BIOPREPARADNESS IN 2010 SUMMIT

Washington DC
September 23, 2010

Good afternoon everyone.

Thank you, Dr. Inglesby, for that introduction, and thank you to the UPMC Center for Biosecurity for hosting this important event. It' s a promising sign to see so many great leaders gathered here today to focus on these important issues.

When you become HHS Secretary, you know that, eventually you will be tested by a public health crisis. I just didn' t expect it to happen on my first day on the job.

But there I was, less than an hour after taking my oath, in the Situation Room, being briefed by John Brennan, the President' s Advisor for Homeland Security and Counterterrorism on the H1N1 flu. And what we all knew from the start was that we had to act quickly.

The first thing our CDC scientists did was work with their colleagues around the world to rapidly identify and characterize the virus. The next steps followed just as fast.

We prepared lab kits and got them out to every public health lab in the country in record time. CDC developed a candidate vaccine strain, NIH ran clinical trials to find correct dosages and we sent it off to manufacturers. The FDA moved as fast as possible to inspect and license vaccine facilities. We released a significant share of our national stockpile of antivirals. BARDA used contracts we already had with vaccine manufacturers and quickly signed production agreements. CDC, FDA, DOD and others worked closely to set up extensive safety monitoring systems which tracked the safety of the vaccine as it was used.

Thanks to these coordinated steps among all the HHS agencies, we were able to develop a safe vaccine and distribute it in record time.

And thanks to the hard work of thousands of people at the federal, state and local level, we were able to avoid the worst predictions.

But our job is to ask ourselves everyday: how can we make our public health defense even stronger? And our H1N1 experience taught us two valuable lessons.

First, it confirmed that our public health response is only as strong as its weakest link.

The H1N1 flu tested our entire public health system. How well we were able to respond depended on the strength and numbers of our health care workforce. It depended on whether we had enough hospital beds and working emergency rooms. It depended on our ability to coordinate across government agencies and how well we could execute a national response strategy on the local level. It depended on how well informed and engaged the public was. It even depended on the international community' s response. With so many factors in play at once, coordination was key.

So it was a good reminder that to be ready for the next public health crisis, we need to focus on our entire end-to-end response, from how we assess and identify threats to how we distribute and administer products to counter those threats in cities and towns across the country

This was one of the goals we had in mind when we passed the Affordable Care Act six months ago. And although it is not often referred to this way, it is one of the strongest public health bills our nation has ever seen.

It makes a historic investment in our health care workforce. And it creates a new $15 billion Prevention and Public Health Fund that distributed nearly $43 million in grants just a few days ago to state, local, and tribal governments to improve their public health services.

We' ve got a long way to go, but a recent CDC report showed that state and local health departments have made significant progress in a number of areas from being able to reach ninety percent of our laboratories 24 hours a day, 7 days a week to having more than ninety percent of laboratories using rapid methods to communicate with nearby labs on matters related to outbreaks and normal surveillance.

So the first lesson we're taking away is that we need to invest in our entire end-to-end response from the scientists doing disease surveillance to the doctors and nurses providing vaccines.

The second lesson was that we needed to make serious investments in our countermeasure enterprise

As quickly as we acted on H1N1, there was one fundamental problem we couldn't overcome: we were fighting the 2009 H1N1 flu with vaccine technology from the 1950s. We could race to begin vaccine production, but there was nothing we could do if the virus grew slowly in eggs. We could make deals with foreign vaccine producers ahead of time, but we still wouldn't have as much control over the vaccine as we have with companies based in the U.S.

We were working to squeeze every last bit of efficiency out of a safe, but outdated technology. It was like an old car we had tuned up but still didn't accelerate like we needed it to. And for us, the conclusion was clear: if we wanted to avoid these problems in the future, we needed to make some long-term investments to develop vaccines that were just as safe and effective, but could be produced faster and more reliably.

And that was true not just for vaccines, but for all medical countermeasures, whether it's vaccines, antivirals, antibiotics, diagnostics, or medical equipment. As our most direct response to public health threats, countermeasures are often our most effective. In a public health crisis, they can frequently be the best protection we have.

But the closer we looked at our countermeasure process, the more leaks, choke points, and dead ends we saw.

In an age of new threats, we weren't generating enough new products. In a business where delays cost lives, we couldn't develop and manufacture countermeasures fast enough. And at a moment when the greatest danger we face may be something we've never seen before, like a drug resistant superbug, we didn't have enough flexibility to adapt to unforeseen threats.

That' s why, last December, with the encouragement and strong support of President Obama, I called for an unprecedented review of our entire medical countermeasures enterprise.

Led by Dr. Nicole Lurie, our Assistant Secretary for Preparedness and Response, that review drew on dozens of conversations with state and local health departments, industry groups, venture capital experts, academics, scientists, and biotech developers around the country.

The vision they laid out was of a nation with, quote: " the nimble, flexible capacity to produce medical countermeasures rapidly in the face of any attack or threat, known or unknown, including a novel, previously unrecognized, naturally occurring emerging infectious disease."

Many of the barriers to that vision were immediately obvious.

Today, too many promising ideas get lost or dropped along the way. A scientist can make a discovery without realizing it could be turned into a useful countermeasure. Or they may see its potential, but not know what to do next. Or a company may not be able to get the investment they need to move forward.

For industry, there' s simply little incentive for private companies to produce medical countermeasures for rare conditions like the Ebola virus or radiation poisoning. Yet in the event of an Ebola outbreak or a nuclear explosion, these countermeasures would be critical.

There are also regulatory obstacles. One of the hardest parts about getting a product from the test tube to our national stockpile – especially for rare or emerging diseases – is making sure it' s safe and effective and meets manufacturing standards. But for too long, we' ve underinvested in the tools, models, methods and knowledge needed for making these assessments – what you all know as regulatory science. Because of this underinvestment, we' re often testing and producing cutting-edge products using science that' s decades-old.

Finally, even if new countermeasures do make it to market, we don't always have the capacity, modern technology or equipment to produce them with the quantity and speed we need. We saw that with H1N1 when we were able to develop a safe vaccine and distribute it in record time – yet still had our production peak three weeks after the peak of flu season. If the threat had been more deadly or less familiar, we could have paid a far higher price.

Faced with these findings, we knew we couldn't afford to keep pumping money into a leaky pipeline.

That's why in the coming months, our department will move forward in five areas where we believe we can make big improvements in our public health defenses.

First, we'll upgrade regulatory science at the Food and Drug Administration to modernize product development and evaluation. By identifying and solving scientific problems earlier, we can take products across the finish line faster, confident in their safety and effectiveness.

Second, we'll work closely with developers to establish facilities capable of providing core product development and manufacturing services right here in the United States.

On September 15 we released a draft solicitation for new Centers of Innovation for Advanced Development and Manufacturing facilities that will work to develop new flexible manufacturing platforms while giving us a dependable domestic source of surge capacity for flu vaccine so that we won't have to rely on foreign producers, as we did during the H1N1 crisis. These Centers will also serve as a resource where small biotech companies with big ideas can get the regulatory and manufacturing support they need to bring their products to market.

And I hope all of you will send us your input and comments on the solicitation so we can be sure we get the most benefit from this critical investment.

The third area we're moving forward is an effort to nurture discoveries in their earliest stages by taking full advantage of the incredible resources and years of experience at the

National Institutes of Health. This will include creating new facilitator teams to guide scientists and their discoveries through the development process.

And just this week, we have awarded eight contracts to businesses with the goal of advancing innovative tools and techniques that reduce the time and cost of development, testing, and production of medical countermeasures – and improve the safety, efficacy, and ease of their use.

Fourth, we' ll reduce the time it takes to get flu vaccines to people by producing vaccine seed strains that can grow better, and by modernizing potency and sterility testing methods. These are the same steps recommended in a report from the President' s Council of Advisors on Science and Technology, they' ll ensure we' re better prepared for flu seasons to come, And the CDC, FDA, BARDA and NIH are already engaged in a planning framework to address each of these needs.

Finally, we' ll explore the possibility of launching a non-profit Strategic Investment organization that can provide critical financial and business planning support to small companies with big ideas that have huge potential to improve our public health preparedness.

In the coming years, HHS will direct nearly $2 billion in preparedness funds to these five areas, helping us build a countermeasures enterprise with the solid base of discovery, clear regulatory pathway, and agile manufacturing that' s necessary if we' re going to be able to respond to any threat at any time.

We' re working to upgrade our entire end-to-end response, from how we assess and identify threats to how we distribute and administer products to counter those threats in cities and towns across the country.

Preparing for the next public health crisis is a job that never stops.

Last Friday we awarded a contract to create a next-generation anthrax vaccine. We all remember the anthrax scares of years past. Next time we want to be ready with a plan of action and treatment that will neutralize the threat and reduce its health impact.

We have also bolstered our Strategic National Stockpile with the nation's first smallpox vaccine for certain immune-compromised populations. This means that in the event of a smallpox attack on our population, our public health infrastructure will be able to better protect our most vulnerable populations, such as those with HIV, and keep them from being further sickened by the outbreak.

There is an old saying in sports that most victories are won on the practice field. That's also true in public health. No amount of hard work at the height of an emergency can make up for inadequate planning. Shortcuts in preparation quickly lead to shortfalls in results when a crisis hits.

That's why we must work steadily towards our ultimate goal of being ready for any threat at any time. We have a long way to go, but we are headed in the right direction.

Thank you.