PALLONE STATEMENT AT HEALTH HEARING ON DRUG PROVISIONS WITHIN THE FDA GLOBALIZATION DISCUSSION DRAFT

May 1, 2008

"Good morning. Today the Subcommittee is meeting to review the drug provisions of the Food and Drug Administration Globalization discussion draft. This is the second hearing on the draft that Chairman Dingell, Mr. Stupak, and I released a few weeks ago. Last week, we discussed the food-related provisions in the bill, today we will be focusing on the drug-related provisions.

"In recent years, there have been a number of revelations about drug safety that have shaken public confidence in the Food and Drug Administration's (FDA) ability to ensure that consumers are using safe and effective drugs. Tens of thousands of patients have been placed in harms way due to the failings of our current drug safety system. And while we boast that America has the safest drug supply in the world, clearly, more needs to be done. The American people must be able to trust that the drugs they take to save their lives will not cause additional harm.

"Earlier this week, the Subcommittee on Oversight and Investigations of the Energy & Commerce Committee held a hearing to examine the events of the recent tainted Heparin tragedy. The Heparin case resulted in the deaths of at least 81 Americans, caused 785 severe allergic reactions in the U.S., and affected patients in 10 other countries. The O&I findings revealed that not only are FDA's inspection policies inadequate but worse, they actually could have contributed to the Heparin-related deaths.

"This is simply unacceptable. I am outraged by the fact that this type of situation could have ever occurred, and I would like to express my sympathy to the individuals and families affected by the incidence. Congress must do more because right now I am worried that without Congressional intervention, this could happen again. We have an obligation to the American people to ensure that the FDA has the resources it needs to protect them from these types of situations.

"We have heard from a number of sources including the GAO, the FDA's Science Board, and other stakeholders that the FDA is woefully under-funded and that this under-funding is the driving force behind the agency's inadequacies. And finally, the agency itself, during a hearing on Tuesday, confirmed this fact, stating it needs $100 million dollars more for domestic inspection and regulation activities and $225 million additional dollars to adequately inspect and regulate foreign manufacturers. Clearly, the paltry $11 million dollar budget for foreign inspections in 2008 doesn't even come close to being enough to enable the FDA to ensure a safe drug supply.

"Today, 80 percent of all active ingredients in drugs sold in the U.S. are made in other countries, and yet the FDA only inspects foreign facilities, in countries such as China and India, once every 30 years. The draft we are discussing today would change that. As with the food companies, it will require all facilities, foreign and domestic, to register annually with the FDA, providing the agency with an up-to-date list of all drug manufacturing facilities and active ingredient manufacturing facilities.

"It will generate the revenue needed to allow the FDA to conduct frequent inspections of all facilities by charging an annual fee that we are fully intending to specify in the final bill. It establishes new and stronger enforcement tools that the FDA can use against bad actors and requires manufacturers of drugs and biologics to test their products carefully for contaminants. And I do also want to point out that the funding proposed in this discussion draft is intended to supplement, not supplant, current FDA appropriations.

"I feel confident that we will be able to put together a strong bill and I am pleased that the industry, pharmaceutical companies, biologics companies, and generic companies, have been so willing to cooperate and assist us in our endeavors. We have even received letters of support for this bill from leading drug manufacturing companies. I know there are still a few areas that we need to work on and some details we need to iron out, and I look forward to hearing your testimony today highlighting those areas.

"I also understand that my colleagues Mr. Buyer and Mr. Matheson are particularly concerned about the surge in counterfeit drugs in the market place and I welcome a discussion of their proposed legislation, HR 5839 'Safeguarding America's Pharmaceuticals Act' during today's hearing. Particularly, I am looking forward to a discussion around the issue of leveraging information technology to protect our nation's drug supply.

"It has been identified in multiple GAO reports that the FDA is currently operating with a severely under-equipped information technology system, which may also have played a role in the Heparin case.

"While I applaud the initial progress that has been made on FDA's part by hiring a new Chief Information Officer and centralizing the existing systems, more can be done to support the agency in their IT investments, which I believe will not only benefit the patients but will also enable the agency to be more efficient and effective in carrying out their required tasks.

"Patients and their health care providers must have confidence that the medicines they take to treat diagnosed illnesses meet the highest standards of safety and efficacy. And again I look forward to hearing from today's witnesses and the discussion around some of these issues. I thank you all for being here with us. And I now recognize my colleague from Georgia, Mr. Deal, for five minutes for his opening statement."