TESTIMONY OF RALPH G. NEAS

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THE GENERIC PHARMACEUTICAL ASSOCIATION

PRESCRIPTION DRUG SHORTAGES: EXAMINING A PUBLIC HEALTH CONCERN AND POTENTIAL SOLUTIONS

BEFORE THE

UNITED STATES SENATE

COMMITTEE ON HEALTH, EDUCATION, LABOR AND PENSIONS

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Good morning Chairman Harkin, Ranking Member Enzi and Members of the Senate Committee on Health, Education, Labor and Pensions. Thank you for asking me to participate in this very timely and important hearing.

I am Ralph G. Neas, President and CEO of the Generic Pharmaceutical Association. GPhA represents the manufacturers and distributors of finished dose generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals and suppliers of other goods and services to the generic industry. Generic pharmaceuticals now fill 78 percent of all prescriptions dispensed in the U.S., but consume just 25 percent of the total drug spending.

According to an analysis by IMS Health, the world's leading data source for pharmaceutical sales, the use of FDA-approved generic drugs in place of their brand counterparts has saved U.S. consumers, patients and the health care system more than $931 billion over the past decade — $158 billion in 2010 alone — which equates to $3 billion in savings every week.

GPhA is the third major coalition that I have had the privilege of leading. For 15 years, I served as the Executive Director of the Leadership Conference on Civil and Human Rights, a 60-year-old coalition of nearly 200 organizations that is the legislative arm of the civil rights movement.

For the past several years, I was the President and CEO of the National Coalition on Health Care, the nation's oldest and most diverse health care reform coalition. The 80 organizations that make up NCHC represent consumers, health care providers, large and small businesses, unions, older Americans, medical societies, minorities, pension funds, religious denominations and people with disabilities.

Personally, I am strongly committed to the perspective of patients. Thirty-two years ago I came down with Guillain-Barre Syndrome (GBS), an often serious neurologic disorder, usually reversible, that kept me in the hospital for 155 days. More than half of those days were spent in the intensive care unit unable to speak, on a respirator, and totally paralyzed. That harrowing experience led me to help found the GBS Syndrome Foundation International, which now represents 35,000 former GBS patients. In October, we celebrated our 30th Anniversary. With these experiences in mind, I am proud to be here today representing GPhA and I am equally proud of the work our member companies are doing to resolve drug shortages.

Introduction

I would like to begin today by commending the Committee for your focus on this important issue. As members of the public who also are affected by shortages, the generic pharmaceutical industry is devoted to working with all stakeholders to minimize current shortages and mitigate factors that could contribute to future shortages. We are acutely aware of the distress caused to patients, families and clinicians by the shortage

of critical drugs. Drug shortages represent a complex, multi-faceted issue and our industry has, and will continue, to work tirelessly to be part of the solution.

Why are Shortages Occurring?

Before examining how best to respond to drug shortages it is important to understand why they are occurring. Contrary to some media reports, drug shortages are typically not caused by a manufacturer's decision to voluntarily discontinue supplying the product, and manufacturers do not — and would never — deliberately reduce the supply of essential medicines to push prices up. There can be no question that generic manufacturers are in the business of supplying medicine and assuring that consumers and patients have access to the drugs they need.

Causal factors of drug shortages, rather, are numerous and do not apply in every case. They include everything from an insufficient supply of available raw materials to meet demand, to inadequate and delayed communications about shortages — both within the supply chain and also within and among the Food and Drug Administration's (FDA) enforcement and drug shortages personnel.

GPhA also acknowledges that while factors contributing to drug shortages are many and complex, roughly half of the reported shortages have been attributed to problems associated with the manufacturing and release of generic sterile injectable products. The manufacturing community has been responsive to this issue and has been

extremely active in working with all stakeholders, and especially the FDA, to find suitable solutions that accelerate the availability of critical drugs in short supply. GPhA and our member companies have spent months working with both policymakers and manufacturers to develop strategies to alleviate shortages and better collaborate with other stakeholders.

I have also paid close attention to recent Congressional hearings examining the economics of drug shortages and potential economic incentives. I am pleased to see that new and innovative ideas to address the problem of drug shortages continue to be discussed by the Congress. After speaking to GPhA's membership, our member companies have indicated that improved communication, an expedited process for qualifying alternative suppliers and increased collaboration among stakeholders would address the causes of the vast majority of shortages.

Insufficient Communication

As the regulatory authority charged with maintaining oversight of the U.S. drug supply, the FDA has stepped up its enforcement efforts to unprecedented levels in recent years. Due to the efforts of the FDA, the U.S. drug supply remains the safest in the world. GPhA applauds these efforts and is committed to working with the agency to ensure that patients continue to receive safe and effective generic medications. With the implementation of these expanded enforcement measures, however, comes a need for industry and the FDA to communicate effectively at all stages of the process. Otherwise,

these efforts may have the unintended consequence of adversely affecting our country's supply of critical drugs. Indeed, more than half of the current drug shortages have stemmed from regulatory concerns.

One way to avoid such unintended consequences is by implementing processes whereby remedial measures could be implemented without completely disrupting the manufacturing of necessary products. Through additional remedial measures, the FDA could maintain its vigilance over the safety of the U.S. drug supply, while still ensuring that patients are receiving the medication they need. It is critical that the FDA and industry increase early communication relating to all proposed or contemplated regulatory actions that would affect our country's supply of critical drugs.

Qualifying Alternative Suppliers

Another important factor to note is that the pharmaceutical marketplace overseen by the FDA today is one that has become increasing global. Nearly 40 percent of all prescription drugs dispensed in the United States are now manufactured outside of the country, and nearly 80 percent of the ingredients in our drugs are manufactured abroad. According to FDA estimates, the number of drug products made outside of the United States doubled from 2001 to 2008.

Manufacturers face significant delays in the process to qualify alternate Active Pharmaceutical Ingredient (API) suppliers and secondary or redundant manufacturing

facilities. As a result, many drugs only have one API supplier approved in their applications and are qualified in just one facility. This is in contrast to many other regions of the world, where supplemental API suppliers can be approved in as little as 30 days. Similarly, a prior approval supplement can take multiple years in the United States while similar changes are accomplished in Europe and elsewhere within a much shorter time frame.

The FDA should bring its oversight in this area up to date with today's global pharmaceutical marketplace. A more streamlined and timely process for qualifying new or alternate raw material suppliers and alternate manufacturing facilities would allow manufacturers to increase production of medicines in short supply sooner.

Collaboration Among Stakeholders is Needed

We believe these changes would provide a strong start toward reversing the drug shortages currently afflicting patients and preventing further ones from occurring. But as an industry whose entire business model is to make quality medicines available and affordable to all, we are acutely aware that a lack of supply of a critical drug can be devastating, even if it impacts only one patient. Despite all of the factors currently contributing to shortages, there are still numerous opportunities for generic manufacturers, and all stakeholders, to work together in an effort to solve the problem.

With this in mind, the generic pharmaceutical industry has spearheaded the development of an unprecedented multi-stakeholder communication tool, which we believe will accelerate the recovery of critical drugs in short supply to patients in need. This database of information, which we have labeled the Accelerated Recovery Initiative, or ARI, can be utilized by all stakeholders involved in the manufacturing and distribution of vulnerable drugs in shortage — including, but not limited to manufacturers, wholesalers, distributors, Group Purchasing Organizations (GPO's) and the FDA — in order to accelerate the recovery of critical drugs in short supply to patients in need. In addition, this multi-stakeholder approach will provide additional information to focus on decisions and actions proposed by regulatory agencies and their potential impact on critical supply. Let me provide some more details.

Accelerated Recovery Initiative (ARI)

A group of generic manufacturers, including both members of GPhA and non-members, representing approximately 80 percent of the generic sterile injectable products sold in the U.S. today, are proposing to take unprecedented steps to establish tools and practices that are specifically designed to accelerate the recovery of critical drugs in short supply. The goal of ARI is to put in place industry practices that provide a more accurate, timely and comprehensive view of the current drug shortage situation, provide greater visibility to shortages and establish practices that allow for potential, voluntary production adjustments to lessen or eliminate the impact of a current shortage. Given the nearly 200 products currently identified by the FDA Drug Shortage staff, the initial

scope of the initiative will focus only on those products deemed most critical, which currently focuses exclusively on sterile generic injectable products. We will continue to fine tune the inclusion criteria with a focus on products that have few manufacturing options and no therapeutic alternative.

As I noted, this initiative is predicated on voluntary communication between an independent third party and stakeholders involved in the manufacturing and distribution of generic injectable drugs in shortage, including, but not limited to: manufacturers, wholesalers, distributors, Group Purchasing Organizations (GPO's) and the FDA. In addition, this multi-stakeholder approach will provide additional information focusing on real time decisions and actions proposed by regulatory agencies and their potential impact on critical supply.

In order for this type of initiative to work, each stakeholder involved in the manufacture, supply and distribution of critical drugs in shortage that is willing to participate will communicate necessary information to the FDA Drug Shortage staff. Safeguards will be put in place to ensure that market and manufacturing information is treated with appropriate care.

Further, this initiative will not limit or restrict competition, and will not in any way deal with pricing information. It will also require prior acceptance by the Federal Trade Commission and the Department of Health and Human Services.

The primary focus of the ARI is to gather the current and future supply information from stakeholders for those products identified as meeting the critical criteria. This will then be used to determine current and potential supply gaps, with a focus on those products where a shortage is expected to last longer than 90 days. This type of information will increase early visibility and communication between the FDA and industry relating to current and potential drug shortages.

The supply information will be gathered and disseminated by an impartial third party in compliance with all current market regulations and under terms of strict confidentiality. This independent third party will be supplied with data related to drugs currently in shortage or expected to go into shortage, including the name of the drug, the expected duration of the shortage and internal reviews to identify production capabilities to respond to any market shortage. Wholesalers and distributers will also supply product availability data to assure a complete review of all available inventories. The independent third party will then aggregate the data to provide an overall view of the projected available supply by product, as defined by critical product criteria, compared to the total market need. If the data reveals gaps in market supply that require FDA intervention, the information will be provided by the independent third party to the FDA Drug Shortage staff so that they may help to develop solutions with the manufacturers.

In addition, wholesalers, distributors, distribution partners and GPO's also have an important role to play. It is necessary for both wholesalers and GPO's to establish a "critical drug supply program" that will be implemented during the time when a drug in

shortage is in a supply recovery period. A supply recovery period is the time in which a product is in shortage and has not returned to market demand levels. The focus of the program will be to assure that timely and accurate information is readily available to all affiliated members, institutions and customers.

The last step of ARI focuses on FDA. The agency deserves tremendous credit for the work it is currently doing to expedite regulatory reviews and work closely with manufacturers. However, there is still more that must be done, and manufacturers would be aided by a formal process specifically designed to facilitate communications related to drug shortage regulatory issues. The formation of a FDA drug shortage management team could more effectively address current drug shortages and minimize future shortage events. The industry strongly encourages the establishment of a high-level FDA drug shortage management team, which would include representation from key agency offices. This team would provide an avenue for timely access to FDA decision makers by the pharmaceutical industry to review strategies for addressing or averting drug shortages. This high-level FDA team would also be empowered to evaluate issues such as expediting reviews of pending supplements, which enable industry to address shortages of critical drug products.

From an industry perspective, the formation of such a team that includes high-level representatives from the FDA's Center for Drug Evaluation and Research medical staff, Office of Compliance, Drug Shortage staff and Office of Regulatory Affairs could provide

the expertise and the appropriate level of authority to effectuate rapid decisions on steps to address drug shortages.

We recommend that industry work with FDA and other stakeholders to implement the ARI communication tool in parallel with our other recommendations in order to increase the channels of communication and strengthen our collective ability to supply patients with the medicines they critically need.

Conclusion

In conclusion, Mr. Chairman, GPhA is committed to working with the FDA and all stakeholders to minimize current drug shortages and prevent future shortages from occurring. Nothing is more important to our industry than ensuring patients have access to the lifesaving generic medications they require, and with a joint effort among all involved, we believe we can make a significant step toward accomplishing this goal.