

Statement of

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COMMITTEE ON ENERGY & COMMERCE

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1. INTRODUCTION

Mr. Chairman and Members of the Committee, I am Benjamin L. England, an attorney in the Washington, D.C. offices of the law firm of Jones Walker. I am a 17-year veteran of the U.S. Food and Drug Administration (FDA), during which time I held the positions of Regulatory Microbiologist in FDA's Baltimore Microbiology Laboratory, Consumer Safety Officer and Compliance Officer in FDA's Baltimore District Office, Special Agent with FDA's Office of Criminal Investigations in the Miami Field Office, Compliance Officer in FDA's Miami Resident Post, and Regulatory Counsel to FDA's Associate Commissioner for Regulatory Affairs (or ACRA) in Headquarters. I resigned my most recent FDA position as Regulatory Counsel to the ACRA in July 2003 -- a position I held in FDA for over three years as a Title 42 appointee. During my last three years at FDA, I was a key point person for Customs and Border Protection, I chaired the FDA's Counterfeit Drug Working Group, instituted the Joint Agency-Industry Working Group to combat product counterfeiting and tampering, which laid the ground

work for the preparation of FDA's initial Counterfeit Drug Task Force report, and co-chaired FDA's Import Strategic Plan Steering Committee.

I am now an attorney in private practice representing domestic and foreign companies before and against various federal agencies related to the manufacture, distribution, importation and exportation of FDA and USDA regulated commodities. I spend much of my time assisting foreign companies and importers in complying with the myriad of federal and state regulatory requirements prior to the process of importation into the U.S.

Along with my colleague, Mr. Carl Nielsen, who is also before you today testifying on his own behalf, I established the Agency's first series of Import Enforcement Training Courses, and with a few dedicated FDA and Customs officials, trained nearly every FDA import inspector, investigator, import program manager, and compliance officer in the effective use of Customs enforcement tools against products imported in the U.S. in violation of FDA requirements.

At the outset, I am pleased the Committee has taken up the issue of safety risks associated with imported products – and to focus today specifically upon FDA's foreign drug inspection program. But as the Chair will know, this is not a new discussion. Eight years ago FDA came before this Committee to answer questions about the very same topic based upon the Committee's thorough investigations into a series of imported counterfeit bulk drug cases initiated by FDA in the very early 1990s. The FDA's foreign drug inspection program, its import programs, and its information technology (IT) systems, which are overburdened with the responsibility of managing data about both, were broken then and, quite frankly, they remain broken today.

2. THE IMPORTED DRUG SAFETY CHALLENGES FACING FDA

It is important to provide some framework for this discussion. In an attempt to avoid duplicating the efforts of multiple witnesses I will keep my remarks to this end brief. Nevertheless, they are critical to understanding the balance of my testimony today. We must bear in mind that although we are discussing a very important concern – FDA’s inability to inspect a sufficient number of foreign drug establishments for current good manufacturing practices (cGMP) compliance to ensure the safety of imported drugs – this topic still represents only one component of the entire import risk matrix confronting the agency.

FDA designed its current import program in the 1970s based upon a century old statutory regime. When section 801 of the Food Drug & Cosmetic Act (FDCA) was enacted very few FDA-regulated products were imported into the U.S. Prior to NAFTA and this country’s participation with other international trade agreements, the majority of FDA-regulated imports consisted of ingredients and components intended for further domestic manufacturing. The most common inbound shipment consisted of break bulk (or noncontainerized) cargo arriving at seaports. The primary strategy at that time was to examine and test some products at the border but to primarily rely on FDA’s domestic inspections to evaluate the quality of imported ingredients and components.

According to FDA data, from 1991 to 2000 FDA-regulated imports increased by 272% and in 2001 alone there were more than 7 million imported commercial lines of entry.¹ In 2002,

¹ A commercial line of entry is the equivalent of a line on a commercial invoice covering the sale of a product from a foreign exporter to a U.S. importer, owner, or consignee. A line may consist of a single laser DVD reader from Taiwan, regulated by FDA as an electronic product, or it may consist of 10 x 40 foot refrigerated containers of cantaloupes from Mexico. With regard to drugs, a line may be a shipment of 10 cases of retail ready over-the-counter (OTC) tablets of acetaminophen or a container of several metric tons of relatively pure bulk active pharmaceutical ingredients. A single invoice may have one or dozens of lines. FDA counts its import transactions by commercial line of entry. Each FDA-

approximately 7.8 million lines of FDA-regulated commercial shipments were imported. From 1997 to 2002, the number of imports of every kind of FDA-regulated product at least doubled. This year, in 2007, FDA anticipates as many as 18 million commercial lines of entry under its jurisdiction will be imported – representing a second doubling in the sheer number of entry transactions since 2002. FDA’s resources directed at assessing the safety of imported products has remained static throughout the entire time period.²

Based upon my experience at FDA, which is further informed by recent statements from FDA in the press and in testimony before various congressional committees, roughly 60% of the total number of commercial lines of entry are food imports; 25% consist of imported medical devices; and 10% consist of imported drugs and biologics. Using these proportions, FDA is responsible for ensuring the quality, safety and efficacy of nearly 2 million imported drug shipments per year. These shipments range from small international courier packages containing several bottles of prescription pharmaceuticals to forty-foot container-loads of metric tons of bulk APIs for further manufacturing and processing.³

Since 1993, finished-product manufacturing in many FDA-regulated industries, including pharmaceuticals, has shifted to foreign markets. Now the answers FDA previously obtained

regulated line is subject to FDA jurisdiction based upon the legal definitions of the various products in the FDCA.

² More regrettably, even though roughly half of all FDA-regulated products consumed in the U.S. are either manufactured in whole or in part in a foreign country, as I recall by the summer of 2003 approximately only 7 out of every 100 dollars spent by FDA regulating products under the Agency’s jurisdiction was focused on FDA’s import or foreign programs.

³ This estimate does not include drug shipments received through the international mail system at the twelve international mail facilities around the country. Those small mail shipments are excluded because they are generally of a lower value and do not reach the threshold of a formal entry. The international mail system remains an un-automated, paper-based system and packages coming through it are not routed through FDA’s electronic import screening system. They are off-line and virtually unevaluated for risk, unless a wary, experienced Customs official targets a package for further FDA review. However, even in those situations, FDA can review only a very small fraction of the packages targeted by Customs.

about the quality and safety of ingredients through its domestic inspection program lay thousands of miles beyond U.S. borders – and far beyond traditional FDA oversight. Yet FDA has continued to rely primarily on border examinations, label reviews, and a finished-product testing to identify problems with the vast majority of imported products under its jurisdiction.

In drug manufacturing, a product’s ingredients are highly critical to ensuring finished product quality, safety, and efficacy. A remarkable amount of active pharmaceutical ingredients (APIs) are manufactured in foreign countries as are inactive (excipient) ingredients. FDA’s foreign inspection regime may cover API manufacturing intended for application and prescription drug finishing, but for over-the-counter (OTC) products, the agency is virtually absent in the foreign market and at the border.

2. TEN YEARS’ BACK

A. Defining the Universe

One particularly disconcerting issue that came to light during the hearings before this Committee in 2000 was FDA’s inability to clearly identify the number for foreign manufacturing facilities exporting drugs to the U.S. For instance, FDA stated that it is “hindered by not having a complete list of foreign facilities manufacturing drug products for the U.S. market,” which “indicate[d] a need to improve the Agency’s information databases on foreign firms exporting drug products to the U.S.”⁴ This lack of a quantifiable foreign drug manufacturing universe completely undermines FDA’s ability to assess the risks associated with products emerging from that universe. Further, it disables this Committee’s capacity to conduct oversight.

⁴ See Statement of Dennis Baker, Associate Commissioner for Regulatory Affairs, FDA, Before the Subcomm. on Oversight & Investigations, Comm. on Commerce, U.S. House of Representatives, <http://www.fda.gov/ola/2000/importeddrugs.html> (June 8, 2000).

In 2000, FDA's list of "uninspected" foreign API manufacturers exporting to the U.S. ranged from 242 to 4,600, depending upon the criteria used to populate the list.⁵ The reasons for such disparity include the FDA's multiple, "siloed", antiquated and non-integrated IT systems; the lack of a meaningful gatekeeper for the Agency's drug establishment registration process; the Agency's insistence to mitigate the usefulness of FDA's historical import entry (OASIS⁶) transactional data, and a redefining of the very term in question: "uninspected foreign firms." Ordinarily, FDA answers this question with respect to "foreign drug firms that *should be* inspected by FDA." Following that framing, FDA typically characterizes the question as solely relating to foreign firms manufacturing prescription or application⁷ finished drugs or APIs. This recharacterization alone results in a substantial downward departure of the magnitude in the number of foreign firms of regulatory significance.⁸

⁵ See Statement of Jane E. Henney, M.D., FDA Commissioner, Before the Subcomm. on Oversight & Investigations, Comm. on Commerce, U.S. House of Representatives, <http://www.fda.gov/ola/2000/counterfeitdrugs.html> (Oct. 3, 2000).

⁶ "OASIS" is an acronym that stands for FDA's "Operational and Administrative System for Import Support." See FDA's discussion of OASIS at http://www.fda.gov/ora/import/oasis/home_page.html.

⁷ Application drugs include those that are subject to an FDA New Drug Application (NDA), Abbreviated NDA (ANDA), New Animal Drug Application (NADA), or Abbreviated NADA (ANADA). It also may apply to Investigational New Drugs (INDs) depending upon whether the agency is seeking to promote an expansive view (*e.g.*, the scope of its jurisdiction under the law) or minimalist view (*e.g.*, its inspectional duties under the law). In many cases, the same API may be used for manufacture of an application or non-application drug (*e.g.*, an OTC drug product) or in the human or animal drug market.

⁸ Note that on the same date as Dr. Henney's October 2000 testimony (*see* n.7) FDA created, populated, and issued an Import Alert affecting the smaller number (242) of these foreign API firms. In FDA's own opinion the Agency could not determine from a review of their own internal data systems that these 242 firms had ever been inspected. See Detention Without Physical Examination of APIs that Appear to be Misbranded Under 502(f)(1) Because They Do Not Meet the Requirements for the Labeling Exemptions in 21 C.F.R. 201.122, at http://www.fda.gov/ora/fiars/ora_import_ia6666.html (issued Oct. 3, 2000, last updated Aug. 25, 2006). The body of that import alert contains a clear example of the agency's recharacterization to reduce the size of the uninspected foreign firm universe. The alert states, "OASIS records indicate that a large volume of bulk chemicals which can be used as APIs in human medicines *that require NDAs, ANDAs, or INDs* are being offered for entry into the U.S." See *id.* FDA then exempts from the guidance in the alert those APIs intended to for pharmacy compounding (whether of a

Today, it is apparent that all of these factors persist at FDA and the agency is still struggling to identify the scope of the universe of foreign drug firms under its jurisdiction – whether we speak in terms of all foreign firms exporting drugs for human or animal consumption or merely foreign firms that FDA believes “should be” inspected. Lacking the ability to identify the larger, total universe of foreign drug firms exporting drugs to the U.S., the attempt to reduce that total to a more manageable “high risk” universe for targeting inspections has little foundation in reality. Consequently, FDA’s current range of foreign drug firms exporting drugs to the U.S. that *should* be inspected by FDA is from 3,000 to 6,700.⁹

B. Identifying and Assessing FDA’s Tools for Managing Imported Drug Risks

In 1998, the Government Accounting Office (GAO)¹⁰ reported that FDA relied on “15 separate [data] systems to identify foreign pharmaceutical manufacturers, plan foreign inspection travel, track inspection results, and monitor enforcement actions.” FOOD AND DRUG ADMINISTRATION: Improvements Needed in the Foreign Drug Inspection Program, GAO Report to the Chairman, Subcommittee on Oversight and Investigations, Committee on Commerce, House of Representatives, at <http://www.gao.gov/archive/1998/he98021.pdf> (Mar.

prescription or OTC finished drug) or for manufacturing into an OTC drug product. Ironically, a manual count of the number of firms on FDA Import Alert 66-66 reveals that today there are currently 243 firms subject to the alert’s regulatory guidance.

⁹ These numbers are derived from two separate FDA data systems and thus the disparity. The lower number is reportedly from FDA’s Drug Registration and Listing System (DRLS). The higher number is a downward departure from data stored in ORADDS, the OASIS data warehouse. Therefore, the lower number is taken from the process whereby foreign manufacturers report data to FDA in order to meet two of the most basic minimum requirements to export drugs to the U.S.: drug registration and drug listing; and the higher number is taken from the process whereby Customs brokers report to Customs and to FDA through OASIS the identity of foreign manufacturers *actually* exporting drugs to the U.S. This discrepancy alone is troubling. It is unclear over what time frame the two numbers were derived and whether they correlate. Further, it undercuts FDA’s traditional argument that OASIS data is unreliable simply because it represents self reporting through the importation process. DRLS also represents self reporting to FDA, and in the import declaration environment, there is another agency, Customs and Border Protection, that strictly governs and enforces proper data reporting.

¹⁰ Since renamed the “Governmental Accountability Office”.

1998). This is, in large part, a continuing problem at FDA. These multiple “siloes” IT systems were created for disparate reasons, and therefore, they house and track data in formats that render them of limited value to import inspectors, compliance officers, and the Agency’s foreign trip planners and foreign inspection schedulers. It is clear that they still produce widely varying results when used to identify the universe of foreign drug firms of regulatory significance. The lack of integration in FDA’s IT systems to a great extent is a result of a lack of integration within the agency itself. Consequently, FDA’s IT systems are built around its organizational stove pipes, resulting in systems that are not designed to talk to each other and are not formatted to dispense data upon inquiry to support programs in other branches of the agency.

The GAO also reported in 1998 that “FDA conducts infrequent routine inspections of foreign [drug] manufacturers to ensure that they continue to comply with U.S. quality standards, although routine [cGMP] surveillance inspections constitute FDA’s most comprehensive program for monitoring the quality of marketed pharmaceutical products.” While the number of foreign firms exporting drugs to the U.S. increased during the 1990s, the agency’s foreign inspections and resources for import operations (and, incidentally, its IT budget) remained disproportionately static or dwindled. The FDA’s inspection cycle for drug firms in India and China, by way of example, was reported in the 1998 GAO report to run between 4 and 5 years, in contrast to the domestic industry, which was (and is) inspected nearly every other year.

Today, using the smallest FDA inventory estimate of 3,000 foreign drug establishments that *should* be inspected (*e.g.*, prescription and application drugs and API manufacturers), maintaining a 5-year surveillance, cGMP inspection cycle would require FDA to conduct 600 such inspections annually. I find no one who reasonably argues this number of foreign inspections is attainable at FDA’s current resource level or as long as the agency spends the vast

percentage of its resources on domestic industry compliance. Achieving a more appropriate 2-3 year inspection cycle among this same population would require FDA to conduct approximately 1,250 (on average) foreign surveillance, cGMP inspections per year. In addition, for the Agency to be capable of assessing the compliance status of foreign firms *between* inspections would require a complete reinvention of the agency's import program and IT systems.

Fundamentally speaking, the import and IT reinvention process to better manage risks associated with imported drugs cannot be limited to the resources available to conduct foreign inspections. Otherwise, FDA will continue to cast its foreign inspection risk assessment/mitigation net just wide enough to capture the narrowest and highest therapeutic or manufacturing process risks, such as prescription drugs or sterile manufacturing processes. Instead, the questions should be: "Which foreign facilities should be inspected? And which import shipments should be intercepted based upon **all** available risk data?" Answering either question using only 3,000 to 6,700 prescription or application foreign drug manufacturers as your universe presumes OTC drug shipments are low risk – but that is purely a presumption. Where this presumption persists the diminishing percentage of inspected foreign firms vs. those that *should* be inspected results in a substantially smaller and arbitrarily defined failure to manage imported risk.¹¹ Consequently, legislating or funding into this presumption excludes

¹¹ The GAO observed the same problem when discussing this issue with FDA in the 1990s. In the 1998 report, the GAO states,

In developing its new four-tiered [foreign] surveillance inspection strategy, however, FDA did not include all foreign pharmaceutical manufacturers that it should consider for a routine surveillance inspection. According to FDA data, *about 3,200* foreign manufacturers have submitted information to FDA listing pharmaceutical products that they intend to export to the United States. However, FDA prioritized for routine surveillance inspections only the 1,100 foreign pharmaceutical manufacturers that it had previously inspected. Consequently, FDA's scheduling strategy does not account for almost two-thirds of the foreign manufacturers that may be exporting pharmaceuticals to the United States.

risks that are likely quite substantial. Further, it perpetuates the problem the Committee has been trying to resolve for at least the last ten years.¹²

When FDA is virtually absent in the foreign market assessing compliance with cGMPs, the Agency is left with attempting to assess risks associated with foreign sourced drugs and drug ingredients using its import operations. The import program, however, focuses primarily on FDA approved application, facility registration, and drug listing database submissions, label reviews, and finished product testing. These approaches are woefully inadequate to assess the cGMP compliance and therefore the quality and safety of imported drugs. Although testing can tell FDA something about the quality and even the safety of an imported product, finished product testing at the border (or anywhere along the supply chain) is not a statistically valid method for predicting the safety of later or earlier untested shipments – even other shipments from the same processor.

Where product (and patient) safety is so dependent upon an ongoing and rigorous manufacturing quality system, finished product testing is not even a valid way to determine product safety within the same shipment. Compliance with FDA’s drug cGMP program is the only (current) framework within which the agency can justify relying upon the results obtained from finished product test. Finished product testing is confirmatory only. Without an assessment and understanding about the conditions of manufacture within the facility, the

GAO Report at 26 (emphasis added). Ironically, ten years later FDA is doing the same in its reporting to GAO and this Committee, except now the number of facilities that *should* be inspected has itself risen to 3,000 to 6,700 establishments. Of course, FDA has since abandoned its four-tiered targeting strategy for foreign firms because it never got around to inspecting tiers III and IV and so there was no purpose in distinguishing among them. Today we learn that FDA has 600 foreign drug firms identified in its systems that are making and exporting “unknown” drugs.

¹² Take, for example, the numerous press accounts and FDA notices regarding the presence of diethylene glycol (DEG) contamination (or substitution) in glycerine-based drug ingredients or finished products – all of which were discovered in OTC drugs or non-active drug ingredients (excipients).

finished product test results are anecdotal at best. Such an approach cannot predict, measure, assess, or assure drug safety.

Any question about this premise is laid to rest with a simple hypothetical observation: If, during a facility inspection, FDA were to find a drug company's cGMP program rested upon establishment registration, drug listing, labeling compliance, and finished-product testing the Agency would shut the facility down, seek a mass seizure, force a (voluntary) recall, pursue civil disgorgement and probably criminally prosecute its operators. Yet, to the greatest extent, that is the near equivalent of FDA's current imported drug evaluation program. Lacking a robust foreign drug inspection program, which takes into consideration all elements of prescription *and* non-prescription foreign drug manufacturing in its scheduling and preparation, promotes a "catch me if you can" foreign drug compliance culture.

3. FDA's Recent Public Discussions Regarding Imported Product Risks

Before I discuss proposed solutions to the drug importation problems, I would like to note a few additional examples where FDA is attempting to redefine what it is currently doing as "risk management." For instance, I have previously noted in similar settings that FDA has implied its import electronic screening system (OASIS) is assisting in assuring the safety and compliance of imported products – but it is not. OASIS is a static, hard rules based system. It only looks for things it is specifically instructed to look for among data elements derived primarily from an invoice, shipping manifest or bill of lading. Such documents simply do not contain information about the manner in which a product was manufactured or the ingredients or components used to prepare the product.

The most common OASIS preset screening combinations are shipper or manufacturer identity plus FDA product code or country or region plus FDA product code. These data

combinations are used to implement FDA's import alert system. However, even when an import alert "hits" in the system, a human entry reviewer must still physically read through dozens of pages and scour through perhaps hundreds of written data elements to see if OASIS is correct before automatically detaining a shipment based upon the alert. OASIS is not integrated with other FDA legacy systems; therefore, import inspectors, import entry reviewers and import compliance officers must enter and exit dozens of data bases in any given hour to determine whether data submitted through OASIS is accurate and truly applicable to an imported shipment. The waste in full time equivalents is probably incalculable and FDA's current resource management systems do not capture this waste. Although OASIS assists in work flow management and tracks import transactions, it performs no affirmative compliance or safety assessment. Furthermore, the import alert system is only risk based to the extent that it "hits" for further review shipments that correspond to data already determined by a prior import examination. Each Import Alert is populated by evidence of situations that have already been discovered. Therefore, the system does not assist FDA in targeting future inspections.¹³

Recently, FDA admitted these facts during a hearing before the Subcommittee on Agriculture Appropriations in the House Committee on Appropriations.¹⁴ Yet, FDA persists in claiming that the agency "currently screens electronically-submitted information on all incoming shipments, and then uses a risk-based approach which targets [FDA's] inspectional resources at

¹³ Although Import Alert data, based upon prior FDA foreign inspections, is integrated into OASIS, that screening is not based upon prospective risk management but is a reactive implementation of already discovered problems. It is good the Agency has integrated Import Alert screening into OASIS, but it is not the kind of risk assessment that helps FDA determine what to inspect next.

¹⁴ During this hearing Dr. Steven M. Solomon, FDA's Deputy Director of the Office of Regional Operations in the Office of Regulatory Affairs, acknowledged that my characterization was fundamentally correct. Sept. 25, 2007.

products having the greatest potential for causing harm to public health.”¹⁵ This latter assertion implies that FDA has developed a risk-based approach for assessing and targeting incoming imported products for the greatest potential for causing public harm and then applies that risk-based approach to the electronically (OASIS) submitted data. The two assertions cannot coexist. OASIS lacks the capacity to evaluate any imported data, irrespective of product, country of origin, manufacturer, or FDA requirement. Therefore, the only screening that can be occurring in OASIS is based upon the invoice data submitted into the system and preset rules, as defined by prior examinations (import alerts), drug registration and listing, and invoice data, which have no relation to compliance of the foreign drug manufacturer on most important drug quality, safety, and efficacy level – cGMP compliance.

This mischaracterization of the capabilities of FDA’s IT systems carries over to its implementation of the “Bioterrorism Act”¹⁶ requirement to for food importers to provide prior notice of imported food shipments and the Agency’s explanation of what the International Trade Data System was designed or is capable of doing. FDA states, for example, “[o]ne of the most important provisions [of the Bioterrorism Act] is the requirement that FDA be provided prior notice of food (including animal feed) that is imported . . . into the U.S. This advance information enables FDA, working closely with [Customs and Border Protection], to more effectively target food that may be intentionally contaminated with a biological or chemical agent or which may pose a significant health risk to the American public.”¹⁷ FDA fails to

¹⁵ See Statement of Steven M. Solomon, D.V.M., M.P.H., Deputy Director of the Office of Regional Operations, Office of Regulatory Affairs, before the Comm. on Ways and Means, Subcomm. on Trade, at <http://www.fda.gov/ola/2007/importsafety100407.html> (Oct. 4, 2007).

¹⁶ See Public Health Security and Bioterrorism Act Preparedness and Response Act of 2002 (Bioterrorism Act), Sec. 307, P.L. 107-188, June 12, 2002.

¹⁷ See Solomon, *supra* n. 12.

address the fact that the prior notice submission amounts to little more than the invoice data that already appears in the electronic entry submitted to OASIS – plus some arrival and facility registration information. The food facility registration program, however, suffers from the same weaknesses as the drug registration program – it is entirely disconnected from manufacturing and processing data and there is no registration gatekeeper on the portal. Any of us could register ourselves as foreign drug, device, food, or cosmetic manufacturing facilities – or all four – and obtain the registration numbers.

As stated previously, these challenges to identifying, assessing and mitigating or interdicting risks associated with imported products did not arise recently. Yet contrary to all logic a post-NAFTA FDA has continued to pursue a doomed pre-NAFTA paradigm. It is even more troubling that FDA has failed to implement literally hundreds of proposed solutions to specific import and foreign inspection problems which would have enabled FDA to begin to progressively focus its limited resources where the risks are indeed greatest. Those proposals were made internally through the Import Strategic Plan (ISP) over four years ago. In the meantime, FDA regulated imports again increased from approximately 10 million to 18 million commercial lines of entry.

Given these circumstances, increasing funding to support FDA's current import and foreign drug inspection programs, without requiring a significant change in its approach would, in my opinion, produce far additional waste, result in even more shipping delays for compliant and safe import shipments, and provide little basis for consumer (or congressional) confidence in the safety of imported drugs. Attempting to build on existing efforts and operations is predestined to fail because it would be based upon too many false presumptions. A drastic internal change is needed.

4. The Bioterrorism Act

On June 12, 2002, President George W. Bush signed the Bioterrorism Act into law and dramatically enhanced FDA's import authority for imported *foods*. Most notably, section 302(a) of the Bioterrorism Act amended Section 801 of the FDCA directing FDA to give "high priority to increasing the number of [import] inspections . . . for the purpose of enabling [the agency] to inspect food offered for import at ports of entry into the United States, with the greatest priority given to inspections to detect the intentional adulteration of [imported] food." Furthermore, section 302(b) directs FDA to "improve its information management systems that contain information related to foods imported or offered for import into the United States for purposes of improving the ability of [FDA] to allocate resources, detect the intentional adulteration of food, and *facilitate* the importation of food that is in compliance with [the FDCA]." 21 U.S.C. § 381(h)(2).

This second legislative mandate essentially establishes the framework within which the balance of the new food safety and security authorities were to be implemented. More significantly, this subsection provided a blueprint for the agency to redesign its import policies, programs, and operations through the ISP process. FDA has persisted in ignoring these mandates for imported foods. Perhaps by Congress' reiteration of this principle for imported drugs, devices, and cosmetics, the agency would understand how the provision relates to international risk management; by incorporating a comprehensive risk-based foreign inspection regime for all drug facilities and quantifying the risk-mitigation value of other regulatory programs already being pursued by the agency and industry. In my opinion, 21 U.S.C. § 381(h)(2) should be extended to all FDA-regulated imported commodities, including imported drugs. With such language, the industry would be empowered to present to FDA ways that

foreign sourced drugs can be demonstrated as safe and effective and of appropriate quality, enabling FDA to focus its foreign inspection and import oversight resources where the risks are greatest.

5. The Import Strategic Plan

A. Missed Opportunities for Change

One of the most important messages today is that FDA's foreign drug inspection program is only one means for FDA to assess and mitigate risks related to imported drugs. Foreign sourced drugs, whether finished or ingredients, active or inactive, must also pass through the bottleneck of FDA's and Customs' import assessment. Although it is true that FDA's import program is woefully inadequate today, only addressing imported drug risks in terms of increased foreign inspections leaves open risks that may arise in between foreign inspections – even if conducted every 2-3 years, or in the product supply chain (*e.g.*, product counterfeiting, commingling, or tampering). Further, as FDA will never cross enough foreign thresholds to enable the Agency to apply inspection data on all imported drug shipments – more than additional resources for foreign inspections is needed.

Shortly after September 11, 2001, FDA's Leadership Council established an Import Strategic Plan Steering Committee. By spring 2003 the Import Strategic Plan was virtually complete. FDA developed the ISP from the contributions of more than one hundred Agency experts in all product Centers, field and headquarters components, laboratories, international programs staff, the General Counsel's Office and the Office of Policy, Planning and Legislation.

The ISP's principles were simple but far reaching: Push the current FDA import evaluation process from the extremely limited border transaction to a life-cycle process, which:

- Intentionally gleans information from all points along an article's supply chain;

- Assesses that information based upon FDA requirements and risk of harm;
- Delivers the assessment to border inspectors, compliance officers, and electronic screening systems for reliable targeting decisions; and
- Results in the facilitation of safe products and enforcement against products that are unsafe.

Under the ISP, three subcommittees were created to assess import safety risks and propose agency solutions along the component parts of the international supply chain, including: foreign operations, border operations and domestic operations. Two cross cutting subcommittees were tasked with tying these supply chain components together: Information Technology and Applied Science and Technology. Each committee was to find information FDA could use to assess risk and develop solutions for mitigating risk earlier in the supply chain rather than later. Meanwhile, the IT and Science subcommittees identified solutions implementing the proposals and reducing time frames where risk targeting indicated a need to inspect and test incoming goods. At the request of the Leadership Council, the ISP subcommittees and steering committee value-ranked the proposed action items for enhancing import safety and estimated their costs as of Spring 2003.

The significance of the ISP and its proposed action items rests in what it represents: an internal agency demand for a dramatic shift in thinking about the identification, assessment and mitigation of risks in the international supply chain. Many of the ISP proposals are indeed costly. However, many could have been implemented nearly immediately and would have begun the process of increasing FDA's import efficiency and effectiveness using existing resources. It is this shift in thinking that FDA's middle and upper management has resisted. But

I believe that all involved in the ISP process recognized the import problems – even in 2003— are complex and cannot be solved with FDA’s traditional regulatory approaches and philosophy.

B. Some Proposed Changes Going Forward

First, any action by this Subcommittee should include a significant resource investment targeted directly for reengineering FDA’s stove-piped IT systems. IT improvements recommended in the ISP are a contingency for executing any serious risk-targeting strategies for foreign inspections and import interdiction of unsafe drugs.

Second, I recommend the establishment within FDA of an organization reporting to the Commissioner with the mission of focusing on enhancing the safety of imported products – all products. We believe fixing FDA’s import and foreign inspection problem requires it be broken free from the domestic programs, which produce much of the bureaucratic inertia against change in this area. A new organization would enable proper staffing, allocation of human resources at ports of entry, management and implementation of ISP-based strategies. It should be responsible for all import and international focused work-planning activities; conducting facility inspections of foreign processors and importers; overseeing and conducting border operations; conducting foreign government and industry assessments and training; and support trade negotiations in a manner to enhance safety of imported products. To accomplish this, the new organization should be directly funded, rather than receiving its funding through the product Centers. A basic persistent infrastructure to manage risks associated with all imported commodities must be maintained regardless of year-to-year changes that may appropriately occur in program directions.

Third, section 302(b) of the Bioterrorism Act, which enables FDA to implement risk-based strategies for managing food imports, should be expanded to cover all other FDA-regulated products including drugs.

Fourth, FDA should publish and begin implementing the ISP in accordance with the plan's guiding principles, goals, and themes.

Fifth, FDA should begin developing programs for obtaining information from third parties about the cGMP compliance status and supply chain security programs of foreign drug facilities that are *not* inspected by FDA. This additional risk data may come in the form of third party inspection and certification companies, accompanied by a robust auditing process on both sides of the border, foreign inspectorates, or other U.S. Government Agency inspections and information. Obtaining and assessing all available risk data would enable FDA to (a) better target its foreign inspections; (b) interdict and examine high-risk imported drug shipments (related to product safety); (c) follow up in the domestic market those shipments that proceeded through the border with inadequate inspections; and facilitate imported drug shipments that are likely to have been manufactured in accordance with FDA's cGMP requirements. This would permit the agency to focus its most earnest import inspection and examination efforts on shipments representing known and unknown risks.

Sixth, FDA requires additional resources to conduct more foreign inspections and import examinations and to develop and publish meaningful Agency guidance relating to identifying and managing risks in the full life cycle of imported products.

Seventh, FDA should rely on Customs and Border Protection and the Department of Homeland Security (DHS) to manage security risks associated with FDA regulated imports. DHS' security programs should be expanded to incorporate *product* security risks (such as

product counterfeiting and tampering) rather than focusing solely upon the security of in-transit cargo or inbound containers.

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I thank the Subcommittee Chair and Members for the opportunity to discuss these important issues and we look forward to answering any questions.