

TESTIMONY OF

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**EXAMINING THE INCREASE IN DRUG SHORTAGES**

BEFORE THE

U. S. HOUSE REPRESENTATIVES  
COMMITTEE ON ENERGY AND COMMERCE  
SUBCOMMITTEE ON HEALTH

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Good morning Chairman Pitts, Ranking Member Pallone and Members of the Subcommittee. Thank you for giving me an opportunity to discuss the critical issue of drug shortages.

I am Jonathan Kafer, Vice President of Sales and Marketing for Teva Health Systems, and I am here today on behalf of Teva Pharmaceuticals. Teva is a world leader in brand, generic, and biologic pharmaceutical products. We are proud to manufacture life-saving and life-changing medicines that are in nearly every medicine cabinet in America. Every minute 1,203 prescriptions are filled with Teva products. It is our highest priority to provide quality medicines to those who need them. Any drug shortage or lack of access to our products is contrary to our mission as a company and is met with immediate action. In my remarks I would like to shed some light on why drug shortages are occurring, discuss what Teva is doing to ensure patient access, and offer some solutions to help avoid future drug shortages.

### ***Current Landscape***

As the Subcommittee is well aware, the list of drugs in short supply is growing longer, and more and more patients do not have access to the pharmaceutical products that they have relied on for many years. Drug shortages are a complex and multi-stakeholder issue, and it is incumbent on active ingredient suppliers, generic and brand manufacturers, wholesalers and distributors, health care providers, and government agencies to work together to resolve this issue.

## ***Causes of Drug Shortage***

There are many factors that impact the availability of critical drugs within the supply chain. Factors that lead to significant shortages are most often due to unanticipated events that can create an immediate impact on availability.

In order to maintain a consistent supply of pharmaceuticals, it is imperative for a manufacturer to have a qualified and reliable source of active pharmaceutical ingredient (API). The qualification process to identify an appropriate API supplier for any drug product can be a very onerous one. To qualify and gain FDA approval for a new API supplier or alternate manufacturing site for an already approved supplier can take as long as 2 – 3 years. Because this process is so lengthy, many drugs have only one API supplier and one manufacturing site approved in their applications. If, for any reason, the API supply is insufficient, i.e., there is a sudden increase in demand for the product or there are difficulties encountered at a particular manufacturing site, a drug shortage can easily be the outcome.

These same circumstances can impact supply indirectly as they can create unanticipated forecast demands on the remaining manufacturers to increase production levels to cover the shortfall. This dynamic is particularly challenging if the product is a controlled substance. From our work with the DEA and FDA, we know that it is a difficult balancing act to ensure availability of controlled substances to patients in need while also striving to curb abuse and diversion. In an effort to control the supply of these medicines, the DEA makes yearly allocations of controlled drugs to the respective

manufacturers of these products. In many instances, however, the use of a drug product changes over the year due to increased usage or shifting of markets. This can result in a shortage of these products, because without access to more of the controlled active ingredient, manufacturers are unable to increase supply. Currently, there are a number of controlled drugs on the American Society of Health-System Pharmacists (ASHP) shortage list.

Many life-saving therapies that are experiencing shortage are injectable products. Although several of these medicines have been available to the public for decades, they are complex and require specialized facilities. As appropriate, the FDA closely regulates these products and facilities and continues to require updated product specifications and other manufacturing requirements in order to maintain the highest quality standards for these products. Although the number of manufacturers that produce injectable medicines has increased over the past several years, the specialized nature of the products and facilities necessary limits the number of producers available to ease a drug shortage.

Whether a shortage is the result of a short supply of ingredients or from manufacturing difficulties at a single manufacturer, the fundamental problem that we encounter is that it can take a considerable amount of time to correct a shortage or increase production of a product.

### ***What Teva is Doing to Increase Access***

Despite the challenges, Teva continues to make every possible effort to supply patients with needed medicines including making significant investments and enhancements to existing facilities and quality programs. We have worked closely in conjunction with FDA to alleviate shortages. To better understand how we work closely with the FDA, I'd like to share with you the steps we have taken to alleviate shortages for the product Leucovorin. Leucovorin is an injectable drug that is given to patients receiving chemotherapy to protect them from negative side-effects and improve the effectiveness of the cancer treatment. The market experienced a shortage of this product when all three manufacturers of leucovorin, including Teva, experienced short and long term supply challenges. Teva, in conjunction with the FDA, worked to provide a temporary importation of the European Union (EU) approved Leucovorin Calcium Folate Solution for Injection to the United States market to address the current shortage. While there is still much work to be done in order to ensure all patients in need of this product have access, this example does illustrate the efforts that have been made by both Teva and the FDA to communicate with one-another and develop workable solutions for the benefit of patients.

### ***Potential Solutions***

As I said at the beginning of my testimony, this is a multi-faceted problem that involves a number of stakeholders. Not surprisingly, there is no silver bullet solution. In order to

adequately address drug shortages, more than one solution will be required. For example, it is important to improve the avenues of communication so that shortages can be averted or, at least, solutions can be more readily implemented. From the time of the initial filing of the application through the ongoing compliance and review process, it is imperative that the communication between the manufacturing facility and the FDA is one that enables visibility amongst all parties. If an enforcement action is proposed or contemplated that would significantly curtail the manufacturing capability of a major supplier of critical drugs, the long-term effect of that action should be discussed among the affected manufacturers, the FDA regulators (FDA's Office of Compliance and FDA's Office of Regulatory Affairs) and FDA's Drug Shortage Team before the action is taken. Having the opportunity to discuss the compliance issues with the inspectors during and after the inspection will greatly assist the industry in both resolving the issues and as well as expediting the remediation of the site with minimal impact to the production of products whose supply could be negatively impacted.

When drug shortages do occur, expedited review to qualify new manufacturing facilities and API suppliers, e.g. expediting pending Prior Approval Supplements (PAS's), greatly speeds the reintroduction of products back to the market. This is occurring to some extent currently, however, steps could be taken to establish a more formal process through the revision of current regulations and guidances .

One strategy manufacturers employ to maximize the utilization of capacity and assure an adequate supply for patients is to transfer products to other manufacturing locations. For U.S. supply, approval for new facilities requires a PAS, an inspection and a

triggering submission, and under routine circumstances may take up to 24 months. In other highly regulated markets, such as Europe, this can be done with notification to local authorities upon operational readiness, and generally would be approved immediately following inspection of such facilities. Approval for additional technologies at an already approved facility (example adding capsule manufacture and packaging) requires a PAS in the U. S. In contrast, this can be done with no additional regulatory approval in other regions. FDA should re-evaluate the regulations and guidances relating to these changes and make revisions that would more easily accommodate these changes.

For shortages that involve controlled substances and DEA quota of active ingredients, one proposed solution is to require collaboration between the FDA Center for Drug Evaluation and Research divisions and the Attorney General to establish a process that would streamline manufacturing production quotas in response to drug shortages of controlled substances. In this way the cessation of production by one manufacturer triggers the timely transfer of quota to another manufacturer in order to maintain a steady supply of product in the market. The multiple government Centers, Offices, and Agencies with responsibility for the approval, compliance and control of drugs should be required to regularly communicate and coordinate activities such that any action taken does not leave medications in short supply. Shortages must be avoided where possible and alleviated in an expedited manner.

## ***Conclusion***

In conclusion, Mr. Chairman, Teva will continue to work closely with FDA and Congress to solve drug shortages when they occur and to prevent future shortages.

Thank you. I would be happy to address any questions the Subcommittee may have.