Witness:
Mr. George Barrett
Teva North America
President and Chief Executive Officer

Testimony

Chairman, Members of the Committee, my name is George Barrett, President and CEO of Teva North America.

First, I wish to thank you for inviting Teva to participate in this round table discussion today on such an important topic.

Teva is a vertically-integrated global pharmaceutical company founded in Israel in 1901, and is the second largest pharmaceutical manufacturer in the United States based on numbers of prescriptions dispensed. Teva North America is headquartered in North Wales, Pennsylvania and has United States manufacturing facilities located in several states. With more than 230 products on the US market, Teva manufactures approximately one out of every sixteen prescriptions dispensed in the United States. Additionally, Teva is one of the largest producers of anti-infective agents in the United States.

Teva holds a unique position from which to view the bioterrorism discussion. Although Teva is best known as the US market's largest generic player, we are also a developer and manufacturer of patented, researched-based pharmaceutical products – we produce and market the leading pharmaceutical product for the treatment of Multiple Sclerosis. Because of our dual role, we have a deep appreciation for the fine balance between encouraging innovation and ensuring access to affordable medicines.

It is also worth noting that, because our parent company is headquartered in Israel, we have a particular familiarity with the threat of terrorism and regard today's discussion with the utmost seriousness.

We at Teva share a deep commitment to ensuring that the United States is well-prepared to counter a bioterror attack. Teva strongly supports initiatives designed to bring more rapidly and efficiently produced pharmaceutical products to counter a bioterrorism attack. Indeed, we believe that S. 3 and S.975, as introduced this year, contain some commendable and workable provisions that provide substantial incentives for pharmaceutical companies to respond to the challenge of producing needed countermeasure pharmaceutical products. These include tax credits, needed product liability relief, and direct grants.

What do these promising proposals have in common?

Broadly speaking, the promising aspects of these 2005 bills have four key characteristics in common. Specifically, these provisions are 1) transparent, 2) proportional, 3) provide linkage between the incentive and the relevant investment, and 4) allow continued timely access to affordable generic versions of life saving drugs to the people who need them

most – the sick and the elderly. By transparency, we refer to a process which is clear and economically visible and predictable. By proportional, we mean the benefits should be commensurate with the effort. Any further legislative incentives must, in our view, reflect these four key characteristics which Congress embraced in Bioshield I.

Unfortunately, in our view, some of the additional incentives proposed in S. 3 and S. 975 – specifically the "wild card" patent term extension provisions, the new patent restoration provisions, and the proposed expansion of existing regulatory exclusivity periods – fail to reflect these characteristics and would erode the carefully crafted balance struck by Congress when it passed the Hatch-Waxman amendments. The effects of these harmful proposals will be felt by American consumers through increased health care costs in the U.S. More specifically,

The♣ proposed "special patent term extension," commonly referred to as the "wild card extension," would extend a patent for up to two years on any patent of the drug company's choosing – even those products wholly unrelated to any bioterrorism countermeasure. Any proposal of this sort fails all four tests in that it lacks transparency, proportionality, and linkage, and would delay generic access for potentially scores of crucial drug products. The result would be to dramatically increase the cost of health care in this country, and place the added cost burden disproportionately upon the sick and elderly. We urge Congress to reject any wild card extension proposal as it moves forward with Bioshield II legislation.

The pending bills would also add new patent extension♣ restoration incentives. These proposals also lack transparency, linkage, and proportionality, and would, by their nature, further delay access to affordable generic drugs. For example, the proposed extension mechanisms do not include any of the carefully balanced limitations of the current pharmaceutical patent term restoration law – specifically the 5-year cap on any restoration and the 14-year cap on the total effective patent term after a restoration. Moreover, contrary to existing law, these extensions would give full credit for time spent prior to submission of a New Drug Application for a product, thus diluting the incentive to proceed expeditiously in developing a product for submission to FDA for approval. Thus, this policy could substantially increase the costs of pharmaceutical products to consumers and both public and private payers. These proposals should also be rejected by Congress, but at a minimum must restore carefully crafted Hatch-Waxman limitations4, 5, 6 and would need to be substantially reworked to provide clear and direct linkage of the extension to the actual development and deployment of truly novel countermeasures. Furthermore, the truly novel countermeasure should pass two tests: 1) it should be required to show clinical superiority to existing countermeasures and 2) it is unique, i.e. there is no other practicable countermeasure readily available.

One pending bill, S. 975, would, in certain circumstances, double the♣ length of the existing 5-year New Chemical Entity ("NCE") exclusivity and the 3-year "clinical trial" exclusivity, and would expand the 7-year Orphan Drug Exclusivity to 10 years. This proposal is highly disproportionate to the effort needed to qualify for these extensions, suffers from a lack of transparency, and would substantially delay access to affordable

medicines. Any proposal of this nature should therefore also be rejected.

I would like to add that one should look with suspicion at any proposal that seeks to use the threat of trade sanctions as a way of forcing patent extensions and data exclusivity provisions on a non-domestic pharmaceutical producer, which would lead to the unintended result of increased pharmaceutical prices for American consumers.

It is in this context that we regard certain provisions of S.3 and S.975 as inconsistent with the goal of bringing novel countermeasures to the market, while at the same time preserving access to affordable medicines. Each of these bills contains harmful incentives which disconnect the rewards from the investment. As introduced, certain provision of these bills would have the unintended effect of delaying generic drugs to market and increasing health care costs in the US.

Of the annual $235 billion spent in 2004 on prescription drugs in the United States, the generic segment accounted for only about 10% of the costs. This is true, despite the fact that over 50% of the prescriptions were filled with a generic pharmaceutical product. Consumers, businesses, health plans, and the government all benefit from the availability of generic pharmaceuticals. Any delay in the flow of generic products into the market will have a crippling cost impact on American private and public purchasers and a disproportionate affect on society's most vulnerable. Clearly, this is a result that America can ill-afford at this time.

What approach should Congress consider in pursuing Bioshield II legislation?

Congress should consider the role of pharmaceutical manufacturing in the biodefense effort in the broadest of ways. This requires not only that we encourage the development of novel treatments with appropriate incentives, but also requires that we pay particular attention to procuring the appropriate products in the fastest way possible.

Much of the public discussion has centered around encouraging the "major" research-based pharmaceutical companies to engage in this activity working on countermeasures. Yet today, three of the five largest producers of pharmaceutical products in the U.S. are "generic drug" companies. Another company among the top five has a very large generic pharmaceutical division. These are companies with enormous productive capacity, multipurpose facilities, and extensive distribution operations, and as a result, high operational flexibility. Teva alone produces and distributes well over 200 generic products for the US market and is one of the world's largest producers of anti-infective agents. We would encourage you to consider how to mobilize our nation's entire productive capacity to help counter a bioterror threat.

Legislation should focus more closely on the production, procurement, and distribution aspects of a bioterror response system. Part of that system should include mechanisms for rapid technology transfer to manufacturers where a needed countermeasure is in short supply or cannot be produced by the company that may be the sole current producer. Companies like Teva have the capacity and flexibility to respond to this need and can

begin producing large quantities of pharmaceuticals on short notice. However, the normal regulatory procedures used to qualify a new manufacturing site are time consuming, which could delay emergency access. Expedited regulatory pathways for such manufacturing site changes are necessary to assure rapid response to any bioterror attack.

Congress should, in much the same way it procures military equipment in a time of war, establish a direct procurement system as part of the defense budget to obtain needed pharmaceutical countermeasures. This would build on the work of Bioshield I, with companies bidding on contracts to provide specifically requested countermeasures at negotiated prices. We strongly advise that Congress add a guaranteed stockpile purchasing component to this direct procurement system.

We believe that participation in the cost of clinical trials would be the most direct and appropriate incentive to encourage the development of novel countermeasures. The risk associated with clinical trials is the largest cost a company faces in evaluating a pharmaceutical development project. We would recommend that Congress include clinical costs in procurement contracts. Direct support for clinical trials would be a fair and workable system and would help support the goal of encouraging the development of countermeasures. Indirect subsidies, such as patent/exclusivity extensions, will undermine the ultimate objective.

Finally, we have a policy recommendation to help rapidly identify and widely disseminate information on drugs known to be effective against many potential bioterror weapons. Specifically, a "Medical Expert Biodefense Task Force" should be established to review data relating to available drugs, biologics, antibiotics, and devices that may be effective in treating, preventing, identifying, or detecting harm from potential bioterror weapons. This information would then be used by the Department of Health and Human Services Secretary to immediately inform health care prescribers of the currently available products that are suitable for treating or responding to bioterrorism health threats, thus expediting the range and use of treatment options available for health care professionals and patients. By reviewing available medical literature to identify bioterror pathogens and agents for which reliable evidence exists as to the efficacy of existing treatments, America's security could be quickly and cost-effectively enhanced – without the need for unnecessary and cost inefficient intellectual property-based incentives.

Preparing our nation to respond to a bioterrorism threat will not come without a significant federal investment. It is far better, however, to have a direct system of procurement paid for out of the defense and homeland security budgets (with the burden falling equitably among all Americans), than to create a far more expensive and elaborate, loophole-laden patent or exclusivity incentive scheme that shifts the cost onto the health care system. A direct system would successfully, efficiently, and cost-effectively encourage the pharmaceutical industry to provide needed countermeasures.

Teva will continue to support measures which encourage the development of novel biodefense countermeasures, among them tax incentives related to development and manufacturing, product liability relief, research and development grants, guaranteed

stockpile purchasing, and other approaches as described above. Such approaches would be consistent with the essential characteristics of transparency, proportionality, and providing linkage between the incentive and the relevant investment without compromising America's access to affordable medicines on a timely basis.

Finally, Teva is prepared to do its part in this overall biodefense effort.

Thank you, Chairman, Members of the Committee, for allowing Teva to share our thoughts with you today.