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ONE HUNDRED TENTH CONGRESS

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**"DIMINISHED CAPACITY: CAN THE FDA ASSURE THE SAFETY AND SECURITY
OF THE NATION'S FOOD SUPPLY – PART 2"**

JULY 17, 2007

Mr. Chairman and Members of the Subcommittee, today the Subcommittee begins the second in a series of expected hearings concerning the adequacy of Food and Drug Administration's (FDA) efforts to ensure the safety of the Nation's food supply. As part of this inquiry, Committee staff have reviewed thousands of pages of documents and conducted numerous interviews of industry experts and current and former FDA employees. Per your instructions, we also visited numerous ports of entry and FDA laboratories and field offices. The FDA offices visited included the Detroit, San Francisco, Los Angeles, Denver, Kansas City, Winchester (MA), Atlanta, New York, and San Juan, Puerto Rico district offices and/or laboratories. Minority Staff participated in most of these interviews and site visits.

Chairman Stupak asked the staff to focus on three critical areas of food safety that were raised by the testimony of the April 24, 2007, hearing:

- The extent to which FDA is protecting Americans from contaminated food imports;
- The extent to which FDA's proposed reorganization of its field operations, including FDA's decision to shut down 7 of its 13 laboratories, is consistent with the Agency's charge to ensure the safety of the Nation's food supply;¹
- The extent to which FDA's continued use of voluntary guidelines of certain products that have been implicated in recent food poisoning outbreaks are adequate to ensure the safety of the Nation's food supply. These products include both domestic and imported leafy greens, peanut butter, imported vegetable protein, imported seafood, and imported toothpaste containing the deadly chemical diethylene glycol.

¹ Federal responsibility for food safety is shared by FDA and the U.S. Department of Agriculture (USDA). FDA's authority extends to approximately 80 percent of the food supply.

Preliminary findings confirm the results of the Subcommittee's April 2007 hearing that FDA has failed to adequately respond to increased imports of foreign food products. Recent accounts of tainted imports from China provide additional evidence, simply stated, that FDA lacks sufficient resources and authority to ensure food safety and legislation will be needed to correct these deficiencies.² The current proposal to change FDA's structure and management would appear to exacerbate the current food safety situation. Lastly, FDA's current regulatory approach, which relies upon voluntary guidelines for most domestic and imported foods, appears inadequate in responding to the changing food industry.

1. FDA Regulation of Food Imports is Minimal

Committee staff learned that FDA inspects less than 1 percent of all imported foods and samples only a fraction of those it inspects. While the number of FDA inspectors has been falling since 2003, the importation of food products into the United States has nearly doubled.

Our review of operations in San Francisco typifies the problem with the current FDA inspection system. It was apparent from interviews and observations that it is physically impossible for FDA's San Francisco staff to perform more than a cursory review of most imports. The San Francisco office has four entry reviewers to oversee thousands of entry lines per day. A typical reviewer's day involves examining 600 food entries, 300 medical device entries, 25 reagent entries, and 25 drug entries on a computer screen. This is about 1 entry line every 30 seconds. However, due to the volume of entries and the time required to take action, less than 30 seconds is spent on most of them. A single entry of Chinese herbs can take more than an hour to review. Even the simplest action involves several minutes, *e.g.*, e-mailing a broker for additional information. If an entry review results in a recommendation for a site visit, the Compliance office must make a determination of whether to send an investigator. Compliance must also decide on whether to sample the shipment.

Determining what requires further examination is also complicated by differences and discrepancies in the way imported food is identified. For food, FDA categorizes entries by product codes, but Customs and Border Protection (CBP) categorizes entries by tariff codes, an entirely different system. Brokers often miscode entries and product descriptions are poor, particularly for products imported from China.

FDA's Uncritical Reliance on Private Laboratories Causes Problems

One particularly important problem that staff field investigation uncovered dealt with the unverified reliance by FDA on the use of private laboratory tests to release suspect imports. Committee staff was told by FDA inspectors that FDA permits importers to take possession of even highly suspect goods and arrange for their testing by private laboratories. Import alerts that contain the instruction "detention without physical examination," such as the import alert issued

² See Appendix to staff statement that summarizes a sample of recent news articles concerning unsafe food products from China.

on April 27, 2007, with regard to vegetable protein (wheat gluten, etc.),³ do not literally mean “detain,” but allow delivery to the importer.

Once there have been five consecutive analyses by private laboratories that find no violations, the importer is no longer required to conduct testing on products of that exporter and the goods may proceed into the consumer market without further action, even if the food is covered by an alert. FDA does not require a separate bond be posted by the importer taking delivery. Further, FDA neither accredits nor debars private laboratories that analyze imported food samples, despite the fact that these laboratories often use incorrect methods or report incorrect results.

Officials at all FDA labs visited by Committee staff were critical of private laboratory testing. An FDA Deputy Lab Director, who performs private laboratory reviews, said that some private laboratory work is “decent,” while some is “scary.” He believes that none of the private laboratory analyses are completely accurate. In general, he described private laboratory work as “not good” and “spooky.” An FDA Science Branch Director concurred with this assessment. He commented that private laboratory work is “shoddy” because results are driven by financial rather than scientific concerns.

FDA has the option of sending an inspector to gather samples to be examined in a FDA lab, but rarely does so—only a minute fraction of the 25,000 daily food shipments are ever tested by a Government laboratory. When analyzing samples of imported food, FDA labs often find problems that private labs did not uncover.

Another problem related to imports identified by FDA field staff was that only 20 percent of food imports appear in FDA’s food import computer system (OASIS) for review by the field inspection force. Review criteria are established by FDA’s Division of Import Operations and Policy (DIOP) in Washington and FDA field input is minimal. FDA field inspectors complained to Committee staff that 75 to 80 percent of all individual import entries are not flagged, and therefore, have never been subject to cursory computer inspection of their paperwork by field inspectors who are experts at identifying suspect shipments.

FDA Can Learn from Other Federal Agencies to Better Screen Imports

FDA’s approach to this complex, large, and growing problem is strikingly different from the approach taken by other Federal agencies charged with equally important border inspection responsibilities. Although FDA’s entry reviewers, investigators, and compliance officers are clearly unable to keep up with the flood of imports, FDA has no plans to increase its import staff, but does plan to shut its San Francisco laboratory. In contrast, CBP will be adding 35 new “agricultural specialists” in San Francisco, funded by the user fees that CBP is authorized to charge. FDA has no user fees to pay the cost of monitoring food imports and its proposed fiscal

³ See FDA Import Alert No. 99-29 (April 27, 2007).

year 2008 budget and proposed reorganization indicate that it is not seeking additional resources for this purpose.

Compared to USDA, FDA's resources and activities appear to be woefully short of its food import responsibilities. FDA is responsible for assuring the safety of 80 percent of the food supply, but lacking a user fee system, is able to inspect only about 1 percent of all food imports, and does not ensure that foreign food processors and suppliers meet U.S. food safety standards. In contrast, USDA is responsible for only 20 percent of the food supply, but has a user fee system that allows it to inspect 16 percent of meat imports. In addition, USDA will not permit meat to be shipped to the U.S. unless the exporting country meets USDA regulatory standards. USDA also restricts the ports of entry of meat products to 10 ports. In contrast, FDA does not require comparable regulatory standards and permits imports to enter into the Customs territory of the United States at any of the 326 ports of entry, despite the lack of FDA presence at most of these ports.

Pet Food, Wheat Gluten, and other Vegetable Proteins May Highlight FDA Over-Reliance on OASIS

The recent recall of contaminated wheat gluten and other vegetable proteins highlights the dangers from an over-reliance on the OASIS system that removes 80 percent of the so-called "low risk" imports from any field inspection.

On March 15, 2007, FDA was informed that pets had been dying from kidney failure from eating what was eventually determined to be 95 varieties of pet food manufactured by Menu Foods. Moreover, the common ingredient was wheat gluten, a widely used vegetable protein obtained from ChemNutra, a Las Vegas importer of Chinese ingredients for the pet food and dietary supplement industries. FDA labs in Cincinnati and Kansas City discovered that an industrial chemical, melamine, had been mixed with the wheat gluten in order to artificially elevate its protein content.

An April 27, 2007, Import Alert issued by FDA provided that 8 vegetable proteins (wheat, rice, corn, soy, and mung glutens and proteins) covering 10 tariff codes be "detained without physical examination," as described above. Despite the regularly accepted meaning of the word "detain," this designation did not result in these vegetable proteins being embargoed. These products were delivered to the premises of the importer, and the importer was required to submit samples to private laboratories for testing. As noted above, FDA laboratory officials believe this is not a reliable means for determining the safety of food products.

In contrast to FDA's handling of these imports, CBP, on its own initiative, decided to detain all such imports from China in the 10 tariff codes, pending testing by Government laboratories. All such imports were to be detained at a Customs Examination Station (a warehouse under CBP control), and samples from each lot would be taken and supplied to both Customs and FDA laboratories. FDA officials in San Francisco and Los Angeles were initially

unaware of the CBP initiative and did not appear pleased with the deviation from established the FDA procedure. Ultimately the Agencies coordinated their efforts.

CBP informed Committee staff that those 10 tariff codes produced about 21,000 entry lines on 17,000 entries (many CBP entries contain more than 1 line because they contain more than 1 product) from approximately 1,000 different exporters to the United States annually. This does not include human food, pet food, or animal feeds at risk of containing the suspect vegetable proteins.

Until the high number of pet deaths became evident in March 2007, these vegetable proteins and the animal feeds that contained them had been among the imports FDA never inspected under their OASIS review system. Testimony from the April 24, 2007, hearing reflects that there is no difference in the wheat gluten sold for human food, pet food, or animal feed. Vegetable proteins containing melamine have now been found in chicken, hog, and fish feed.

On April 30, 2007, FDA made assignments to all Districts to inspect and gather samples from food processors that use the suspect vegetable proteins as ingredients in their food products. The number of firms to be inspected, however, is small. For the entire West Coast and for States as far away as Hawaii and Utah, only 34 food processors have been selected for inspection. Fortunately, no vegetable protein was found to contain melamine in any human food processor. A bakery in Seattle was found, however, to have a single unopened bag of ChemNutra wheat gluten.

Country of Origin Regulations Appear Inadequate

The true country of origin of imported wheat gluten and of vegetable proteins is also a matter of some controversy. Committee staff was told that Europe generally, and the Netherlands specifically, is the principal source of wheat gluten imports. Staff witnessed, however, the unloading of wheat gluten declared as coming from China in 50 pound bags marked with the "Wind Mill" brand of a Dutch firm, Meelunie (see attached photos). The bags gave no indication that the product was from China, but indicated the supplier was in "Amsterdam-Holland."

Customs officials informed Committee staff that the Country of Origin regulations now merely require that the purchaser be aware of the correct source of the goods. When the staff inquired as to how any downstream purchasers were to know the true origin of this apparently-Dutch wheat gluten, CBP informed them that if the importer were not the end user of the product, they would have an obligation to inform all their customers of the true country of origin and so on throughout the supply chain. Once the Wind Mill bags enter commerce, however, CBP loses control. Apparently there is no requirement that the consumers of the bread, candy, dietary supplements, or other final products be told of the actual original source of the ingredients. Furthermore, the purchasers of pet food, meat, or fish that have been fed Chinese vegetable proteins are never informed of the country of origin of the final product components.

CBP did indicate the importer might be required to mark the bags, since CBP had no assurance that the true origin would be known downstream.

Since food processors are not required to inform consumers of the origin of its ingredients, Americans have no avenue with which to seek damages from companies that sell products whose ingredients are suspect. Further, the minimal inspection of imported food also means that false country-of-origin labeling is rarely detected.

Seafood Imports Remain Especially Problematic

On July 10, 2007, FDA issued Import Alert #16-131 requiring that all catfish, shrimp, and other specified farm-raised fish from China be “detained without physical examination.” China had been importing fish that were contaminated with fluoroquinolones and other antibiotics as well as malachite, an anti-fungal treatment that is a suspected carcinogen. Malachite is found in ponds and tanks containing fish not intended for human consumption. Other chemicals that are not approved for use in food have also been found in these imports. Antibiotics in food are a public health problem because they promote resistance to drugs that kill infections.

The July 10, 2007, alert notes that 80 percent of the seafood consumed here is imported and 40 percent of that is farm-raised. China produces 70 percent of the farm-raised fish worldwide and exports about 80 percent of its production. The timing of the import alert, however, is curious. From the staff field investigation, it was learned that FDA has known for years about the widespread use of antibiotics and fungicides to treat farm-raised fish from China. It appears, however, that only after the Subcommittee and other Congressional committees began to investigate FDA’s less-than-aggressive approach to the regulation of fish imports, did FDA issue its alert.

FDA field staff expressed their hope that this will mark a renewed concern by their Agency of other known problems with the safety of fish imports. For example, melamine has recently been discovered in the feed for farm-raised fish in Canada, Washington, Alaska, and Oregon. The Canadian producer of the feed has recalled the product, but FDA has yet to announce plans to deal with the fish that were fed the contaminated feed. Committee staff learned that China and Vietnam are also the major source of fish with dangerous levels of histamines due to improper storage.

Another safety concern uncovered by the staff’s fieldwork relates to seafood products and the manipulation of laboratory testing. As noted earlier, one of the questionable activities that FDA policy permits is for importers to become exempt from import alerts by having their product test negative in a private lab five consecutive times. Import alerts have long applied to Mercury and other heavy metal contamination in large fish. Tuna and other large fish, such as Mahi-Mahi and swordfish, with time accumulate mercury from contaminated water. Smaller fish have less time to accumulate such toxins.

FDA laboratory staff warned Committee staff that one of the schemes employed by importers to evade the import alert is to import five separate entries of smaller fish from a certain country or importer covered by an import alert to more easily pass the private laboratory testing. Once their import alert status is removed, they can return to importing larger varieties of fish. One FDA San Francisco laboratory seafood expert told Committee staff that over half of the swordfish on American tables would likely fail mercury testing because of this scheme.

Carbon Monoxide Processing Masks Decomposition

Committee staff learned from its field interviews that large numbers of seafood imports from Asia are arriving in airtight packages containing significant concentrations of carbon monoxide. Carbon monoxide treatment makes seafood appear fresh, regardless of its condition. In San Francisco, the staff learned that fully 20 percent of the fish tested that were imported in a carbon monoxide environment were rejected because of decomposition or histamine contamination. Based upon its investigation, the staff believes that this problem is not unique to San Francisco, but is widespread throughout the Nation.

The issue of using carbon monoxide to manipulate the appearance of food products is not new. For example, Chairmen Dingell and Stupak, along with a number of food safety experts, questioned the safety of meat and fish packaged in an environment containing carbon monoxide with the FDA Commissioner and the HHS Secretary last year. In response, FDA assured them that there was no health concerns associated with artificially disguising the color of meat with carbon monoxide.

Since then, the Committee has sought from FDA any records regarding problems with seafood imports, generally, and those packed in atmospheres containing carbon monoxide, specifically. Although both Majority and Minority staff were shown such records in the field by concerned FDA inspectors, none of the documents examined or discussed during two staff visits to San Francisco have been delivered to the Committee to date.⁴

The problems involving packaging fish in an environment of carbon monoxide raise additional questions about FDA's approval of this process as GRAS (Generally Recognized As Safe) for food products. In San Francisco, the staff was told that the entry of decomposed fish packed in an atmosphere of carbon monoxide dates back to the 1990s. The problem reached such a level of concern in 1999 that FDA issued an import bulletin, advising inspectors to watch out for tuna packed in carbon monoxide.

Despite the import bulletin issued in 1999, in 2001, the Center for Food and Applied Nutrition (CFSAN) approved the retail sale of tuna treated with carbon monoxide as GRAS.

⁴ FDA has furnished the Committee with documents reflecting their refusing entry to nine shipments of fish packed with carbon monoxide because of decomposition so far this year in the port of New York, but not the records in San Francisco or elsewhere. Given the paucity of testing done by FDA in general, even these records from one port demonstrate a troubling number of harmful entries disguised by this FDA-approved method.

Technically, the CFSAN approval was for tuna packaged in “tasteless smoke,” a packaging atmosphere containing carbon monoxide that, in fact, does not cure the fish, but merely preserves the color indefinitely like any other carbon monoxide-containing airtight packaging. The GRAS determination was made by FDA, despite the fact that the European Union bans this dangerous and deceptive practice. Although FDA has subsequently cancelled the import bulletin, the staff was told by FDA field officials in San Francisco and New York that the spoilage problem with carbon monoxide-treated fish has not abated.

Despite these events, in 2004, FDA accepted petitions regarding meat packaged in carbon monoxide as GRAS. This decision permits meat that is well past the time when it is safe to consume to appear as red and fresh as when it was first packaged. The Committee is in the process of trying to determine exactly what CFSAN analysts knew about the problem with decomposed fish, when they permitted both fish and meat packaged in an atmosphere of carbon monoxide to be sold to unsuspecting consumers.

Poisoned Toothpaste Highlights Additional Problems

While not a food per se, FDA handling of the toothpaste from China laced with diethylene glycol (DEG) is demonstrative of several shortcomings of FDA’s handling of imports. In 1997, FDA witnessed 88 deaths in Haiti from cough syrup laced with diethylene glycol, the chemical most often found in antifreeze. The children’s medicine was imported from China. The diethylene glycol was apparently substituted for the more expensive ingredient, glycerin. Last year, 100 people in Panama and 5 people in China died from ingesting medications contaminated with this same chemical. This year, toothpaste imported from China into the United States and seven other countries has been found to contain this poison.

It was not until June 7, 2007, however, that FDA issued an import alert to detain, on the importers’ premises, toothpaste containing DEG and named several Chinese exporters of the product to the U.S. The import alert was amended to include toothpaste packaged with toothbrushes after the San Juan FDA District decided, on its own authority, to inspect retail stores and discovered the presence of diethylene glycol in products that combined toothbrushes with the deadly toothpaste. Their investigation revealed that this combination product was still entering the U.S. market because brokers were declaring the shipments as brushes, not toothpaste.

Counterfeit Colgate-brand toothpaste, labeled as originating from South Africa, that may contain DEG was also discovered during this investigation. Its true country of origin is in doubt. Pictures of some of the toothpaste entries from San Juan are attached.

Committee staff has learned that the San Juan FDA laboratory is no longer permitted to analyze food samples—even though Puerto Rico, as an island, imports most of its food. Thus, FDA now requires that samples of fresh produce that regularly contains illegal concentrations of pesticides from the Dominican Republic must be shipped to Atlanta for analysis.

2. FDA's Proposed Reorganization of its Field Staff would Likely Expose Americans to Even More Danger from Unsafe Food, particularly Imported Food

No Justification Given for Major Reorganization

FDA has announced its intentions to conduct a sweeping reorganization of its field operations in the midst of probably one of the most serious assaults upon food safety since the agency's creation. FDA proposes eliminating 5 current regional offices and reduce the districts from 20 to 16. The district offices to be eliminated in the consolidation are San Juan, Northern New Jersey, Cincinnati, and either Denver or Kansas City. As part of its reorganization plan, FDA is also proposing to close 7 of its 13 laboratories. These include Detroit, San Francisco, Denver, Kansas City, San Juan, Philadelphia, and Winchester, Massachusetts.

Despite repeated requests from the Committee, FDA has failed to provide any analysis justifying this radical reorganization. FDA has failed to provide us with any independent cost-benefit analysis for their proposal. The rationale for choosing which districts to close is not discernable from the documents supplied to the Committee. Decisions regarding district closures appear to be related, in part, to prospective retirement or current vacancies among District Directors.

On the surface, the proposed closings appear to be counterproductive and may needlessly increase taxpayers' costs. For example, even though a very high percentage of drug manufacturing occurs in San Juan and New Jersey, FDA is proposing the closure of these offices and laboratories in Philadelphia and San Juan. The Puerto Rico closures will transfer oversight of drug inspections to the Orlando, Florida, District Office and testing to the Atlanta laboratory. Gathering relevant personnel will either result in tremendous additional expenses or, more likely, less enforcement.

Committee staff was told that among the more indefensible parts of the reorganization proposal is the consolidation of the compliance function into 10 locations. This means, for example, that compliance recommendations regarding Agency action from a San Francisco inspection will be applied in Seattle. Compliance officers make decisions regarding which shipments to inspect, which to sample, and what actions should be taken in response to the inspection findings. No compliance officer that staff questioned thought having the Compliance Director located in a separate office made sense. It would appear that this proposal would make the decision to take regulatory action—an already cumbersome task—even more difficult.

FDA is also proposing to consolidate the entry review function into six locations. Under the current program, a very high percentage of import review is already conducted at headquarters. As previously mentioned, the OASIS system currently removes 80 percent of so-called "low risk" imports from any field inspection. Thus, a very high percentage of food entries are not examined by inspectors at the port who are best positioned to judge the bad actors, the

importers that cheat, the brokers that misclassify, and imported products that arrive in unusual locations. Under the new consolidation, those port inspectors will be totally removed from the identification process. All decisions concerning such inspections will be decided at the six designated locations, not in the field. Committee staff was told that this consolidation is equivalent to having bureaucrats in Washington and a few regional locations determine the assignments for the local police forces.

Likewise, the Committee staff was told that it would appear that the retirement of the District Director in Denver has prompted a decision to split the Kansas City District and move Denver into the District with Kansas and Nebraska, and placing Iowa and Missouri in the Chicago District. Given the character of the primary regulated industries in those States, it is difficult to understand how splitting up a District that requires experts in veterinary medicine and animal feed industries (and now apparently pet food as well) would be productive.

The rationale for closing more than half of FDA's laboratories, at a time when food safety is considered a public health crisis, is not discernible from the records provided to the Committee. The ostensible rationale is that there are a limited number of laboratories that FDA can maintain at a world-class level. Since FDA has not provided an analysis demonstrating any cost-savings associated with the lab closures, their rationale implies that synergies exist in mega-labs; however, no documents have been produced by FDA to support that suggestion. When the Government Accountability Office examined this question, they found that midsize labs were more efficient.

Committee staff was informed by FDA field staff that there will be a tremendous loss in experience as laboratory analysts retire or resign, rather than be relocated. In addition, recent history suggests that it will be extremely difficult to replace the scientists necessary to conduct high-level laboratory activities. When FDA closed labs in 1994, only 17 percent of the affected laboratory analysts elected to transfer. Under the current lab closure proposal, only two analysts in San Francisco, one in Denver, two in Massachusetts, and six in Kansas City have indicated that they may accept a transfer to another lab. Hence, a significant level of expertise is expected to be lost.

Also, taxpayers will not benefit from the substantial sums of money FDA has recently spent accrediting these labs, signing new leases, and rebuilding or refurbishing offices that they now propose to close. For example, the staff noted that the food laboratory equipment, and all but one of the lab structures visited, appear to be modern with long-term leases or outright ownership at each location.

FDA was given four months to produce the documents relating to the lab closures. Prior to last week, FDA has produced only four boxes of paper. Each production included an assurance that the production was essentially complete. The early document productions were noteworthy for the absence of internal documents critical of the reorganization and documents from the field.

More importantly, FDA has not furnished the Committee with documents that suggest the Agency has any plans to hire personnel with equivalent skills at its new locations. In fact, the experience it claims will be replaced cannot be duplicated by new hires over a reasonable period of years. Many of the laboratory employees are renowned in their fields.

The staff was repeatedly told that the only credible explanation for this seemingly incredible decision is that the Office of Regulatory Affairs management intends to contract out the work. The staff was told, however, that State labs will not purchase the millions of dollars in equipment and hire the necessary analysts unless there is an expectation that the transferred work will be permanent. Private laboratories have the drawbacks noted previously.

The critical question of how the work of half of FDA's current labs is to be performed after they are closed remains unanswered by FDA reorganizers. It is difficult to avoid the conclusion that, in fact, FDA management has decided to drastically reduce the sample analyses performed in its own labs and to contract out the remainder.

Labs Due to Be Closed Possess Unique Capabilities

The Committee staff was able to visit all of these labs, except for Philadelphia, in the course of the Subcommittee's investigation and questions the justification for such drastic actions, especially in light of the recent recalls and import alerts. Two of the labs visited by staff, Detroit and San Juan, are almost exclusively devoted to analyzing drugs. Detroit has been an important food lab given the volume of food imported over the Ambassador Bridge from Canada. In this regard, it is important to note that while Canada has a comparable regulatory system, not all imports crossing the border into Detroit originate in Canada.

FDA has limited most of the Detroit laboratory's work to "drug stability analysis," which involves testing related to government stocks of drugs. The staff has been advised by the Department of Defense that such activity saved the Government \$600 million last year, or about 1/3 of the total FDA budget—a very profitable endeavor for the United States Government. The drug stability work was performed by eight full-time equivalents (FTEs) in Detroit and three FTEs each in Philadelphia and San Juan.

It should be noted that 60 percent of U.S. pharmaceuticals are manufactured in Puerto Rico. Many of the inspections cannot be done without a laboratory analyst. Most of the private sector laboratory employees are far more comfortable explaining their work in Spanish. If the seasoned laboratory staff currently in Puerto Rico is lost, FDA will be forced to find comparably skilled bilingual chemists and, once trained, and pay their travel expenses to Puerto Rico. It should be noted that many inspections of drug manufacturing take longer than the FDA estimate of five days.

Committee staff was initially sent to these laboratory locations to examine the work that FDA had done in the melamine investigation. Only Kansas City, a laboratory in the heart of the pet food and animal feed industries, was allowed to analyze food and feeds for melamine.

Although the Kansas City lab has done yeoman's work, analyzing more than 400 samples in a little over 6 weeks time, it was not the only FDA lab capable of performing this work. Notwithstanding their capability, however, it appears that, for unexplained reasons, other FDA labs due to be closed under the proposed reorganization were denied the \$20 standard test needed to detect melamine and were forbidden to analyze samples of pet food, vegetable proteins, or other materials that may have been contaminated by Chinese imports. Instead, the Agency spent some fraction of the \$2.6 million in Food Emergency Response Network grants to pay some or all of the 8 university laboratories that have cooperative agreements with FDA to complete testing. To what extent the results of these laboratories could be used in court is problematic, given the chain of custody issues raised by a number of FDA officials during the course of the Committee's investigation.

At best, this was a decision to waste Federal tax dollars, since the work was contracted out to State and university laboratories when in-house was available to perform at least some of the work. Moreover, there are indications that this type of out-sourcing is ineffective. It was an outside laboratory that first pronounced the contaminant in pet food as rat poison. The Cincinnati and Kansas City FDA laboratories discovered the melamine and developed the methods for detection. The Denver lab developed the method for analyzing melamine in fish.

Kansas City, like other FDA labs, was the beneficiary of modern equipment and an expanded work force five years ago as part of the ramp-up decreed by Congress in the Bioterrorism Act. It is a centerpiece for rapid analysis of threats to our food security. Nevertheless, and again for no apparent reason, Kansas City has been identified for closure.

The staff investigation also highlighted the importance of the San Francisco lab in dealing with unsafe imports, especially from the Far East, and with domestic issues related to the Salinas Valley. That laboratory has been a significant force in the interdiction of problematic seafood. The staff was told that FDA lab analysts are regularly recruited by FDA investigators to conduct pre-dawn inspections of seafood importers and processors because of their experience and training in identifying problem seafood. Committee staff learned that the lab's reputation for effectiveness is so well known that many unscrupulous importers of farm-raised shrimp and other fish are now sending their questionable products via air or "in bond" to be "entered" in Las Vegas, in part to avoid the scrutiny that the seafood would face in San Francisco and the other West Coast seaports.

Both the State of California and FDA inspectors involved in the produce investigation told Committee staff that the closure of the San Francisco lab would be a great loss to the California Food Emergency Response Team. Committee staff were told that laboratory analysts are often needed to go into the field with investigators. These officials feared that this would be

unlikely if the lab were closed. They warned of a significant loss of expertise.

Officials also advised the staff that it is crucial to have a local lab to analyze the samples. It takes less than two hours to get to the San Francisco lab from the Salinas Valley. The time it takes to get samples from the field to the lab is crucial because enrichment of the samples must be complete within 24 hours. If samples had to be shipped, it is likely that enrichment would not be timely. Further, samples cannot be shipped on the weekend. The FDA officials told Committee staff that when samples are collected on the weekend, San Francisco provides an analyst in the lab. Another concern regarding samples that must be shipped is that they are temperature sensitive. The San Francisco lab puts a priority on analyzing produce and fish samples collected and warned that other labs may assign priority to the collections of investigators in their own District.

The San Francisco lab employs a seafood sensory expert inspector with such unique skills that he appears to be the only FDA employee qualified to identify where to take samples in seafood shipments. In addition, State officials indicated their concerns that outbreaks in California involving produce will overwhelm the five microbiologists in the State lab, if San Francisco is shut down, and other labs are too distant to effectively analyze lettuce or spinach produce.

Committee staff also learned that the Winchester Engineering and Analytical Center (WEAC) in Massachusetts is the only FDA lab that performs radionuclide analysis on food. This means that the WEAC lab is the only facility that has full analytical capability and expertise in detecting radiological contaminants in food products. Over 350 samples per year are analyzed for radionuclides in food. Analysis is done on both imported and domestic food, with domestic foods being analyzed the majority of the time. During and after the Chernobyl disaster and the Three Mile Island Accident, WEAC performed radionuclide analyses on food and ensured that the Nation's food supply was free from radiological contamination. WEAC's analytical capabilities and expertise are relied upon by Federal, State, and local governments for the investigations of food safety violations linked to radiological incidents.

WEAC is part of the Food Emergency Response Network (FERN). FERN is a network of Federal and State labs that is responsible for analyzing food samples in the case of a biological, chemical, or radiological attack. WEAC's radionuclide section is the Lead Project Coordinator for the radiological component of FERN. In the event of an emergency, WEAC has emergency response responsibilities. WEAC is the sole FDA laboratory for radionuclide analysis in the event of a nuclear disaster and/or counterterrorist event. WEAC has a memorandum of understanding with USDA/Food Safety and Inspection Service, whereby WEAC would analyze USDA regulated products for radiological contamination as part of an emergency related to an actual or threatened act of deliberate contamination of the food supply. WEAC also will assist New England in the radionuclide analysis of food samples collected as part of an emergency. WEAC performs other FERN activities as well. WEAC is conducting counterterrorism food research at the University of New Hampshire due to a concern that the Plague bacterium might

be used to deliberately contaminate the Nation's food supply. WEAC is evaluating a capture system in the hope that more laboratories might be capable of isolating and identifying the bacterium.

The Denver lab is also a member of FERN. The Denver lab is the only full-service FERN laboratory slated to close under ORA's current plan. Six analysts at the lab currently are assigned to FERN work. The Denver FERN lab specializes in the analysis of cold sterilants used to decontaminate pathogens such as anthrax. The only other FERN lab that performs this type of work, WEAC, is also listed for closure.

The Denver lab is also home to the Animal Drug Research Center (ADRC). While one or two other individuals within FDA do the same type of work as ADRC, no other lab has a center dedicated to the work. ADRC is staffed by three research chemists with doctoral degrees in analytical chemistry. None of these three doctors would transfer were the Denver lab to close. ADRC develops methods to detect animal drug residues in animal and seafood tissues and in products such as milk and honey. In the past 15 years, ADRC has developed methods for over 30 drug residues in fish and shellfish. The methods that are developed and validated by ADRC are then transferred to regulatory programs within FDA and to State, Federal, and international laboratories. ADRC is responsible for developing more than 60 percent of all seafood testing methods used by FDA. As noted earlier, ADRC recently developed a method for detecting melamine in fish tissue—a procedure the Center developed in only four days.

The Denver Lab also has a Veterinary Drug Section. This section is responsible for analyzing products for illegal residues of various drugs, fungicides, and growth promoters. Animal feeds, farmed fish, seafood products, dairy products, honey, and a variety of other products are all analyzed at the lab. The Denver lab is the only FDA lab to have a section devoted to testing animal feeds and is the only lab to test milk for antibiotics. Analysts in the section average 22 years of experience and the section has two GS-13 Specialists.

Other areas of expertise in the Denver lab include the following: a BSE (Mad Cow Disease) team; a *Salmonella* Serology Team that identifies organisms found in foods and animal feeds; and an Antibiotic Resistance Team that analyzes the susceptibility of organisms to antibiotics to track trends of antibiotic resistance. The Denver lab has a National *Salmonella* Expert and is the only FDA lab performing antibiotic resistance testing. Other food work that the Denver lab performs includes a variety of procedures to detect pathogens in domestic and imported food and filth detection.

3. The Spinach and Peanut Butter Food Poisoning Outbreaks May Highlight FDA Flaws in Voluntary Compliance Approach to Regulation

The recent outbreaks of E. coli 1057H7 in spinach, the Tennessee strain of salmonella in peanut butter, and melamine contaminated pet food were highlighted at the Committee hearing

on April 24, 2007. The hearing featured the testimony of victims of the food poisoning and the companies responsible for processing the contaminated food.

Committee staff was asked to analyze the two domestic incidents to understand their regulatory implications. In doing so, the staff visited both San Francisco and Atlanta and interviewed FDA personnel involved with inspection of the Natural Selections plant that shipped the contaminated spinach and the ConAgra plant that shipped the contaminated Peter Pan peanut butter.

The staff investigation raises questions about the adequacy of FDA's regulatory approach to both domestic and imported food. Except for four food groups—fish, citrus juice, low-acid canned foods, and infant formula—FDA relies almost entirely on the voluntary efforts of domestic food processors to self-police their activities. Many industry experts and FDA staff insist that recent events require a different approach from FDA in the future.

Committee staff learned that produce from the Salinas Valley of California has been the source of 10 food poisoning outbreaks over the past 11 years. FDA officials attributed the increase in outbreaks of contaminated spinach, and other leafy greens to a variety of reasons: changes in the diet of consumers, widespread distribution of produce around the country and world, larger lots of produce, and increased reporting and better tracking of outbreak statistics.

The staff was told that FDA has refused to issue binding rules for the production and processing of fresh produce. Ironically, because of the serious serial outbreaks, some in the California produce industry have sought compulsory rules, but FDA still insists on only issuing voluntary guidelines. The most recent guidelines do not provide guidance for testing protocols.

The California Department of Food and Agriculture does have a Marketing Agreement for the industry (http://www.cdfa.ca.gov/mkt/mkt/pdf/lgph_agreement.pdf). Apparently, 90 to 95 percent of the total volume of leafy greens produced in California is covered by the agreement. Buyers may only purchase produce from certified growers/producers. Being too close to a ranch or a stream and various other factors are reasons a grower would not be certified. Audits are performed and a certification stamp appears on the packaging of qualifying products.

Investigators and compliance personnel in San Francisco advised Committee staff that until compliance with good agricultural practices is mandatory, nothing will change. Likewise, they told the staff that FDA must be more forceful in demanding access to sites and records in the course of their inspections.

Committee staff learned that during inspections, prior to the spinach outbreak last fall, Natural Selections had refused to supply test results. The staff was informed in late May 2007 that the firm had not followed its own Standard Operating Procedures (SOPs) in that it used recirculated water that was not sanitized prior to its reintroduction into the production process. Apparently, Natural Selections added chlorine, by hand, whenever the operator thought it

necessary, rather than employing an automated injector. Further, the individuals employed as quality assurance analysts were not professionally trained and did not have scientific credentials. While the staff was informed of the aforementioned regulatory breach, we were told that the Establishment Inspection Report (EIR) of Natural Selections spinach investigation was not complete, despite that fact that CalFERT issued its report on March 21, 2007.

The inspectors were also hampered by the firm's refusal to permit photographs. Inspectors apparently found mold and other evidence of improper sanitizing in tubing and nooks and crannies of processing equipment. Produce investigations are hampered by the lack of mandatory good manufacturing practices and the right to examine test data and other records. Fortunately, the State of California has authority that FDA lacks, so they are a regular source of information and cooperation.

Peanut butter

A similar lack of aggressiveness on the part of FDA may have contributed to the peanut butter contamination deaths and illnesses. At the April 24, 2007, hearing, the Committee learned that FDA received a tip from a former ConAgra employee that salmonella was found in the company's finished product testing on two days in October 2004. When FDA sent an inspector into the plant in February 2005, ConAgra refused to supply him with the October 2004 microbiological testing records except for 2 days that showed no contamination. The company claims that its plant management merely followed company protocol and asked that the request be submitted in writing.

When interviewed, the FDA inspector did not recall that ConAgra agreed to supply the records upon written request, and the request is not noted in the Establishment Inspection Report. The inspector concedes, however, that such a request would have been a common occurrence for ConAgra and other food processors.

Subsequently, Committee staff learned that it is FDA policy not to request such records in writing. Section 703 of the Federal Food, Drug, and Cosmetic Act provides that if a firm supplies records in response to a written request, they cannot be criminally prosecuted for the information contained in such records. Large food processors understand this provision and have policies, such as ConAgra had in place in 2005, that dictate test results and other critical records such as the Standard Operating Procedures (SOPs) for plants only be furnished to FDA in response to a written request. ConAgra announced a change in policy shortly before they testified on April 24, 2007.

In an attempt to understand why FDA does not routinely request such critical records in writing, particularly when a threat to the public health has been alleged and/or when the failure to obtain such records results in a NAI (No Action Indicated) for an investigation, the Committee staff directed the question to officials in Atlanta, Kansas City, San Francisco, and ORA headquarters. The field inspection manual only provides that an investigator obtain his or her

supervisor's permission to request records in writing. In practice, any such request would go to the District Director. Inspectors told Committee staff that most often they had never heard of such a request being approved or, if they had heard of such an approval, it was a "once in a career event."

Committee staff was told in San Francisco that if an allegation were received regarding such a serious health threat as salmonella being found in testing and the lot destroyed, as was the case in the 2004 Peter Pan peanut butter case, they would notify the State of California, who would acquire the records under separate authority. This was not described as the usual practice elsewhere.⁵

With the exceptions of the four food categories noted above, FDA has no rules governing testing protocols, record retention, SOP adequacy, manufacturing, quality assurance and control, or the right to examine any records that a food-processing firm chooses to keep voluntarily. While the impact of the absence of effective regulation is more obvious in fresh produce, the staff learned that even fully-processed foods such as peanut butter can be a threat to the public health when voluntary controls fail.

4. Conclusion

It is important to stress the preliminary nature of these findings. As of the writing of this testimony, the Committee has not yet received all of the documents requested from FDA. Some of these requests are nearly six months old. In addition, Committee staff has not had the opportunity to fully explore new technologies or industry proposals potentially available for better food safety, or to fully explore FDA's international program and the unique challenges and opportunities that it may face both logistically and politically.

⁵ When CDC traced the food poisoning outbreak to Peter Pan Peanut Butter last winter, ConAgra shut down the plant and FDA went in for another inspection. FDA withheld the inspection report from the Committee, claiming that the inspection was still on going. During the Atlanta visit, Committee staff was provided with a copy of the EIR for the plant inspection from February 14, 2007, through March 2, 2007. In fact, this EIR was approved on April 10, 2007, two weeks before the April 24, 2007, hearing. ORA headquarters was upset that the Committee obtained the report even well after the hearing. Atlanta also furnished the staff with the lab results of the peanut butter jars obtained from the ConAgra inventory during and after the inspection. The FDA lab analysis found 14 out of 130 jars tested were contaminated with the Tennessee strain of Salmonella.

ConAgra maintained that their micro testing had not turned up any salmonella since the October 2004 results. When confronted with the outbreak phenomena, the company blamed a roof leak in late July or early August as the source of the contamination. The positive FDA test results, however, involved lots of peanut butter with production dates as late as January 2007. This EIR and test results indicate that the problem was not related to a finite period of time. More importantly, the fact that ConAgra did not detect the salmonella in their in-house testing suggests that the testing protocol was not sufficiently sensitive.

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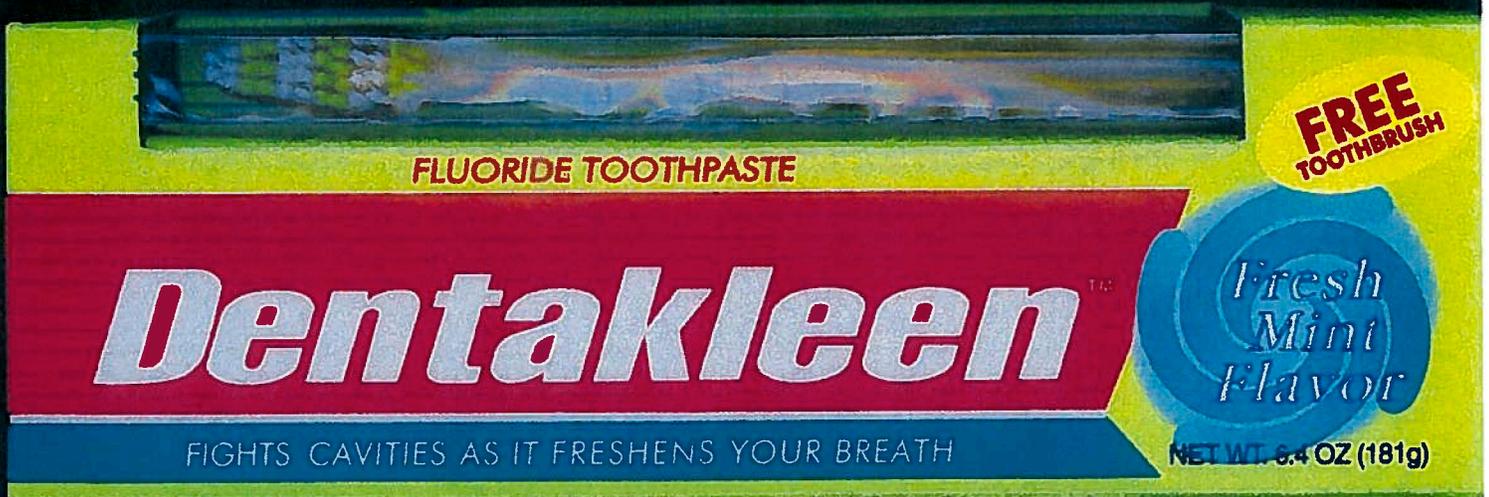
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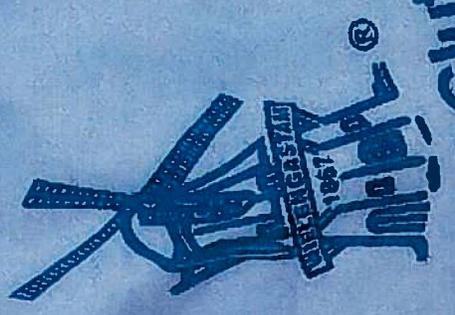
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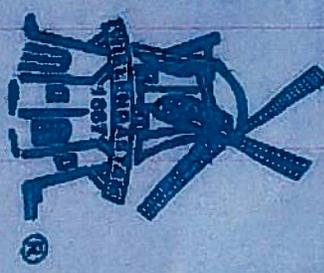


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