The American Medical Association Third National Congress on Health System Readiness

December 1, 2009 – Washington, D.C.

Thank you, Dr. Patchin, for that introduction, and good morning, everyone.

I want to thank the American Medical Association for hosting this event. Everyone knows America's doctors provide terrific care. But people don't always appreciate how critical our doctors are during emergencies like pandemics. You're on the front lines, helping Americans understand the best ways to stay healthy and safe.

I've seen that firsthand in the last six months, working with the AMA on everything from making sure no American goes without an H1N1 vaccine because they can't pay…to getting our health care system ready for the next public health emergency. And I want you know how much we value your partnership.

Since we're here today to talk about responsiveness, I also want to acknowledge Dr. Nicki Lurie, our terrific Assistant Secretary for Preparedness and Response, and Dr. Robin Robinson, who's leading our Biomedical Advanced Research and Development Authority – we call it BARDA for short – which helps develop our public health countermeasures.

From the day President Obama took office, he promised to bring great scientists and doctors into this administration. And he said, we're actually going to listen to them. That second part is important. When it comes to public health emergencies, science will guide our response. That's been especially true for the H1N1 flu, and I want to thank Nicki and Robin and the rest of our great H1N1 team for working non-stop with our partners in the public and private sectors to keep Americans safe this flu season.

Today, we face a wider range of public health threats than ever before in our history. It could be anthrax delivered in an envelope. It could be a dirty bomb set off in a subway car. It could be a new strain of flu that our bodies have no immunity to.

These public health emergencies test our entire public health systems. How well we're able to respond depends on the strength and numbers of our health care workforce. It depends on whether we have enough hospital beds and working emergency rooms. It depends on our ability to coordinate across government agencies and how well we can execute a national response strategy on the local level. It depends on how well informed and engaged the public is.

But the success of our response often depends most of all on what we call medical countermeasures. These are the treatments, vaccines, prophylaxis, diagnostics, personal protective equipment, and non-pharmaceutical aids like ventilators that help reduce the spread of infections, reduce health consequences, and ultimately save lives. As our most direct response to public health threats, countermeasures are often our most effective. In a crisis, they can frequently be the best protection we have.

But the countermeasure that saves the day during a quick-hitting public health emergency can often take years to discover, develop, manufacture, and distribute. That vaccine that saves your life during an epidemic may have started as a basic research project in a government lab 20 years ago. After that, it had to be tested to make sure it was effective and safe. Then someone had to figure out how to make it safely in large quantities – and pay for it. Then it needed to be stockpiled, and someone had to come up with a plan for how to get it to you.

In the middle of a crisis, it's easy to see why each of these steps is critical. But once the scary details of the crisis fade from memory, it's easy for other priorities to take over. And like a lot of countries, we've often failed to make the kind of long-term investments in countermeasures we need to stay safe when these low-frequency, high-consequence events occur.

The 2009 H1N1 flu is a great example. I started dealing with H1N1 literally from the moment I was sworn in. Less than an hour after taking my oath, I was in the Situation Room being briefed by John Brennan, the President's Advisor for Homeland Security and Counterterrorism. And what we all knew from the start was that we had to act quickly.

The first thing our 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. We developed a candidate vaccine strain and 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. We used contracts that we already had with vaccine manufacturers to quickly sign production agreements.

Thanks to these steps, we were able to develop a safe vaccine and distribute it in record time. As of today, we have 69 million doses of the vaccine allocated, with more coming in every day. And yet, we've still had challenges.

As quickly as we acted, 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 vaccine 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 if they were based in the U.S.

We were working to squeeze every last bit of efficiency and dependability 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 in developing countermeasures that were just as safe and effective, but could be produced faster and more reliably.

This wasn't a new idea. We've talked about updating our vaccine technology for years. What is new is that we're backing up our talk with action and resources. For example, last week, Novartis opened the first American cell-based vaccine plant in Holly Springs, North Carolina with HHS support.

When this plant is up and running in 2011, it will be able to produce vaccine for a significant share of our population within 6 months of the onset of a pandemic. What's even more important is that this process will end our reliance on egg-based technology. That will allow the plant to produce vaccine faster and with no danger of egg-based allergies. If you want to expand production, all you need to do is get another tray of cells out of the freezer.

This is a big step. But it's only one step. This facility still might produce only half of what we need during a given pandemic. And even though cell-based vaccine production is a big improvement over the system we have now, we will still have to grow the vaccine. Which means there's a risk it could grow too slowly.

That's why we're also investing to develop even more advanced vaccine technologies that promise to be even faster and more dependable. For example, we've supported a company in Connecticut that's taking a new approach to vaccine production. Instead of

trying to grow a version of the whole virus, they're just growing the part of the virus that generates the immune response. We can't say for sure what technologies will emerge. What's important is that we're making progress.

And after talking to our partners across government, in states, and in industry, we've realized that we have the chance to make the same kind of progress for countermeasures against a wide range of threats. But we also realized that there are a lot of obstacles standing in the way.

For example, we rely on the NIH and Defense Department for most of our early research, but we don't do a great job focusing that research on our top priorities. So we don't get enough discoveries that are candidates for advanced development. Then, even when we do get candidates for advanced development, they're often not advanced enough for BARDA to take over. And even when we end up with a useful countermeasure, there might not a big enough incentive for a company to manufacture it on a significant scale. As a pharmaceutical company, you can usually count on the CDC to buy some of a countermeasure to replenish its stockpile. But in many cases, that's an insufficient market.

So there are gaps at every stage in the process from the laboratory to the factory floor that are slowing or stalling the development of key countermeasures. And in this age of growing public health threats against which countermeasures are often are best defense, that's dangerous. The H1N1 flu has been devastating, especially for children. But we have experience dealing with flus. We don't know what's coming: the next public health emergency we face could be much worse.

That's why I'm asking Dr. Lurie and the Office of the Assistant Secretary for Preparedness and Response to lead a review of its entire public health countermeasures enterprise, to be completed in the first quarter of next year. We're going to look at how our policies affect every step of countermeasure development and production and then ask: how can we do better? And then we're going to put those answers into action.

I called for this comprehensive review because in order to get the 21st-century countermeasures we need to keep us safe, we don't just need 21st-century technology. We also need 21st-century financial, legal, and regulatory frameworks that create incentives for companies to build these advanced countermeasures. When a vaccine is delayed on the production line, it's easy to see and get upset. But we pay the same price when a life-saving discovery never makes it to the factory in the first place.

The ultimate goal of this review is a modernized countermeasure production process where we have more promising discoveries, more advanced development, more robust manufacturing, better stockpiling, and more advanced distribution practices. In other words, we want to create a system that can respond to any threat at any time. The kind of system that is so dependable and comprehensive that it deters potential bioterrorism attacks and makes our enemies say, "It's not worth the effort."

This is our goal. Under the review I've announced today, we'll look for the fastest ways to move to new technologies that will let us quickly produce countermeasures that are more dependable and more robust. Not just for flu and not just for infectious diseases, but for all the public health threats we face today.

And though I've asked for the review by early next year, this will be an ongoing process. We realize the worst thing we could do is undertake a new effort now while the H1N1 flu is fresh in our minds and then forget about it next spring when flu season ends. What we will strive for is a process of continuous innovation that blends the best available science with the right kind of market environment. Preparing for the next public health emergency

is a full-time job and we need to do it whether there's another crisis going on or not.

We also understand that countermeasures are just one weapon in our public health arsenal. To prepare for the public health threats of the future, we must also strengthen our surveillance capability. We must strengthen our health care workforce. We must strengthen our ability to execute a strategy at different levels of government. This is another lesson from our H1N1 experience. You're only prepared for a public health emergency if your entire health care system is prepared.

We know this transformation won't happen overnight. But we're going to do everything we can to speed it along.

Thank you.

Secretary Kathleen Sebelius