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U.S. House of Representatives
Committee on Energy and Commerce
Washington, DC 20515–6115

JOHN D. DINGELL, MICHIGAN
CHAIRMAN

December 13, 2007

The Honorable Michael O. Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Leavitt:

We are in receipt of the recently signed Memorandum of Agreements between China and the United States regarding the safety of drugs and medical devices and the safety of food and animal feed, all of which are increasingly imported into the U.S. from abroad. According to information provided to the Committee on Energy and Commerce, on December 11, 2007, the U.S. Department of Health and Human Services (HHS) and the State Food and Drug Administration (SFDA) of the People's Republic of China (PRC) signed a Memorandum of Agreement (MOA). It is our understanding that the agreement is designed to enhance the safety of drug products, excipients, and medical devices exported to the U.S. from China. Further, we also understand that on December 11, 2007, HHS and the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ) of the PRC also signed an MOA. This agreement is designed to ensure the safety of food and feed exported to the United States from China.

Specifically, the proposed agreements between HHS and SFDA regarding drug products, excipients, and medical devices establish:

> …a bilateral mechanism to help ensure these imported products meet standards for safety and effectiveness by building quality into the process from the start. SFDA will require firms that manufacture certain products intended for export to the United States to register with SFDA. SFDA will also work toward a system that will enable it to certify that firms that manufacture products, and the products themselves, meet HHS/Food and Drug Administration (FDA) requirements.

The proposed agreement between HHS and AQSIQ establishes similar cooperation regarding food and feed imported into the U.S. from China. This agreement creates a "bilateral mechanism to provide greater information to ensure products imported into the United States from China meet standards for quality and safety."

While we applaud any efforts to work more closely with China, or any major exporter to the U.S. market, it is difficult to understand exactly how these agreements will materially benefit U.S. efforts to safeguard its food and drug supply given the paucity of resources available to FDA.

The Committee has held numerous hearings regarding FDA's efforts to protect Americans from unsafe food and drugs. The conclusions drawn from these hearings suggest that lack of resources is a major factor in FDA's inability to do its job. For example, the Committee held a hearing in November 2007 on FDA efforts to inspect foreign drug producers that are exporting drug products to the United States. The Committee's own investigation and a U.S. Government Accountability Office (GAO) audit found that FDA resources were completely inadequate for inspecting foreign firms with any meaningful frequency. For example, while current law requires that FDA inspect once every 2 years a U.S. domestic drug manufacturing firm that sells in the U.S. market, GAO found that FDA had only enough resources to inspect foreign firms on average once every 13 years. Moreover, the information technology (IT) systems used by FDA to prioritize and track drug producers who export drug products into the U.S. were found to be antiquated and ineffective.

Unfortunately, both GAO and this Committee have found that this lack of resources is endemic throughout FDA and is beginning to have profound consequences on the agency's capability to truly protect American citizens. For China—one of the largest producers of drug products for the U.S. market and the partner in these recently-signed agreements—FDA has only been able to inspect between 10 and 20 firms each year against a backlogged inventory of more than 700 firms, which are only growing in number. At this rate, FDA can only inspect a Chinese exporting drug firm once every 40 to 50 years. This is unacceptable, and raises the question of how these newly-signed agreements will improve FDA's ability to safeguard the Nation's imported drug supply.

Similar resource shortcomings plague the agency's ability to inspect our Nation's imported food supply. In 2007, the Committee held four hearings that highlighted a series of major problems regarding FDA's ability to assure the safety of this Nation's food supply, including the safety of imported food. For example, the Committee found that in the last decade, the volume of both FDA-regulated imports and Chinese food imports have tripled. Unfortunately, FDA resources have not increased proportionately with this increase in food imports, and FDA does not have the ability to protect Americans from unsafe, imported food because the agency has so few inspectors. FDA inspections of imported food have dropped drastically from 50,000 in 1972 to 5,000 in 2006—a 90 percent reduction. FDA now inspects less than 1 percent of all imports and only a fraction of that number are even tested.

The Committee also found that FDA lacks the resources and thus the capability to perform overseas inspections of food and feed processing establishments. It is evident from the Committee's investigation that ensuring the safety of food imported from China will require a more thorough and vigorous program of inspection and laboratory testing in China and the U.S. The MOA appears to attempt to address some of these deficiencies; however, it is questionable whether this agreement goes far enough to ensure the safety of imported food from China

because it does not address one of the major root causes of these failures—a lack of resources to inspect and oversee the manufacturing processes of these exporters to the United States.

In sum, throughout the course of the several investigations by this Committee relating to both food and drug imports, the primary tools and resources used by HHS and FDA to safeguard Americans against substandard imports appear underfunded and overstretched. These tools and resources include both human capital, i.e., those who inspect and test production sites that manufacture or process food and drug products for export, as well as the myriad IT systems, particularly those used by FDA both abroad and at our domestic ports, to manage foreign inspection and import processes.

While we generally support any efforts to enhance cooperation with foreign governments to increase regulatory cooperation, we fear these efforts are of minimal value if the present reality of workload to resource ratios are not fully recognized and addressed by your Department. To this end, the Committee intends to continue its investigation into both missions of the FDA and HHS regarding the importation of food and drug products into our country. Moreover, we intend to examine very closely how your Department will address the numerous shortcomings identified by this Committee, GAO, and your FDA Science Board, which recently released a scathing report regarding FDA's ability to undertake its core mission and protect Americans from tainted or substandard food and drugs.

Given our ongoing concerns regarding the safety of imported food and drugs and the inability of your Department—most specifically FDA—to adequately regulate them, we request that your office brief Committee staff as soon as possible regarding these recently-signed agreements and why your Department believes they will materially change the multitude of shortcomings indentified this past year in FDA foreign inspections of drug. We also request that both you and Commissioner von Eschenbach be available to testify before this Committee's Subcommittee on Oversight and Investigations on this matter as soon as Congress returns in 2008.

Thank you for your cooperation in this matter. Should you have any questions about this request, please contact us or have your staff contact John F. Sopko, Chief Counsel for Oversight, at (202) 225-2927.

Sincerely,

John D. Dingell
Chairman

Bart Stupak
Chairman
Subcommittee on Oversight and Investigations

cc: The Honorable Joe Barton, Ranking Member
Committee on Energy and Commerce

The Honorable John Shimkus, Ranking Member
Subcommittee on Oversight and Investigations