

## **Policy Address by Congresswoman Rosa DeLauro**

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George Washington University School of Public Health and Health Services,  
Project on Scientific Knowledge and Public Policy

Congresswoman DeLauro's prepared remarks:

Dr. Susan Wood, thank you for that generous introduction. I am honored to be here and to have this opportunity to lay out my ideas. Susan, you have been a friend and adviser for a long time, and a tireless champion of women's health and rights. For years, policy makers in Washington sought your opinion and expertise, a leader in government and academia.

Whether you were laying it on the line at the FDA or leading the Congressional Caucus for Women's Issues, you have been in the thick of some of our most important recent debates about biomedical research, women's health, family planning and health care reform. Today, right here from George Washington University, you continue to shape the debate - framing our discussion to ensure science takes center stage when we make critical decisions about research, public safety, and our health. Thank you.

And a special thanks as well to Dean Ruth Katz and the entire George Washington School of Public Health and Human Services, for welcoming me so warmly here today. Yours is a unique institution and a valuable resource for our nation -- not only today, but in the years ahead when your students will be making the decisions that form our nation's public health policy. Professor David Michaels, thank you for your work on diacetyl.

And I am glad to see a number of representatives from the FDA here as well. I know it often seems like I come down on the FDA pretty hard, pretty frequently. But I assure you, my intention is not to make you a target: I appreciate that it is, in many ways, this administration's decisions which have the most direct and often limiting effect on how you can do your job and serve the public. I look forward to continuing to work with all of the talented individuals at the FDA.

I am delighted to see so many friends and colleagues in the audience today. In fact, I have been very fortunate to spend a lot of time with many of you lately. Over the last two-and-a-half weeks, we have been taking part in what has felt like an ongoing public conversation about the state of our nation's food safety system.

In a wide-ranging series of policy speeches, hearings and dialogues, together with policy makers, regulators, consumer advocates, and industry leaders, I have tried to ask some probing questions and highlight some of the most urgent challenges facing our food safety system and threatening our public health. Over the past few weeks we have discussed a new path to reform, and I hope many of the stakeholders have felt welcome to join that discussion.

A few weeks ago, I spoke at a Pharmaceutical Marketing event in Philadelphia where we examined both the benefits and the serious problems with Direct-to-Consumer advertising. In the last Congress, I introduced legislation that would impose a moratorium to ban advertisements for

a three-year period after approval. A new concern emerging in this area are ads for medical devices such as hip and knee replacements, giving no indication of the potential complications and side effects from the major surgery they require. I may introduce a new version of this bill to include these devices, as well.

Of course, this conversation came just a few days after the House passed its final version of the Prescription Drug User Fee Act. I would have liked to see some stronger provisions make it into PDUFA, such as mandatory recall authority, but was pleased that at least the new legislation requires the Secretary to issue guidance for the conduct of clinical trials with respect to antibiotic drugs. It also improves the citizen petition process, and makes post-market drug safety information transparent and more accessible to the public.

We cannot overlook the FDA's challenges when it comes to drug safety. For the first time, user fees will be applied directly for post-market safety studies. But if the post-market surveillance these user fees generate is proven ineffective, we must explore opportunities for additional reform.

Fulfilling the FDA's drug safety responsibility also means establishing an effective review system rooted in respected advisory committees with minimal conflicts of interest. And it means addressing the Inspector General's latest report which suggests the FDA does not know just how many clinical trials are being conducted and currently audits too few testing sites. These are some of our most pressing public health issues, and we need to continue looking at them closely. I intend to call a hearing of the Agriculture Appropriations Subcommittee on drug safety in the near future.

Just last Tuesday, as Chairwoman of the Agriculture Appropriations Subcommittee I called a hearing on the Safety of Food Imports. It was a long but productive hearing, where we heard from Caroline Smith DeWaal from the Center for Science in the Public Interest, Dr. David Acheson, Joseph Levitt representing the Grocery Manufacturers Association, and a number of other FDA veterans who offered an insider's view from decades of experience at the agency.

Two days later, I talked with the Consumer Federation of America and the Grocery Manufacturers Association, at the National Food Policy Conference, and addressed many of the particular challenges facing the FDA, as well as the USDA and our food safety system in general.

Then in the wake of this weekend's recall of a stunning 21.7 million pounds of beef, due to possible E. coli contamination -- I traveled to Chicago, the city that one hundred years ago, inspired Upton Sinclair's muckraking novel *The Jungle*. I spoke at the Food Law and Regulation conference there sponsored by Food Chemical News, and laid out some guiding principles for new FDA authorities when it comes to imports.

The fact is they are long overdue. When thousands of pets began to die from contaminated pet food that originated in China, the news forced us to wake up and take a hard look at the entire food safety system abroad. We began to ask if our nation had the strategy, resources and

commitment to address food safety in a period of growing dependence on imports from China, Asia, Mexico and other countries.

Our renewed attention revealed inadequate protections overseas and at our ports here at home. We learned of unsanitary conditions, intentional contamination and the deceptive labeling of products imported to the United States. In the first four months of 2007, U.S. inspectors refused 298 shipments from China - but the sad truth is only 1 percent of shipments were even checked.

Dr. David Acheson, the FDA's point person on food safety, who followed me on the program in Chicago, and joined me in a question-and-answer session, has often stated that we will not be able to inspect our way out of this problem. And I agree. There is no system that could physically handle the entire ever-increasing volume of food imports that continues to enter our borders every year.

Too often, it seems as if this administration is more focused on trade relations than consumer safety, more on public relations than public health. Even in the face of recent industry interest in seeking more of a formal regulatory scheme and inspections, the FDA would not -- or did not have the institutional clout to make it happen. Increased trade should never require us to compromise our standards of health and safety.

With so much immediate pressure on the system, we need to make some immediate changes that can make a very big difference. Let me lay out some of these short and medium-term changes that can have a real impact on our food safety before we can act on more fundamental reforms.

The United States should empower the FDA, with the authority to:

- \* One, authorize the FDA to inspect overseas plants and make access to foreign plants a condition of entry to the U.S. This is a big change, but during the pet food recall, we saw why: the FDA was unable to gain access to the plants in China to conduct an adequate investigation and it became clear that freer inspections abroad must be part of the equation.
- \* Two, impose fines on those who have imported unsafe or adulterated foods. This represents a new approach, when it comes to pushing back at offenders.
- \* And three, require importers to better document the source of imported foods and food ingredients.

At the same time, with our global food supply in mind we need to start moving toward a more fundamental transformation of the way the FDA oversees food imports. That means a concerted effort to both:

- \* Work with major trading partners to forge equivalence agreements, establishing certification programs as the basis for ensuring that imported products will meet U.S. standards in advance; and

\* Collaborate with the private sector to encourage greater reliance on private certification systems to verify that effective preventive measures have been observed in producing goods intended for import.

I think there is real momentum in this nation for reform – addressing not only a rising flood of imports, but also the serious need to reexamine our entire food safety system here at home. I know we can do so in a way that benefits both the consumer and the industry.

To be sure, that process must include addressing the challenges that face the USDA today. I will continue working to push FSIS to slow down its implementation of Risked Based Inspection until the agency can obtain the comprehensive scientific data it needs. Today the USDA currently lacks this data and moving forward would be misguided and potentially dangerous.

That is why I am also opposed to the ill-advised FSIS decision to grant China equivalency status so that it may export processed poultry back into the United States as long as the raw meat was originally slaughtered here in the US or Canada.

Ultimately, this administration has a responsibility to ensure ANY reform we make to our food safety system actually improve resource allocation and safety.

That is why I am here to speak to you today, not about the immediate measures, but about a new path toward fundamental reform -- about the best approach to restructuring the FDA in order to better position that agency to respond to emerging threats to our food supply.

With a real concerted effort -- a bold, energized campaign -- we can pursue serious, sweeping change. We can move openly and urgently toward a unified, effective food safety system which focuses on prevention not just reaction, makes the most effective use of limited resources, and addresses both domestic and imported food safety. These are the basic and guiding principles -- but for too long they have been compromised by outdated oversight laws that are putting lives at risk.

Today, there are 15 different agencies currently responsible for administering 30 laws related to food safety. It is time to consolidate many of these functions and provide a regulatory structure that takes full advantage of the great work being done by the scientists at the FDA and state laboratories as well.

It is possible, through a streamlined regulatory structure to require regular inspections of all food processing plants, increase oversight of imported foods, provide for outbreak surveillance, require the tracing of foods to point of origin, and ensure effective public communication.

We should be striving to achieve these goals - above all else. That is why today, I want to outline a blueprint of The Food Safety Modernization Act, driven by a new perspective and renewed energy while keeping in mind the existing federal regulatory structure.

The Food Safety Modernization Act would create a Food Safety Administration within the U.S. Department of Health and Human Services with responsibility for administering all food safety

issues currently administered by the FDA. While, maintaining the USDA's independent, food safety responsibilities, the new law would establish a Commissioner of Food Safety and Nutrition Policy -- a presidential appointment requiring advice and consent of the Senate -- to lead the new Food Safety Administration, reporting directly to the Secretary of Health and Human Services. A parallel position to the Commissioner of a renamed Federal Drug and Device Administration.

By following this path, we can aggressively confront four serious flaws that currently plague our food safety system and place the public health at great risk. The Food Safety Modernization Act may be new, but the basic principles for reform remain unchanged.

First, and most fundamentally, I believe we need to address a scattered and diffuse organizational structure designed years ago that was not designed strategically, and does not function effectively today. The current system emerged piecemeal, over many decades, in response to particular health threats or economic crises.

Today, we suffer from its fragmented legal and organizational structure without enough resources or authority to protect the American public. Food safety within the Department of Health and Human Services is buried beneath three levels of bureaucracy, and even within the FDA, the lines of communication and authority require streamlining.

Second, we are raising the visibility of food safety - recognizing that it must be a top priority. For too long, food safety has been a second class citizen within the FDA. The public's interest in curing disease and the corporate interest in developing and promoting new drugs and devices have often trumped concerns about food safety. We can no longer rely on self-regulation, in has gone too far. In Congress, my colleagues too often follow the same pattern -- relegating food safety to second tier status. By giving food safety its own home, we can, for once, provide the structure, stability, and authority for reform to take root.

Third, food safety deserves a better platform to compete for vital resources and funding. That represents a marked difference from its current circumstances: Currently, the Office of Management and Budget sees the FDA as just one small part of the Department of Health and Human Service budget. Then, within the FDA, food safety must compete with a whole host of other needs for limited funds.

In recent years, that process has had a direct impact on the FDA's ability to protect the public health. FDA is responsible for overseeing approximately 210,000 domestic food establishments. However, the number of field staff has dropped by 12% since 2003 leading inspections to be cut by nearly half between 2003 and 2006.

But let us be clear: if the funding level for the FDA in the House bill becomes law, the agency will have received an additional \$231 million since FY 2006. SO clearly the FDA is receiving additional funds – the real question should be where are the funds going and how are they being spent? Does this administration support leaders and foster a culture that is truly passionate about protecting public health? Or does it have other competing priorities?

That is why we are starting already, with this year's spending bill, directing the FDA to submit a plan to begin changing its approach to food safety with the fiscal year 2009 budget. This will give the Committee time to review the plan before the funds to implement it become available on July 1, 2008.

Finally, The Food Safety Modernization Act addresses a serious vacuum in leadership. Today, there is no high-ranking food safety official in the US government to provide leadership during a time of crises. To be sure, the FDA Commissioner recently appointed Dr. Acheson to be our nation's new food safety "czar," but with little new authority, it is a title and nothing more.

In reality, presidents choose FDA Commissioners to address drug issues. By creating and appointing a dedicated Commissioner for Food Safety with the president's ear and real authority, we may actually have a champion of public health in charge of protecting it.

I want to be clear: we are not walking away from a single food agency or the reform that it promises. I believe that in order to begin fixing our broken food safety system, we must act now and this is the best way forward. We have further to go, to be sure, but with this first step, we will have come a great distance.

We know why this legislation is necessary. The consequences of our current food safety laws and a lack of leadership are clear. Instead of stepping up and following through with its own investigations, this administration has dropped the ball. Instead of proceeding with the necessary action that its own evidence so clearly demands, it sat on its own hands.

A 2005 report showed that inspectors were looking into findings of salmonella from a ConAgra peanut butter plant as far back as October 2004. Among other things, there were insects in some equipment, water leaking onto products. It was not until peanut butter from this very plant sickened 400 people in 44 states, that the FDA finally took action.

Similarly, FDA inspectors knew about foodborne illness caused by fresh or fresh cut lettuce and spinach as far back as 1995. Yet, they failed to take the necessary steps to save the lives of three people killed by E. coli just this last year. And for the past six-years, the FDA knew about seafood imports from China, yet just recently issued an import alert. Prevention, early detection, and control measures must be in place at every step of fresh produce production to help minimize food safety risks. Voluntary guidelines have not effectively prevented food safety problems related to fruits and vegetables. And until we establish mandatory recall authority, the FDA under this administration is not really being serious.

These are not isolated incidents either; time and again we have allowed producers to police themselves while people and pets unknowingly remain at risk. The process creates a treacherous no-man's-land -- a strange place where products are identified as unsafe but, left uninvestigated, untouched, and unchanged -- they are still out there, still on the market to put us at risk.

It was at last week's hearing, where I heard yet again, quite a lot of talk from my Republican colleagues about so-called "acceptable risk." Some have even suggested that our current food safety system is plenty safe just as long as we step back and allow the market to run its course.

But the fact is, if something is broken, we cannot expect it to function properly, efficiently, or safely - and we should not have to rely on it for protection. The 76 million Americans who are sickened, 375,000 hospitalized and the 5,000 who die every year from foodborne illness are not an insignificant number - especially if you are one of them.

If the lettuce in your salad gives you Norovirus. If the tomatoes you eat lead to a case of severely debilitating Salmonella. Or if your two-year-old child suffers kidney failure from E. coli, spends ten devastating days in the hospital, before dying - these are more than just numbers, they are people who counted on a system that was supposed to protect them, but failed. They are not insignificant and they deserve far better.

With so much at stake we have an obligation to continue fighting this administration's staunch bureaucratic resistance -- whether it opposes an integrated, cost-effective food safety system or a straightforward process to ensure the safety of fresh produce.

Together, we must continue asking whether our food safety system has the ability and the will to act in the public interest? We can never stop working to restore and uphold the FDA's commitment to its original mission -- protecting public health and ensuring consumer confidence.

I want you to know that I am ready to work with you. It is about collaborating with our consumers, our businesses, our scientists, and our government to find their common purpose and meet our obligations to the American people.

The Food Safety Modernization Act, our work over the last few months, and our goals for the future are clear: while the world continues to change, our current food safety system has not. While disease and pathogens evolve, our policies grow obsolete. By creating a separate Food Safety Administration and Commissioner of Food Safety within Health and Human Service we can bring our current food safety system out of the past. It is about time.

Together, we can act now to make it happen, transform the FDA's the culture, and begin a new movement that puts public health first. Thank you.