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Opening Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
“Legislative Hearing to Address Bioterrorism, Controlled Substances,
and Public Health Issues”
Subcommittee on Health
July 21, 2011

Thank you, Mr. Chairman, for holding today’s hearing on three important pieces of public health legislation: H.R. 2405, the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011; H.R. 1254, the Synthetic Drug Control Act of 2011; and the soon-to-be-introduced Enhancing Disease Coordination Activities Act of 2011.

I am pleased that we have once again come together on a bi-partisan basis to move forward with these bills. Although our work is not quite complete, I have every confidence that we will reach agreement on the substance of all three bills and that members on both sides of the aisle will be supporting them. I want to thank you, Mr. Chairman, and your staff, as well as all the members of the subcommittee, for working with us to make this happen.

This bi-partisan approach has been the foundation upon which each of the proposals we will discuss today has been developed.

The Pandemic and All-Hazards Preparedness Reauthorization Act reauthorizes and makes minor improvements to programs and activities first established in both the 2004 Project Bioshield Act and the 2006 Pandemic and All-Hazards Preparedness Act, also known as PAHPA. These programs are critically important to help ensure that our nation is well prepared to successfully manage the effects of natural disasters, infectious disease outbreaks, and acts of bioterrorism.

In reauthorizing these programs and activities, there are a number of issues we are exploring and would like to hear more about during today’s hearing. In my view, surge capacity – the ability of our health care system to respond to mass casualty emergencies – and biosurveillance – the ability to detect natural or manmade hazardous or disastrous events as soon as possible – deserve special attention. So does the state and local public health infrastructure needed to support these kinds of efforts.

The role of the FDA in dealing with various public health emergencies of great enormity is especially critical. Of particular importance is how FDA provides appropriate guidance and feedback to sponsors of medical countermeasures about the regulatory pathway they must follow in developing their products. I have concerns about the new Regulatory Management Plan that is proposed in H.R. 2405. But I believe we can achieve the balance necessary to make certain that the communications process functions as it should – on the one hand, allowing FDA the flexibility it needs to deal with regulatory science issues of great complexity and on the other hand, providing countermeasure developers with the predictability and guidance they need to continue and grow their work.

We should also consider the idea of allocating some of the Bioshield funds to FDA in support of its countermeasure review process. This approach would allow FDA's work to complement the efforts of both NIH and BARDA. Clearly, we cannot permit resource constraints to stand in the way of FDA's ability to complete its reviews, putting in potential jeopardy, the entire Bioshield enterprise.

Other subjects we want to look at include the unique needs of children in disasters – an issue Congresswoman Eshoo has been championing. And the Administration's strategic investor proposal – the creation of a nonprofit firm to help companies developing critical technologies to obtain necessary capital. But like the other issues I have just mentioned, I am confident that all of these matters will be resolved in a bi-partisan manner and in a way that improves PAHPA in all its many programs and activities.

Let me now speak briefly about the other two bills we will discuss today and are working on with our Republican colleagues. H.R. 1254, the Synthetic Drug Control Act of 2011, adds specified synthetic versions of drugs of abuse to Schedule 1 of the Controlled Substances Act. These designer drugs can be very unsafe, causing convulsions, anxiety attacks, and dangerously elevated heart rates, among other conditions. H.R. 1254 would enable the Drug Enforcement Agency to take appropriate enforcement actions to get them off the street and away from our nation's youth.

Finally, the Enhancing Disease Coordination Activities Act provides direct authority to the Secretary of the Department of Health and Human Services to establish disease-specific interagency coordination committees and lays out the parameters for these committees. The proposal is modeled on the highly successful Interagency Autism Coordinating Committee which we learned about at last week's hearing.

Again, I want to thank you, Mr. Chairman, and the members of the subcommittee for the cooperation with which we have worked on all three bills we consider today. I look forward to a successful conclusion of this effort as well as to hearing from today's witnesses. Thank you all for joining us.