Testimony of

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October 6, 2004

Testimony Before the
Joint Senate Judiciary and H.E.L.P. Committee
Hearing On S. 666, BioShield II
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Chairman Gregg and Ranking Member Kennedy, Chairman Hatch and Ranking Member Leahy, I am Kathleen Jaeger, President and CEO of the Generic Pharmaceutical Association.

On behalf of GPhA and its members, we thank you for this opportunity to testify on ways we can partner with you to strengthen our response to bioterrorism threats against America.

I want to assure Members of both Committees, as well as all Americans, that the generic pharmaceutical industry stands ready to serve in any way to help our nation address the threat of terrorism. The members of the generic pharmaceutical industry represent a powerful production engine that can be - and is being -- brought to bear to respond to and defend against bioterrorism attacks. Our ability to manufacture and distribute safe and effective pharmaceutical products is unmatched. We are here to support the Administration, the Congress, first responders, and the American people in the preparation for an event or in response to biological, chemical, or nuclear assault.

In my testimony today, I plan to talk briefly about the strong foundation program set forth in BioShield I and identify the provisions of S. 666 that could, if enacted, build on that strong foundation in a positive fashion. I also will address the four provisions of S. 666 which would have unfortunate negative spillover effects on the health care system as a whole, potentially resulting in tens of billions of dollars in needless spending.

GPhA is committed to working with you to strengthen BioShield I in ways that will accelerate research, development and manufacturing of novel countermeasure agents1, as well as diagnostic and environmental warning/detection devices. We believe that this committee can and should strengthen BioShield I by considering the addition of certain incentives, such as needed product liability protections, expanded tax incentives, additional federal research dollars, and fast tracked FDA review of drug and device applications. GPhA, however, believes that four provisions currently included in S. 666 will:

1) reverse current law that enables the timely introduction of generic drugs;

2) create a "wild card exclusivity" that will unnecessarily cost healthcare providers and consumers billions of dollars; 1 The term "novel" as used throughout this document means new molecular entities and new and modified vaccines.

3) excessively and unnecessarily increase market exclusivity on nearly any drug that can be broadly defined as a "countermeasure" --- again adding unneeded and unsupportable costs; and

4) create open-ended patent extensions for broadly defined countermeasures - that may or not be developed and manufactured for the government.

We believe that legislation to ensure that America is fully prepared for any threat must not become the vehicle for special interest proposals that will throw the competitive pharmaceutical market out of balance. We support efforts to strengthen BioShield I in a manner that meets the dual challenge our nation currently faces. First, we must preserve the security of our nation in a time of terrorist threat. Second, we must simultaneously ensure that America's healthcare system can meet the immediate need for more affordable medicine for all consumers. Both of these challenges must be kept in balance, as we seek to further strengthen BioShield I.

A. Generic Industry Background To provide context to our testimony, GPhA represents manufacturers and distributors of generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. In the 20 years since the enactment of the Hatch-Waxman Act, generic drugs have come to be widely accepted as the therapeutic equivalents of brand-name drugs, and the resultant savings have totaled hundreds of billions of dollars.

More than 51% of the American prescriptions last year were filled with affordable generics; yet, generics represent less than 8% of the total pharmaceutical expenditures for last year. Patients rely on generics to improve their lives, and the nation relies on generics to help keep U.S. health care affordable. Among the many products that our members produce are generic antibiotics that CDC has identified as drugs of choice for treating many of the diseases listed as possible targets for countermeasures. And because we are leading producers of pharmaceutical products based on number of doses manufactured each year, our member companies can and should be considered as a valuable resource in responding to any widespread bioterrorist threat to Americans.

I. Building on the Strengths of BioShield I

Since the terrible events of September 11th three years ago, and the subsequent introduction of anthrax spores into the U.S. mail, the nation has been shocked into recognition of our vulnerability in the face of possible terrorist incidents involving biological, chemical, and nuclear materials or agents. There is general consensus that our arsenal of vaccines, diagnostic tools and other biomedical countermeasures to combat such threats is seriously deficient.

2 Generic pharmaceutical products are used to fill over one billion prescriptions each year, yielding savings
of tens of billions of dollars to consumers, insurers, businesses, and government.

The enactment of BioShield I (P.L. 108-276) in July of this year was a watershed event in the nation's preparation to meet such threats. This landmark legislation, proposed by the President and sponsored by Senator Gregg, gives the federal government many of the tools needed to stimulate research, research on, and development and production of novel biomedical countermeasures. It enables the Secretary of HHS to expedite the procurement and simplify the acquisition of countermeasures, and empowers the Secretary to declare emergencies and take steps to get needed countermeasures to affected members of the public. The new law enables the Secretary to make available during emergencies specific drugs and other biomedical countermeasures that have not yet been approved for general consumption.

In many ways, Project BioShield exemplifies what can result when the federal legislative process works best. It is well crafted and carefully thought out. It establishes direct accountability to designated Congressional committees and mandates a follow-up GAO report.

This legislation emphasizes the best features of government procurement and contracting in preparing the nation to meet biomedical threats. And, already, we are seeing representatives of the pharmaceutical industry, the federal government and academia responding to the new law's incentives and call for action. Nonetheless, even prior to the enactment of Bioshield I, questions arose about possible shortcomings, especially with respect to product liability concerns associated with necessary biomedical countermeasures. Fortunately, S. 666, the legislation before you today, includes several key provisions that could potentially strengthen Project BioShield.

II. The Promising Provisions of S. 666 (Extension of Bioshield I) We believe that four provisions of S. 666 look promising in that they may offer significant incentives for enhancing our readiness as a nation.

First, S. 666 responds to onerous product liability concerns that could hinder product development and production. The legislation as proposed would extend the protections of the Smallpox Emergency Personnel Protection Act of 2003 to the approved countermeasures under this legislation. Such a measure could help reassure both investors and manufacturers by reducing their legal risk from involvement at all stages in the development, production, and distribution of qualified biomedical countermeasures.

Second, S. 666 provides additional tax credits and tax incentives to encourage investment in countermeasures. This provision could provide more attractive incentatives to small to medium size companies, as well as help attract the venture capital for smaller start-up firms who could research, develop and produce novel countermeasure agents.

Third, S. 666 provides for FDA "fast track" review of countermeasures falling under the agency's jurisdiction. This provision will help expedite the review, approval and availability of needed countermeasures in a timely fashion.

Finally, S. 666 establishes a Terror Weapon Countermeasures Purchase Fund with authorization for expanded funding for procurement of countermeasures. This provision could furnish pre-production payments to those developing countermeasures, yielding fiscal stability which is of a particular concern of smaller companies.

Each of these provisions builds on the strong foundation laid by Project BioShield. Each is clearly linked to promoting the development and production of needed biomedical countermeasures. None of these has any apparent negative consequences for other actors in the health care or security arenas. It is important to note that when S. 666 was introduced, BioShield I had not yet been enacted.

In the interim period, it has become clear that minor revisions will strengthen its implementation. GPhA encourages Congress to consider extending Bioshield I to include one or more of these promising concepts.

II. The Harmful Provisions of S. 666

Four of the provisions contained in S. 666 as proposed would create substantial opportunities for special interests to game the system and would establish loopholes that will harm, rather than help, American consumers. In fact, many of these loopholes previously have been proposed by special interests over the past 20 years in an effort to delay or prevent generic competition for brand name drugs. Each time, these proposals have been defeated and the best interests of American consumers have prevailed. In addition, given that many barriers to the more timely introduction of generic drugs were closed as part of the Medicaid Reform Act of 2003, it is alarming that they now appear attached to legislation whose goal is and should be American preparedness.

GPhA believes that Congress cannot allow the approval of S. 666 because the bill is overly broad in that fails to: (1) require research on, and development and manufacturing of novel countermeasure agents for purposes of receiving incentives under the bill; (2) set research, development and manufacturing priorities for countermeasure agents; and (3) require deliverables either in the form of disseminating the research or producing product for stockpiling. Moreover, S. 666 includes four seriously harmful provisions that will penalize consumers to the tune of billions of dollars in lost pharmaceutical savings, in the name of preparedness.

These four provisions alone will create devastating effects on the current healthcare system by: undermining the balance of Hatch/Waxman Amendments; increasing the incentive for brand pharmaceutical manufacturers to participate marginally in bioterrorism research while reaping "wild card exclusivity" for any drug of their choosing, whether related to bioterrorism or not; and/or providing patent extensions and exclusivity that are ill-advised and open-ended.

3 GPhA is analyzing the antitrust provision and its implications as set forth in S. 666, and would be pleased
to provide input on this provision in the near future, upon request.

There is no question that these four provisions will generate higher drug costs. They will impede access to affordable generics. They will pose major economic challenges to already overburdened private and public third party payers, including employers, insurers, consumers and such government programs as Medicare and Medicaid. The damage to an already fragile healthcare environment could hardly be more ill-timed, given growth in the number of uninsured Americans, serious deficits in the Medicare and Medicaid programs, soaring health insurance

premiums, and the numerous other crises facing the healthcare system. Let me discuss each of these provisions individually.

A. Generic Industry Penalty Provisions First, S. 666 contains two generic industry penalty provisions which strike at the heart of the Hatch-Waxman Act - legislation that created the generic pharmaceutical industry and permitted the generation of tens of billions of dollars in prescription drug savings every year.

The first generic penalty that threatens our nation's healthcare system would grant a brand product a five-year market extension added to a patent term or other exclusivities when a generic company files an application containing the requisite patent certifications in accordance with the Hatch-Waxman Act. This provision essentially repeals the Bolar Amendment, which for two decades has enabled generic manufacturers to develop a generic in advance of the expiration of the patents on a brand product as long as this use is reasonably related to meeting FDA approval requirements. Bolar allows generic manufacturers to develop their product so that it can be marketed immediately upon the expiration of the brand product patents.

If the filing of a generic product application is allowed to trigger an automatic market extension, the introduction of competitively priced generic drug will be delayed by five years. This generic penalty provision will condemn American consumers to the payment of higher brand prices with little benefit to bio-terrorism preparedness. Yet lost savings is not a prerequisite for ensuring America's safety against bio-terrorism threats.

In addition, another penalty that would be imposed under S. 666 will penalize generic manufacturers who attempt to challenge the patents of brand-name manufacturers and fail. Today, if a patent challenge fails in court, the brand product continues to be patent protected. Under S. 666, the failure by a generic company to succeed in a patent challenge will have the additional effect of granting the brand company an unearned extension of five years of market exclusivity. The intent of the patent challenge component of Hatch/Waxman was to create a mechanism for challenging suspect patents, with consumers receiving the benefit of immediate savings if the generic company prevailed. Taxol is the best example of the value of the patent challenge process. By proving that the patents protecting this product were invalid, the generic industry delivered more than $11 billion in savings to American consumers. Not only would this penalty create a significant disincentive for generic patent challenges, it would penalize consumers.

The following two examples clearly define the penalties generic companies will face, and for which the public will have to pay. It must be understood that the trigger, the filing of a generic application with patent certification, is required by federal law for all generic applications. Therefore, the mere filing of a generic product application under current law is an automatic trigger for exclusivity extensions.

In the first scenario, under S. 666, a patent on a brand product has expired. When the generic company files its application with FDA for this product, which is no longer has patent protection, it must certify that the patent has expired. This certification will trigger a five-year exclusivity extension. Brand companies will be able to resurrect exclusivity on drugs no longer under patent protection.

Under the second scenario, the filing of an application for a generic version of a brand product with a certification that provides that the generic company is waiting to market its product until after patent expiry results in a five year exclusivity extension for the brand product. In other words, this filing, part of the current generic application process and required by federal law, automatically triggers additional five years of exclusivity under S. 666.

Unless these penalties are removed from S. 666, the effort by Congress to strengthen our nation's responsiveness to bioterrorism will in effect create a mechanism that resurrects exclusivity or extends patents. We will, in the name of preparedness, have dismantled any opportunity to continue to provide American consumers with drugs they can afford in a timely manner.

B. Wild Card Exclusivity

The second negative provision of S. 666 is the so-called wild card exclusivity. Under this provision, a brand name manufacturer that conducts research on a possible biomedical countermeasure--or acquires such research more than one year before certification -- receives an incentive of two years of additional market exclusivity on any drug it chooses. There are two significant problems with this provision. First, the bill offers no benchmark on the dollar magnitude of the investment in research or acquisition of research. A de minimis investment in research could buy a brand company billions of dollars in unearned revenue on any of its blockbuster drug products.

Second, this "wild card" exclusivity adds significant uncertainty regarding access to affordable medicines for our nation's healthcare system. An example makes this clear.

Patent 1 for blockbuster drug L is scheduled to expire in two years and the product itself is not eligible for any patent extensions or marketing exclusivity. In preparation for the patent expiry, generic companies invest in the research, development, FDA approval and production of generic versions of Product L. They receive FDA approval and are prepared to launch generic product L upon the patent's expiration. Two weeks prior to launch, the innovator applies its "wild card," gained as a result of perhaps a minimal investment in development of a countermeasure on a totally different product. Consumers, government, and private insurers will unexpectedly and unnecessarily have to continue to pay high monopoly prices for the expensive, brand name product, which has no relation to bioterrorism protection.

This wild card exclusivity represents the worst sort of cross-subsidy, essentially taking money from those who must pay for the drug, in the form of higher out-of-pocket costs, higher copayments, increased health insurance premiums or higher costs to government purchasers. This provision hurts all Americans with little benefit to national safety. Thus, the wild card concept must be removed, because it creates an unbalanced incentive for insubstantial investments in counterterrorism measures. If we do not remove this wild card from S. 666, we will be giving a blank check to brand phrma payable against the American public.

C. Extended Market Exclusivity The third negative provision of S. 666 increases brand product market exclusivity in three instances for most of today's commercially marketed drug products. One component of this provision would increase the period of market exclusivity from five to 10

years for any new molecular entity with as little as one identified use as a biomedical countermeasure.

The second component grants an additional 7 years of market exclusivity (up to 10 years) for a new use or dosage form of an existing marketed drug that can be used as a broad countermeasure agent. Further, it extends orphan drug exclusivity for broad countermeasures from 7 to 10 years. Finally, this component of S.666 extends the period during which generic manufacturers would be prevented from filing abbreviated drug applications from 4 to 9 years after the period of market exclusivity began. It is important to understand that market exclusivity is independent of the term of a drug's patent. These extensions of market exclusivity could thus work to lengthen the period of monopolistic pricing by these brand drugs and obstruct the entry of lower cost generics into the market for longer periods.

While it may seem ridiculous, the case can be made that any product could be granted additional exclusivity for something as simple as the conversion from a tablet to capsule dosage form, or liquid to solid dosage form. Or, if it could be shown that chemicals widely used, such as Zoloft® for depression, Plavix® for hear attacks, Effex® for anxiety, and Imitrex® for migraines, could play a role in treating the symptoms of a bioterrorism attack, additional exclusivity would be automatic under S. 666.

D. Patent Extensions

Fourth and finally, S. 666 provides open-ended patent extensions for broadly defined countermeasure agents for the full period of regulatory review, which is defined as the time from when the patent is issued to the date of FDA product approval. As drafted, the bill sets no limitations on the number of years for such patent extensions, nor are there any limitations on the number of patent extensions per product. In extreme cases, this provision could be used for drugs that have long been off patent but for which their use as a bioterrorism countermeasure has subsequently been identified. In such cases, these provisions of S. 666 could be used to reinstate patents for drugs, forcing generic alternatives off the market for unlimited number of years - which would equal the time in which the Patent and Trademark Office (PTO) granted the patent until the time FDA approved a countermeasure use. This provision also duplicates patent extensions already granted by PTO to compensate for time spent in PTO review, effectively giving brand manufacturers "double indemnity." Lastly, extended monopolies of currently marketed products can serve as a disincentive to brand companies to perform new research and development, including research and development on novel countermeasure agents. Again, as we always point out, competition - not indefinite product monopolies -- spurs innovation and presents a win-win situation for all.

In summary, the two provisions of S. 666 - the two penalties for generic manufacturers and the wild card exclusivity provision - that can harm consumers and delay access to more affordable generic medicines clearly have at best a tenuous linkage to the development and production of a novel countermeasure agent. The other two provisions--extensions of market exclusivity and patent extensions for the full period of regulatory review--are insufficiently defined under S. 666 and are so overly broad in that they apply to today's commercial marketed pharmaceuticals that they are ripe for widespread abuse.

Clearly, all four of these provisions would inflate drug prices, impose major obstacles to the entry of generic drugs into the market, and worsen the crisis faced by every American who must pay for all or a substantial portion of his or her prescription drugs, including millions of the uninsured and older Americans. They serve little sound purpose for strengthening BioShield I, and in fact, exact an exorbitant price from American consumers for no additional protection from terrorism. These provisions should once again be left on the cutting room floor as Congress recognized when it passed Bioshield I the first
time.

IV. Appropriate Authority GPhA believes that certain provisions of S. 666 have the potential to strengthen the research on, and development and production of novel countermeasure agents. However, we question whether establishing authority for these provisions within Homeland Security is wholly appropriate. We suggest that the Department of Health and Human Services, which already has direct authority over such important agencies as CDC, FDA, NIH, and the Public Health Service, may be better equipped to execute the objectives of BioShield I and extension thereto.

Similar to Bioshield I, S. 666 directs the Secretary of Homeland Security to develop a list of biological, chemical, and radiological agents that can be used as weapons of mass destruction and against which the development of new countermeasures is in the national security interest. Yet, the bill defines countermeasure agent as any drug product to treat, diagnose or prevent illness or conditions that are caused by being exposed to 55 overly broad possible target agents. Some of the identified agents are so ubiquitous that they are responsible for common infections found in tens of thousands of patients across this country each year, such as E.coli, Salmonella, etc. The bill needs substantial refinement if we are to adequately prepare this country for a potential bioterrorism event; rather, than providing a substantial windfall to the special interest of brand pharmaceutical companies.

Again, Bioshield I sets forth sufficient criteria to establish what are novel countermeasure agents and the means of researching, developing, manufacturing and procuring novel countermeasure agents, as well as needed diagnostic and environmental detection and warning systems.

Moreover, HHS, not Homeland Security, is the agency designated under Bioshield I to oversee this worthy and vitally important program. Certainly, more of the needed expertise and experience for developing countermeasures would seem to reside in HHS. We believe that the development of an appropriate definition of bioterrorism threats, and appropriate countermeasures, is a scientific one. We believe that the expertise to answer these questions, and develop an appropriate list of applicable countermeasures is unique to the Department of HHS and its agencies. Not placing this authority in the realm of science invites special interests to potentially "game the system" at the expense of Americans. We would propose that the responsibility for aligning America's brand and generic pharmaceutical industries to potential bioterrorism needs should remain with HHS.

V. Future Role of Generic Biologics As an ancillary issue, we note with interest the provisions of S. 666 related to expansion of the nation's capacity to produce biologics. S. 666 directs the Secretary of Homeland Security to conduct surveys of biologics manufacturing facilities and to determine whether additional facilities are needed. It also charges the Secretary with determining

whether technical advances might boost the nation's biologics output capacity and lower the costs of biologics. In addition, the bill establishes a biologics manufacturing investment credit, and would even preempt state and local zoning laws to facilitate the location of biologics manufacturing facilities.

GPhA shares the sponsors' concern about the nation's biologics manufacturing capacity and the costs of biologics. GPhA firmly believes that the time has come for the nation to actively explore ways in which generic firms might enter the biopharmaceutical field with similar price reductions to those which have accompanied the introduction of generic drugs. As Senator Hatch and members of the Judiciary Committee will recall, they held a hearing in June on the topic of "The Law of Biologic Medicine." Only last month, FDA held a public forum to discuss the science supporting generic biopharmaceuticals. Aggressively pursuing the creation of a regulatory process for generic biologics will address issues of manufacturing capacity and cost.

GPhA believes that our members have the scientific, development and manufacturing expertise necessary assure the nation of a supply of affordable generic biologics to address the need for countermeasures against agents used by terrorists.

VI. Summary

GPhA and its member companies strongly support the common overarching goal of both Bioshield I and S. 666, namely: to ensure that America has an adequate supply of drugs and other products that would serve as countermeasures to attacks by terrorists using biological, chemical, or nuclear weapons.

Specifically, GPhA strongly supports exploring the concept of extending Bioshield I to include three features of S. 666: (1) reducing product liability exposure of pharmaceutical manufacturers, (2) providing additional incentives in the form of tax credits and public funding, and (3) "fast tracking" the approval by FDA of countermeasure drugs and other agents. GPhA also supports additional funding for federal countermeasure research for novel drugs, vaccines, diagnostic tools and environmental detection devices.

GPhA, however, has grave concerns about four provisions of S. 666 that extend current patents, offer wild card exclusivity, penalize new generic drug development, and create unearned and unnecessary market exclusivity. These four provisions are extremely threatening to the economic viability of our nation's health care system.

GPhA respectfully urges the joint committees, as Congress did the first time around, to drop these four anti-consumer, anti-competitive provisions from the debate relating to extension of Bioshield I.

The responsibility of the Congress to protect American consumers extends beyond ensuring countermeasures for bioterrorism. It also includes ensuring that bioterrorism does not become the mechanism for economic disaster that rescinds the billions of dollars in savings this industry has created for American consumers. We must keep America safe from threat. But we must also ensure we do not threaten the health of consumers by placing life-saving prescription drugs once again out of their economic reach.

Thank you.