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

HEARING ON THE DRUG AND DEVICE PROVISIONS OF THE "FOOD AND DRUG ADMINISTRATION GLOBALIZATION ACT"

SUBCOMMITTEE ON HEALTH
MAY 1, 2008

Mr. Chairman, Ranking Member and Distinguished Members of the Committee:

Thank you for the opportunity to participate in today's hearing on the drug provisions of the "Food and Drug Administration Globalization Act of 2008." I am Lori Reilly, Vice President of Policy & Research at the Pharmaceutical Research and Manufacturers of America (PhRMA), and I am testifying on behalf of Billy Tauzin, PhRMA's President and Chief Executive Officer. PhRMA is the nation's leading trade association representing the research-based pharmaceutical and biotechnology companies that are devoted to inventing new, life-saving medicines that help patients achieve longer, healthier, more productive lives.

In 2007, America's biopharmaceutical research companies invested an estimated record $58.8 billion in research and development. PhRMA members alone invested an estimated $44.5 billion in 2007 in discovering and developing new medicines, and patients and their health care providers quite reasonably expect these medicines to safely and effectively treat the diagnosed medical condition. America's patients trust that the drugs they and their loved ones take meet the high standards set by the Food and Drug Administration (FDA) for safety and efficacy and are not substandard or

counterfeit, and they rely on our complex and comprehensive regulatory system to ensure that is the case. Patients also depend on a secure pharmaceutical supply chain, and this is a responsibility our companies share with the FDA. The increasing globalization of the pharmaceutical supply chain presents new challenges that require us and the FDA to be more adaptive and flexible in our oversight of entities located around the world. The lifeblood of America's research-based pharmaceutical companies is dependent on a safe, secure prescription drug supply chain and that is why our companies go to great lengths to help assure the quality, safety and integrity of materials used from third party sources in our finished products. This is also one of the reasons PhRMA has urged Congress to increase appropriations to FDA. A strong, well-funded FDA is critical to the health and safety of the American public, both for the purposes of helping to assure the safety, effectiveness and availability of medicines and to help ensure continued access to innovative new therapies for American patients.

Today, my testimony will focus on the current regulatory structure governing prescription drugs sold in the U.S., including a discussion of the importance of quality systems and the Good Manufacturing Practice (GMP) requirements applicable to drugs, which are the gold standard for pharmaceutical manufacturing worldwide. Next, I will briefly discuss the application of GMPs to active pharmaceutical ingredients, and describe additional mechanisms to help assure the quality, safety, and integrity of prescription drugs marketed in the U.S. Third, I will discuss PhRMA's concepts to help preserve the continued safety and security of our nation's prescription drug supply and how those concepts are reflected in the recent "Food and Drug Administration Globalization Act of 2008" discussion draft. Finally, I will offer initial thoughts on H.R.

5839, the "Safeguarding America's Pharmaceuticals Act of 2008," which was recently introduced by Reps. Buyer and Matheson.

I. Current Regulatory Structure Governing Prescription Drugs in the U.S.

The regulatory system that governs the development, approval, marketing, and surveillance of new drugs in the United States is the most complex and comprehensive in the world. To ensure that Americans have the safest drug supply in the world, it has become increasingly comprehensive and robust over time. As far back as 1938, the Federal Food, Drug, and Cosmetic Act (FDCA)[1] — which remains in place today — prohibited the marketing of any drug not shown to be "safe for use under the conditions prescribed, recommended, or suggested" in its labeling.[2] In 1962, FDA obtained explicit authority to demand proof that a drug is effective and to prescribe the tests that a manufacturer must perform before its product can be approved for marketing.[3]

Since that time, several amendments have expanded, strengthened, and refined the FDA regulatory scheme.[4] These include the Prescription Drug Marketing Act of 1987 (PDMA), authored principally by Reps. Dingell and Waxman. Under the PDMA, which Congress passed following an investigation of incidents of counterfeit drugs reaching American consumers, closed the U.S. prescription drug supply to products that

1 Pub. L. No. 75-717, 52 Stat 1040 (1938).

2 21 U.S.C. § 355(d)(1).

3 Pub. L No. 87-781, 76 Stat 780 (1962), codified at 21 U.S.C. § 355(d)(5).

4 See, e.g., the Durham-Humphrey Act, Pub. L. No. 82-215, 65 Stat. 648 (1951) (concerning prescription requirement); the Drug Listing Act of 1972, Pub. L. No. 92-387, 86 Stat. 559 (1972); the Orphan Drug Act, Pub. L. No. 97-414, 96 Stat. 2049 (1983) (subsequently amended); the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984); the Drug Export Amendments of 1986, Pub. L. No. 99-660, 100 Stat. 3743 (1986), the Prescription Drug Marketing Act of 1987, Pub. L. No. 100-293, 102 Stat. 95 (1988) (subsequently amended); the Generic Drug Enforcement Act of 1992, Pub. L. No. 102-282, 106 Stat. 149 (1992); and the Prescription Drug User Fee Act, Pub. L. No. 102-571, 106 Stat. 4491 (1992).

have circulated overseas, beyond the jurisdiction of FDA and outside the control of the manufacturer. The PDMA, coupled with exacting FDA regulatory requirements such as GMPs, has helped significantly minimize the possibility that a consumer receives a counterfeit drug.

A. Quality Systems and Good Manufacturing Practices: The FDA's "Gold Standard" for Pharmaceutical Manufacturing

As a consequence of this comprehensive framework, FDA currently regulates virtually every stage in the life of a prescription medicine sold in the U.S., from pre-clinical testing in animals and human clinical trials before the medicine can be marketed, to manufacturing, labeling, packaging, and advertising when the drug is marketed, to monitoring actual experience with the drug after its sale to consumers.

More specifically, manufacturers of pharmaceuticals sold legally in the U.S. must comply with the "gold standard" of quality manufacturing – FDA's GMP regulations. The GMP regulations are applicable to all pharmaceuticals sold in the U.S., wherever they are made, and extend to all components of a finished drug product, including active pharmaceutical ingredients (APIs), without regard to where those ingredients are sourced. These regulations are extensive and thorough and require manufacturers to build quality into the design and production of pharmaceuticals, thereby helping to assure the safety, integrity and quality of every product approved and sold in the U.S. from the outset. Pharmaceutical manufacturers employ extensive quality systems and take extraordinary measures to secure the supply chain throughout the life cycle of the product since any loophole or breakdown in the pharmaceutical distribution system may provide an opportunity for diversion or counterfeiting to occur.

FDA's GMP regulations are based on the fundamental quality assurance principle that quality, safety and effectiveness "cannot be inspected or tested into a finished product," but instead must be designed and built into a product.[5] While FDA inspections are an important part of FDA's regulatory authority and oversight, GMPs represent a comprehensive, systems-based approach that requires a company to build quality directly into the entire manufacturing operation, in order to ensure that the process itself is under control and therefore will consistently produce a drug product that meets designated specifications. No amount of FDA inspections or testing by itself can assure the safety, integrity or quality of a finished drug product. Instead, inspections are one important mechanism for FDA to verify that pharmaceutical manufacturers have in place adequate quality systems and are complying with GMP requirements.

At their core, FDA's GMPs require that each manufacturer have in place a quality control unit that has the responsibility and authority to approve or reject all raw materials, packaging materials, labels, and pharmaceutical ingredients. As FDA has noted, "[i]mplementing comprehensive quality systems can help manufacturers to achieve compliance with" FDA's GMP requirements.[6] These requirements touch on all aspects related to the manufacture of a pharmaceutical product, including, in addition to the requirement to establish and maintain a quality control unit:

- **Design and Construction Features.** Buildings and facilities used in the manufacture, processing, packing, or holding of drug products or intermediates should be of suitable design, size, construction and location to facilitate cleaning, maintenance, and proper operations.

[5] 61 Fed. Reg. 20104, 20105 (May 3, 1996).
[6] FDA, Draft "Guidance for Industry: Quality Systems Approach to Pharmaceutical CGMP Regulations," Sept. 2006, at 3.

- **Processing Equipment.** Manufacturers must assure the adequacy of manufacturing equipment design, size, and location; equipment construction and installation; equipment cleaning and maintenance procedures; and equipment cleaning methods.

- **Control of Ingredients.** Manufacturers must maintain and update as appropriate detailed written procedures that describe the purchase, receipt, identification, quarantine, storage, handling, sampling, testing, and approval or rejection of raw materials.

    - Upon receipt and before acceptance, each container or grouping of containers of raw materials must be examined visually for appropriate labeling, container damage, seal integrity (where appropriate), and contamination.

    - Representative samples of each shipment of each lot must be collected for testing or examination in accordance with an established procedure.

- **Production and Process Controls.** Manufacturers establish and follow written production procedures to help assure that pharmaceutical ingredients and intermediates exhibit the appropriate quality and purity.

- **Packaging and Labeling Controls.** Manufacturers must establish and follow written procedures describing the receipt, preparation, identification, storage, handling, sampling, examination, and testing of pharmaceutical labeling and packaging materials. These materials must be representatively sampled and examined or tested before use.

- **Laboratory Controls.** Manufacturers must implement procedures to determine compliance with specifications for the acceptance of each lot of raw materials, containers, intermediates, and ingredients. Manufacturers must conduct tests on each lot of pharmaceutical ingredients or intermediates to determine satisfactory conformance to established quality specifications and lack of objectionable microorganisms.

- **Batch Records.** Any production, control, or distribution record associated with a batch of active ingredient or finished medicine must be retained for at least one year after the expiration date of the batch and available for FDA inspection.

- **Distribution and Complaint Files.** Manufacturers must keep distribution records of the person to whom they shipped the finished product, date, quantity shipped, and lot number. Manufacturers must establish and follow written procedures describing the handling and retention of all complaints and investigations involving the possible failure of a product to meet any of its specifications.

- **Manufacturing Process Validation.** A manufacturer must establish and follow a detailed written program for assuring that its specific manufacturing process is capable of performing in a consistent manner and results in a homogeneous product that consistently meets predetermined specifications. This involves creation of a protocol that outlines all manufacturing steps, equipment, sampling, and acceptance criteria.

- **Change Control.** To provide for ongoing manufacturing improvements, a formal system must be established to evaluate and approve proposed changes to specifications, test procedures, raw materials, facilities, equipment, processing, and packaging materials.

- **Control of Contaminants.** Manufacturers must implement written procedures to prevent chemical, biological, and physical contamination, including cross-contamination in ingredients and intermediates.[7]

B. Active Pharmaceutical Ingredients and GMPs

As stated above, FDA's comprehensive regulations are designed to help assure the safety and efficacy of pharmaceutical products in the U.S. These requirements extend to all components of a finished drug product, including bulk APIs, which are the ingredients used in prescription drug products that give a drug its pharmacological effect.[8] APIs may be sourced domestically or in foreign countries and subsequently used in the manufacture of a finished drug product sold in the U.S. Recent news stories have focused attention on the use of APIs that are produced in countries such as China and India and then used to manufacture finished prescription drug products sold domestically. To be clear, APIs are considered "drugs" by FDA, and as such, are also subject to FDA's GMP requirements, similar to finished pharmaceuticals.[9] FDA's expectations for APIs include:

- Personnel, facility and equipment requirements;
- Control of raw materials, including visual examination and sample testing to verify the identity of each raw material;
- Performance of appropriate laboratory tests on each lot of active pharmaceutical ingredients to determine conformance to established specifications;
- Microbiological testing as appropriate;
- Establishment and testing against impurity profiles;
- Stability testing;
- Retention of samples representative of each lot;
- Validation of manufacturing processes;

[7] See generally, 21 C.F.R. Parts 210 and 211.
[8] FDA defines API as "any component that provides pharmacological activity or other...effect in the diagnosis, cure, mitigation, treatment of prevention of disease, or to affect…structure or any function of the body of man or animals."
[9] 21 U.S.C. § 321(g).

- Packaging, labeling and storage controls;
- Retention of applicable production, control, or distribution records; and
- Detailed written procedures addressing all aspects of the production of active pharmaceutical ingredients, and to analyze the impact of any changes to the process.[10]

Pharmaceutical companies are ultimately responsible for the testing and validation of the safety, purity and consistency of APIs used in the manufacturing of finished drug products. Manufacturers are required to disclose the source of the API used in their applications for drug approval submitted to the FDA. Many companies often choose to employ vendor qualification programs to audit potential suppliers prior to engaging in transactions with an API supplier. The Agency also has authority to inspect domestic and foreign API manufacturing facilities, and conducts those inspections either directly or through inspection of finished product manufacturers.

In sum, pharmaceutical manufacturers comply with rigorous controls over all aspects of the pharmaceutical manufacturing process – known as GMPs – which are recognized world-wide as the "gold standard" for pharmaceutical manufacturing. The complex and comprehensive GMP provisions help assure that raw materials and components used in the manufacture of prescription drugs are safe, pure and potent, without regard to where they are sourced, and help to assure that a quality product is produced every time.

II. Preserving and Improving the Safety and Security of our Nation's Prescription Drug Supply

[10] FDA, Draft "Guidance for Industry: Manufacturing, Processing, or Holding Active Pharmaceutical Ingredients," March 1998.

The prescription drug supply system in the U.S. is extremely safe and arguably the best and safest in the world. And, while a great deal of recent attention has been placed on the rate of FDA's foreign inspections, it goes without saying that while extremely important, FDA inspections of domestic and regulatory facilities manufacturing pharmaceutical products are just one important piece to helping assure the quality, safety, efficacy, and integrity of the prescription drugs Americans take. Other key pieces include the establishment of quality systems and adherence to FDA's GMP requirements, as described above, as well as postmarket surveillance activities, including adverse event reporting, recordkeeping and reporting obligations, and prescription drug establishment registrations and product listings. All of these activities are part of the FDA's comprehensive system designed to help assure the safety of prescription drug products in the U.S. Each component in this system plays an important and critical role and the importance of the entire system – and each component in that system -- should be recognized in any policy debate.

Even with FDA's comprehensive regulatory system, there is evidence that additional safeguards could be added to the already robust U.S. drug regulatory and oversight system to help ensure that American consumers are adequately protected. In order to preserve the safety and integrity of our country's drug supply, Congress could consider several additional measures or safeguards, which I will outline below.

Before I do so, however, I want to reiterate the importance of protecting and preserving the sanctity of the current prescription drug supply chain. While this hearing and the legislation that is the subject of this hearing focuses primarily on issues related to FDA's foreign inspections capabilities, a key component of any safe system is a

secure supply chain. As such, one basic element to preserve the safety of our country's drug supply is maintenance of a closed distribution system. Our current system is by and large a "closed" distribution system and even with such a system, from time to time counterfeit and tainted products surface, and the public health could be placed at risk. Domestic challenges thus remain great. These challenges would, however, be multiplied exponentially by the added complexities and burdens of an expanded international supply of drugs from various wholesalers and pharmacies. In fact, the European Commission recently reported the seizure of a total of more than 2.7 million medicinal products (articles) at EU customs borders in 2006. This is an increase of 384% compared to 2005.[11] As such, Congress should reject proposals, such as proposals to legalize prescription drug importation, which would further strain and compromise the FDA's ability to protect Americans from potentially dangerous counterfeit medicines and maintain the current "closed" distribution system.

In response to concerns regarding the rate and extent to which FDA is currently conducting inspections of foreign drug establishments, PhRMA is pleased to offer the following ideas for consideration as Congress examines this important issue. At the outset, let me make clear that PhRMA member companies are used to and comfortable undergoing FDA inspections. Rather, PhRMA offers the following ideas to help all of us gain a greater understanding of the scope of foreign entities manufacturing products and components destined for sale in the U.S., and to help increase FDA oversight of such activities occurring beyond our borders while at the same time not weakening our

[11] http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/counterf_comm_2006_en.pdf

existing regulatory system, which is the strongest in the world. The draft includes several proposals to modify FDA's inspection and oversight of drug products introduced into U.S. commerce. PhRMA also has proposals to respond to concerns underlying the modifications suggested in the draft bill. Included below is a comparison between the current discussion draft and our proposals.

A. Formal Assessment and Establishment Registration

Congressional testimony has revealed a great deal of disparity in the number of foreign facilities that exist and thus are subject to FDA inspections. Further, concern has been expressed about the interoperability of the Agency's databases for tracking and monitoring foreign establishments and their inspection outcomes. In order to appropriately address these concerns, we propose two ideas: (1) a formal assessment of and recommendations regarding the rate and frequency of FDA foreign inspections, and (2) registration with FDA for all foreign facilities, to the extent such entities are not required to do so under current law.

GAO (or a similar entity) should be asked: (a) to assess the number of foreign facilities and the adequacy of the FDA's current information technology systems to track those facilities; (b) make recommendations regarding the appropriate frequency of inspection for foreign facilities manufacturing products destined for U.S. markets; (c) make recommendations regarding resources and staffing needed to improve FDA's information technology infrastructure, and (d) make recommendations regarding the number of FDA inspectors necessary to conduct the recommended number of FDA foreign inspections. We understand that parts of this study may be underway by GAO.

PhRMA agrees with the concept that all foreign establishments manufacturing products or components destined for import into the U.S. should be directed to register with FDA and list their products, to the extent they are not already required to do so under current law. By requiring such facilities to register, the FDA will be able to establish a single database that will contain information on all facilities that manufacture products or components of products that are sold in the U.S. This will allow the FDA to ensure that foreign inspections are occurring on a regular basis. While such information reportedly exists, Congressional testimony suggests that it appears in several different formats and databases managed by FDA, and, therefore, it is not easily accessible by Agency personnel.

B. Funding Mechanisms

A strong, well-funded FDA is critical to the health and safety of the American public, both for the purposes of helping to assure the safety, effectiveness and availability of medicines and to help ensure continued access to innovative new therapies for American patients. With respect to funding, section 201 of the discussion draft sets up a new annual registration fee for drug and device establishments "for the purpose of defraying the costs of inspecting establishments registered" with the FDA and a new annual importer registration fee.

In general, user fees for FDA have worked to support other FDA functions. As you know, PhRMA and its member companies endorsed the creation of user fee programs to fund FDA's review activities in the original Prescription Drug User Fee Act of 1992. With regards to whether user fees are appropriate to fund increased foreign inspections, questions that must be addressed include how such fees would be

assessed and constructed, and what guidance and parameters would be set around the timing, scope and designated activities supported by any user fee. Key issues will include the amount of any user fee, whether such fees are capped, whether such fees would sunset, and whether any fees would be linked to appropriated dollars. Moreover, any new user fees should not supplant appropriations and should support specific, identified FDA activities.

We also believe that the Agency is currently underfunded and as a result it has become increasingly difficult to meet its many mandates. In our view, it is in the best interest of the public health and safety for Congress to significantly increase appropriated resources to help the FDA carry out its vital mission. The FDA's responsibilities have consistently expanded; however, appropriated funding has not kept pace to meet the Agency's increasing regulatory responsibilities and demands. We look forward to continuing to work with Congress on these important issues and urge Congress to increase appropriations to help the Agency meet its mandates.

C. Enhancements to FDA's Current Inspection Regime

Sections 202, 403 and 404 of the discussion draft set out targeted reforms to the FDA's current inspection regime, including a two-year interval for foreign inspections, as well as a requirement for an initial facility inspection before a product may be offered for entry into the U.S., and a recommendation to consult with Congress before FDA seeks to close or consolidate any of its federal testing laboratories or district offices. We agree with the Committee that the rate of FDA foreign inspections should be increased, and that FDA should increase its foreign inspectorate.

Increase FDA Foreign GMP Inspections. We also believe, consistent with the policy goals outlined in the discussion draft, that while FDA has broad authority to conduct inspections of domestic and foreign facilities, it currently conducts limited numbers of GMP inspections of foreign facilities, including API manufacturers. Therefore, we recommend that FDA generally increase its GMP inspections of foreign facilities, including API manufacturers, to help ensure that GMPs are being followed. The targeting of these increased foreign inspections should be accomplished by utilizing the risk-based approach described below.

Establish FDA Regional Offices around the world. Additionally, the current discussion draft would amend section 704 of the FDCA to require FDA to establish and maintain a corps of inspectors dedicated to inspections of foreign facilities. We support this effort, and suggest that these foreign offices could include FDA personnel dedicated to educating and training foreign government personnel regarding the importance of the FDA's quality system and good manufacturing standards to helping ensure product quality, safety and efficacy. FDA personnel stationed in FDA worldwide offices could also conduct or assist with inspections of foreign entities manufacturing or processing products for import into the United States. Establishing worldwide FDA offices in specific regions and/or countries could help ensure that foreign governments receive hands-on, side-by-side training from FDA itself, and that FDA inspectors conducting inspections in foreign countries are dedicated employees to that office and thus are more familiar with the country, its language, and the facilities located therein. In addition, this would be responsive to concerns regarding the Agency's current reliance on employee volunteers to conduct inspections in foreign countries.

Use of Risk-Based Approach to Prioritizing Foreign Facilities for FDA Inspections. The current discussion draft directs FDA to conduct inspections of foreign facilities at least once every two years, which would be consistent with FDA's mandate for inspecting domestic establishments. While conducting foreign establishment inspections every two years is a laudable goal, it's important to recognize that it will take time – possibly years -- for FDA to recruit and train investigators in conducting foreign inspections. Therefore, PhRMA believes that Congress should give FDA the flexibility to develop a risk-based approach to efficiently use its resources to prioritize foreign establishments for inspections, particularly in light of the practical realities regarding the time it will take to establish an enhanced FDA foreign inspectorate. In our view, categorizing and prioritizing FDA inspections of foreign establishments based on the risks they present – and relying on set criteria such as compliance history, time since last inspection, and type of products produced – will enhance the FDA's ability to target its inspection resources efficiently and effectively.

The use of risk-based approaches to GMP inspections is not a new concept.[12] In fact, the Administration has endorsed the use of risk-based models in other regulatory contexts (such as to focus FDA inspections of food facilities and in the recently-issued Import Safety Action Plan). Three categories of risk should be created -- high, moderate, and low – and FDA's inspection resources should be targeted to facilities that are highest priority in this classification. Criteria should be set out in any new legislation to guide FDA's placement of specific foreign establishments into each risk category. These criteria could include: (a) compliance history; (b) time since last inspection (by

[12] See e.g., "FDA Guidance: Risk-Based Method for Prioritizing GMP Inspections of Pharmaceutical Manufacturing Sites – A Pilot Risk Ranking Model," (Sept. 2004).

FDA/qualified third party/audit by finished product manufacturer for component supplier); (c) type of product imports (e.g, Class III medical device, sterile drug products), including any unique considerations presented by the patient population to be treated by the product; (d) volume of product imports; and (e) geographic location, if Congress deems appropriate. FDA should also retain flexibility to move foreign facilities within the three risk categories. For example, a formerly high-priority facility with a good track record of FDA compliance over a period of time should be allowed to be moved to the moderate or low- priority category. Similarly, foreign facilities that present unforeseen risks based on new information should be able to be ranked in another priority category.

A risk-based approach would allow the agency to prioritize its inspections and maximize its resources to conduct foreign inspections. Moreover, a risk-based approach will give the FDA flexibility to efficiently and effectively target its resources to foreign establishments that it identifies as the highest priority.

Use of Accredited Third Parties. In recognition of the fact that the Agency does not have unlimited resources and in order to help ensure that foreign inspections occur on a more regular basis, Congress should consider allowing FDA to use accredited third parties to conduct some foreign inspections (such as those classified in the moderate to low risk categories). These inspections would not necessarily take the place of FDA inspections, which are a necessary and important part of its mandate. Nonetheless, it would give the FDA flexibility to maximize its resources without foreclosing its ability to inspect any facility. Granting FDA the flexibility to use accredited third parties as appropriate to help assure moderate and low risk foreign

facilities continue to meet FDA requirements would allow the Agency to focus its resources on inspections of foreign facilities the Agency has determined are of the highest priority.

D. Enforcement Authorities and Penalties

Refusal or Delayed Entry into the U.S. Section 202 of the Committee's most recent discussion draft provides that a registration could be suspended if the establishment – or any employee of an establishment – "delays, limits or denies" an FDA inspection under the FDCA. In our view, failure to register with FDA or to participate in FDA's foreign inspection program should be considered grounds for refusal of products offered into the U.S., and could be coupled with other existing penalty mechanisms, as appropriate. In recent testimony before the Oversight & Investigations Subcommittee, the FDA Commissioner stated that FDA believes products should be refused admission into the U.S. if the Agency "encounters undue delay, limits, or denials of access to foreign manufacturing sites".[13] Clearly delineating the conduct that would satisfy these criteria will be important, but FDA and Customs and Border Protection should be able to refuse or delay entry into the U.S. of products manufactured by facilities in foreign countries that fail to register with FDA as required or do not undergo an FDA inspection as required.

[13] Statement of Andrew C. von Eschenbach, M.D., Commissioner of Food and Drugs, U.S. Food and Drug Administration, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives, "FDA Actions to Improve Safety of Medical Products with Foreign Components," April 22, 2008, at 13.

Limited Waiver or Exemption from Import Delays or Refusals in Limited Circumstances Congress could consider granting discretion to the FDA to allow a limited waiver or exemption from any new authority to refuse or delay products for entry into the U.S. for: (a) products or components used in clinical trials or other qualified investigations; (b) products or components used to manufacture products in short supply or orphan products; (c) as necessary to protect the public health (at FDA's discretion); (d) products or components imported or offered for import by a company that has recently qualified its downstream supplier (e.g., finished product manufacturer attests to quality and purity of components used in finished product whether manufactured by affiliate or third party); (e) intra-company transfers where the parent company is in compliance with FDA requirements and has submitted to required FDA inspections; or (f) products or components necessary for use in medical emergencies or to respond to a bioterror attack or pandemic. These exemptions would help ensure that FDA has the flexibility to protect patient safety and ensure vital clinical research is not unduly compromised due to supply shortages.

Increase Criminal Penalties for Counterfeiting. Recent media reports regarding a contaminated drug product entering the U.S. suggest adulteration of a product component that was not readily detected and may have been intentional. Counterfeiting of pharmaceutical products is a significant concern, and counterfeiting of finished pharmaceuticals is expected to increase to $75 billion in sales by 2010, according to the Center for Medicines in the Public Interest.[14] However, the current

[14] WHO IMPACT Fact Sheet, No. 275, Nov. 14, 2006, available at: <http://www.who.int/mediacentre/factsheets/fs275/en/index.html>.

penalties for counterfeiting a drug product are less than the penalties for counterfeiting a single dime. The penalties associated with counterfeiting should be commensurate with the significant public health threat posed by counterfeit drugs; and sufficient to deter counterfeiting activities, particularly by organized crime. Accordingly, Congress should increase the maximum penalty for counterfeiting drug products from 3 years to 20 years.

III. "Safeguarding America's Pharmaceuticals Act of 2008"

Finally, I would like to provide our preliminary comments on H.R. 5839, the "Safeguarding America's Pharmaceuticals Act of 2008." PhRMA commends Congressmen Buyer and Matheson for their leadership on this issue and their tireless efforts in working with all stakeholders on this bill. PhRMA also appreciates the thoughtful and phased process set out in the bill to apply anti-counterfeiting technologies to prescription medicines based initially on the potential risks posed by counterfeiting and diversion of such products. Supply chain security is the responsibility of all parties involved in the distribution of products to American patients. It is important to recognize that any requirement to apply electronic technologies to prescription drug products will necessarily need to be applied using a phased approach, both in terms of the scope of products selected, and phased across all partners in the prescription drug supply chain.

In PhRMA's view, any legislative or regulatory requirements to authenticate products and pass pedigree information should be uniform, should apply to all parties in the pharmaceutical supply chain, and should recognize the recent federal requirement

for a standardized numerical identifier. The bill introduced by Reps. Buyer and Matheson meets these criteria.

In our view, the only effective way to combat counterfeiting is to adopt a multi-pronged strategy that addresses weaknesses throughout the distribution system. There is no technological "magic bullet" that will prevent counterfeiting, and the Buyer-Matheson allows the use of flexible technologies. PhRMA member companies currently employ and routinely enhance a variety of anti-counterfeiting technologies, including covert and overt features on the packaging of high-risk prescription drugs. Many companies have also adopted certain business processes to better secure the supply chain and help facilitate the early detection of criminal counterfeiting activity. PhRMA also supports raising the minimum licensure requirements for wholesale distributors, to prevent diverters and counterfeiters from re-locating to states without strong licensure requirements. We also support increasing federal oversight over repackaging operations, which has been identified as a weak spot in the drug distribution system and increased penalties for drug counterfeiters, as previously stated.

Finally, the proliferation of differing state and federal requirements in this area would create confusion and could potentially negatively impact the pharmaceutical supply chain; therefore, one uniform, national standard is necessary. The "Safeguarding America's Pharmaceuticals Act of 2008" sets up a process to create a single, national standard, and thus, appropriately recognizes the need for uniformity in this area.

While these comments are preliminary, we appreciate your demonstrated leadership on this issue and look forward to continuing to work with Congress and other interested stakeholders to help assure that the integrity of America's drug supply system continues to be safeguarded from the increasing worldwide counterfeit threat.

IV. Conclusion

PhRMA believes a science-driven, risk-based approach to conducting FDA foreign inspections is the most efficient and effective means to target FDA's resources. Moreover, PhRMA encourages Congress to appropriate sufficient resources to help the FDA meet its statutorily-prescibed mandates. PhRMA also supports a uniform national standard for the application of any electronic anti-counterfeiting technologies to prescription drug products.

We commend the Committee for its thoughtful approach to helping ensure that the health and safety of American patients is protected. We recognize the importance of ensuring that the regulatory system in place today for prescription drugs remains the best in the world and the safest in the world. The recent events regarding a contaminated drug product entering the U.S. underscores the potential that exists for unsafe and potentially dangerous counterfeit drugs to enter the U.S. should Congress act to open our borders to more expansive prescription drug importation proposals. Our system today is very, very good but even good systems can be improved upon. We look forward to continuing to work with the Committee on these important legislative issues and with the FDA to help make our current robust system even safer and

stronger. Thank you for the opportunity to testify today and I welcome any questions you may have.