

## **“FDA’s Food Safety Vision: Public Health Partnerships to Prevent Foodborne Illness”**

Michael R. Taylor  
Senior Advisor to the Commissioner  
Food and Drug Administration

13<sup>th</sup> Annual PulseNet Update Meeting  
5<sup>th</sup> Annual OutbreakNet Meeting

Snowbird, Utah  
September 22, 2009

I am honored and grateful to have been invited to participate in this meeting and to speak with you tonight.

I am honored in part because the invitation came from people working on the front lines to protect public health, often under very challenging circumstances – people I respect very much and whose partnership over the years has meant a great deal to me personally.

In fact, fifteen years ago, when I was appointed to be Administrator of USDA’s Food Safety and Inspection Service, in the aftermath of the Jack-in-the-Box E. coli outbreak, one of the first things I did, before even starting the job, was go to Atlanta to get educated about foodborne illness by Rob Tauxe and Patty Griffin.

Rob and Patty got me off to a great start in that job and have been valued colleagues ever since, as is the whole team of dedicated people working on food safety at CDC and in state and local health departments.

I also feel honored to be here because the invitation came before I took on my current role at FDA, based on work I had done with a number of you in my research role at the George Washington University School of Public Health.

For much of the last two years, with support from the Robert Wood Johnson Foundation, I had the good fortune to work with the associations representing state and local health officials and food safety regulators on a project to map out an agenda for strengthening state and local roles in the nation’s food safety system. ASTHO, NACCHO and AFDO were funded collaborators but representatives of CSTE, NEHA, and APHL also participated actively in the project.

The product of that project was a report we issued in April of this year under the title “Stronger Partnerships for Safer Food.” This collaboration with state and local officials

made a big difference in my personal understanding of the challenges many of you face every day and makes me particularly appreciative of being here and being able to reflect on the topic of food safety partnerships from my new vantage point at FDA.

And the central message I'd like to deliver tonight is this: We are today at a moment of rare opportunity *and* necessity to construct a whole new level of partnership to prevent foodborne illness. It must be a partnership that empowers the full range of people working on food safety at federal, state and local levels to succeed in their common cause of preventing foodborne illness.

The partnership we need would bring together epidemiologists, environmental health specialists, laboratorians, regulators, and many others in a way that respects and fulfills what each has to contribute. And it's a partnership in which the whole is much greater than the sum of the parts.

In the next few minutes, I'd like to review briefly my understanding of the opportunity and necessity for such partnership and then outline some of the things on which I hope we can work together to bring it about.

I'll start with the necessity. As most of you know, FDA's vision for food safety is a public health prevention vision. While much of what FDA has done historically on food safety has contributed to prevention, the agency has long been hampered by outdated statutes and practices that focus most of the agency's efforts on reacting to problems after they occur.

In its 2007 Food Protection Plan, FDA laid out an approach for preventing foodborne illness, based on the risk-based targeting of preventive controls wherever hazards can be reduced throughout the food system.

This focus on prevention is just good public health policy, but it also reflects what we've learned from experience can work to reduce the risk of foodborne illness.

The Obama administration has embraced and expanded on the prevention approach to formulate a comprehensive food safety vision, grounded fundamentally in the principle of prevention. The administration did this through the President's inter-agency Food Safety Working Group, which brought together senior officials and experts from CDC, FDA, and USDA to map and oversee major food safety reform.

And Congress is now working on legislation that would make prevention the central focus of the federal food safety program, as a matter of law.

And it's the prevention vision that makes partnership absolutely essential to FDA.

This is because, for FDA, implementing the idea of risk-based prevention requires the agency to work in three broad domains, all of which demand partnership and better integration of federal, state and local efforts.

First, we will be working to understand and target the most significant risks and causes of foodborne illness. The human illness data derived through FoodNet and the other surveillance efforts undertaken by many of you, in collaboration often with CDC, are indispensable for this purpose, as is the analysis of these data.

Second, we will be working in the domain of adopting science-based and prevention-oriented food safety standards to reduce the likelihood of harmful contamination and the risk of foodborne illness. Setting such standards and achieving high levels of compliance with them is FDA's core function as a food safety regulatory agency, but we rely for the most part on others to generate the data needed to set standards, and we depend on collaboration with the states to oversee and help ensure compliance.

Finally, our focus on prevention means we must continue our efforts to detect and respond promptly to outbreaks, both to contain them and learn from them for future prevention purposes. This is, of course, what PulseNet and OutbreakNet are all about, and there is no domain of food safety activity that is more dependent on partnership than outbreak response.

We are keenly aware and respectful of the fact that State and local health departments, sometimes with the support of CDC, play the primary frontline role in detecting and investigating clusters of disease that may be foodborne. But we also know that strong partnership between FDA and CDC and with our state-level counterparts can contribute to the timeliness and effectiveness of the initial investigation and remains essential once an FDA-regulated product is implicated.

People in this room can be proud of the fact that the level of partnership among our agencies on outbreak detection and immediate response has increased sharply in recent years and is bearing real fruit. In fact, PulseNet and OutbreakNet are two of the most compelling examples of what partnership across agencies and levels of government can do, as are CalFert and the other rapid response teams that FDA is supporting to integrate state and local efforts on outbreak response.

Other examples include the recently issued CIFOR guidelines to improve outbreak response, CaliciNet for detecting norovirus outbreaks, NARMS for following trends in anti-microbial resistance, and eLexNet for sharing food contamination data.

Now there is always more we can do to improve our detection and containment of outbreaks, but the success of FDA's prevention vision also depends heavily on learning from outbreaks to inform future standard setting and other prevention efforts. Getting to root causes and discovering prevention opportunities is inherently a team enterprise. It can require public health and multi-disciplinary scientific experts at all levels of government, including epidemiologists, environmental health specialists, laboratory scientists, clinical microbiologists, and food scientists.

Regulators in federal, state and local agencies must also be involved in learning from outbreaks. This is both because they have relevant expertise and because they have to use what's learned to set science-based standards. So too must be involved experts from the agricultural and food industries that must implement preventive measures and meet FDA standards in their business operations.

So, the necessity for building partnerships, at least from FDA's vantage point, is clear. Without them, we will fail. With them, we'll succeed.

But what makes for a greater opportunity today than ever before to take our partnerships to a new level? For me, it's the fact that we are no longer alone in understanding the need for partnership.

Ten years ago, state and federal food safety regulators began calling for an integrated national food safety regulatory system, but got little real support from lawmakers. Likewise, federal, state and local health officials have collaborated for years on food safety matters, as evidenced by your presence here, but until now you've been largely on your own, with no real mandate for partnership coming from elected officials and certainly little or no dedicated resources.

Things are different now. Integration of food safety efforts and real partnership is the policy of the Obama Administration, and I am confident Congress will act soon to make stepped up collaboration the law of the land, with provisions directing integration and partnership contained in both House and Senate versions of pending food safety legislation.

It is real progress that the necessity of partnership to improve food safety is embraced at the highest political levels. It also is real progress that FDA and its regulatory counterparts in state and local government are engaged in a renewed 50-state process to build integrated inspection and compliance programs.

And, when it comes to detecting, responding to and learning from outbreaks, I think we could fairly readily flesh out a common vision for a strong, seamless team effort, building on CIFOR and other efforts.

The hard question then becomes: How do we build the mechanisms needed to fulfill the common vision? How do we actually operate as a seamless team?

I certainly don't claim to have all the answers to these questions, but I can identify three broad areas in which I think we need to be working together to take our current outbreak response partnership to a new level. And then I'll conclude by suggesting some specific tasks I think we should be tackling.

Broadly speaking, we need first to invest the resources and person power that first-rate outbreak response requires.

It is hollow to express high aspirations and a new common vision for outbreak response if we ignore or do not address the workforce crisis in key public health disciplines, the persistent and worsening resource constraints facing state and local public health agencies generally, and the resulting gaps in modern laboratory capacity, information systems, and other needed public health infrastructure.

Second, we need to more clearly define roles and responsibilities within a seamless team effort to detect, contain and learn from outbreaks. This must start at the federal level, where FDA and CDC have already taken concrete steps in this direction through co-location and sharing of staff resources and are in active dialogue about ways to further clarify and strengthen our working relationship.

I can also say that the FDA-USDA relationship has never been stronger; and the CIFOR guidelines provide an excellent starting point for efforts to improve the federal-state-local interaction on multi-state outbreaks.

And third, we need to create operational mechanisms that make it possible for people to work together. In resource-constrained government institutions, even people who are eager to work across agency lines are often stymied by the pressures of their day jobs and driven apart by other centrifugal forces. It takes more than good will to overcome these forces.

So, what should we be doing? What specific things should we be working on to fulfill our common vision?

I'll suggest five.

First, I'd like to see CDC and FDA work jointly on a budget initiative to increase federal funding in support of needed state and local capacity for outbreak response. We need to invest more in federal-level capacity as well, but it's important for policymakers to recognize that adequate state and local capacity to respond to major outbreaks serves important national interests and deserves stepped up federal support.

Second, we need to better coordinate and improve how we collect information, both in surveillance and outbreak investigation settings. In outbreaks, this means being able to collect, manage and analyze information using 21<sup>st</sup> century tools that help ensure we are getting the most public health value from our collective effort.

Third, we need to continue working on impediments to information sharing among government agencies at all levels and in both directions. We can't work as a seamless team if we're not on the same page information wise. Some of the impediments to information sharing reflect legitimate competing values, and patient privacy remains a paramount value we all share. But other impediments are embedded in policy, legal concerns and traditional practices that need to be rethought.

Fourth, we need to take the next steps in clearly defining roles and responsibilities in multi-state outbreaks, including between federal agencies and among federal, state and local agencies. Much progress has been made, but there is more to do to achieve clarity on the locus of decisionmaking as investigations involving multiple agencies unfold, who coordinates and makes decisions about tracebacks, and how we communicate with industry, victims of foodborne illness and the general public.

Finally, I think we need to look hard at the possibility of establishing, at least at the federal level, a multi-disciplinary, inter-governmental team of professionals whose fulltime job is to work together on outbreak response. Such a team would be the vehicle for having clearly defined leadership roles and better communication among federal agencies and with state partners at each stage of an investigation and response effort. It could function essentially like a unified ICS team in appropriate cases, but it would also work between outbreaks on planning and capacity building for outbreak response, helping develop innovative new investigative techniques, and coordinating and supporting follow up efforts to learn from outbreaks.

This last idea flows from some of the other suggestions and concerns I've outlined tonight. For just about all concerned, outbreak response falls into the category of "other duties as assigned." We don't invest enough resources, and we don't give people who know how things can be improved the time and space to do it. Such a team would not – indeed, could never – displace the front line professionals in state and local agencies who respond to outbreaks. It would rather support them and help us all build a system of outbreak response that plays a powerful role in preventing foodborne illness.

My purpose tonight has been to signal where FDA is going on food safety and to make clear that we consider partnerships like PulseNet and OutbreakNet, as well as the many others we can imagine, absolutely crucial to our long-term success.

Preventing foodborne illness demands a team effort. It depends on partnership. And I pledge FDA's long-term commitment to partnering with all of you.

Thank you again for including me in your meeting.