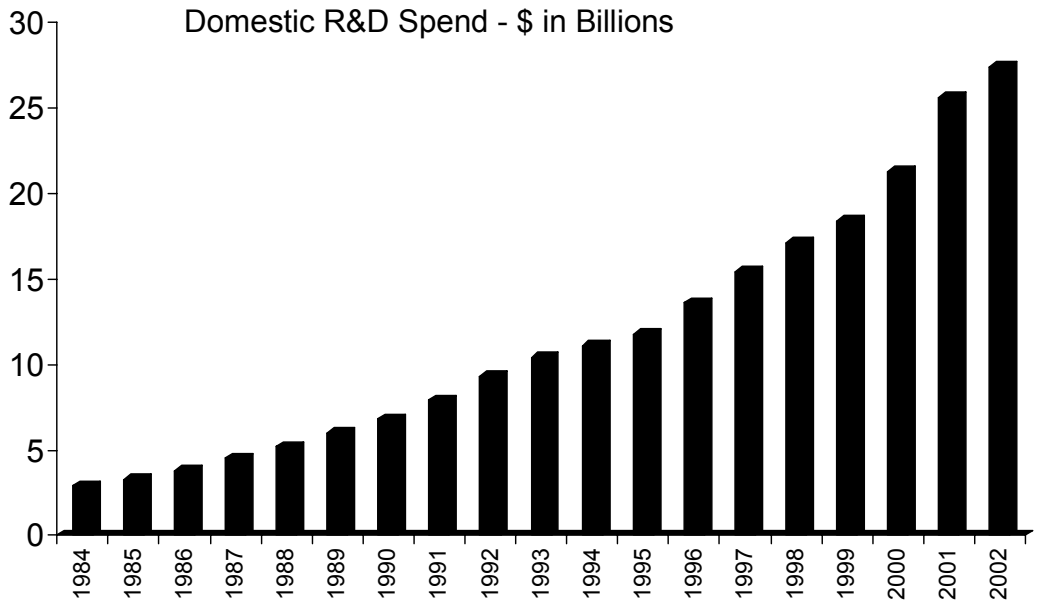
3. What factors influence, and how do companies determine, research and development (R&D) expenditures?

As mentioned above, GPhA is committed to a balance between innovation of new, life-saving medicines and access to affordable pharmaceuticals. To that end, we are committed to the preservation of intellectual property protections both in the United States and abroad as the incentive and reward for innovation of new and vital medicines. Indeed, many of GPhA's member companies hold patents of their own. GPhA also supports another key factor influencing R&D — the existence of a competitive pharmaceutical market. When faced with generic competition, brand pharmaceutical manufacturers must invest in new product development in order to remain viable. For example, using mail-order delivery, the substitution rate for generics for managed care patients can reach as high as 90 percent within one week after market entry. This competition has a profound effect on brand market share.



As such, this highly competitive environment promotes investment in R&D. Since the enactment of Hatch-Waxman, R&D investment by brand manufacturers has increased more than 500 percent. By removing barriers to robust competition in the pharmaceutical marketplace, countries can foster the innovation of new therapies. [13]

[13] See P. Danzon "Testimony to the Task Force on Drug Importation," April 27, 2004, "The U.S. competitive model…yields much stronger incentives for innovation than regulatory systems that constrain prices for innovative drugs and also undermine competition from generics."



This approach rewards both the consumer and the manufacturer by encouraging research and development of new products now and providing a pathway for affordability in the future.

4. Could OECD countries reduce costs by increasing the use of generic drugs? What steps would the governments need to take to facilitate the use of generic drugs?

If foreign governments implemented aggressive generic substitution measures, they would likely realize savings that equal or exceed those gained through price controls while at the same time spurring the introduction of high-quality drugs that benefit consumers. As previously stated, in the United States, 51% of all prescriptions filled are with generics, but they only account for 8% of the total drug costs. According to a study published by Tim R. Covington, Executive Director of The Managed Care Institute at Samford University, an increase of only 1% in the nation`s generic prescription utilization rate (approximately 27 million scripts) would generate a payer savings of $1.3 billion each year.

The United States has adopted many different strategies for increasing substitution for generics by consumers. They include:

1. **Rigorous Federal Generic Abbreviated Approval Program: Yielding Consumer Confidence**
   U.S. law demands that generic pharmaceuticals must be the same as their brand counterparts. FDA assures that the generic product will provide the same medicine and produce the same medical results as that of the brand product. And, thus, FDA ensures that the variability of switching between a brand and U.S. generic product is not different than the variability between

prescription refills of the same brand product. The only difference is cost.

2. **State Substitution Laws**
   Most states have generic substitution laws that encourage the dispensing of generic pharmaceuticals, including mandatory substitution models. Also, some state programs have used more aggressive formulary and co-payments measures to provide an incentive to consumers to use generics.

3. **Economic Dispensing Incentive**
   Pharmacist and other healthcare providers have economic incentives to dispense U.S. generic pharmaceuticals.

4. **Health Plan Benefit Design**
   Health benefit plans and government programs that cover prescription drug costs for their beneficiaries have used among other things, formularies, mandatory substitution, tiered co-payments, step therapy programs, and other means to encourage generic use.

5. **Consumer Education**
   Public and private entities provide educational consumers on the value of generic pharmaceuticals.

In the United States, government agencies, private market payers, and other interested groups have sought to educate consumers on generic drugs. Generic drugs are exactly the same as their brand equivalent and required to be approved by FDA to be interchangeable. Driving consumers to generics by formulating preferred options through formularies or creating incentives for consumers through the differential of out-of-pocket costs between brands and generics have both proven successful for controlling costs in America without controlling prices being charged by the manufacturers.

The strength of the U.S. generic industry also been enhanced by several key congressional measures contained within the section 11 of the MMA, which have enabled generic drugs to enter the market more quickly. The provisions address among other things:

- Restoring the Value of Generic Exclusivity Reward to challenge questionable brand patents that needlessly block generic competition.

- Preserving the Roche-Bolar provision that allows generic firms to develop drugs prior to patent expiry so that consumers will have timely access to affordable medicine.

- Eliminating multiple thirty month stays that needlessly delayed the introduction of affordable medicines.

- Shoring up the ability to bring a Declaratory Judgment action to secure timely resolution of patent disputes.

Yet, more can be done to further enhance the United States' utilization of generic pharmaceuticals and, thereby provide consumers and health care providers with additional cost savings. 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.

CONCLUSION

As the Commerce Department produces its report on drug pricing practices of countries that are members of the Organization for Economic Cooperation and Development (OECD) and their effects on the United States, GPhA appreciates the opportunity to provide information on how generics can play an important role in providing access and savings. The generic drug industry in the United States has seen substantial growth over the past 20 years thanks to the Hatch-Waxman Act of 1984, which struck the balance between innovation and access. If countries with strict price regulations were to liberalize their regulations and provide incentives to encourage a vibrant and competitive generic drug market, the savings from generic utilization would provide access to quality medicine and also yield significant financial headroom to fund new innovative medicines. Also, a strong generic industry would produce more savings over time than the current pricing systems the foreign countries may have now, as well as spur innovation of new medicines.

Americans have access to both the newest medicines and affordable generic drugs thanks to open competition, protections for intellectual property, strong access provisions and rewards for taking risks. If other countries were to open their markets to true competition and infuse strong generic utilization policies into their health care system, utilization rates for generics should increase and lower overall drug expenditures.