

Regulatory Reform Testimony

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Mother of an Hepatitis A Victim
Senate Government Affairs Committee
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My name is Sue Doneth and I am a working mother of 3 children in Marshall, Michigan. Thank you Senator Thompson and Senator Levin for inviting me to participate in this hearing about S.981.

One year ago, I had never given a public speech and had never been involved in civic pursuits. I did not consider myself an activist, food safety or otherwise, and still have to pause when I hear myself labeled as such. However, once my daughter, my family, and my community was severely affected by foodborne illness, I could no longer remain uninvolved. When hundreds of school children in Marshall, including my daughter Lindsay, innocently consumed contaminated strawberry shortcake as a part of a school lunch and became violently ill as a result, I was outraged.

To date, there are over 350 hepatitis A victims in Calhoun County. One year after the original outbreak, people are still contracting the virus.

Lindsay was hospitalized after she spent three days with severe abdominal cramps, vomiting, fever, and splitting headaches. She refused to eat or drink. She didn't want to go to the hospital because it hurt to move.

I have never seen a child so sick and I cannot describe to you what it is like to witness a child so ill, especially when that child is your own. She continued to vomit and her stomach pain increased. She was on continuous IV fluid, pain medication, and anti-nausea drugs.

On the second day of her hospitalization, she stopped talking and would barely open her eyes. We could tell she was in pain when her small eyebrows would furrow and tears would silently run down her face. I remember my child whispering to me through dehydrated, cracked lips, "Mommy, it hurts everywhere." She hadn't eaten or taken a drink in over a week, yet she continued to try to vomit. She would endlessly heave trying to rid the poison that had overtaken her body and with each convulsion, she would continue to cry because she couldn't breathe and her liver was so enlarged and inflamed that the movement was excruciating for her. She was hospitalized for six days and had lost 10% of her body weight. Approximately 4 months after she contracted hepatitis A, Lindsay suffered from shingles. In the past year, she has been diagnosed with asthma and now uses an inhaler. She continues to complain of unexplained back and joint pain, she has experienced hair loss and returned to the doctor on several occasions with unexplained skin rashes.

Hundreds of people in my community suffered from hepatitis A due to the contaminated strawberries served in the school lunch. Over 11,000 were administered IG shots to protect them from the virus. Lindsay missed approximately 3 weeks of school during the acute phase of the hepatitis A illness, and when she did return to school she went 1/2 days frequently as she was unable to complete a full day of school due to fatigue. She was forced to quit the dance classes she has taken

since she was 4 years old as she was physically unable to keep up. In addition, my husband and I missed several days from our jobs caring for her during her recovery.

Several factors converged to cause the hepatitis A outbreak in Michigan. The most important being a lack of produce safety oversight. Contaminated fresh produce continues to be a growing threat to American consumers. The Centers for Disease Control and Prevention records show that contaminated produce caused 2% of identified foodborne illness outbreaks from 1973-1987, but that figure jumped to 5% from 1988 to 1991. New pathogens like Cyclospora and E. coli O157:H7 are increasingly linked to contaminated produce and there is little consumers can do to protect ourselves from the deadly pathogens that lurk in foods that are eaten raw.

I am pleased to see that Senator Levin is a cosponsor of a food safety research bill with Representative Stabenow, which indicates that he is aware of the gaps in the current food regulatory system. The hepatitis A epidemic in my community highlighted the tremendous inadequacy of government agencies to enforce existing rules and, in fact, there really aren't any rules to protect consumers from contaminated produce--foreign or domestic.

I have three main concerns about S. 981:

1) This bill would place more regulatory control in the hands of business. Although the federal government is the main entity gathering and generating data such as foodborne illness statistics and pathogen prevalence, the peer review panels required in the bill exclude government's own health and safety experts from participating in risk assessment and cost benefit analysis reviews. If government experts aren't on the panels, and only one or two consumer organizations can hire the credentialed staff required to sit on committees, than the panels will be dominated by the business community which, after the federal government, predominantly hires these specialists.

People with a financial interest in regulations reviewed by advisory committees are granted access to participate without any requirement to disclose their financial interests. I fail to understand how it would benefit the public to have scientists employed by food companies sit in judgment of rulemaking that could potentially cost their own industry money.

Committees reviewing safeguards, risks assessments, and cost benefit analysis would not be subject to the Federal Advisory Committee Act to ensure that decisions affecting the public is conducted in a manner that is open to the public.

A basic tenant of democracy is government by the people, yet participating in government as a citizen is almost impossible if one works full time and lives outside of the beltway. Most foodborne illness victims are average people like myself. I have donated hundreds of hours working on food safety issues -- educating myself Donate to S.T.O.P. policy and food safety and participating in the complicated bureaucratic process we refer to as democratic government. The provisions of S. 981 will make citizen participation even more burdensome. Public interest groups and individuals like myself simply don't have the resources to participate in the processes outlined in S. 981.

First, government panels usually require travel, which takes time and money. Many committees provide no financial compensation for participants. Members of trade associations and business executives are compensated by their employers to participate in these panels. Members of S.T.O.P. participate in government as their employers and personal budgets allow. For instance, I am using my last vacation day to be here to testify today. My family did not take vacation last year, nor will we take one this year, because of the personal vacation time that I use to participate in food safety forums. Fortunately, I receive paid vacation time. Many Americans do not.

Second, some government committees require certain credentials for participation, such as a public health or microbiology degrees. Although no one is better equipped to judge the severity and cost of foodborne illness than a victim, we would be excluded from participating.

Yet, as difficult as it is now to be heard as food safety policy is being formed, our input will diminish tremendously if biased review panels are allowed to repeatedly re-examine rules that were developed through fair and open processes. Our efforts will be divided between maintaining food safety advances of the past and urging future improvements.

2) S. 981 would force agencies to divert staff and money from protection and enforcement to devote resources to duplicative and unnecessary reviews. Everyone knows that government resources are limited. With a staff of under 700 inspectors assigned to approximately 53,000 food facilities, FDA clearly has an appalling lack of resources. FDA inspected establishments are inspected approximately once every ten years.

FDA and other weak agencies cannot afford the luxury of self reflexive review exercises demanded by S. 981. The tremendous strain on agencies already faced with limited personnel and resources would hinder rather than help protection of the public. FDA already meets the risk assessment and cost benefit analysis requirements demanded by Executive Order #12866. The agency needs to use its small staff on the tasks that will best protect the public -- enforcement of current food safety rules and development of needed safeguards such as produce GMPs and HACCP.

The judicial review provisions of S. 981 could place another burden on agencies like FDA by funneling resources into defending lawsuits. Proposed rules are frequently challenged, and this bill could lead to every major public health rule finding its way to court, where endless proceedings will delay the implementation of much needed safeguards, such as improved inspection to detect pathogens like E.coli O157:H7 and salmonella in food.

3) S. 981 will diminish the focus of public health and safety laws from protecting the public to justifying public health and safety protections in light of subjective cost estimates and risk assessments.

Public health and safety should be the paramount concern of lawmakers. The Lindsay Doneths of the world are not expendable in the pursuit of grand philosophical experiments and cheaper, less burdensome regulations. The public is not impressed when they hear officials say the U.S. has the safest food supply at the lowest cost.

They want to hear we have the safest food supply in the world, period. And they want this statement to be true, which it isn't.

It is very easy for businesses to quickly quantify their costs and benefits, but calculating human health risks, costs, and benefits requires subjective analysis. The outcome will depend upon the data collector, the data available, and the political environment. Several years ago, USDA placed food marketing concerns above public health. In 1992 the threat of illness was downplayed in USDA consumer education literature describing E. coli O157:H7 as a urinary tract infection. Clearly, USDA had not invested much in gathering information about E. coli O157:H7 if they published such glaring misinformation in public documents. I strongly believe that under the former leadership at USDA, research and data collection for foodborne illnesses and pathogen prevalence would have continued to stagnate.

The number cruncher has a lot of influence over outcomes. For example, the data collector can choose to interpret E. coli O157:H7 illness narrowly and limit costs of complications only to those associated with renal function. By following these guidelines the USDA Economic Research Service (ERS) estimates that the average E. coli O157:H7 induced Hemolytic Uremic Syndrome (HUS) costs approximately \$36,185. To their credit, ERS notes that many HUS patients experience complications such as blindness, neurological damage, reduced respiratory function, pancreatic destruction, and cardiac damage. The mother of Damion Heersink, an actual HUS victim, calculated that his medical bills totaled approximately \$300,000, while the parents of HUS victim Haylee Bernstein estimate their medical expenses at \$500,000. Other members of S.T.O.P. who have actually paid for the expenses of HUS would attest to similar medical costs.

I appreciate the opportunity to bring these issues to your attention today. While I do not question that the drafters of S. 981 have good intentions, I hope you will agree with me that several provisions in the bill are cause for concern. As a citizen who has suffered as a result of gaps in our nation's food safety net, I strongly urge you to oppose this bill.

Thank you.