BIOTERRORISM, CONTROLLED SUBSTANCES, AND PUBLIC HEALTH ISSUES

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED TWELFTH CONGRESS

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C O N T E N T S

BIOTERRORISM, CONTROLLED SUBSTANCES, AND PUBLIC HEALTH ISSUES

THURSDAY, JULY 21, 2011

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:03 a.m., in room 2123 of the Rayburn House Office Building, Hon. Joseph Pitts (chairman of the subcommittee) presiding.

Members present: Representatives Pitts, Burgess, Shimkus, Rogers, Myrick, Murphy, Gingrey, Latta, McMorris Rodgers, Cassidy, Guthrie, Upton (ex officio), Pallone, Dingell, Towns, Capps, Baldwin, Green, and Waxman (ex officio).

Staff present: Clay Alspach, Counsel, Health; Gary Andres, Staff Director; Jim Barnette, General Counsel; Sean Bonyun, Deputy Communications Director; Brenda Destro, Professional Staff Member, Health; Andy Duberstein, Special Assistant to Chairman Upton; Debbee Keller, Press Secretary; Ryan Long, Chief Counsel, Health; Carly McWilliams, Legislative Clerk; Andrew Powaleny, Press Assistant; Chris Sarley, Policy Coordinator, Environment and Economy; Heidi Stirrup, Health Policy Coordinator; Phil Barnett, Democratic Staff Director; Stephen Cha, Democratic Senior Professional Staff Member; Alli Corr, Democratic Policy Analyst; Eric Flamm, FDA Detailee; Ruth Katz, Democratic Chief Public Health Counsel; Karen Lightfoot, Democratic Communications Director and Senior Policy Advisor; and Karen Nelson, Democratic Deputy Committee Staff Director for Health.

Mr. PITTS. The subcommittee will come to order. The chair will recognize himself for 5 minutes for an opening statement.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Today's legislative hearing will focus on H.R. 2405, the Pandemic and All-Hazards Preparedness Act of 2011; H.R. 1254, the Synthetic Drug Control Act of 2011; and the Enhancing Disease Coordination Activities Act of 2011.

Our witness for the first panel will be my friend and fellow Pennsylvanian, Representative Charlie Dent. His bill, H.R. 1254, the Synthetic Drug Control Act, addresses a growing problem in many States and gives law enforcement additional tools to deal with the very real dangers of synthetic drugs.

H.R. 1254 would prohibit the sale of synthetic drugs that imitate the hallucinogenic and stimulant properties of drugs like marijuana, cocaine, and methamphetamines. While these drugs are synthetic, they are just as dangerous as the real thing, but they are not illegal.

Along with banning these synthetic drugs, the bill would also allow the Drug Enforcement Administration (DEA) to temporarily schedule a new substance for up to 3 years instead of the current standard of up to 18 months.

Next, the subcommittee will examine Representative Rogers' bill, H.R. 2405, the Pandemic and All-Hazards Preparedness Act of 2011, which would reauthorize certain provisions of the Project Bioshield Act of 2004 and Pandemic and All-Hazards Preparedness Act of 2006 (PAHPA). These laws help protect our country against pandemics and attacks from chemical, biological, radiological, and nuclear weapons.

Among the reauthorizations in the bill are the Biomedical Advanced Research and Development Authority (BARDA), which helps to ensure that early-stage research leads to tangible medical countermeasures that can be used to save lives in an emergency, and the reauthorization of Project Bioshield's Special Reserve Fund, which helps procure medical countermeasures against anthrax, smallpox, botulism, and other threats for the Strategic National Stockpile.

Finally, the Enhancing Disease Coordination Activities Act of 2011 would allow the Secretary of Health and Human Services to establish committees based on existing interagency coordinating models that will help coordinate disease-specific research and other activities currently spread across the department.

[The information appears at the conclusion of the hearing.]

I would like to thank all of our witnesses today, and I would like to yield the remainder of my time to Representative Rogers.

[The prepared statement of Mr. Pitts follows:]

Rep. Joseph R. Pitts
Opening Statement
Energy and Commerce Subcommittee on Health
"Legislative Hearing to Address
Bioterrorism, Controlled Substances and Public Health Issues"
July 21, 2011

The Subcommittee will come to order.

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- the Enhancing Disease Coordination Activities Act of 2011.

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Finally, the Enhancing Disease Coordination Activities Act of 2011 would allow the Secretary of Health and Human Services to establish committees based on existing interagency coordinating models that will help coordinate disease-specific research and other activities currently spread across the Department.

I would like to thank our witnesses today, and I yield the remainder of my time to _____.

OPENING STATEMENT OF HON. MIKE ROGERS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. ROGERS. Thank you, Mr. Chairman, for holding this very important hearing.

Last month, I introduced H.R. 2405, legislation to reauthorize the Pandemic All-Hazards Preparedness Act. I want to thank Gene Green and Sue Myrick for being original cosponsors on this bill, which will also reauthorize Project Bioshield's Special Reserve Fund.

It has been almost 10 years since 9/11 and the anthrax attacks that followed, and while they haven't had a successful terrorist attack on U.S. soil, our enemies are still working every single day to kill innocent Americans. Bioterrorism remains a very real threat to our country, which is why I think this bipartisan legislation is so important.

Over the last 10 years, we have made significant progress in our ability to protect the public from CBRN threats. Congress created Project Bioshield in 2004, creating a market guarantee that prompted the private sector to develop countermeasures for the Federal Government. In 2006, we also created the Biomedical Advanced Research and Development Authority (BARDA), which helped bridge the "valley of death" that prevented many countermeasure developers from being successful.

Today, we have numerous vaccines and treatments in the Strategic National Stockpile that will save lives in the event of an attack. And while we hope that we never have to use these medical countermeasures, they are essential to protecting the public health from a bioterrorism attack. Simply put, we must always be prepared.

I would also like to thank Mr. Pallone and Mr. Waxman for working with us on this bipartisan basis to move this legislation through the committee. The issue has always been a bipartisan effort, and I appreciate their willingness to partner with us. I also look forward to hearing from Dr. Nicole Lurie, the HHS Assistant Secretary for Preparedness and Response who oversees the entire medical countermeasure enterprise. It is an important role in protecting the country and I am pleased that they have also worked with us on this critical legislation.

Thank you again for holding this hearing, Mr. Chairman, and I yield back my time.

Mr. PITTS. The chair thanks the gentleman and asks unanimous consent to enter the statement of Joe Rannazzisi of the Drug Enforcement Administration into the record. Without objection, so ordered.

[The information follows:]

Department of Justice

STATEMENT

OF

JOSEPH T. RANNAZZISI
DEPUTY ASSISTANT ADMINISTRATOR
OFFICE OF DIVERSION CONTROL
DRUG ENFORCEMENT ADMINISTRATION

BEFORE THE

SUBCOMMITTEE ON HEALTH
COMMITTEE ON ENERGY AND COMMERCE
UNITED STATES HOUSE OF REPRESENTATIVES

AT A HEARING ENTITLED

"LEGISLATIVE HEARING TO ADDRESS BIOTERRORISM, CONTROLLED SUBSTANCES AND PUBLIC HEALTH ISSUES"

JULY 21, 2011

Statement for the Record of
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration
United States Department of Justice

U.S. House Committee on Energy and Commerce, Subcommittee on Health
"Legislative Hearing to Address Bioterrorism, Controlled Substances and Public Health Issues"

July 21, 2011

Chairman Pitts, Ranking Member Pallone and distinguished members of the Committee on Energy and Commerce, Subcommittee on Health, on behalf of Administrator Leonhart and the Drug Enforcement Administration (DEA), I appreciate your invitation to submit written testimony today regarding the growing threat of synthetic drugs in the United States and DEA's efforts to combat the emerging challenges presented by synthetic cannabinoids and stimulants.

Introduction

Over the past couple of years, "herbal incense" products marketed in the U.S. as being "legal" and providing a marijuana-like high when smoked have become increasingly popular, particularly among teens and young adults. These products consist of plant material that has been laced with substances (synthetic cannabinoids) that claim to mimic Δ9-tetrahydrocannabinol (THC), the primary psychoactive active ingredient in marijuana. These substances have not been approved by the FDA for any indication, and there is no regulatory oversight of the manufacturing process for the substances or the associated products. Brands such as "Spice," "K2," "Blaze," and "Red X Dawn" are labeled as herbal incense to mask their intended purpose.

There is also a growing abuse of a variety of synthetic compounds that produce stimulant effects when ingested, snorted and intravenously injected. These synthetic stimulants, which are based on a variety of known compounds, such as "MDPV" (3, 4-methylenedioxypyrovalerone), mephedrone (4-methylmethcathinone), and methylone (3,4-methylenedioxymethcathinone) are sold under the guise of "bath salts" or "plant food," in retail outlets and over the Internet. They are marketed under names such as "Ivory Wave," "Purple Wave," "Vanilla Sky," and "Bliss." In addition to their psychoactive effects, they also have potentially harmful side effects when ingested, snorted and intravenously injected. These products are not approved by the FDA for any indication and are not currently in any schedule under the Controlled Substances Act (CSA).

Both synthetic cannabinoids and synthetic stimulants are "designer drugs" that are manufactured and distributed in an attempt to circumvent the CSA. They are marketed in a manner so as to mask their intended purpose and are labeled with a statement that the package contents are "not for human consumption," or are "for novelty use only." The purpose of this statement is to circumvent the Controlled Substance Analogue Enforcement Act of 1986 (as

amended), which states that controlled substance analogues shall, "*to the extent intended for human consumption*," be treated as a controlled substance in Schedule I. 21 U.S.C. § 813 (emphasis added). The manufacturers and retailers who make and sell these products do not fully disclose all of the product ingredients and never disclose the active and potentially harmful ingredient(s). These products are sold at a variety of retail outlets, in head shops, and over the Internet from both domestic and international sources.

The manufacture and sale of "designer drugs" that are synthesized for the sole purpose of achieving the pharmacologic effects of some controlled substances is not a new phenomenon. History is replete with examples of substances that were synthesized to mimic the effects of a specific controlled substance in order to circumvent the provisions of the CSA. Historically, the introduction of "designer drugs" into the marketplace was generally similar to that of illicit controlled substances: covert meetings and sales on street corners, back alleys, and in dark clubs. In many instances, the ingestion of these drugs led to tragedy. Today, the marketing of such "designer drugs" has ushered in a new era of drug distribution. No longer are these substances sold in a covert manner to thwart law enforcement efforts. Instead, the substances are sold at retail outlets in plain view with the instructions, "not for human consumption" in products labeled as incense, bath salts, and plant food. Substances that are just as dangerous as their controlled substance counterparts are marketed as harmless sundry items in an attempt to protect the manufacturers, distributors and retail sellers from criminal prosecution. But these particular incense, bath salts, and plant food items are really nothing more than a means to make psychoactive substances available to the consumer.

Situational Overview

Incense-Herbal Products (Synthetic Cannabinoids)

Background

Since 2009, DEA has received an increasing number of reports from poison control centers, hospitals, and law enforcement agencies concerning products containing synthetic cannabinoids. Emergency room physicians report that individuals who use these types of products experience dangerous side effects, including: convulsions, anxiety attacks, dangerously elevated heart rates, increased blood pressure, vomiting, and disorientation. Because these substances pose a threat to the public health and safety, at least 38 states have taken action to control one or more of these chemicals. The Comprehensive Crime Control Act of 1984 amends the CSA to allow the Attorney General to place a substance temporarily in Schedule I when it is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. § 811(h).

In February 2011, the DEA Administrator used her authority to issue a final order which was published in the Federal Register on March 1, 2011 (76 Fed. Reg. 11075) temporarily placing five synthetic cannabinoids into the CSA pursuant to the temporary scheduling provision of the CSA. These five substances are:

1-pentyl-3-(1-naphthoyl)indole **(JWH-018);**
1-butyl-3-(1-naphthoyl) indole **(JWH-073);**

1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole **(JWH-200);**
5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol **(CP-47,497); and**
5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (**cannabicyclohexanol**; CP-47,497 C8 homologue).

As a result of this order, the full effect of the CSA and its implementing regulations, including criminal, civil, and administrative penalties, sanctions, and regulatory controls of Schedule I substances will apply to the manufacture, distribution, possession, importation, and exportation of these synthetic cannabinoids. In response to both Federal and State controls, the designer drug market has transitioned to new structurally similar substances.

The Comprehensive Crime Control Act of 1984 (Pub. L. 98-473), which was signed into law on October 12, 1984, amended section 201 of the CSA (21 U.S.C. § 811) to give the Attorney General the authority to temporarily place a substance into Schedule I of the CSA for one year, without regard for the requirements of 21 U.S.C. § 811(b), if he finds that such action is necessary to avoid imminent hazard to the public safety. The Attorney General may extend the temporary scheduling for up to six months during pendency of proceedings under 21 U.S.C. § 811(a)(1). A substance may be temporarily scheduled under the emergency provisions of the CSA if it is not listed in any other schedule under section 202 of the CSA (21 U.S.C. § 812), and if there is no exemption or approval in effect under 21 U.S.C. § 355 for the substance. The Attorney General has delegated his authority under 21 U.S.C. § 811 to the DEA Administrator. 28 CFR § 0.100.

In a letter dated October 6, 2010, the DEA Deputy Administrator, now Administrator, transmitted notice to the Assistant Secretary for Health of the Department of Health and Human Services (HHS) of her intention, as per section 201(h)(4) of the CSA (21 U.S.C. § 811(h)(4)), to temporarily place JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol into Schedule I of the CSA. In response to this notification, the HHS Assistant Secretary for Health communicated in a letter dated November 22, 2010, to the then-Acting Administrator of DEA that there are no exemptions or approvals in effect for JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol under Section 505 of the Federal Food, Drug and Cosmetic Act (21U.S.C. § 355). The substances are not listed in any other schedule in 21 U.S.C. § 812.

A Notice of Intent to temporarily place JWH-018, JWH-073, JWH-200, CP-47,497, and cannabicyclohexanol into Schedule I of the CSA was published in the Federal Register on November 24, 2010. 75 Fed. Reg. 71635. Before making a finding that temporary placement of a substance into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors (factors 4, 5, and 6) set forth in section 201(c) of the CSA. 21 U.S.C. § 811(c). These factors are: the history and current pattern of abuse; the scope, duration, and significance of abuse; and what, if any, risk there is to the public health, including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution . 21 U.S.C. § 811(h)(3).

As explained in the March 1, 2011 Final Order, the temporary placement of these five synthetic cannabinoids into Schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. First, these substances are not intended for human consumption, yet there has

been a rapid and significant increase in abuse of these substances in the United States. As a result of this abuse, several synthetic cannabinoids are banned/controlled in at least 38 states in the United States as well as in several countries, and all branches of the U.S. military prohibit military personnel from possessing or using synthetic cannabinoids. Second, before these substances were temporarily controlled as Schedule I substances, law enforcement agencies seized them in conjunction with controlled substances; and based on self-reports to law enforcement agencies and health care professionals, synthetic cannabinoids were being abused for their psychoactive properties. Third, numerous state and local public health departments and poison control centers have issued health warnings describing the adverse health effects associated with synthetic cannabinoids. These five substances have the potential to be extremely harmful and, therefore, pose an imminent hazard to the public safety.

According to a recent press release from the American Association of Poison Control Centers, poison control centers received 2,915 calls relating to these products in 2010 and as of May 31, 2011, poison centers had received 3,094 calls for 2011. Many of these calls originated from or en-route to a healthcare facility. Case reports describe psychotic episodes, withdrawal, and dependence associated with use of these synthetic cannabinoids, similar to syndromes observed in marijuana
abuse.

History and Current Pattern of Abuse

"Synthetic cannabinoids" are a large family of compounds that are functionally (biologically) similar to THC, the main psychoactive ingredient in marijuana. Synthetic cannabinoids, however, are not organic but are chemicals created in a laboratory.

Two of the five synthetic cannabinoids (CP-47,497 and cannabicyclohexanol) were first synthesized in the early 1980's for research purposes in the investigation of the cannabinoid system. JWH-018, JWH-073, and JWH-200 were synthesized in the mid-1990s and studied to further advance the understanding of drug-receptor interactions regarding the cannabinoid system. Synthesized as research tools, no other known legitimate uses have been identified for these five synthetic cannabinoids. Furthermore, these five synthetic cannabinoids are not approved by the FDA forany indication.

The emergence of synthetic cannabinoids is relatively new to the U.S. "designer drug" market. Since the initial identification of JWH-018 by U.S. forensic laboratories, many additional synthetic cannabinoids including JWH-073, JWH-200, CP-47,497, cannabicyclohexanol, and many others have been identified in related herbal incense products. These synthetic cannabinoids have purported psychotropic effects when smoked or ingested. These chemicals are typically found in powder form or are dissolved in solvents, such as acetone, before being sprayed on the plant material comprising the "herbal incense" products.

The popularity of these THC-like synthetic cannabinoids has significantly increased throughout the United States, and they are being abused for their psychoactive properties as reported by law enforcement agencies, the medical community, and in

scientific literature. They are marketed as a "legal" alternative to marijuana or other drugs. They are also popular among those individuals who are subject to urinalysis testing, such as those individuals who are under the supervision of a drug court and those on probation or parole.

Some of the product names include, but are not limited to, "Spice," "K2," Zohai," "Dream," "Genie," "Sence," "Smoke," "Skunk," "Serenity," "Yucatan", "Fire," and many more. These products are labeled "Not for Human Consumption" and are typically advertised as herbal incense by Internet retailers, tobacco shops, head shops, liquor stores, and other domestic brick and mortar retail venues. These marketing techniques result in the perception that products that contain THC-like synthetic cannabinoids are "legal" alternatives to marijuana. No evidence exists that these synthetic cannabinoids add value to genuine incense products—there is no scent or odor associated with these substances.

According to Internet discussion boards and law enforcement encounters reported directly to DEA, synthetic cannabinoids are sprayed on plant material which provides a vehicle for the most common route of administration - smoking (using a pipe, a water pipe, or rolling the drug-spiked plant material in cigarette papers). These materials are then packaged in small pouches or packets sold over the Internet, in tobacco and smoke shops, drug paraphernalia shops, gas stations, and convenience stores as herbal incense products. The retail sale of these products gave customers of all ages direct access to synthetic cannabinoids and the corresponding THC-like effects of these products. Research articles propose that the packaging is professional and conspicuous and targets young people, possibly eager to use cannabis, but who are afraid of the legal consequences and/or association with illicit drugs.

Scope, Duration, and Significance of Abuse

According to forensic laboratory reports, the initial appearance of these synthetic cannabinoids in herbal incense products in the United States occurred in November 2008 when U.S. Customs and Border Protection first encountered products such as "Spice." Prior to arriving in the U.S. market, synthetic cannabinoids were marketed in herbal incense products in several European countries. After experiencing numerous health-related incidents such as elevated heart rates, psychosis, and paranoia.Many countries in the European Union, plus Japan and Russia have banned these products/chemicals.

In addition to increasing concerns by members of the medical community, the increasing abuse of synthetic cannabinoids is also demonstrated by the
increase in federal, state, and local law enforcement activity associated with these substances. The National Forensic Laboratory Information System (NFLIS), a national repository for drug evidence analyses from forensic laboratories across the United States, has reported in excess of 6,000 reports regarding synthetic cannabinoids. These exhibits came from 40 states to include Alabama, Arkansas, California, Florida, Hawaii, Iowa, Indiana, Kansas, Kentucky, Louisiana, Minnesota, Missouri, North Dakota, Nebraska, Nevada, Oklahoma, Pennsylvania, South Carolina, Tennessee, and Virginia.

Even though there is no evidence of legitimate non-research related uses for these

synthetic cannabinoids, multiple shipments of JWH-018 and JWH-073 were encountered by U.S. Customs and Border Protection in 2010, and recent reports detail new synthetic cannabinoids being encountered in multi-kilogram shipments even though there is no known legitimate use for these new substances. One enforcement operation encountered five shipments of JWH-018 totaling over 50 kilograms (110.2 pounds) of powder. In addition, bulk quantities of JWH-018 and JWH-200 were encountered by law enforcement in 2010. For example, in Casper, Wyoming, DEA agents encountered large quantities of herbal incense products laced with the synthetic cannabinoid JWH-018, in conjunction with the seizure of methamphetamine and other illegal drugs, while executing search and arrest warrants.

Risk to the Public Health

Health warnings have been issued by numerous state and local public health departments and poison control centers describing the adverse health effects associated with the use of these synthetic cannabinoids and their related products, including agitation, anxiety, nausea, vomiting, tachycardia (fast, racing heartbeat), elevated blood pressure, tremor, seizures, hallucinations, paranoid behavior, and non-responsiveness.

Smoking synthetic cannabinoids for the purpose of achieving intoxication and experiencing the psychoactive effects has been identified as a reason for emergency room visits and calls to poison control centers. In a fact sheet issued by the National Drug Court Institute, the problem of synthetic cannabinoid abuse is described as "significant and disturbing." This is supported by information that was communicated to DEA from one of the major private toxicology laboratories. Specifically, laboratory findings from drug screens for the period July 2010 through November 2010, showed over 3,700 specimens tested positive for either JWH-018 or JWH-073. They also indicated that they were finding 30-35% positivity for specimens submitted by juvenile probation departments.

Based on law enforcement encounters reported directly to DEA, when responding to incidents involving individuals who have reportedly smoked these synthetic cannabinoids, first responders report that these individuals have suffered from intense hallucinations. Emergency department physicians and toxicologists have also reported the adverse health effects associated with smoking herbal incense products laced with these substances. Law enforcement agencies have recently reported examples of suspected *Driving under the Influence of Drug* incidents that were attributed to the smoking of synthetic cannabinoids. For example, in September 2010, police in Nebraska responded to an incident involving a teenager who had careened his truck into the side of a residence. After striking the residence and several more items, the teen continued several more yards before coming to a complete stop. Prior to crashing the truck, the individual had driven past a junior high school and nearly struck a child. Upon further investigation, the driver of the vehicle admitted to smoking "Wicked X," a product marketed as "herbal incense" and known to contain synthetic cannabinoids, prior to the accident. Preliminary toxicology reports at the hospital indicated that the individual did not have any alcohol or other illegal substances in his system and further analysis of biological specimens identified metabolites of JWH-018.

Detailed chemical analyses by DEA and other agencies have found these synthetic cannabinoids spiked on plant material in herbal incense products marketed to the general public. Product analyses have found variations in both the type of synthetic cannabinoid and the amount of the substance found on the plant material. As proposed in scientific literature, the risk of adverse health effects is further increased by the fact that similar products vary in the composition and concentration of synthetic cannabinoids spiked on the plant material.

Self-reported abuse of these THC-like synthetic cannabinoids either alone (*e.g.*, in pills or with the substance in powder form) or spiked on plant material appear extensively on Internet discussion boards, and abuse has been reported to public health officials and law enforcement agencies. The abuse of these substances in the smoked form (sprayed on plant material) has been corroborated by forensic laboratory analysis of products encountered by law enforcement agencies.

According to U.S. Customs and Border Protection, a number of the products and synthetic cannabinoids appear to originate from foreign sources. Product manufacturing operations encountered by law enforcement personnel establish that the herbal incense products are manufactured in the absence of quality controls and devoid of governmental regulatory oversight. Law enforcement personnel have encountered the manufacture of herbal incense products in such places as residential neighborhoods. These products and associated synthetic cannabinoids are readily accessible via the Internet.

In May 2011, law enforcement encountered a warehouse in Maryland that was used to process large quantities of bulk material into retail level products which contained the synthetic cannabinoid JWH-018. Investigators determined that this was a large-scale operation.

Even though several of these compounds have been controlled/banned in some states, and temporarily scheduled by DEA, unscrupulous scientists are able to continue to provide retailers with "legal" products by developing/synthesizing new synthetic cannabinoid products that are not covered under state/Federal regulatory, administrative or statutory actions. Retail entrepreneurs are able to procure new synthetic cannabinoid products, which have comparative psychoactive properties, with relative ease. In fact, after DEA took action to temporarily schedule the five (5) initial cannabinoids, retailers began selling new versions of the products that do not contain the banned cannabinoids, but instead contain new versions of the JWH compounds. Retailers also began labeling their products as being devoid of temporarily scheduled substances--in some cases later found to be untrue. Additionally, some retailers are provided with a "chemical analysis" purporting that the new product line does not contain any of the banned cannabinoids, yet failing to identify what is actually in the product.

In Kansas, a major manufacturer/distributor of synthetic cannabinoid products told a law enforcement officer, "...if the compound that he is using, JWH-250, is banned, he would just switch and treat his dried plant material with another legal compound."[1] There may be in excess of 100's of cannabinoids that have yet to be introduced into the marketplace. Manufacturers and

[1] Testimony of Police Chief James D. Hill, City of Salina, Kansas Association of Chiefs of Police Representative before the Kansas Senate Committee on Public Health and Welfare, March 3, 2011.

distributors will continue to stay one step ahead of any state or Federal drug-specific banning or control action by introducing/repackaging new cannabinoid products that are not controlled.

There are also financial incentives that drive the wholesale and retail distribution of these products. Affidavits were filed by Plaintiffs in the United States District Court, District of Minnesota, in support of a motion for preliminary injunction and restraining order that attempted to enjoin the government from proceeding with the temporary scheduling of JWH-018, JWH-073, JWH-200, CP-47,497 and cannabicyclohexanol.[2] Each of the Plaintiffs, in a sworn affidavit, claimed that "outlawing" synthetic cannabinoids would have detrimental effects on their respective businesses. In total, these four Plaintiffs estimated their gross profit from the sale of these products to be in excess of $3.5 million annually. They stated that the sale of cannabinoid products represented more than 50% of total sales of L.P.O.E., Inc., a Minnesota corporation; more than 70% of total sales of Hideaway, Inc; approximately 41.27% of gross profits (from April 2010 to September 2010) of Down in the Valley, Inc; and approximately 57% of Disc and Tape, Inc sales (affiant estimated that he would lose over $6000 per day in sales if he had to stop selling the product).

It is clear that the income generated from distributing these products is, and will continue to be, a driving factor for retailers to seek/find substitute products that are not yet controlled or banned by Federal or state action. This is reminiscent of the typical illicit drug dealer cost-benefit analysis, in which the potential for financial gain far outweighs the potential for legal consequences. The large profits and the fact that these chemicals can be easily synthesized to stay one step ahead of control, indicate there is no incentive to discontinue retail distribution of synthetic cannabinoid products under the current statutory and regulatory scheme. Although many good corporate citizen retailers will discontinue the sale of these products in support of public health and safety, many will not, instead opting for the profits realized to help their financial "bottom line."

Synthetic Stimulants

Background

Another serious drug threat that has recently emerged is the growing distribution and abuse of a class of synthetic substances that have stimulant/psychoactive properties when ingested and that are sold as "bath salts" or "plant food." On February 1, 2011, Director of the Office of National Drug Control Policy Gil Kerlikowske issued a press release concerning the emerging threat of synthetic stimulants. In his statement, Director Kerlikowske stated, "I am deeply concerned about the distribution, sale and use of synthetic stimulants-especially those that are marketed as legal substances. Although we lack sufficient data to understand exactly how prevalent the use of these stimulants is, we know they pose a serious threat to the health and well being of young people and anyone who may use them."

These products are sold under a variety of brand names including "Ivory Wave", "Vanilla Sky", "Energy-1" (NRG-1), "Ocean Snow", "Hurricane Charlie", "White Lightening", "Red Dove", "Cloud-9", "White Dove", "White Girl" and many others. They are indirectly marketed

[2] L.P.O.E, Inc v. U.S. Drug Enforcement Administration Civil Case No. 10-VC-4944.

as "legal" alternatives to the controlled substances cocaine, amphetamine, Ecstasy (MDMA or 3,4-methylenedioxymethamphetamine) and methcathinone. The most prevalent synthetic substances encountered within these products include MDPV (3,4-methylenedioxypyrovalerone), mephedrone (4-methylmethcathinone) and methylone (3,4-methylenedioxymethcathinone). These drugs have been distributed and abused in Europe, particularly Great Britain and Germany, for several years. Mephedrone was first detected as a drug of abuse in Europe in November 2007.

These synthetic substances are suspected to be manufactured in bulk quantities in countries such as China, Pakistan, and India, and some of the actual products may be packaged for wholesale distribution in intermediate locations such as Eastern Europe.

The appearance of these designer drugs in products being sold in the United States has proliferated because of the Internet. These substances are marketed as "research chemicals," "plant food," or "bath salts," not for human consumption, to circumvent the CSA. Products are sold in powder or pill form that can be easily ingested. Marketing in this manner attempts to hide the true reason for the products' existence -- the distribution of a psychoactive/stimulant substance for abuse. As with the synthetic cannabinoids, these synthetic stimulants are sold at smoke shops, head shops, convenience stores, adult book stores, and gas stations, in addition to over the Internet. Retailers that sell these products post a disclaimer on their websites that their products are "not intended for human consumption," in an attempt to circumvent statutory and regulatory controls. Websites often list products containing these synthetic stimulants as "plant food;" however, the powdered form is encapsulated in gelatin capsules, and dealers offer "discreet delivery" to the potential customer. Additionally, these products retail at prices that are considerably higher than legitimately marketed plant food or bath salt products. They are even known on the street by nicknames such as "Meow Meow," "drone," or "Molly."

To date, twenty-nine states have enacted controls in response to the "bath salt" phenomenon. Additionally, the trend in the development, distribution, and consumption of this class of substances in Europe has resulted in the United Kingdom and Germany banning products containing these substances.

Scope, Duration, and Significance of Abuse

The substances sold as "bath salts" and "plant food" products are based on the schedule I controlled substance cathinone, which is a potent central nervous system stimulant. Cathinone is an active ingredient in the leaves of the khat plant. Synthesized cathinone-like compounds have been reported as substances of abuse in some European countries since the early 2000s. These substances currently have no known medical use.

Effects have been described as being similar to those caused by other stimulants such as methamphetamine, MDMA, and cocaine. These synthetic substances are abused for their desired effects, such as euphoria, alertness, talkativeness, and sexual arousal. They are increasing in popularity as substances of abuse because they are marketed as "legal highs."

NFLIS has received over 1,000 reports from analyzed seizures related to these substances. To date, poison control centers in the United States have received hundreds of calls from at least 45 states and the District of Columbia related to the side effects of and overdoses from the use of these products. According to a recent press release from the American Association of Poison Control Centers, poison control centers received 303 calls relating to these products in 2010 and as of June 30th, 2011, poison centers have received 3,740 calls for 2011. There is very limited information regarding the biological effects of these substances, and it is unknown what may be the potential acute and long-term effects on humans.

What is known about these substances is disconcerting. There have been reports in the media of overdoses from ingestion of "bath salt" products which resulted in emergency room visits, hospitalizations, and severe psychotic episodes, some of which have led to violent outbursts, self-inflicted wounds, and, in at least one instance, suicide. Abusers of "bath salt" products have reported that they experienced many adverse effects such as chest pain, increased blood pressure, increased heart rate, agitation, panic attacks, hallucinations, extreme paranoia, and delusions.

Some users have reported anecdotally that they have "crashed" or "comedown" from mephedrone with effects similar to those they experienced from "coming down" from ecstasy and cocaine. Users of "bath salt" products self-administer the drugs by snorting the powder, smoking it, or injecting themselves intravenously.

Current Efforts and Challenges - Temporary Scheduling and Prosecution under the Analogue Statute

As previously mentioned, the DEA Administrator published a final order on March 1, 2011, placing five synthetic cannabinoids into Schedule I of the CSA pursuant to the temporary scheduling provisions of the CSA. During the temporary scheduling period, DEA will continue to gather and analyze scientific data and other information collected from all sources, including poison control centers, hospitals, and law enforcement agencies, in order to demonstrate that these substances should be permanently scheduled.

DEA is gathering scientific data and other information about synthetic stimulants as well as evaluating their psychoactive effects to support administrative action to schedule these substances under the CSA. Once data have been gathered to meet the statutory criteria to immediately schedule these stimulants, DEA will publish a notice of intent to temporarily place them into Schedule I. 21 U.S.C. § 811(h).

The challenge with synthetic stimulants is that, as stated above, there are a number of other stimulants that could easily be substituted into new "bath salt" products should mephedrone and MDPV be placed in Schedule I.

Currently, there may be in excess of one hundred other chemical substances that are suspected synthetic cannabinoids or synthetic stimulants. In order to establish controls over these substances, DEA must first establish that each chemical is an "analogue." The primary challenge to preventing the distribution and abuse of a controlled substance *analogue*, as

opposed to a controlled substance *per se*, is that the latter is specifically identified (by statute or regulation) as a controlled substance to which clear statutory controls automatically attach, while the former is not specifically identified (by statute or regulation) and is not automatically subject to control.

Under 21 U.S.C. § 802(32), as interpreted by the weight of court decisions, the government can prove that a substance is an analogue if: (1) the chemical structure of the substance is substantially similar to the chemical structure of a schedule I or II controlled substance; AND (2) the substance is pharmacologically similar to or greater than a schedule I or II controlled substance, *i.e.*, has a similar or greater pharmacological effect on the central nervous system; OR (3) with respect to a particular person, that such person represents or intends the substance to have a pharmacological effect substantially similar to or greater than a schedule I or II controlled substance.

These statutory criteria require extensive investigation and analyses, as well as a qualified expert's opinion regarding the chemical and pharmacological characteristics of the substance.

The major differences between a substance specifically controlled under the CSA and a substance treated as an analogue in terms of preventing diversion and abuse include:

- Additional investigation is necessary on each and every potential analogue case to ascertain whether the substance was "intended for human consumption."

- It is acceptable for a forensic chemist to present testimony regarding laboratory analysis results in order to identify a controlled substance, while additional testimony is necessary from experts in different scientific disciplines to establish that a particular substance is an analogue.

- In criminal prosecutions involving analogue substances, an additional burden is on the government to establish, through experts in the field of chemistry, that the substance is substantially similar in chemical structure to a schedule I controlled substance. This is by its nature an "opinion" and therefore subject to opposing views from other expert chemists.

- In criminal prosecutions involving analogue substances, an additional burden is on the government to establish, through experts in the field of pharmacology, that the substance is substantially similar in pharmacological activity to a schedule I controlled substance. Such expert testimony can be based on pharmacological models that are subject to opposing views from other expert pharmacologists.

- A single successful prosecution under the analogue provision of the CSA does not render the substance an analogue in subsequent prosecutions. Each prosecution must establish that the particular substance is an analogue under the statutory definition, as set out above.

Because of these considerations, the current availability of the "analogue" process to prevent diversion and abuse of synthetic cannabinoids and stimulants is not adequate to address the problem, necessitating more assertive action through direct scheduling of these substances.

The problems posed by synthetic cannabinoids raise international concerns as well. The synthetic cannabinoid issue has been addressed in regional and international fora, such as the Organization of American States Inter-American Drug Abuse Commission (CICAD) and the United Nations Commission on Narcotic Drugs (CND). At the 2010 meeting of the CND, a resolution was adopted on synthetic cannabinoids. The resolution highlighted the growing abuse and trafficking in these substances--which are not controlled under the international drug control treaties. The resolution called upon countries to, *inter alia*, pay particular attention to the emerging trends in the widespread distribution of products containing synthetic cannabinoids and to consider adopting national legislation to control the use of synthetic cannabinoids.

Controlling the distribution and abuse of newly synthesized analogues is challenging because, as DEA investigates, researches, and develops evidence pertinent to potential analogue substances in support of administrative control, illicit drug makers abandon these substances and create *new* analogue substances. Such a circular pursuit requires the expenditure of substantial scientific and investigative resources and continually leaves government scientists, regulators, and investigators one step behind the traffickers.

Conclusion

The increasing manufacture, distribution, and abuse of synthetic cannabinoids and synthetic stimulant compounds continue to pose a significant challenge. Although not specifically the focus of this hearing, there are other drugs of concern that also pose significant challenges, including the 2C family of drugs (dimethoxyphenethylamines) that are synthetic psychedelic/hallucinogens. Recently, a 19-year-old male in Minnesota died of cardiac arrest after allegedly ingesting 2C-E, one of the substances within this class. Nevertheless, the DEA is committed to using all of the civil, administrative, and criminal authorities at its disposal to fight this growing problem on all fronts.

In fact, DEA's New York Field Division Bath Salts Task Force (BSTF), in conjunction with the U.S. Marshalls, recently arrested a major distributor of synthetic stimulants that were masked as "bath salts," as well as employees of the retailers that sold the drugs. During the investigation, some of the retail employees discussed how to ingest the "bath salts," and one employee advised that the drugs would not appear in a urinalysis. Over the course of the investigation, the BSTF purchased more than a kilogram of "bath salts." The BSTF also seized approximately 40 kilograms of the drug, valued at approximately $2 million on the street.

As noted, these purportedly legitimate, "legal" products that are marketed as "bath salts," "plant food," and "incense," are clearly a pretense for unlawful activity. This is particularly evident when one compares the cost of these products to similar, legitimate bath salts, plant food, and incense that are purchased at retail outlets or via the internet. For example, a 1.5 pound (681 grams) container of legitimate plant food for sale by a local retailer sells between $5 and $12. On the other hand, a 250 milligram (0.250 grams) package containing mephedrone and marketed

as "plant food" sells for $25. The same is true for the bath salt products containing MDPV, which cost the consumer $100 for a 3.5 gram package, compared to legitimate bath salts, which sell for approximately $15 per pound (454 grams). These types of retail sales also beg the question: Why would a retailer need to "discreetly" package and ship legitimate products, unless the products are subversive?

The challenge to controlling these substances individually through administrative actions pursuant to the CSA is that the manufacturers of these substances circumvent the statutory criteria by manipulating the chemical structure of the compound. They can create substances that are pharmacologically similar to a schedule I or II controlled substance, that may or may not be chemically (structurally) similar to a schedule I or II controlled substance. The statute requires both pharmacological and chemical similarity in order to be an analogue. Even more alarming is that the structure of a chemical substance can be manipulated in *endless variations* while the pharmacological activity of the substance may increase or remain substantially unchanged. As a result, it is almost impossible outside of a controlled laboratory environment to determine the chemical composition, and the quantity, potency, and type of synthetic ingredients in these substances. It is equally challenging to determine what the potential harmful effects may be due to human consumption.

The Department of Justice is supportive of working with the Congress to protect the public health and safety and to ensure that the Attorney General has the necessary tools to administratively control emerging drug threats in a timely manner. Challenges will persist in controlling new emerging drugs of abuse, particularly in addressing analogues of identified schedule I substances; however, unilateral action by the Congress to place these dangerous substances directly into the schedule and affording the DEA additional time to complete administrative scheduling actions pursuant to the CSA's temporary scheduling provision is beneficial to the public's health and safety.

In closing, DEA will continue to work with its local, state and federal counterparts to protect the public against the dangers of these ever-changing synthetic cannabinoids, stimulant compounds and "designer" drugs.

Mr. PITTS. The chair recognizes the ranking member of the subcommittee, Mr. Pallone, for 5 minutes for opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Chairman Pitts, and thank you for holding today's hearing on these important health bills. I am encouraged that this hearing marks two bipartisan hearings in a row for this subcommittee and I support all three bills under consideration. And I thank our witnesses for joining us today.

Over the past 10 years, this Congress—rightfully so—has placed a high priority on biodefense. In 2004, we passed the Project Bioshield Act with tremendous bipartisan support. Democrats and Republicans worked together to establish a process that would help our Nation respond to bioterrorism threats and attacks. This goal was to encourage the development of new bioterrorism countermeasures.

Unfortunately, at first the program had limited success. This committee recognized its shortfalls and in 2006 worked to amend the program to help fix some of the problems. Specifically, it provided the Department of Health and Human Services with the additional authorities and resources necessary to rapidly develop drugs and vaccines to protect citizens from deliberate, accidental, and natural medical incidents involving biological pathogens, as well as chemical and radiological agents. It also helped to build the Nation's health infrastructure.

In addition, a single point of authority within HHS was created for the advanced research and development of medical countermeasures to quickly make important procurement decisions. The new position of assistant secretary for preparedness and response (ASPR) has since led the Federal Government's effort.

And today we consider H.R. 2405, the Pandemic and All-Hazards Preparedness Act of 2011, which attempts to further strengthen these programs. Specifically, it clarifies ASPR's role in these efforts and attempts to improve coordination and accountability.

We have worked very closely with the Republicans on this bill, and while there are still some minor outstanding issues, I am confident they can be settled. I know some of my colleagues also have issues they would like to see addressed—specifically, the ways in which we can enhance the Nation's ability to care for pediatric populations and the critically ill or injured in the event of a public health emergency, and I hope we can incorporate these important ideas in some way into the reauthorization bill.

Another bill we are considering today is the Synthetic Drug Control Act introduced by Representative Charles Dent, who joins us today. It is quite alarming to hear some of the stories you have shared, as well as other members, whose constituents have been able to utilize these products to the detriment of their mental and physical health, and in some cases, costing them their lives. It appears these imitation drugs are not illegal and I support strengthening the Federal Government's ability to keep these harmful and dangerous drugs off the street.

Lastly, we are discussing the Enhancing Disease Coordination Activities Act of 2011. This year, HHS is devoting over $900 million and 72,000 full-time employees to carrying out their mission "to help provide the building blocks that Americans need to live healthy, successful lives." As such, tackling the countless diseases we face is a major component of their work. For a large and complex organization with an even greater charge, the flexibility to form coordinating bodies to better organize research and public health activities is ideal.

The committee recently considered the Combating Autism Reauthorization Act of 2011, a bill that seeks to address autism spectrum disorders, a major public health problem in New Jersey and across the Nation. The original program created the interagency Autism Coordinating Committee, which, as we heard last week, has been largely successful. So I am encouraged that it can and should serve as a model for the creation of other disease-specific coordinating committees. The Enhancing Disease Coordination Activities Act of 2011 will give the secretary explicit authority to create committees that would not only streamline activities within the Department but also would stimulate partnerships between public and private organizations. Especially at a time when we are faced with such limited resources, coordinating activities across public and private sectors is critical.

So I look forward to working with you, Chairman Pitts, as we move on these critical pieces of legislation through this committee and onto the House Floor.

And I now would like to yield what time I have left to Ms. Baldwin.

OPENING STATEMENT OF HON. TAMMY BALDWIN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WISCONSIN

Ms. BALDWIN. Thank you. I want to thank you, Mr. Chairman and Ranking Member Pallone, for holding this important hearing on bipartisan measures that focus on our Nation's public health preparedness. I am not going to be able to offer my entire opening statement, so I ask unanimous consent to insert that for the record in its entirety.

Mr. PITTS. Without objection, so ordered.

Ms. BALDWIN. Thank you. But I did want to point out that earlier this year I introduced a bipartisan bill called the Critical Care Assessment and Improvement Act with my colleague from Minnesota Erik Paulsen. The bill seeks to identify gaps in the current critical care delivery model and bolster our capabilities to meet future demands. I am hopeful that we will be able to incorporate some of the relevant provisions of that act into the Pandemic and All-Hazards Preparedness Act as we look towards that reauthorization. And in that vein I look forward to working with my colleagues on both sides of the aisle to do so as this legislation moves forward.

Again, Mr. Chairman and Mr. Pallone, thank you so much for holding this bipartisan hearing. I yield back.

[The prepared statement of Ms. Baldwin follows:]

Opening Statement of The Honorable Tammy Baldwin
Subcommittee on Health
Legislative Hearing to Address Bioterrorism, Controlled Substances and Public Health Issues
July 20, 2011

Mr. Chairman and Ranking Member Pallone—thank you for holding this important bipartisan hearing to discuss our nation's public health preparedness.

While we have made great strides in improving our medical preparedness and response capabilities since Congress last authorized the Pandemic and All-Hazards Preparedness Act (PAHPA) in 2006, I believe many of us would agree that more can be done to enhance this legislation—particularly when it comes to ensuring that our medical response systems are prepared to care for the critically ill and injured in the aftermath of a public health emergency.

Whether we face a pandemic like H1N1 or a natural disaster like Hurricane Katrina, the critical care delivery system—which treats patients who illnesses present a significant danger to life, limb, or organ function—is an integral component of our nation's medical response.

Earlier this year, I introduced the bipartisan Critical Care Assessment and Improvement Act, H.R. 971, with my colleague from Minnesota, Erik Paulson. This bill seeks to identify gaps in the current critical care delivery model and bolster our capabilities to meet future demands.

And relevant to today's hearing, my bill would also improve federal disaster preparedness efforts to care for the critically ill and injured. Specifically, my bill seeks to address the shortage of critical care providers within our government medical response teams; ensure the effective and rapid deployment of medical professionals and medical supplies during a health emergency; and require planning for the evacuation of patients in the ICU during a national emergency.

I look forward to working with my colleagues on both side of the aisle to incorporate important provisions from my bill into the reauthorizing legislation, including the author of the bill, Mr. Rogers. Thank you for the time, Mr. Pallone, and I yield back.

Mr. PITTS. The chair thanks the gentlelady and now recognizes the chairman of the full committee, Mr. Upton, for 5 minutes.

OPENING STATEMENT OF HON. FRED UPTON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MICHIGAN

Mr. UPTON. Well, thank you, Mr. Chairman. And first I want to congratulate you and your wife on 50 years of bliss tomorrow. Formally, 50 years. Yes. I also want to thank you for holding today's hearing on bioterrorism, controlled substances, and public health legislation. I look forward to hearing from the witnesses on these important pieces of legislation, particularly our good friend, Mr. Dent of Pennsylvania.

Congressman Mike Rogers—the good Mike Rogers—recently introduced H.R. 2405, the Pandemic and All-Hazards Preparedness Act of 2011. This bill reauthorizes provisions of the Project Bioshield Act of '04 and Pandemic and All-Hazards Preparedness Act of '06, laws we passed in the wake of September 11 to build the Nation's health infrastructure and foster the development of medical countermeasures so the Nation could better respond to terrorist attack.

Congressman Dent introduced H.R. 1254, the Synthetic Drug Control Act, to prohibit the sale of synthetic drugs that imitate the effects of drugs like marijuana, cocaine, and other methamphetamines. These synthetic drugs are certainly just as harmful and dangerous as those drugs, but due to a loophole in the law they are not illegal. This bill solves that problem.

Finally, the Enhancing Disease Coordination Activities Act of 2011 would improve the coordination of research and other activities conducted or supported by HHS. Inspired by the success of the Interagency Autism Coordinating Committee, the bill would allow the HHS secretary to establish committees that coordinate research and other activities on specific diseases and conditions. The bill also would enable the HHS secretary to conduct a review of existing, disease-specific committees at HHS to determine the benefits of maintaining them. So as I said at last week's hearing, we must find a way to have our agencies work better together with a common strategic vision, and I think these bills do that.

I yield the balance of my time to Dr. Burgess.

[The prepared statement of Mr. Upton follows:]

Opening Statement of Energy and Commerce Committee
Chairman Fred Upton
Health Subcommittee Legislative Hearing to Address Bioterrorism,
Controlled Substances and Public Health Issues
Thursday, July 21, 2011

Thank you for holding today's legislative hearing on bioterrorism, controlled substances and public health legislation. I look forward to hearing from the witnesses on these important pieces of legislation, including from my good friend, Congressman Charlie Dent of Pennsylvania.

Congressman Mike Rogers recently introduced H.R. 2405, the Pandemic and All-Hazards Preparedness Act of 2011. This bill reauthorizes provisions of the Project Bioshield Act of 2004 and Pandemic and All-Hazards Preparedness Act of 2006, laws we passed in the wake of September 11 to build the nation's health infrastructure and foster the development of medical countermeasures so the nation could better respond to terrorist attacks.

Congressman Charlie Dent introduced H.R. 1254, the Synthetic Drug Control Act, to prohibit the sale of synthetic drugs that imitate the effects of drugs like marijuana, cocaine and methamphetamines. These synthetic drugs are just as harmful and dangerous as those drugs, but due

to a loophole in the law they are not illegal. Congressman Dent's bill would solve that problem.

Finally, the Enhancing Disease Coordination Activities Act of 2011 would improve the coordination of research and other activities conducted or supported by the Department of Health and Human Services. Inspired by the success of the Interagency Autism Coordinating Committee, the bill would allow the HHS Secretary to establish committees that coordinate research and other activities on specific diseases and conditions. The bill also would enable the HHS Secretary to conduct a review of existing, disease-specific committees at HHS to determine the benefits of maintaining them. As I said at last week's hearing, we must find a way to have our agencies work better together with a common strategic vision.

I thank the Chairman for holding this hearing, and I look forward to moving these bills through the committee soon.

OPENING STATEMENT OF HON. MICHAEL C. BURGESS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS

Mr. BURGESS. I thank the chairman for yielding.

I appreciate the fact that we are having a legislative hearing, and certainly I hope the committee will move expeditiously on all three.

Let me comment, because of the briefness of the time, on the Pandemic and All-Hazards Preparedness Act of 2011. This program was launched after the terrorist attacks in 2001 and set the framework for new medical countermeasures to respond to any attacks in the future. This program encourages and spurs market entry and competition and ingenuity into the private market. In the aftermath of an attack, we need to be assured that there is an adequate supply of countermeasures for the Strategic National Stockpile, and this program helps to accomplish that goal.

I certainly want to thank Congressman Rogers from Michigan for his hard work on this legislation, for his willingness to walk through the shallow of the valley of death, literally, and move this bill along. I also want to thank him for his inclusion of H.R. 570, the Dental Emergency Responders Act, which provides clear authority for dental professionals to participate in supporting medical and public health measures in response to disasters.

So I certainly look forward to working with the chairman and to Mr. Rogers on this bill and see to the passage of H.R. 2405 as well as the other bills before us. I will be happy to yield any time I have remaining to any other member on the Republican side who wishes to comment or an opening statement. If not, Mr. Chairman, I will yield back to you.

Mr. PITTS. The chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Waxman, for 5 minutes.

OPENING STATEMENT OF HON. HENRY A. WAXMAN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF CALIFORNIA

Mr. WAXMAN. 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 Control Drug 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 bipartisan basis to move forward with these bills. Although our work is not quite complete, I feel confident that we will work out the substance of these bills for further discussion.

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 bipartisan 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 programs and activities first established in the 2004 Project Bioshield Act. These programs are critically important to help ensure that our Nation is well prepared to successfully manage the effects of natural disasters, infectious disease out-

breaks, and acts of bioterrorism. In reauthorizing these programs and activities, there are a number of issues we are exploring and would like to hear about during today's hearing. In my view, surge capacity, the ability of our healthcare 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. I have concerns about the new Regulatory Management Plan that is proposed in 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; on the other, 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 would want to look at include the unique needs of children in disasters, an issue that Congresswoman Eshoo has been championing, and the administration's strategic investor proposal. And like the other issues I have just mentioned, I am confident that all these matters will be resolved in a bipartisan negotiation.

Let me now speak briefly about the two other bills in our hearing today. The Synthetic Drug Control Act adds specified synthetic versions of drugs of abuse to Schedule 1. These designer drugs can be very unsafe causing convulsions, anxiety attacks, and dangerously elevated heart rates, among other conditions. This bill 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 HHS to establish disease-specific interagency coordination committees and lays out the parameters for these committees. This will be modeled on the highly successful Interagency Autism Coordinating Committee, which we learned about in 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 under consideration. I look forward to the hearing today and to working out our issues. And I have less than a minute if anybody on our side would like a minute? If not, I yield back the time.

[The prepared statement of Mr. Waxman follows:]

Statement of Rep. Henry A. Waxman
Ranking Member, Committee on Energy and Commerce
Subcommittee on Health Legislative Hearing
To Address Bioterrorism, Controlled Substances, and Public Health Issues
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.

Mr. PITTS. The chair thanks the gentleman. That concludes the members' opening statements. I would like to thank all the witnesses on both panels for agreeing to appear before the committee today. We will go to Panel 1. Congressman Charlie Dent represents Pennsylvania's 15th Congressional District. He is the author of H.R. 1254, the Synthetic Drug Control Act. Representative Dent, you may begin your prepared testimony.

STATEMENT OF HON. CHARLES W. DENT

Mr. DENT. First, I want to thank the committee and the subcommittee. Thank you, Chairman Pitts, Ranking Member Pallone, Chairman Upton, Ranking Member Waxman, for this opportunity to talk to you today about this very important issue.

Now, it was a little under a year ago at this time that the issue of synthetic drugs or designer drugs was first brought to my attention by a constituent named Alana Marshall, whose son had been abusing legal substitutes for marijuana. And in fact, just a couple of months ago I went to the Children's Hospital of Philadelphia where they had seen very little of this issues in synthetic drugs, bath salts, et cetera, and now they are seeing a case every single day. That is how prevalent this has become in such a very short period of time.

These synthetic cannabinoids affect the brain in a manner similar to marijuana, but they can actually be much more harmful. Synthetic marijuana or cannabinoids are just one category of designer drugs. Even more potent substances have properties similar to cocaine, methamphetamine, LSD, and other hard street drugs. These substances are marketed as innocent products like bath salts, plant food, incense, and they are sold under brand names familiar to their users such as K2 Spice, Vanilla Sky, Ivory Wave, but these are total misnomers. They are designed to facilitate their legal sale. These drugs have really no legitimate purpose. And these bath salts, by the way, are things you would never put in your tub. Some people are confused by that that actually think they are what people put in their tub. That is not the case at all.

Over the past year, there has been a sharp increase in the number of reports detailing horrific stories of individuals high on synthetic drugs. A man in Scranton, Pennsylvania, stabbed a priest and another jumped out a three-story window. Both were high on bath salts. Several deaths from West Virginia to Florida have been attributed to overdoses of synthetic drugs. Senator Grassley of Iowa has introduced a bill with provisions similar to the one in this one, H.R. 1254, named after one of his young constituents who tragically took his own life while high on synthetic marijuana. A man in my district was arrested this past May for firing a gun out of a window in a university neighborhood. The police charges indicate that the individual injected himself with bath salts and he later told the police he thought there were people on the roof watching him.

Finally, you know, I was approached by another distraught mother from my district whose son was hospitalized for over 2 weeks after suffering liver failure and other complications after injecting himself with bath salts. These substances pose a substantial risk both to the physical health of the user as well as to the safety

of those around them when these drugs contribute to dangerous psychotic behavior, suicide, and public endangerment. The fact that these drugs are legal in many States contributes to the misconception that they are safe and the use of these easily recognizable brand names and logos on the packaging promotes the concept of a consistent product. Significant variation of potency from one unit to the next has led recurrent users to inadvertently overdose.

You know, and one of the major difficulties in combating these designer drugs is the ability of the producers to skirt the law with different chemical variations. You know, by modifying the formula in some minor way, producers can generate a new compound which circumvents legal prohibitions but has similar narcotic events. And that is why we have H.R. 1254, this Synthetic Drug Control Act of 2011, and we drafted this in consultation with other law enforcement officials, particularly the DEA, and this legislation has three principle components: prohibition of broad structural classes of synthetic marijuana or the cannabinoids; prohibition of other designer drugs such as bath salts—that is methylenedioxypyrovalerone (MDPV) and others—and there is an expansion of the DEA's existing authority temporary ban of substance from 1–1/2 to 3 years. And that is very, very significant, that additional time.

Under current law, if the DEA and the Department of HHS can prove that a substance is dangerous, that is important, but they also are lacking in legitimate value while it is temporarily banned. So the prohibition becomes extremely important. I can't emphasize this enough, this authority for DEA. You know, I should mention, too, that there are a lot of States out there right now to pass laws. Pennsylvania, my State, just passed a law last month that had banned many forms of these synthetic drugs, but Federal action is certainly necessary to prevent these drugs from being obtained by simply crossing State lines or increasingly ordering them over the internet.

And I think every State representative on this panel—except Ohio, but Representative Latta will fix that—has enacted laws restricting some synthetic drugs in one form or another. So all your States have already taken some action, and that I think you should be commended. So Texas, Michigan, Kentucky, New Jersey, Illinois, New York, North Carolina, Georgia, Wisconsin, Washington State, you know, they are all really taking some action—Louisiana, Arkansas, Utah. So State-by-State differences in which individual substances are controlled and how strongly makes for a confusing legal patchwork, and this bill will provide for a national ban on these dangerous drugs.

You know, as we speak, the Senate Judiciary Committee right now is marking up a companion synthetic drug legislation, and so I really would encourage this subcommittee, then the full committee to take up H.R. 1254 as soon as possible and report it. I do really appreciate this. This is a very serious public health issue and it is just getting worse by the day. These drugs come into this country usually by Europe, start in Asia, head to Europe, so we usually have a good idea of what is coming here. The DEA is on top of this but they really do need this additional authority. And again, I appreciate your consideration.

Thank you again, Chairman Pitts, Ranking Member Pallone.

[The prepared statement of Mr. Dent follows:]

Testimony of Congressman Charles W. Dent (PA-15) before the Subcommittee on Health of the Committee on Energy and Commerce.
Hearing on Bioterrorism, Controlled Substances, and Public Health Issues.
July 21, 2011
Summary

- The issue of synthetic or designer drugs was first brought to my attention by a constituent whose son had been abusing legal substitutes for marijuana.

- These "synthetic cannabinoids" affect the brain in a manner similar to marijuana but can actually be even more harmful.

- Synthetic marijuana (synthetic cannabinoids) are just one category of designer drugs. Even more potent substances have properties similar to cocaine, methamphetamine, LSD, and other hard street drugs.

- These substances are marketed as innocent products like bath salts, plant food, or incense, and they are sold under brand names familiar to their users, such as K2, Spice, Vanilla Sky, or Ivory Wave, but these are total misnomers designed to facilitate their legal sale. These drugs have no legitimate purpose.

- Over the past year, there has been a sharp increase in the number of news reports detailing horrific stories of individuals high on synthetic drugs.

- The fact that these drugs are legal in many states contributes to the misconception that they are safe, and the use of easily recognizable brand names and logos on the packaging promotes the concept of a consistent product.
    - Significant variation of potency from one unit to the next has led recurrent users to inadvertently overdose.

- One of the major difficulties in combating these designer drugs is the ability of the producers to skirt the law with different chemical variations.
    - By modifying the formula in some minor way, producers can generate a new compound which circumvents legal prohibitions but has similar narcotic effects.

- H.R. 1254, the Synthetic Drug Control Act of 2011, drafted in consultation with federal law enforcement, has three components:
    - Prohibition of broad structural classes of synthetic marijuana (synthetic cannabinoids);
    - Prohibition of other designer drugs such as bath salts (Mephedrone, MDPV, etc); and
    - Expansion of the Drug Enforcement Agency's (DEA) existing authority to temporarily ban a new substance from 1.5 years to 3 years.
        - Under current law, if the DEA and Department of Health and Human Services (HHS) can prove that a substance is a) dangerous and b) lacking in legitimate value while it is temporarily banned, the prohibition becomes permanent.

- A growing number of states, including Pennsylvania, have enacted bans on many forms of synthetic drugs, but federal action is necessary to prevent these drugs from being obtained by crossing state lines or ordering them over the Internet.

Testimony of Congressman Charles W. Dent (PA-15) before the Subcommittee on Health of the Committee on Energy and Commerce.

Hearing on Bioterrorism, Controlled Substances, and Public Health Issues.

July 21, 2011

Chairman Pitts, Ranking Member Pallone, members of the subcommittee, thank you for allowing me to testify today on the very important matter of synthetic drugs. I appreciate the committee's interest in my bill, H.R. 1254, the Synthetic Drug Control Act of 2011.

The issue of synthetic or designer drugs was first brought to my attention less than a year ago by a constituent whose son had been abusing drugs that went by names like K2 or Spice and acted as legal substitutes for marijuana. These drugs are classified as "synthetic cannabinoids," artificial drugs which affect the brain in a manner similar to marijuana. However, these drugs can in fact be even more harmful than the substances they simulate, increasing heart rate and blood pressure and producing dangerous psychotic side effects that have led to suicides and accidental deaths.

Synthetic cannabinoids are just one category of designer drugs. Even more potent substances, such as mephedrone and methylenedioxypyrovalerone (MDPV), often sold as "bath salts" or "plant food," have properties similar to cocaine, methamphetamine, lysergic acid diethylamide (LSD), and other hard street drugs. These substances are marketed with innocent sounding names, but these labels are total misnomers designed to facilitate their legal sale. These drugs have no legitimate medicinal or industrial purpose, just as actual bath salts have no hallucinogenic properties.

Shortly after I spoke with my constituent about her son's experience with synthetic marijuana last year, the number of news reports detailing horrific stories of individuals high on synthetic drugs virtually exploded. A man in Scranton, Pennsylvania stabbed a priest, and

another jumped out of a 3-story window, both high on bath salts. Several deaths from West Virginia to Florida have been attributed to overdoses of synthetic drugs. Senator Chuck Grassley of Iowa has introduced a bill, with provisions similar to H.R. 1254, named after one of his young constituents who tragically took his own life while high on synthetic cannabinoids. A man in my district was arrested this past May for firing a gun out of his window in a university neighborhood. Police charges indicate he had injected himself with bath salts, and he later told police he had thought there were people on the roof watching him. Finally, I was approached by another distraught mother from my district whose son was hospitalized for over two weeks after suffering liver failure and other complications after injecting himself with bath salts. These substances pose a substantial risk, both to the physical health of the user, as well as to the safety of the user and those around him when these drugs contribute to dangerous psychotic behavior, suicide, and public endangerment.

The fact that these synthetic drugs are legal in many states contributes to the misconception that they are safe. Additionally, the use of easily recognizable brand names and logos on the packaging promotes the concept of a consistent product. Americans frequently buy their favorite brand-name consumer products, knowing that the familiar label bears the promise of the same user experience time and again. However, the producers of synthetic drugs do not exercise the kind of quality control that manufacturers of legitimate products employ. One dose of a given "bath salt" drug might be significantly more or less potent than the next, even though the packaging is identical. This has led to recurrent users inadvertently overdosing after receiving a much stronger dosage than they were expecting.

In order to ensure that these dangerous products are removed from retail outlets and their production and sale banned in the United States, I introduced H.R. 1254, the Synthetic Drug

Control Act of 2011. This legislation, which was drafted in close consultation with federal law enforcement, has three principle components: prohibition of synthetic cannabinoids; prohibition of other designer drugs such as bath salts; and enhancement of the Drug Enforcement Agency's (DEA) existing authority to take dangerous new substances off the street.

One of the major difficulties in combating these designer drugs is the ability of the producers to use different variations of a chemical to skirt the law. By modifying the formula in some minor way, producers can generate a new compound which circumvents legal prohibitions but has similar narcotic effects. This legislation addresses broad structural classes of synthetic cannabinoids in an effort to form as comprehensive a ban as possible. It also targets some of the most popular designer drugs listed on the DEA's list of "drugs and chemicals of concern."

Finally, H.R. 1254 enhances the DEA's ability to impose a temporary ban on new drugs. Under current law, the Administrator of the DEA may place any compound into the appropriate schedule of the Controlled Substances Act for up to 18 months. In order to make the ban permanent, DEA and the Department of Health and Human Services (HHS) must prove that the drug is both harmful and lacking in legitimate medicinal or industrial value. If this cannot be demonstrated in time, the ban expires and the substance is removed from the temporary schedule, thus complicating any pending trials involving the drugs in question. For this reason, the DEA has historically been hesitant to use its emergency scheduling authority. H.R. 1254 would simply double the amount of time DEA and HHS have to make their case against a drug, giving them a maximum of three years to make their findings. Because synthetic drugs are usually produced in Southeast Asia and make their initial appearance in Europe before arriving in the United States, American law enforcement is usually aware of which designer drugs are about to hit domestic

markets before they arrive. This extended timeframe will better allow DEA to use its temporary scheduling authority to block new drugs from ever being sold in the United States commercially.

I am proud to say that Pennsylvania recently joined the growing list of states that have enacted bans on many forms of synthetic drugs. This is a good start, but these drugs can still be easily obtained by crossing state lines or, increasingly, ordering them over the Internet. Synthetic drugs are a national problem, as the subcommittee has shown by including them in this discussion on bioterrorism, controlled substances, and public health. A national solution is required in order to prevent further injury and loss of life. I encourage the subcommittee to take up this legislation and report it to the full committee as soon as possible.

Mr. PITTS. The chair thanks the gentleman for his testimony and thanks him for his leadership on the issue. We look forward to working with you on the legislation. And you may be excused at this time.

And we will call Panel 2 to the witness table. Our second panel consists of two witnesses. Dr. Nicole Lurie is the Assistant Secretary for Preparedness and Response of the Department of Health and Human Services; and our second witness, Dr. Howard Koh, is the Assistant Secretary for Health of the Department of Health and Human Services. Thank you for coming this morning. Dr. Lurie, you may begin your testimony.

STATEMENTS OF NICOLE LURIE, ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE, DEPARTMENT OF HEALTH AND HUMAN SERVICES; AND HOWARD K. KOH, ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES

STATEMENT OF NICOLE LURIE

Ms. LURIE. Good morning, Chairman Pitts and Ranking Member Pallone and distinguished members of the subcommittee.

In 2006, the Congress understood the critical need to strengthen our public health and medical preparedness activities enacting the Pandemic and All-Hazards Preparedness Act, or PAHPA as it is affectionately known. Recent events remind us of the significant challenges that we continue to face from ever-present and always-evolving terrorist threats to unprecedented natural emergencies and how quickly and unpredictably the call comes to respond and support the American people.

Within HHS, PAHPA established the Assistant Secretary for Preparedness and Response as the lead in coordinating Federal health response to disasters. In 2009, I had the privilege of being asked to lead ASPR, a still-young organization with a vital mission to lead the country in preparing for, responding to, and recovering from the adverse health effects of emergencies and disasters. And since that time, ASPR has risen to the challenge in the face of unprecedented events. As we responded, capturing lessons learned along the way, we kept careful note of where legislative changes would enhance our response to efforts in the future. I would like to take a few minutes now to walk you through some of them.

The H1N1 pandemic tested our ability to adapt and respond to a novel influenza strain and required all parts of the healthcare, public health, and response systems to work together and to innovate. One of the most important lessons learned came from seeing that at every step along the way we needed to be able to rapidly get resources to where they needed to go. Consequently, we are interested in authority to temporarily allow States to reassign certain HHS-funded personnel to critical areas of need during a public health emergency.

Both H1N1 and the Japanese nuclear crisis demonstrated the importance of getting countermeasures to those who need them as quickly as possible. Often the speed with which countermeasures are administered is the difference between life and death, and so we would like the authority to issue Emergency Use Authoriza-

tions, or EUAs, prior to an event. This would minimize delays in making critical countermeasures available when needed.

In addition, clarifying FDA's authorities to extend the timeline for safe and effective products through the Shelf-Life Extension Program will facilitate using these products when needed and will make investments go further helping save taxpayer dollars on replacement costs and stockpiling practices.

We have been successful in developing promising safe and effective medical countermeasures and the Bioshield Program has indeed been a critical tool. As demonstrated by the language included in H.R. 2405, your continued support to this program is a clear commitment to the Nation's preparedness.

I would want to highlight that we embrace the whole-community approach articulated by FEMA, particularly in planning for all at-risk individuals. In the countermeasure arena, we have become very aggressive about pursuing medical countermeasure products for children.

The secretary's Medical Countermeasure Enterprise Review recognized that to achieve a modern and flexible enterprise that can quickly develop and produce safe and effective products, we must strengthen each of the enterprise's major components. One recommendation, the Strategic Investor Initiative, will support and accelerate the activities of companies that have innovative products while reducing the probability that the companies will fail because of their inability to manage their business risks.

H.R. 2405 reauthorizes two critical elements of our preparedness enterprise: the Hospital Preparedness and the Public Health Emergency Preparedness Cooperative Agreement Programs. When I visited Missouri after Joplin and witnessed the ongoing response and recover efforts from the tornadoes in May and similarly with the tornadoes in the South before that, it was again clear to me why we need both medical care and public health capabilities.

A central priority for me is the alignment of these two programs, as well as similar grant programs throughout the government to efficiently use limited resources, eliminate duplicative or conflicting programmatic guidance, and reduce the administrative burden for grantees. We anticipate that the PHEP and HPP programs will be aligned in time for the 2012 Grant Guidance. Reauthorizing other programs, including BARDA, the Medical Reserve Corps, the National Disaster Medical System, and the Emergency System for the Advanced Registration of Volunteer Healthcare Personnel will ensure investments continue to support and foster resilient communities.

As identified in the original PAHPA legislation, HHS and specifically ASPR has the lead for coordinating the Federal health response efforts during public health emergencies. In my time as serving as assistant secretary, ASPR has strengthened its leadership role within HHS as well as nationally. Along with our Federal partners, we have improved our coordination of preparedness and response operations, and we have also gotten better at how we coordinate. Our continued progress and improvements along with clarifying and strengthening authorities that I have talked about today will ensure ASPR and HHS have the tools necessary to protect the Nation against public health threats.

We applaud Congress' leadership and vision for enacting PAHPA as the foundation for effective response and recovery to public health emergencies, and I look forward to working with you as PAHPA is reauthorized in this congressional session. Thank you.

[The prepared statement of Ms. Lurie follows:]

Testimony
Subcommittee on Health
Committee on Energy and Commerce
United States House of Representatives

Bioterrorism, Controlled Substances and Public Health Issues

Statement of
Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services

For Release on Delivery
Expected at 10:00am
Thursday, July 21, 2011

Good morning Chairman Pitts, Ranking Member Pallone, and distinguished Members of the Subcommittee. I am pleased to be here today on behalf of the U.S Department of Health and Human Services (HHS) to testify on reauthorization of the Pandemic and All Hazards Preparedness Act (PAHPA; the Act). My name is Nicole Lurie and I serve as the HHS Assistant Secretary for Preparedness and Response. Today, I will discuss how critically important PAHPA is to our public health preparedness and the progress we have made since its enactment in 2006.

First, I would like to recognize the Congress, and especially the Energy and Commerce Committee, for its strong leadership in advancing the public health and preparedness of our Nation. PAHPA has supported our efforts to foster stronger, more resilient communities that are able to respond to, and recover from, public health emergencies. PAHPA established the foundation for a comprehensive preparedness for and response to emergencies. HHS has since built on these authorities to ensure the nation has the tools necessary to save lives.

The Pandemic and All-Hazards Preparedness Act Established a Formalized Approach to Public Health Preparedness

PAHPA strengthened our country's foundation for public health preparedness by helping us address a variety of problems our nation encountered when preparing for, and responding to, disasters. As we have seen from recent emergencies

and disasters – including tornados, floods, an influenza pandemic, earthquakes, damage to a nuclear facility and a large oil spill – there is always an impact to the public's health and medical care.

The Pandemic and All-Hazards Preparedness Act has been instrumental in supporting State and local preparedness and response efforts. Since the passage of the Act, HHS has implemented a number of initiatives to strengthen its preparedness and response activities.

The Pandemic and All-Hazards Preparedness Act designated the HHS Secretary as the lead federal official for public health and medical response to emergencies and incidents, and established my office, the Office of the Assistant Secretary for Preparedness and Response (ASPR). Under the Act, ASPR serves as the principal advisor to the Secretary on all matters related to federal public health and medical preparedness and response and plays a pivotal role in coordinating emergency response efforts across the various HHS agencies and among our federal interagency partners.

Guided by the authorities in PAHPA, HHS established organizational priorities and enhanced its operations and response capabilities. Moreover, to carry out PAHPA authorities, ASPR's mission was defined as leading the country in preparing for, responding to, and recovering from health effects of emergencies and disasters by supporting each community's abilities to withstand adversity, to

strengthen our health and response systems, and to enhance national health security. The future of national public health and medical preparedness and response is a "whole community" approach. We work to build practices nationally that strengthen preparedness efforts implemented by local institutions including state and local government and private sector partners. We strive to create a fundamental body of knowledge for preparedness, response, and recovery and to encourage innovative efforts to build the nation's capacity to stabilize and recover from an event. We are also working to ensure that our public and private sector partners are promoting a culture of budget preparedness to quickly and efficiently get resources where they are needed for the earliest, critical response to a disaster, and then for the longer recovery period.

The National Health Security Strategy Established a Common Strategic Framework to Align National Preparedness Efforts

Since the enactment of PAHPA in 2006, HHS has had many significant accomplishments preparing for, and responding to, public health incidents. To help better align efforts internally; support and promote coordination efforts with federal, state, local, and private sector partners; and be efficient stewards of federal dollars, we released the National Health Security Strategy (NHSS) in December 2009 – a blueprint for preparedness and response. PAHPA required the completion of a NHSS as a first step in ensuring we have a fully integrated and coordinated strategy to address how various sectors of our medical and

public health systems will work together to respond to emergencies and save lives.

The principle at the heart of the strategy is to strengthen and promote resilient communities and health systems that coordinate and work together before, during, and after disasters. National health security is a shared responsibility – from individuals and families, to private industry, to every level of government. The NHSS also promotes building more resilient communities by including at-risk populations in planning all phases of our response. Supporting this strategy, HHS has taken steps to ensure that at-risk individuals – children, pregnant women, senior citizens, individuals with disabilities, and others who have access and functional needs – are included in all planning scenarios, guidance documents, and plans, and will be effectively treated in the event of a public health emergency. HHS also continues to focus on behavioral health as an integral part of building community resilience and enhancing response and recovery.

As required by PAHPA, the NHSS must be delivered to Congress every four years beginning in 2009. This schedule poses a challenge because it is not aligned with the schedule for agency strategic plans as established by the Government Performance and Results Act Modernization Act of 2010 ("GPRA Modernization Act of 2010," P.L. 111-352).,The next iteration of the agency strategic plan is due in 2014, while the NHSS plan is due in 2013.

Recognizing that we have learned a great deal about strategic planning processes in the past four years, we are interested in enhancing operational and long-term planning efforts while also streamlining requirements. In support of the principles of the NHSS, state and local jurisdictions have operational plans that describe operations during incidents caused by pandemic influenza or incidents from another hazard. The influenza plans – required by PAHPA – include a framework that guides communications and logistics, and coordinates general response efforts during pandemic influenza incidents. These pandemic plans have become part of a broader, all-hazards planning framework, with a required set of capabilities necessary to deal with many potential hazards, from a pandemic to an anthrax attack or a dirty bomb. At the time PAHPA was enacted, these plans were a relatively new concept – the original provision was to ensure that plans enhanced preparedness efforts for influenza. The focus on an all-hazards approach toward response capabilities enabled the development of stronger and more flexible plans. In addition, our experience has shown that a biennial reporting process generally is efficient and provides us an opportunity to integrate lessons from state and local plans from the prior year.

The Medical Countermeasure Review Established the Strategic and Operational Plan for HHS Countermeasure Preparedness

To ensure the nation has adequate countermeasures available to respond quickly and efficiently following a chemical, biological, radiological, nuclear (CBRN), or other public health emergency, HHS released the Public Health

Emergency Medical Countermeasures Enterprise Review (MCM Review) in August 2010. This review articulated a vision for a nimble, flexible infrastructure to produce MCMs rapidly in the face of any attack or threat including a novel, previously unrecognized naturally occurring emerging infectious disease. The MCM Review took a 'systems approach' to MCM development. The Review identified "processes, policies, and activities required to conceptualize a product derived from a national requirement and take it through research, early and advanced development, manufacturing, regulatory approval, procurement, and stockpiling." This ground-breaking review looked across the entire spectrum of product development, from early discovery through regulatory approval, and identified the chokepoints where product development was stalling or failing. Chokepoints create technical, business, and regulatory risks for small innovator companies that may lead to the failure of a product due to a funding shortage between the early stages of product development and the procurement of medical countermeasures. To address these chokepoints, the MCM Review recommended a set of interconnected strategies to further MCM development:

- The establishment of a Concept Acceleration Program at the National Institutes of Health (NIH) National Institute of Allergy and Infectious Diseases to work with partner agencies, academic researcher, biotechnology companies, and large pharmaceutical companies to identify promising scientific discoveries and expedite their transformation into practical, usable products;

- The establishment of a private, not-for-profit corporation (Strategic Investor) that would rely on a variety of "venture-enabled" approaches to spur innovation and create a viable biodefense business sector by supporting companies that possess strategic technologies applicable to both commercial and government needs, but which might otherwise lack the necessary financial capital or business acumen to develop a commercially-viable, approved product;

- The establishment of U.S.-based Centers for Innovation in Advanced Development and Manufacturing; and

- An increased investment in regulatory sciences and review capabilities at the Food and Drug Administration (FDA) focused on medical countermeasures (MCMs) for chemical, biological, radiological, nuclear (CBRN) and emerging infectious disease threats, such as pandemic influenza.

The Concept Acceleration Program (CAP) will leverage existing intramural and extramural research programs as well as applied and translational resources throughout the NIH, Centers for Disease Control and Prevention (CDC), FDA, and Department of Defense (DoD) to expedite the translation of promising concepts into candidate MCMs. We are committed to applying $50M towards

CAP activities in FY11. Evaluations are in progress to identify CAP product candidates.

The Strategic Investor would spur innovation and provide the kinds of business and financial services and support that venture capital firms typically provide, while mitigating the risk that biotechnology firms face. The Strategic Investor initiative would promote the transition of MCM development and procurement from a "one bug, one drug" approach to an enterprise capable of responding to any threat at any time. It is important to note that the Strategic Investor initiative is intended to work in concert with the BioShield program, not replace it.

In March, we published a request for proposals for the Centers for Innovation in Advanced Development and Manufacturing, which we will create to reduce risk, increase domestic manufacturing and surge capacity for MCM, and reduce total life-cycle costs through flexible manufacturing. These U.S.-based Centers are expected primarily to provide, on a routine basis, core services to commercial partners who collaborate with HHS's Biomedical Advanced Research and Development Authority (BARDA). These services include advanced development and manufacturing capabilities and other technical services needed by the developers of medical countermeasures for MCMs to address national preparedness and response priorities and needs. In the event of a pandemic, the Centers will also be available to manufacture influenza vaccine and other

biologics, as well as provide training opportunities for the pharmaceutical workforce.

Finally, advancing regulatory science and review capabilities at the FDA will strengthen and clarify the MCM regulatory process, which will help to accelerate MCM development and availability. Regulatory uncertainty is a major barrier to engaging MCM developers in the MCM Enterprise. FDA is addressing these challenges through its Medical Countermeasures Initiative (MCMi), which will promote the development of medical countermeasures by enhancing FDA's regulatory processes and fostering the establishment of clear regulatory pathways for medical countermeasures. The MCMi will also facilitate the timely access to medical countermeasures by establishing effective regulatory policies and mechanisms. The MCMi is designed to address key challenges in three areas: (1) enhancing the regulatory review process for the highest priority medical countermeasures and related technologies; (2) advancing regulatory science for medical countermeasure development; and (3) modernizing the regulatory and legal framework.

Flexibility can help address and help to solve unique scientific challenges posed by some MCMs. FDA benefits from flexibility to address the unique scientific challenges posed by MCM development, distribution, and use. FDA needs adequate time to receive and carefully consider input from stakeholders, including MCM sponsors, or conflict with the Medical Device User Fee and

Modernization Act/Prescription Drug User Fee Act obligations. We would be happy to discuss this further with you and your colleagues on the Committee.

HHS also prioritizes an enhanced approval and authorization process for stockpiled medical countermeasures to ensure products are dispensed as soon as possible following an event. One specific challenge is that the legal implications for using medical countermeasures whose expiration date has been extended under FDA's Shelf Life Extension Program (SLEP) is unclear. Another challenge is the inflexibility of issuing Emergency Use Authorization (EUA) of medical countermeasures prior to a CBRN event. Issuance of EUAs prior to an event could facilitate the prepositioning of products, minimizing delay in dispensing needed products if an event does occur. In addition, there is a lack of clarity that certain actions taken in preparing for or during an emergency will not violate the Federal Food, Drug, and Cosmetic Act (FDCA), including greater flexibility to mass dispense MCMs with instructions for emergency use. Clarifications on these issues could help ensure adequate medical countermeasures are available for dispensing as soon as possible, following the start of a public health incident.

PAHPA Helped Spur Development and Procurement of Medical Countermeasures

The SRF is a secure funding source for the procurement of critical medical countermeasures, such as vaccines, therapeutics, and diagnostics that are close

to, or have achieved, licensure. The SRF, as industry partners and other non-governmental stakeholders have continually asserted, is a market guarantee for medical countermeasure development and clearly demonstrates the U.S. Government's commitment to the procurement of security countermeasures. Finally, the Project BioShield Act provides the Secretary with the authority to authorize the emergency use of unapproved products or the unapproved use of approved products, if certain standards are met.

Since its inception, we have drawn steadily on the use of Special Reserve Funds and have developed and procured:

- Anthrax therapeutics and vaccines;
- Heptavalent botulinum antitoxin;
- Smallpox vaccine for immunocompromised persons;
- Smallpox antiviral drug; and
- A number of MCM products intended for use after radiological or nuclear events.

Using its Advanced Research and Development (ARD) authority, HHS, through BARDA, bridges the "valley of death" – funding a gap that exists between the early stages of product development and the procurement of medical countermeasures under Project BioShield. Current priority investment areas include anthrax vaccines and treatments, broad-spectrum antimicrobial drugs, and treatments and diagnostics for illnesses associated with exposure to

radiation. In FY 2012, the President's Budget requests $765M from Project BioShield balances to support these priorities.

Our ARD activities, combined with changes we have made since the MCM review, are beginning to bear fruit. We have seen a continued growth in interest in companies partnering with BARDA, and now have over 70 products in some stage of development. We have also implemented changes to our own business processes, and have succeeded in reducing our average contracting time. From 2009 to 2010, we reduced the average contracting time from 6.46 to 4.7 months. The SRF has succeeded—and remains important—in attracting biotechnology firms to develop needed medical countermeasures, but these firms have required substantial additional support for advanced research and development.

While the imminent threat of H1N1 influenza has subsided, avian influenza viruses continue to circulate, and critical work continues to prepare for the next influenza pandemic. One of the functions of the Centers for Innovation in Advanced Development and Manufacturing mentioned earlier, in addition to providing development and manufacturing of medical countermeasures to CBRN threats, will be to expand domestic pandemic influenza vaccine manufacturing surge capacity. HHS continues to develop flu antiviral drugs and vaccines and a more robust domestic vaccine manufacturing capability. We are focused on ensuring the nation has access to a safe and effective vaccine as soon as possible following the start of an influenza pandemic. We continue to implement

strategies for producing influenza vaccine more rapidly during an influenza pandemic, including the development and implementation of more rapid testing methods for vaccine release and the establishment of domestic recombinant and cell-based vaccine manufacturing capabilities. Supporting this effort, shortening the time frame for vaccine availability with new and faster product testing and next generation influenza vaccines made in the U.S. will achieve better products faster. I am pleased to inform you that we are already making great progress in these efforts.

HHS Has Significant Accomplishments since the Enactment of PAHPA

We have accomplished much since the passage of PAHPA and were able to respond to a number of public health emergencies including:

- The first pandemic in 40 years;
- An earthquake in the western hemisphere's poorest country;
- An oil spill of national significance in the Gulf of Mexico;
- The 2011 Japan earthquake, tsunami, and associated radiological contamination event; and
- Other domestic events including food-borne outbreaks, E. coli, botulism, salmonella, hurricanes, floods, tornadoes, Avian influenza, West Nile virus, and ricin.

In addition, as I mentioned previously in my testimony, we were also successful in procuring and stockpiling medical countermeasures to protect against CBRN

threats, as well as against pandemic influenza and other emerging infectious diseases. All of the accomplishments were supported through the close collaboration of many at HHS including CDC, NIH, FDA, ASPR as well as the Centers for Medicare and Medicaid Services (CMS), the Substance Abuse and Mental Health Services Administration (SAMHSA), the Office of the Assistant Secretary for Health (OASH), and the Indian Health Service (IHS), just to name a few.

Since I was sworn in as the Assistant Secretary for Preparedness and Response, one thing has been clear - the investments we've made in the last decade have had a positive effect on our ability to respond to health effects of emergencies. In each response, HHS provided support to state, local, or international partners and in return learned valuable lessons to guide future response operations. We are working internally to strengthen and incorporate the lessons learned from these and other recent responses to ensure future response efforts are enhanced.

The earthquake in Japan and subsequent nuclear reactor crisis is an example of a catastrophic scenario that would present formidable public health and healthcare challenges to the U.S. should such an event occur here. We already knew the importance of deploying medical countermeasures as quickly as possible following an incident. However, as a result of this crisis, we are reexamining our policies, plans, and procedures to ensure that we can use and

deploy countermeasures as soon as possible following the start of a public health incident to help reduce morbidity and mortality.

Beyond medical countermeasures, many lessons learned during our 2009 H1N1 pandemic response will strengthen HHS's ability to respond to other emergency events. The 2009 H1N1 experience stressed the interdependence of the public health, pre- and post-hospital care, primary care, hospital care systems and community, education, and business organizations. It also confirmed the need for a "whole community" approach in planning and responding to a disaster, and confirmed that, going forward, we must address the entire healthcare community in our preparedness activities. Specifically during the 2009 H1N1 response, some state and local jurisdictions faced significant staff shortages as they dispensed vaccine to the general population. HHS is examining ways such staffing shortages could be limited and response could be enhanced.

Finally, after our response to the Haiti earthquake, we have taken actions to provide needed services quickly and efficiently following disasters and ensure we have access to information that supports surveillance of the spread of illness. I am pleased to inform you that we have been working to strengthen the National Disaster Medical System (NDMS). NDMS is a Federally-coordinated system closely linked to the Hospital Preparedness Cooperative Agreement program that augments the Nation's medical response capability. The primary purpose of the NDMS is to supplement an integrated National medical response capability for

assisting State and local authorities in dealing with the medical impacts of major peacetime disasters. One major element of this capability is the Definitive Care program which reimburses participating hospitals for medical services provided during emergencies. Currently, the process for making payments to these providers has resulted in some delays in payments. We are exploring ways in which this process can be improved, expediting reimbursement to these state and local providers. Supporting enhanced surveillance efforts, NDMS now uses an Electronic Medical Record (EMR) system that standardizes record keeping and promotes enhanced health surveillance during disasters. These and other enhancements we have made, enable us to better identify population needs as we respond, including in the area of pediatrics. These developments in identifying the needs of populations, specifically pediatric and at-risk populations, will support a better and more focused response in the future.

HHS has a number of programs and tools that aid state and local response and coordinate efforts during disasters. The ASPR Hospital Preparedness Program (HPP) has advanced the preparedness of hospitals and communities in numerous ways, including through planning for all-hazards, increasing surge capacity, tracking the availability of beds and other resources using electronic systems, and developing communication systems that are interoperable with other response partners. We recently issued a report on the Hospital Preparedness Program that describes the achievements of our state partners in building healthcare preparedness across the nation, and illustrates how states

have used the capabilities developed and funded through the program in both large and small incidents. One specific accomplishment detailed in this report is that more than 76 percent of hospitals participating in the HPP met 90 percent or more of all program measures for all-hazards preparedness in 2009. This is a significant accomplishment and clearly demonstrates participants' commitment to investing in preparedness.

In addition to HPP, CDC's Public Health Emergency Preparedness (PHEP) cooperative agreements provide funding to enable state and local public health departments to have the capacities and capabilities to effectively respond to the public health consequences of not only terrorist threats, but also infectious disease outbreaks, natural disasters, and biological, chemical, nuclear, and radiological emergencies. The PHEP program, which includes the Cities Readiness Initiative (CRI), has made great strides in just a few short years, building and sustaining preparedness and response capabilities, along with enhancing state/local public health infrastructure, which supports these preparedness and response capabilities. In fact, we've seen a lot of tangible evidence of program successes—we've heard from a number of states that they've been able to handle the health effects of events, including food-borne outbreaks, influenza, infectious diseases, as well as floods and tornados, without federal assistance as a result of investments and training made through the HPP and PHEP. To promote coordination and efficient use of resources, you may be pleased to learn that ASPR is leading an interagency effort to better align the

HPP and PHEP grant programs to ensure we are efficient with resources and that we eliminate duplicative or conflicting programmatic and administrative efforts for grantees. The core interagency partners critical to the success of this endeavor are ASPR, CDC, the Federal Emergency Management Agency (FEMA) and the Department of Transportation's (DoT's) National Highway Traffic Safety Administration (NHTSA). By streamlining grant mechanisms and maximizing the efficiency of grant management processes, we expect to improve preparedness outcomes and allow for more effective public health and medical care for State and local communities.

In addition, consistent with Presidential Policy Directive 8, we are working toward a framework for priority-setting, review, and reporting measures; development of a common pathway to focus dollars, measure outcomes, reduce duplication, and enhance return on investment and reporting; and enhanced data sharing for improved situational awareness during a response.

Other Important PAHPA Provisions

PAHPA authorized a number of other programs that are set to expire at the end of 2011 include the following: Freedom of Information Act (FOIA) exemptions and Limited Antitrust exemptions; and authorization of appropriations for the Public Health Emergency Preparedness (PHEP), Hospital Preparedness Program

(HPP), the Medical Reserve Corps (MRC), the National Disaster Medical System (NDMS), and the Emergency System for the Advanced Registration of Volunteer Healthcare Personnel (ESAR-VHP).

BARDA, PHEP, HPP, MRC, NDMS, and ESAR-VHP are PAHPA programs that not only work well but also support resilient communities that are better prepared to respond to emergencies and other public health events. PAHPA's FOIA and Antitrust exemptions help ensure the HHS Secretary is able to continue to protect sensitive technical data and scientific information related to advanced research and development of MCMs and is able to convene meetings and consultations on critical medical countermeasure issues.

The Movement of Some Programs within HHS

HHS programs have come a long way since the original PAHPA authorization, and we've made great strides in coordinating across HHS to achieve public heath preparedness. Particularly in today's fiscal environment, we have been very aggressive in eliminating duplication and enhancing efficiencies by drawing on the expertise, capacity, and personnel of HHS partner agencies to make American communities more resilient.

Given our progress and continuing improvements to how we coordinate across HHS, we believe the current processes and systems in place are working. ASPR actively exercises policy direction for public health and medical preparedness

and response programs and activities. We will efficiently and effectively continue to build on the expertise and systems in place, incorporate lessons learned, and continuously improve collaborations with our agency partners on future responses.

Conclusion

Our experiences since the passage of PAHPA have shown clearly that every part of the public health and medical community is critical to building resilience. We applaud Congress' wisdom in enacting PAHPA as the foundation for this approach, which is so critical to our preparedness. .

At this time I would be happy to address any questions you may have.

Mr. PITTS. The chair thanks the gentlelady.
Dr. Koh, you are recognized for your opening statement.

STATEMENT OF HOWARD K. KOH

Mr. KOH. Thank you very much, Chairman Pitts, Ranking Member Pallone, and distinguished members of the committee. I am Dr. Howard Koh, the Assistant Secretary for Health for HHS and I am very pleased to be here to testify on the legislation entitled "Enhancing Disease Coordination Activities Act of 2011."

As the Assistant Secretary for Health, I have the honor of overseeing some 14 core public health offices, 10 regional health administrators and their staffs, and 10 secretarial and presidential advisory committees. Collectively, our Office of the Assistant Secretary for Health implements an array of interdisciplinary programs relating to ensuring the Nation's public health. And in fact our portfolio includes programs in many areas such as disease prevention, health promotion, women's health, minority health, adolescent health, vaccines, fitness, sports, and nutrition, human research protection, among other areas. The mission statement of our offices in fact is "Mobilizing leadership in science and prevention for a healthier Nation." We are very proud of this mission and we are very proud of the efforts of the Department all public health colleagues in fact in helping all Americans reach their highest attainable standard of health.

So in that context, I am very pleased to add some comments about the draft legislation here before us to improve the coordination of research and other activities conducted or supported by HHS that are specific to a disease or condition. I thought it would be useful to share our experience in coordination efforts at HHS because over recent months, our office has helped put forward strategic plans in coordination in a number of areas including tobacco, HIV, racial-ethnic disparities, viral hepatitis, vaccines, multiple chronic conditions, health literacy, and other areas.

I would like to focus on one particular plan as an example of our coordination efforts at the Department and that has to do with tobacco. As you all know, tobacco addiction is one of the most troubling public health challenges of our time, and in fact in the 21st Century it is forecast that tobacco use globally will cause some one billion preventable deaths. And that is a stunning fact that demands our attention and our action.

So to address this public health challenge, the Department last year released its first-ever comprehensive tobacco control strategy called "Ending the Tobacco Epidemic: A Tobacco Control Strategic Plan." This process in fact began in the spring of 2010 when the secretary charged me to convene a coordinating committee across the Department consisting of leaders from every agency to inventory the activities and efforts that were underway and then leverage them together to have maximum impact with our current resources. And we were very pleased to unveil that plan last fall with activities focused on four pillars: engaging the public, supporting State and local efforts, advancing research, and having HHS lead by example.

I am very pleased to report to this committee that already we have seen some results accomplished that would not have been pos-

sible without this high level of coordination and collaboration. For example, just several weeks ago on July 1, the secretary announced that HHS was now completely tobacco-free. And also in recent weeks our Centers for Medicare and Medicaid Services (CMS) has released formal guidance on the Affordable Care Act's expansion of smoking cessation benefits for pregnant women enrolled in Medicaid. Also, CMS has formally announced new options for Medicaid beneficiaries such that administrative reimbursement for quit lines could be put forward. So that is a very important resource to help smokers quit.

We are also pleased to report that this action plan has garnered a lot of support from the general community. For example, just last week, there was a scientific report released showing a significant decrease in smoking in the movies, which contributes to changing the social norm about this very important public health issue. That report cited the HHS tobacco action plan as an example of bringing more attention to mass media efforts around tobacco control as well. So we look forward to presenting more progress on plans like tobacco and many others as an example of our commitment to collaboration and coordination.

The draft legislation here today—"Enhancing Disease Coordination Activities of 2011"—recognizes that important role of cross-departmental coordination and collaboration, and we want to thank the committee for your thoughtfulness and insight in putting that effort forward. I should note, however, that Section 222 of the Public Health Services Act already has the secretary with the authority to create advisory councils and committees and appoint members to those groups. So with that authority, the Department has established a number of advisory committees which allow the Department to get input from external experts and then also allows for the public to engage in the work and policy-development process that occurs at the Department.

The proposed legislation supports very strongly the efforts of coordination collaboration and that spirit, but I do want to note that it may introduce some unintended redundancies. For example, the legislation requires that each coordination committee have a strategic plan every 2 years and update that plan every 2 years. And under the current structure, we have our advisory committees establishing their own priorities and updating plans on a flexible schedule, so the bill's requirement for an every-2-year timetable could take away time and resources that could be better used for implementation.

Another area I do want to mention is potential costs to the Department that could be associated with this legislation. The Department already commits significant resources to existing advisory committees and having to spend even more funds on many more committees could potentially take away dollars from other important endeavors and potentially represent duplication of efforts.

So in closing, I want to thank the committee for its recognition and promotion of the important role that cross-agency collaboration and coordination play in developing strong policy. I would urge the committee to take into account the current system that exists and I believe works well at HHS for establishing and managing advisory groups. And as always, we at the Department look forward to

working closely with you on many, many important areas in public health. Thank you very much and, of course, I am happy to take any questions on these issues.

[The prepared statement of Mr. Koh follows:]

TESTIMONY OF DR. HOWARD KOH

ASSISTANT SECRETARY FOR HEALTH

DEPARTMENT OF HEALTH AND HUMAN SERVICES

ON

Enhancing Disease Coordination Activities Act of 2011

BEFORE THE

COMMITTEE ON ENERGY AND COMMERCE

US HOUSE OF REPRESENTATIVES

Good morning Chairman Upton, Ranking Member Waxman and distinguished Members of the Committee. I am pleased to be here today on behalf of the Department of Health and Human Services (HHS) to testify on the legislation titled *Enhancing Disease Coordination Activities Act of 2011.* My name is Dr. Howard K. Koh, and I am the Assistant Secretary for Health at HHS.

As the Assistant Secretary for Health, I oversee the 14 core public health offices and 10 Secretarial and Presidential Advisory Committees. The Office of the Assistant Secretary for Health, or OASH, implements an array of interdisciplinary programs relating to disease prevention, health promotion, the reduction of health disparities, women's and minority health, adolescent health, HIV/AIDS and chronic infectious diseases, vaccine programs, fitness, sports and nutrition, bioethics, population affairs, blood supply, research integrity and human research protections. OASH also includes the U.S. Public Health Service Commissioned Corps and the Office of the Surgeon General.

The mission statement of the Office of the Assistant Secretary for Health is: "Mobilizing leadership in science and prevention for a healthier nation." In this effort, OASH plays a leading coordinating role in a wide variety of public health and scientific areas. During my first two years as the Assistant Secretary for Health, OASH has undertaken a number of initiatives aligned with the mission of the office. As the goal of your draft legislation is "to improve the coordination of research and other activities conducted or supported by the Department of Health and Human Services that are specific to a disease or condition," I thought it would be useful to discuss a number of areas, specifically tobacco, health disparities and HIV/AIDS, where my office has taken the lead on coordination and collaboration across the Department.

Tobacco

Tobacco addiction is one of the most troubling public health challenges in modern times. In the 21st century, it is forecast that tobacco use globally will cause one billion preventable deaths. This is a startling fact that demands not just our attention, but our action. OASH directly confronted this burgeoning public health problem by leading the development and implementation of the first ever comprehensive tobacco control strategy by the Department of Health and Human Services, "Ending the Tobacco Epidemic: A Tobacco Control Strategic Plan."

I convened a coordinating committee consisting of leaders representing different agencies of the Department to understand the activities and efforts that were currently underway and how we could best leverage these existing resources. A plan was drafted that outlined a collaborative approach that utilized the skills and resources of component parts of the Department that had the opportunity to reduce tobacco-related illness and suffering. This plan focused on four pillars: 1) engaging the public to change social norms around tobacco use; 2) leading by example through the implementation of model tobacco control policies across the government; 3) improving public health by implementing evidence-based tobacco control interventions and policies at all levels of government; and 4) advancing our knowledge by accelerating research to expand scientific understanding and track outcomes of efforts.

The Action Plan was unveiled in November 2010. The coordinating committee is now actively engaged in coordinating strategies across multiple parts of the Department to achieve the goals of the plan and to ensure that the Department works collaboratively on this important effort to reduce smoking rates.

I am pleased to report that already, results have been accomplished that would not have been possible without the high level of coordination and collaboration that occurred in creating this plan. As of July 1, 2011, all Department of Health and Human Services campuses went tobacco free. Additionally, the Centers for Medicare & Medicaid Services (CMS) released guidance on the Affordable Care Act's expansion of smoking cessation benefits for pregnant women enrolled in Medicaid. CMS also announced a Medicaid option to provide administrative reimbursement for "quitlines," an important resource to help smokers quit smoking.

The Action Plan has garnered significant public support from external stakeholders and internally within the Department. In fact, it was recently cited in a CDC Morbidity and Mortality Weekly Report announcing significant decreases in incidences of smoking in movies. OASH has played an active coordination role to ensure that all new Departmental mass media efforts around tobacco control are well coordinated. I expect that, moving forward, the collaboration and coordination efforts at the Department will continue to produce important results that will help reduce smoking rates.

Health Disparities

As has been documented time and again, minority populations in the United States experience significant health disparities, including higher incidence rates of a range of debilitating diseases. There are a significant number of activities addressing the reduction of health disparities within HHS, requiring processes and infrastructure for ensuring effective and efficient coordination of those activities across the Department. These are described in four parts below.

1. HHS Action Plan to Reduce Racial and Ethnic Health Disparities

In April, the Secretary, along with the Assistant Secretary for Planning and Evaluation (ASPE) and me, issued the HHS Action Plan to Reduce Racial and Ethnic Health Disparities. The plan envisions achieving a "nation free of disparities in health and health care" by promoting access to care, strengthening the health care workforce, targeting conditions that impact minorities at a higher rate than the general public, and promoting innovation to confront these challenges. With this plan, HHS commits to: (1) continuously assessing the impact of all policies and programs on racial and ethnic health disparities, (2) assuring that all operating components work collaboratively on strategic plans and coordinated investments, and (3) coordinating monitoring and evaluation of the Department's success in addressing health disparities, with a biannual report of progress to the Secretary.

2. Health Disparities Council

The Secretary also re-established a Health Disparities Council, an interagency coordinating committee, with representation from every component of HHS. The Council representatives for seven of the HHS agencies are the directors of their respective offices of minority health, and the director of the National Institute on Minority Health and Health Disparities. This Council, which is co-chaired by the ASPE and me, provides a forum for sharing information on health disparity reduction programs and policies, leveraging existing HHS investments to more effectively reduce disparities, coordinating and tracking progress on implementation of strategies in the Action Plan, and eliminating any programmatic duplication or unnecessary administrative burdens. The Council has primary responsibility for implementing and overseeing the Disparities Action Plan.

3. Federal Interagency Health Equity Team

As a component of the Department's leadership of the National Partnership for Action to End Health Disparities, HHS established a Federal Interagency Health Equity Team to coordinate efforts aligned under a National Stakeholder Strategy for Achieving Health Equity. This National Stakeholder Strategy is a comprehensive, community-driven approach to reducing health disparities in the U.S. and achieving health equity through collaboration and synergy. The Federal Interagency Health Equity Team, coordinated by HHS, facilitates activities under the National Stakeholder Strategy that increase the efficiencies and effectiveness of policies and programs at the local, tribal, state, and national levels. The Team includes senior representatives of the Departments of Agriculture, Commerce, Defense, Education, Health and Human Services, Housing and Urban Development, Justice, Labor, Transportation, and Veterans Affairs, the Consumer Product Safety Commission and the Environmental Protection Agency (EPA).

4. Health Disparities Dashboard

HHS uses a Health Disparities Dashboard, which compiles data from several key sources, to track national progress on key health disparity indicators on an annual basis. This week, HHS also launched the use of a new implementation monitoring database to track progress on actions that address health disparities throughout HHS. All agencies and offices report progress monthly using this unified database to assure cross-departmental coordination, transparency, and accountability for actions designed to achieve the vision of HHS – "a nation free of disparities in health and health care."

HIV/AIDS

OASH played a pivotal role in coordinating the National HIV/AIDS Strategy (the Strategy) that is now the framework for all of the Department's efforts on HIV/AIDS. The Strategy is an important example of enhancing disease-coordination activities across the Federal government, and it was developed with input from a wide array of public health and healthcare professionals, HIV/AIDS service providers, advocacy groups, community leaders, and people living with HIV/AIDS. The outcome is a comprehensive plan to focus on policies and activities that will help us end the HIV epidemic in the U.S. The goals of the Strategy include: reducing new HIV

infections; increasing access to care and improving health outcomes for people living with HIV; and reducing HIV-related disparities and health disparities.

Another key goal of the Strategy is "achieving a more coordinated response to the epidemic." The Strategy places significant emphasis on better coordination and collaboration of activities within and among agencies and across all levels of government to ensure we achieve the best possible results for the investment of Federal resources, reduce duplication where it may exist, and find more effective ways to share and use available data and research to inform programs, policies, and resource allocations.

When the Strategy was released in July 2010, HHS was among the six designated "lead agencies" to implement it (along with the Departments of Housing and Urban Development, Justice, Labor, and Veterans Affairs and the Social Security Administration). Given that the majority of the Federal government's domestic HIV research, prevention, and care programs are situated within HHS, the Department plays a significant role in implementing the goals of the Strategy. While there has always been collaboration among agencies for various HIV-related initiatives, the Strategy has given HHS a new opportunity to expand that collaboration and make it an intentional feature of our HIV prevention, testing, treatment and research programs.

Specifically, last summer, OASH established a Department-wide National HIV/AIDS Strategy Implementation Group, composed of representatives from nearly every agency within the Department. This group developed the HHS National HIV/AIDS Strategy Operational Plan, an extensive action plan that reflects ongoing efforts to align existing activities with and initiate new activities in support of the Strategy's goals. The Operational Plan is also a detailed summary of the current level of domestic HIV/AIDS spending by HHS, which has provided us with important baseline data against which to gauge unmet need and to assess any future resource alignment. The activities we are undertaking as part of the Operational Plan will require greater or new collaborations across our own agencies, which will lead to more systemic change in order to ensure that HHS resources are leveraged to maximum effect.

Environmental Health

According to the World Health Organization, environmental hazards are responsible for as much as a quarter of the total burden of disease worldwide, and more than one third of the burden among children. Recognizing this connection between health and the environment, HHS is engaged in several important initiatives, bringing together our agencies internally and also working with other Federal departments.

HHS is working with EPA and other Federal departments on the reinvigorated Interagency Working Group on Environmental Justice to address the disproportionate exposure to environmental hazards in minority and low-income populations. HHS has also joined with the Departments of the Interior and Agriculture, the White House Council on Environmental Quality, EPA, and others in the America's Great Outdoors Initiative to create a 21st century conservation and recreation agenda and reconnect Americans, especially children to the outdoors. HHS and EPA are co-chairing the Task Force on Environmental Health Risks and Safety Risks to Children, developing strategies to promote and protect children's environmental health and safety. A final example is HHS's recent partnership with EPA and other Federal departments on the Federal Radon Action Plan to create healthier home environments and reduce individuals' and families' exposure to radon.

Examination of the *Enhancing Disease Coordination Activities Act of 2011*

The *Enhancing Disease Coordination Activities Act of 2011* recognizes the important role that cross-departmental coordination and collaboration play in the work that occurs at HHS on a day-to-day basis. We appreciate this legislation's support of our efforts in regard to this practice.

The Department's commitment to coordination and collaboration provides us with a unique perspective on this proposal. The Department is involved in a broad spectrum of activities that improve the nation's health, including groundbreaking research at the NIH, health promotion and protection through the work of the CDC, FDA and the Agency for Health Research and Quality (AHRQ), and much-needed assistance and services to our nation's neediest and elderly at the Administration for Children and Families (ACF) and the Administration on Aging (AoA).

Under section 222 of the Public Health Service Act, the Secretary of HHS already has authority to create advisory councils and committees and appoint members to those groups. (42 USC

217a). Using this authority, the Department has established a number of Advisory Committees, which we utilize in two important ways. First, advisory committees allow the Department and its components to receive input, advice and information from committee-member experts in the topic areas covered by the groups' charter. Second, advisory committees allow for the public to be engaged in the work and policy development process that occurs at the Department.

Two Secretarial advisory committees and eight presidential advisory committees are operated within OASH, including the the President's Advisory Council on HIV/AIDS, the President's Council on Fitness, Sports and Nutrition, and the Secretary's Advisory Committee on Minority Health. I can say with great certainty that the work of these groups is crucial to informing the Department's progress in a wide variety of areas. At present, there are 84 Secretarial advisory committees dealing with the entire spectrum of research, regulation and policy areas that are under the purview of the Department.

The committees operated by HHS function under the rules set out in the Federal Advisory Committee Act (FACA) (5 U.S.C. App). Rules are in place under FACA to guarantee that the members serving have the expertise necessary to provide substantive advice and input to the sponsoring agency, as well as to ensure that a variety of viewpoints and perspectives are represented on the specific topic areas. Members are also screened to avoid any ethics or conflicts of interest concerns. Lastly, regulations require public notice and opportunities for participation from the general public at meetings. In recent years, a number of FACAs have begun to utilize web streaming and web archiving to allow for more public participation.

Due to the existing advisory committee system in place, the proposed legislation may create redundancies. For example, the legislation requires that each coordination committee develop a strategic plan every two years that makes wide-ranging recommendations. Under the current structure in place at the Department, advisory committees help inform the work of the Department by establishing priorities and by submitting recommendations on a regular basis to the Secretary. These recommendations are taken seriously by the Department. In addition, requiring a strategic plan every two years would seem to be an extraordinary use of time and resources for the coordination committees. Developing and drafting a strategic plan would take away from the ability of the coordination committees to focus on substantive inquiries and analysis.

However, the priority that the legislation places on ensuring members of the proposed coordination committee represent a number of different stakeholders groups is laudable. The benefit of outside advice and input from the full spectrum of interested parties is something that the Department values in its current advisory committee system.

The last area I will focus on is the potential costs associated with this legislation. The administrative costs, the expense of reimbursing members for their travel, and the increased burdens on the Department to coordinate and participate on these coordination committees could represent a significant commitment of funds for the Department. The Department already commits resources to the existing advisory committees. Having to spend even more funds on these coordination committees would potentially take away dollars from other important endeavors, and potentially represent duplication of efforts. Since the coordination committees are envisioned to promote efficiency and eliminate duplication, it would seem counterproductive for their operation to create redundancies and unnecessary costs.

In closing, I thank the committee for its recognition and promotion of the important role that cross-agency collaboration and coordination play in the development of strong public policy. I would urge the committee to take into account the current system that exists at the Department of Health and Human Services for establishing and managing advisory groups. We at the Department stand ready to work with you in moving forward on this important process.

At this time I am happy to address any questions from the committee.

Mr. PITTS. The chair thanks the gentleman and thanks both of our witnesses for your testimony. I will now begin the questioning and recognize myself for 5 minutes for that purpose.

We begin, Dr. Lurie, with you. Congress enacted the Project Bioshield Act of 2004 and the Preparedness and All-Hazards Preparedness Act of 2006 to build the Nation's preparedness infrastructure and foster the development of chemical, biological, radioactive, and nuclear medical countermeasures so the Nation could better respond to attacks. Would you please expand on your comments on how these laws have helped prepare our Nation?

Ms. LURIE. Certainly. Thanks for that question.

As I think we know, the development of medical countermeasures has been a particularly vexing problem because there is by and large not a commercial market for these products. So through these laws, we have a) provided funding to develop these countermeasures, b) provided the assurance that the Federal Government will be a good partner and will purchase these products if in fact private companies come to make them. In doing all of this work and through the enterprise, over time we have continued to strengthen our efforts both to identify what needs to be developed, to identify how it is developed, to strengthen our work with developers and companies, and now to move forward to coordinate the efforts with BARDA in the lead, with FDA, CDC, NIH, and BARDA so that we now have a much more seamless process for countermeasure development.

At the end of the day, however, this stuff takes a long time, it is really expensive, and we have an obligation to the American people to be sure we are prepared. When we started all of this and when you all decided to help cross this so-called "valley of death," we had almost no products in the development pipeline. Now, I am proud to say we have over 70 CBRM products in development and a slue more in the flu area and we have moved forward to procure a number of countermeasures for the Strategic National Stockpile for smallpox, anthrax, botulism, red nuke threats, et cetera. I could go on and on.

Mr. PITTS. Thank you. Your position, the Assistant Secretary for Preparedness and Response, was created in the Pandemic and All-Hazard Preparedness Act of 2006 to lead the oversight and coordination of the entire medical countermeasure enterprise through HHS. Would you give us your insight on the challenges you have faced in leading this enterprise, what we can do to help you in your position, and in the aftermath of the natural disasters and pandemics of the past few years, can you describe some of the challenges that you and your staff have faced, especially related to coordination, flexibility, and communication?

Ms. LURIE. Great. No, I very much appreciate that question as well. You know, I came into this position early on in H1N1 and the importance of coordinating across all of HHS was terribly important, whether it was our public health response or our healthcare response or our countermeasure response, all of those things kneaded together. So through my office and because of the authorities of my office, we have been able in a very regular way to pull together all of the parties end to end on the countermeasures side

and through the response side to be sure everybody is working together.

You know, as do we all, some of the programs are at CDC, some of the programs are at HRSA, some of the programs are at NIH or FDA, and we all meet together under my leadership to identify gaps and to solve problems. I do sit on the secretary's Budget Council. I do have the opportunity to review and provide input into the budget process through that mechanism.

An area that has worked particularly well has been the PHEMCE, or the Public Health Emergency Countermeasures Enterprise, which I lead and chair. And again, through the Medical Countermeasure Review, we have really enhanced the coordination of all of the parties so that now everybody sits at the table and sits at the table with product developers at the beginning, identifies the plan, identifies the gaps, and works together going forward. I would also comment that DOD and DHS participate in this, so our role coordinating there is much broader in fact than just at HHS.

Similarly, on the healthcare delivery system side where we have responsibilities as Mr. Waxman pointed out for medical surge and for working through issues in the emergency care system, we coordinate and work closely with our colleagues at CDC and HRSA and CMS, the National Disaster Medical System and Hospital Preparedness Programs, you know, being two major centerpieces of those.

Mr. PITTS. Thank you. My time has expired. I yield to the ranking member of the subcommittee, Mr. Pallone, for 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

Dr. Koh, if I could start with you, you noted in your testimony that under Section 222 of the Public Health Service Act, the secretary already has the authority to create advisory councils and other committees and to appoint members. As I understand it, the intent of the Enhancing Disease Coordination Activities Act, which is before us today, is not to duplicate that authority but rather to outline the structure and functions of committees' focus on coordinating a specific disease or health condition. The provisions of that bill are modeled on those in the Autism Coordinating Committee, and as we heard in our hearing last week, that has been very successful.

So as we consider this new bill, I wanted to be sure that if and when the secretary elects to establish another disease-related coordinating committee that it operates in an effective and productive way. So based on the experiences you shared in your testimony, are there certain elements of success that have gone into these efforts that should be reflected in the legislation?

Mr. KOH. Well, thank you for that question, Congressman, and also thank you for your commitment to public health in general.

So as I mentioned, we always review the landscape in terms of evolving public health challenges in a magnitude of new issues and then assess the resources and the responsibilities of the various parts of HHS and see how we can coordinate that to the best of our ability. In the examples I cited, many of these had strategic plans which were very, very valuable because it explicitly put forward the resources we had agency by agency and also put forward

common goals and measures by which we would work together and measure success. So that is an effort that I think has been very, very valuable in many of the areas that I have pointed out. And in the interagency Autism Committee, there is an excellent strategic plan that has also been developed with goals and targets that is being followed. So I think the more explicit the coordination and the goal-setting is, that is a major element of success moving forward.

Mr. PALLONE. Now, let me ask Dr. Lurie, my colleagues on the subcommittee—most notably Representative Eshoo—have some concerns that the current programs do not adequately address the needs of the pediatric population and would like to see some enhancements that would assist in the Nation's ability to care for kids in the event of a public health emergency. Kids make up 25 percent of the Nation's population, so it only seems natural to me that we should prepare for their unique needs in the case of an emergency or disaster. So in that regard, I would like to issue some questions.

First, is the Strategic National Stockpile adequately stocked for pediatric populations? If not, how can the Pandemic and All-Hazards Preparedness Act before us today be strengthened to ensure that the SNS has adequate supplies for pediatric populations? And we will start with that, but I have got three questions.

Ms. LURIE. Sure. I think those are great questions. And you know, when I came into this position, I came in facing a pandemic that a) was primarily killing children, and b) I came into it as a mom and looked at this set of issues that relate to strengthening our ability to respond to pediatric issues in all areas. Since this experience, we have done a number of things to strengthen our pediatric footprint. We have hired pediatricians within BARDA and we have also hired and brought on a chief medical officer to really pay attention to the countermeasure development needs. In addition, we have developed a pediatric NOB, interagency workgroup that advises now each stage of development for countermeasure requirement-setting all the way through development and procurement so that we strengthen the pediatric footprint there.

And finally, I have directed my staff to look at every new contract we let to be sure that the development of pediatric countermeasures is there from the get-go so we now have a smallpox antiviral contract that supports pediatric formulation, the new advanced research and development contracts for new broad-spectrum antimicrobials, support pediatric populations. We have funded the development of the palatability studies so that we can——

Mr. PALLONE. Well, let me finish this because my time is almost up.

Ms. LURIE. Yes.

Mr. PALLONE. Is there anything that we don't have in the law that would prevent you from integrating kids into the national preparedness goals? Is there something that we need in the law?

Ms. LURIE. I tried to think hard about that because I am always a big fan of getting the authorities we need. My view right now is that we have made enormous progress with the authorities we have and there doesn't seem to be anything in the way for me of us continuing to make more progress in these areas. At the end of

the day, I will point out that pediatric countermeasures are expensive to develop and test and the market issues there are like the market issues in the rest of the countermeasures sphere but more profound. So from an authorization perspective, I feel like I have what I need.

Mr. PALLONE. Mr. Chairman, I know that time has run out but just when she was saying she was hiring those pediatricians, all I kept thinking was that we better pass our bill with the Graduate Medical, the GMEs, otherwise there won't be any physicians to hire.

Mr. PITTS. I was thinking the same thing.

Ms. LURIE. There we go.

Mr. PITTS. The chair thanks the gentleman and recognizes the vice chairman of the committee, Dr. Burgess, for 5 minutes for questioning.

Mr. BURGESS. Thank you, Mr. Chairman. And Dr. Lurie, thank you for being here. Thank you for helping our office when you first took your position and the H1N1 was clearly making its presence felt in the State of Texas. We felt it acutely. Appreciate the efforts from your office to help us discuss that with the Fort Worth Independent School District during the summer. You were concerned about kids; I was concerned about pregnant women, schoolteachers in particular who would be exposed to large numbers of children during the beginning of the next school year. And it is one thing to close down the schools in May; it is another thing to close them down in September where so much instructional time could be lost in the year going forward. And although, certainly, I know there have been criticisms about how all of that was handled. I think it certainly could have been much more disruptive than it was, and I think that is largely due to your efforts.

The issue of pediatric dosages being available was something I became acutely aware of when contacted by the Tarrant County Health Department that they did not have antivirals available in children's doses and were simply having to make it up as they went along, and that is clearly uncomfortable.

I have got some questions for you about the National Strategic Stockpile. I need to set it up a little bit so bear with me. In July of 2010, I sent a letter to the National Strategic Stockpile, myself and Joe Barton as the ranking member of the full committee and Subcommittee on Oversight and Investigations talking about the preparedness through the National Strategic Stockpile. Ten items were in that letter. Number five was dealing with the stockpile's ability to deliver threat-appropriate materials in the event of something that required national activation. So we were interested in the methods to secure delivery of threat-appropriate materials from both domestic and foreign manufacturing sites in the stockpile activation. The material provided back to me by Dr. Friedan of the CDC on issue number five detailed some of the things that they were doing.

As part of that response, Dr. Friedan referenced the Executive Order 12919, that HHS with the approval of DHS and FEMA may utilize the Defense Production Act authority with respect to health resources. That is pretty broad authority. Essentially, the Federal Government could take over those things if necessary at the time

of a national emergency. But then the question comes up, you know, we have authority over foreign manufacturers and we do rely on foreign manufacturers for materials, masks, gloves, active pharmaceutical ingredients for some of these materials. So, again, the question, then, can you give us a description of how your office coordinates the movement and delivery of special medical countermeasures to ensure the delivery of threat-appropriate materials in the event of a National Stockpile activation? That is one.

And the second is in the event of a global pandemic, can you assure the committee that there are the resources available to ensure threat-appropriate materials will be able to be disseminated among the population?

Ms. LURIE. Great. Well, thank you for both the set up and for the question. But first, let me also thank you for your leadership during the pandemic and your leadership both with the pediatric and the OB community. I think largely because of your efforts in highlighting this issue, we now have record numbers of pregnant women vaccinated for influenza. I think it has made a huge difference. It also led us to think very hard about including OB issues in this pediatric interagency working group so that we are sure that we really nail those issues for both the pregnant women and children as we develop countermeasures moving forward.

Mr. BURGESS. Mr. Chairman, let me just ask unanimous consent. I would like to make copies of Ranking Member Barton's and my letter available to the record as well as the response we got from Dr. Frieden. Let me get this material to you, Dr. Lurie, because this requires some thought and perhaps some research in delivering an answer. But it is important. And really the essential issue is how do we assure that we are going to be able to deliver threat-appropriate materials to the correct places? Yes, we can have broad authority in this country——

Ms. LURIE. Yes.

Mr. BURGESS [continuing]. But what do we do if we are getting that stuff from Mexico, the Philippines, China—fill in the blanks? And that is really my main consideration.

Ms. LURIE. It is an important question. It is something that I think we have a number of answers to and we are continuing to work on, but I think it might use up an awful lot of time.

Mr. BURGESS. All right. We will get that to you in writing.

Ms. LURIE. So if you want to get that to us, we will be happy to get back to you on it.

Mr. BURGESS. Dr. Koh, let me just briefly ask you. You referenced quit lines in your testimony. Is that like a 1–800 number?

Mr. KOH. I think the number is 1–800–QUIT–NOW and it is a coordinated national effort.

Mr. BURGESS. Have you done any studies to see the efficacy of a quit line as opposed to, perhaps, a medically supervised program of Chantix, Wellbutrin, or even medical hypnosis in regards to smoking cessation? I appreciate your leading by example. I think that is great that HHS is smoke-free. We need to work on the White House and the U.S. House, but those are separate considerations of leading by example. I would appreciate you helping me with that. But I would also appreciate if you could give us some information about what research you have done as to the efficacy

of the quit lines as opposed to medical therapy. I was always disturbed in my practice and I was never reimbursed for helping someone with smoking cessation, and yet it might be the single-most thing that you could do to help with their future health if you could get them to quit smoking.

So thank you, Mr. Chairman, for your indulgence. I will yield back.

Mr. KOH. Thank you, Congressman. You raise many good points in your question. And first, I should say that we are very pleased at the increasing attention on prevention in general in the country and with the passage of the Affordable Care Act, there are many preventative benefits that are begin afforded to people, especially in the area of tobacco cessation and tobacco counseling.

Smoking quit lines have been studied very, very carefully and in excellent randomized trials, and those studies showed the benefit have led to the expansion of quit lines across the country. And this 1–800–QUIT–NOW number that is available to anybody in the U.S., and in general, we support using all these measures together—quit line services, counseling, medications when appropriate. We want prevention to be a multi-dimensional effort so we can move people to a tobacco-free future.

Mr. PITTS. The chair thanks the gentleman. Without objection, the letters that you have submitted will be entered into the record. So ordered.

[The information follows:]

ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States

House of Representatives

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July 8, 2010

Mr. Greg Burel
Director, Division of Strategic National Stockpile
Office of Public Health Preparedness and Response
Centers for Disease Control and Prevention
1600 Clifton Road, NE, MS-D-08
Atlanta, GA 30333

Dear Mr. Burel:

We are interested in the operational aspects of the Strategic National Stockpile, particularly the contracting and acquisition process. Congressman Burgess thanks you for briefing his personal office staff on June 10, 2010, on the Strategic National Stockpile. The contents of that meeting were conveyed to him, and he found the information you provided very helpful. To fully understand the methods by which the Centers for Disease Control and Prevention (CDC) guarantees access to critical materials and vaccines that may be needed by our nation in the event of a Chemical, Biological, Radiological, Nuclear (CBRN) event or a naturally occurring pandemic, please respond to the following:

1. What is your understanding of how the Department of Health and Human Services, in conjunction with the Departments of Defense and Homeland Security, derives the projections of the amount of threat-appropriate materials (hereafter noted to refer to pharmaceutical products and medical devices) needed to respond to a foreseen risk, including the role of the Public Health Emergency Medical Countermeasures Enterprise?

2. Please provide a complete list of the stockpiles portfolio of threat-appropriate materials.

3. What is the role of the CDC's acquisition partners in coordination with the Division of Strategic National Stockpile in ensuring that identified threat-appropriate materials are acquired or contracted for acquisition?

4. Please list all current contracts, including the Prime Vender Contracts, relating to securing threat-appropriate materials.

5. Please provide a detailed description of the methods the Division of Strategic National Stockpile undertakes to ensure delivery of threat-appropriate materials, specifically the processes utilized to guarantee shipment and contract fulfillment in time of stockpile activation. Please detail the legal, regulatory, and logistical tools at your disposal to ensure contract fulfillment. Also include methods to secure delivery of threat-appropriate materials from both domestic and foreign manufacturing sites in time of stockpile activation.

6. How has the Division of Strategic National Stockpile begun to adapt to a pandemic threat -- in addition to your core CBRN mission -- and how have these changes impacted the acquisition of threat-appropriate materials?

7. Please explain the role of the Food and Drug Administration (FDA) certification of a threat-appropriate material manufacturer in any contract process undertaken by the Division of Strategic National Stockpile.

8. What are the quality control measures in place to ensure that stockpiled threat-appropriate materials meet FDA standards?

9. What are the quality control measures in place to ensure that unanticipated requirements of threat-appropriate materials meet FDA standards?

10. Are the current Strategic National Stockpile operations, including use of Prime Vender Contracts, sufficient to meet threat identified needs?

Thank you and your staff for fulfilling the critical mission Congress has tasked you. Understanding that answering the above questions may involve interagency communication, please respond to this inquiry within six (6) weeks of the date of this letter. Given the possible sensitive nature of some of the information above, Members and/or staff can be made available for a classified briefing on applicable portions of your response. If you have any questions, or need additional information, please contact the Minority Committee Staff at (202) 225-3641.

Sincerely,

Joe Barton
Ranking Member

Michael C. Burgess
Ranking Member
Subcommittee on Oversight and Investigations

cc: The Honorable Henry A. Waxman, Chairman

The Honorable Bart Stupak, Chairman
Subcommittee on Oversight and Investigations

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

AUG 1 8 2010

The Honorable Michael Burgess
House of Representatives
Washington, D.C. 20515-6115

Dear Representative Burgess:

Thank you for your letter to Mr. Greg Burel expressing your interest in the operational aspects of the Strategic National Stockpile. Below are responses to your inquiries to help you better understand the methods by which the Department of Health and Human Services (HHS), including the Centers for Disease Control and Prevention (CDC) guarantees access to critical materials and vaccines that may be needed by our nation in the event of a chemical, biological, radiological, nuclear event or naturally occurring pandemic.

1. The Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is an interagency effort coordinated by the Assistant Secretary for Preparedness and Response (ASPR) within HHS. The PHEMCE includes membership from CDC, the National Institutes of Health (NIH), the Food and Drug Administration (FDA), the Department of Homeland Security (DHS), the Department of Defense (DOD), the Department of Veterans Affairs, and the Office of the ASPR, including its component, the Biomedical Advanced Research and Development Authority (BARDA). The mission of the PHEMCE is to define and prioritize medical countermeasure requirements; integrate and coordinate research, early- and late-stage product development and procurement activities; and establish deployment and use strategies for medical countermeasures (MCM).

The process of determining MCM requirements for each threat agent begins with the issuance of a Material Threat Determination and a Material Threat Assessment (MTA) by DHS. ASPR staff then do medical and public health consequence modeling to define the medical and public health needs that will result from the scenario as defined in the MTA. Subject matter experts from across the interagency then convene in PHEMCE Requirements Working Groups to determine MCM requirements including the type and quantity of the countermeasure that best mitigate the potential morbidity and mortality. These are then approved by the PHEMCE Executive Senior Council (ESC), comprised of agency heads of CDC, NIH, FDA, and ASPR.

The PHEMCE also conducts the Strategic National Stockpile (SNS) Annual Review, as mandated in the Pandemic and All-Hazards Preparedness Act of 2006. This process allows for a thorough accounting of the SNS contents each year and an evaluation of those contents against

the current MCM requirements. The SNS Annual Review occurs in four phases: Phase I is an internal gap analysis performed by SNS staff to evaluate on-hand inventory against requirements; Phase II is a review by each threat-specific PHEMCE Integrated Program Team (IPT) to prioritize outstanding MCM gaps; Phase III is a cross-cutting prioritization of all identified gaps by the Enterprise Executive Committee; and Phase IV is a presentation of the final report to the PHEMCE ESC for concurrence or further prioritization.

2. The information you requested in the second item of your letter will be provided separately in hard copy for your review

3. CDC's Division of Strategic National Stockpile (DSNS) manages the SNS on behalf of HHS; its acquisition partners include CDC's Procurement and Grants Office (PGO), the Veteran's Administration's National Acquisition Center (VA NAC), and the General Services Administration (GSA). These partners are responsible for awarding contracts in accordance with the Federal Acquisition Regulations to deliver goods and/or services that meet DSNS requirements. PGO, VA NAC, and GSA have staff members dedicated to responding rapidly to DSNS requirements. ASPR/BARDA also awards specific contracts for advanced development of new products for delivery to the SNS under the Project Bioshield procurement process.

Medical countermeasure requirements established by the PHEMCE impact programs across all PHEMCE partners, from NIH's basic research programs and ASPR/BARDA's advanced development programs to DSNS' acquisition and maintenance of the stockpile. These product requirements lead to operational plans to deploy and use those products in a relevant manner for DSNS all-hazards missions. Ancillary support services to manage and deliver DSNS as required for each product are defined by DSNS.

Upon the development of a requirement and identification of funds to support that requirement, DSNS works with acquisition partners to create necessary solicitations and other relevant documents to allow partners to acquire goods and services. DSNS provides access to subject matter experts who work with contracting officers in other activities related to procurements such as technical and economic evaluations of proposals.

4. Please see enclosure for a listing of current SNS procurement contracts by company and product.

5. DSNS' primary objective in stockpiling products is to ensure the availability of threat-appropriate materials on a pre-event basis. DSNS works within requirements defined by the PHEMCE and within limitations of available funds to acquire products rapidly and maintain those stock levels continuously. DSNS contracts are awarded in accordance with the Federal Acquisition Regulations and include specific quantity and delivery requirements. Contracting officers acting to respond to DSNS requirements utilize the full breadth of legal and regulatory tools available to them to ensure contract compliance.

Depending upon the urgency of the Department's need, certain legal mechanisms may be available. For example, the Defense Production Act authorizes specified departments to require priority acceptance and performance of "contracts or orders (other than contracts of employment) [deemed] necessary or appropriate to promote the national defense" and to allocate materials, facilities, and services in the same manner. Once the contract or order is received by the contractor, the contractor is required to fill the requirement before filling orders from commercial sources or lesser rated priority orders. Under Executive Order 12919, HHS, with approval from the DHS Federal Emergency Management Agency (FEMA), may utilize Defense Production Act authority with respect to "health resources," which include pharmaceutical and biological supplies.

6. DSNS has adapted readily to the inclusion of pandemic influenza related material. While designed to address a naturally occurring threat, the management of this material is consistent with the DSNS mission to respond to all-hazards. DSNS has assured that product held for pandemic influenza is maintained as required and positioned for rapid deployment. DSNS has developed and exercised plans to deliver pandemic influenza material as required. DSNS actually deployed a portion of pandemic influenza targeted products throughout the United States and its territories in response to the H1N1 pandemic beginning in the spring of 2009 and continuing into the late fall in the same year. This was the first known mass deployment of any nation's stockpiled pharmaceuticals worldwide. DSNS was able to meet all delivery requirements in a timely manner.

During the response to H1N1, DSNS recognized a need to better understand the status of the commercial supply chain for various products required for H1N1 response. DSNS, in partnership with private sector entities, developed a method to consolidate data and communicate that information to stakeholders and decision makers. This "dashboard" was lauded by many officials as being critical to understanding the availability of material during the event and the effort has been described as "unprecedented" by some industry executives.

DSNS has participated in several after action conferences as well as internally identifying areas for improvement for future pandemic or other responses as a result of the 2009 deployment. DSNS is working toward changes to address areas for improvement. For example, PHEMCE has commissioned a workgroup to identify better requirements for the stockpiling of personal protective equipment, including respiratory protection devices, for future all-hazards events. DSNS is also continuing to look for ways to increase information flow with stakeholders using the "dashboard."

7. Inclusion of pandemic influenza related mission and materials has had no appreciable impact on our acquisition of threat-appropriate materials. DSNS has received funds from supplemental appropriations for this specific purpose. However, the 2009 H1N1 pandemic influenza response did result in the redirection of FY 2009 appropriations for SNS to the purchase of H1N1 vaccines not for inclusion in the SNS. This redirection of funds created gaps

in DSNS' ability to continue to pursue other high priority countermeasure purchases for other threats. DSNS is continuing to seek all resources necessary to pursue high priority PHEMCE-defined requirements.

8. DSNS strives to procure FDA-approved MCM or FDA-cleared diagnostics or devices that are manufactured according to current Good Manufacturing Practices (cGMP). FDA is charged with the inspection of manufacturing facilities and approval/clearance of regulated medical products, as part of a company's application or clearance process. In some cases, a MCM may be procured that is not yet FDA-approved or cleared; in this instance, certain safety data must be known in order for the MCM to be placed into the SNS for potential use under an Emergency Use Authorization (EUA), Investigational New Drug (IND) protocol, or Investigational Device Exemption (IDE).

9. SNS stores its inventory according to manufacturers' specifications outlined in the labeling for each item. SNS has the capability to store its inventory in controlled room temperature, refrigerated or frozen settings, as needed. SNS storage locations are monitored and alarmed for temperature, and any excursions are noted and remedied per standard operating procedures. Each location is inventoried annually by a Quality Assurance/Quality Control function of the DSNS Logistics Branch, and audits are conducted routinely by numerous internal and external entities, including the FDA. DSNS also maintains a Quality Control Unit that has oversight of SNS quality issues.

10. DSNS strives to procure MCM that have been approved by FDA or diagnostics and devices that have been cleared by FDA in the United States and manufactured under current Good Manufacturing Practices (GMP). If a shortage of FDA-approved MCM or FDA-cleared diagnostics and devices arises in an emergency setting, DSNS would work with FDA to identify any possible foreign sources whose products are either manufactured and approved with similar oversight through other national regulatory authorities, or under a U.S. investigational new drug (IND) application whereby FDA can evaluate, in the context of appropriate risk assessment, the product profile for safety, efficacy, and quality. DSNS would work with FDA and the Department of Commerce to see if it would be possible to import such identified MCM into the United States. Unapproved MCM or uncleared diagnostics and devices would have to be used under an Emergency Use Authorization (EUA), an Investigational New Drug (IND) protocol, or Investigational Device Exemption (IDE).

11. DSNS is continually working with PHEMCE to prioritize threat-identified needs based on actual availability of products that meet defined requirements. DSNS further works through PHEMCE to address conflicts between high priority countermeasure needs and available resources to acquire and manage those products. Our primary objective remains to hold product for identified threats in sufficient quantity to address threats prior to an event. DSNS has responded to a number of all-hazards events through its existence. We have not encountered a

situation where the exercise of existing contracts or rapid award of additional vehicles did not meet our response requirements.

DSNS has worked with our acquisition partner, the VA NAC, to define and award a "Prime Vendor" contract to address requirements at the time of need that have not been anticipated for response to threat- identified needs. During events, we have exercised that contract to meet requirements successfully. Further, DSNS works through CDC-assigned contracting personnel during events as an additional resource to acquire necessary products and services. Our ability to procure necessary products during an event is not limited to our Prime Vendor contract.

The limitations DSNS continues to address to respond to known and unanticipated requirements are primarily resource limitations, availability of licensed countermeasures or those that could be used under an EUA for certain threat conditions, and state and local capacity to respond successfully.

Thank you again for your letter and your efforts on behalf of the public's health. A copy of this response will be sent to Representative Joe Barton who cosigned your letter.

Sincerely,

Thomas R. Frieden, M.D., M.P.H.
Director, CDC, and
Administrator, Agency for Toxic
Substances and Disease Registry

Enclosure

SNS Pharmaceutical Contracts		
Function	***Vendor Name***	***Product/service provided***
Med-Surg Prime Vendor	Cardinal	Utilized for routine and emergency response procurements
Pharm Prime Vendor	McKesson	Utilized for routine and emergency response procurements
Product procurement for SNS Managed Inventory	Emergent BioDefense Operations Lansing, Inc	FDA licensed BioThrax® - Anthrax Vaccine Adsorbed (AVA)
Vendor Managed Inventory	Gilead	Cidofovir (Vistide) 375mg, 75mg/ml
Vendor Managed Inventory	Bedford	Rifampin 600mg/vial for injection
Vendor Managed Inventory	Johnson&Johnson	Levaquin, 500mg, 100ml bags
Vendor Managed Inventory	Abraxis	Gentamicin soln. for inj., 40mg/ml x 20ml multi-dose vial
Vendor Managed Inventory	Abraxis	Doxycycline 100mg/20ml vial for inj.
Vendor Managed Inventory	McKesson	Tamiflu 75mg Capsules (Blister Pack) Tamiflu Oral Suspension 12mg/ml 25ml
Vendor Managed Inventory	Hospira	Dextrose 5 NACL .45Injection 1000ml
Vendor Managed Inventory	Amgen	Neupogen Filgrastim, 300MCG/ML, 1ML solution for injection

Mr. PITTS. And the chair now recognizes the ranking member emeritus, Mr. Dingell, for 5 minutes for questions.

Mr. DINGELL. Mr. Chairman, thank you for your courtesy. I will be focusing my questions today on the Pandemic and All-Hazards Preparedness Act. My questions will be directed to Dr. Lurie, and I would like a yes or no response if that be possible.

We have made progress but we know from recent events such as the H1N1 pandemic that more must be done to ensure our Nation's readiness to respond and recognize such events. It is also important to note, as Secretary Napolitano recently did, that one of the evolving threats to our Nation is the use of chemical, biological, or radiological devices.

Now, first question, in your role as Assistant Secretary for Preparedness and Response, you have a responsibility for the preparations to address the threat of bioterrorism. Do you believe that a bioterrorism even from a biological weapon remains at or near the top of the Nation's most serious threats? Yes or no?

Ms. LURIE. Yes.

Mr. DINGELL. Next question, do you believe that we currently have the necessary medical countermeasures stockpiled to respond to a bioterrorist event? Yes or no?

Ms. LURIE. Not completely.

Mr. DINGELL. OK. Would you submit to us a statement showing where you feel we need to have more of these kinds of agents stockpiled?

Do you believe that the U.S. is now in a position to recognize and respond to threats such as a bioterrorist event or an emerging infectious disease outbreak similar to H1N1? Yes or no?

Ms. LURIE. I think we have made a lot of progress. We have more ground to cover.

Mr. DINGELL. But the answer is no?

Ms. LURIE. The answer is no.

Mr. DINGELL. Do you believe that the Congress has allocated sufficient funding to develop and procure proper medical countermeasures? Yes or no?

Ms. LURIE. I think we have made a lot of progress. We have more to——

Mr. DINGELL. The answer is still no?

Ms. LURIE. The answer is still no.

Mr. DINGELL. One of the greatest problems we faced during the H1N1 pandemic was delays and interruptions in the production of a vaccine, which has been an ongoing and continuing problem for many reasons. Your testimony mentions the Centers for Innovation in Advanced Development and Manufacturing as one way to increase domestic manufacturing and surge capacity for medical countermeasures. ASPR put out a request for proposals in March. How many centers will ASPR support?

Ms. LURIE. Well, I should tell you that the deadline for submission is today. We have already been receiving submissions.

Mr. DINGELL. Would you give us, then, for the record an answer to that question?

Ms. LURIE. Sure.

Mr. DINGELL. Now, you state in your testimony that the centers will also be available to manufacture vaccines in the event of a

pandemic. Given this, will you take into consideration geographic questions when choosing where to establish these centers? Yes or no? In other words, are you going to consider geographic questions as to where you are going to locate the centers?

Ms. LURIE. I think the most important factor to consider is whether the proposers can do the job.

Mr. DINGELL. Of course. Now, do you believe that the centers will help reduce U.S. reliance on vaccine manufacturers based overseas? Yes or no?

Ms. LURIE. Yes.

Mr. DINGELL. Would you submit for the record a little monograph as to why you feel that would be so?

Ms. LURIE. Certainly.

Mr. DINGELL. Do you believe that these centers will have a role in supporting small companies who have developed or are currently developing medical countermeasures? Yes or no?

Ms. LURIE. Yes.

Mr. DINGELL. And in the case of places like the University of Michigan or other universities where they have substantial spinoffs, this would be a very big help. Do you agree?

Ms. LURIE. Yes.

Mr. DINGELL. Now, Doctor, as you know, the Department of Defense has put out a request for proposals for advanced development and manufacturing of medical countermeasures. Have you been working closely with DOD to minimize any potential duplication between these centers? Yes or no?

Ms. LURIE. Yes. We have been working very closely from the very beginning, they with our proposal and us with them.

Mr. DINGELL. Would you submit to us, please, a brief statement as to what you are doing and how you expect this to assist you and DOD in avoiding duplications——

Ms. LURIE. Sure.

Mr. DINGELL [continuing]. And other kinds of unfortunate events, please?

Mr. Chairman, I thank you for your courtesy. I yield back the balance of my time.

Mr. PITTS. The chair thanks the gentleman and recognizes the gentleman from Illinois, Representative Shimkus, for 5 minutes.

Mr. SHIMKUS. Thank you, Mr. Chairman. Thank you for attending. I am going to kind of stay on my focus on Dr. Lurie also.

And my first question deals with your proposal to extend the shelf life on NCMs. Why is that important and can you go in a little bit more detail?

Ms. LURIE. Sure. Well, right now——

Mr. SHIMKUS. And I think for those who aren't physicians, shelf life, there is an issue there and we don't know really much about the details.

Ms. LURIE. Right. Well, first, let me say that in all of this our primary concern is continuing to make available safe and effective medical products and countermeasures for the American people in an emergency. Particularly with some of the newer countermeasures that have developed, as well as antibiotics and other things that have been around for a long time, if they are stored properly and according to standards, they remain safe and effec-

tive. It turns out that many of them remain safe and effective and maintain their potency beyond the initial date at which everyone thought that they could guarantee their safety and effectiveness. As long as they still work, as long as they are still tested——

Mr. SHIMKUS. And we know that by pulling them all randomly and checking——

Ms. LURIE. We know by them pulling them off randomly. We know them by testing. And there is a very extensive testing process that goes on.

Mr. SHIMKUS. And the stored agents are basically the ones that we most assume we will need readily available.

Ms. LURIE. So they might be vaccines, they might antimicrobials, they might be antitoxins. So we test all of these regularly as part of our stockpile maintenance.

Mr. SHIMKUS. Let me go to a lot of concerns is what you have on hand and may be used that is not on hand, and the ramp-up of something not expected. And in your testimony you talked about the idea of a strategic investor.

Ms. LURIE. Um-hum.

Mr. SHIMKUS. How does that differ from—well, what is that by definition? Because it is a little vague. And is that similar to a private venture capital firm or are you proposing that the government take the role of a venture capitalist in this and that is what this strategic investor is?

Ms. LURIE. So the strategic investor is a nongovernment, private, not-for-profit entity that does some of the things that venture capital companies do but focuses strategically to meet the Federal Government's needs in areas that is not met now. You know, these Centers for Advanced Development help us with the technical problems companies face.

It is also the case as we have looked at our experiments that a lot of companies fail for business reasons or because they can't leverage other resources that accelerate really great ideas. You know, the intelligence community uses this kind of mechanism to get things that it needs. NASA uses this to get what it needs. And we have researched, I think, this very carefully and think that as one of the components of the Medical Countermeasure Review, making sure the companies succeed or helping companies succeed for business reasons is terribly important. Now, this is envisioned as a private, not-for-profit entity not run by the Federal Government. It is not like the Federal Government is going to get into the VC business.

Mr. SHIMKUS. And that is why we ask these questions——

Ms. LURIE. Yes.

Mr. SHIMKUS [continuing]. Because I think if I was going down and trying to figure out who is this? Who manages this? How is this controlled? And I think you answered that question.

Ms. LURIE. OK.

Mr. SHIMKUS. And I appreciate it.

The last question I have is on the Medical Reserve Corps. How effective has that been in current disasters and how does the Emergency System for Advanced Registration of Volunteer Health Professionals—is that segued into that? Is it fully complementary? And are we seeing some positive results from that?

Ms. LURIE. Sure. So the Medical Reserve Corps is a volunteer cadre of people who sign up in their communities to volunteer in case of emergencies, and they have training and they meet regularly and they are rostered and they are available when something happens. They are not a Federal asset. They are a State and local asset.

Mr. SHIMKUS. And the question is have we seen them called out? I mean is it 5 years old.

Ms. LURIE. They respond a lot to local events——

Mr. SHIMKUS. Right.

Ms. LURIE [continuing]. And in fact make it often so States and locals can handle things on their own and don't need the Federal Government. So yes.

Mr. SHIMKUS. And then how does the Emergency System for Advanced Registration and Volunteer Health Professionals segue into that?

Ms. LURIE. So you know that whenever either a State or the Federal Government calls people up, we want to be sure that their credentialed, they are who they say they are, they have got the skills and the credentials for who they say they are. In an emergency, it is not the time to figure that out. You really want to figure that out beforehand.

You know, I will just point to our experience during Haiti where we have thousands of people who wanted to help. They were all well intentioned. Many of them were extremely well qualified, but we couldn't process and certify all of those people in the middle of a disaster. You have to do that in advance so that you are ready to go when you have a disaster.

Mr. SHIMKUS. I know my time has expired, but the question is is it working? Are we doing it? I know what the real world we want it to be but is it working?

Ms. LURIE. So some States have very, very strong advanced registration credentialing programs, and those are working quite well. We are continuing to provide technical assistance and supports to other States to get up to speed.

Mr. PITTS. The chair thanks the gentleman and recognizes the gentlelady from California, Mrs. Capps, for 5 minutes for questions.

Mrs. CAPPS. Thank you, Chairman Pitts and Ranking Member Pallone for holding this very important hearing.

All too often, disaster preparedness is addressed in hindsight once a disaster has already taken place rather than before when it could have been more effective. I am proud of the work that this committee has done to ensure that we are better prepared today and look forward to reauthorizing PAHPA to ensure that we are even more ready if and when disaster strikes.

Today, we are here working together to ensure that important safeguards are in place and that as the result of this work communities will be able to better respond to and recover from public health emergencies. Dr. Lurie, as you might be aware, my district is home to one of two nuclear power plants that the Nuclear Regulatory Commission recently confirmed are located in the highest seismic-risk areas in the country. In Japan, an earthquake and tsunami breached all the safeguards at Fukushima Power Plant and put numerous communities at risk. Needless to say, my constitu-

ents are very concerned about a similar potential threat in their backyards. And even the NRC has a recent report pointing out numerous safety deficiencies in nuclear plant oversight.

So my concern and question for you is what is the current status of our country's preparedness from your vantage point to adequately address radiation exposure? Are there some particular steps we should be taking that we are not and just your general response?

Ms. LURIE. You know, it is a great question, and I think you know that as a Federal Government we did a nuclear power plant accident exercise a couple of months before the Japan event confirming that nothing is really unthinkable. Since both of those events, we have gone back and we are in the middle of a systematic review of all of our public health gaps in radiologic preparedness. So that is right now underway. That is including an assessment of whether we need to be stockpiling potassium iodide for children and going back and reviewing all of the science related to that.

At the same time, we are very aggressively developing a set of countermeasures for radiologic emergencies not only for the blood and bone marrow suppression but for lung, for the intestinal system, and for skin.

Mrs. CAPPS. Well, I am going to be very interested in what you come up with and I would like to ask if it would be OK with the chairman if we ask for that report to be made available to this committee as soon as it is completed.

Ms. LURIE. We would be delighted to come and brief you about what we have learned——

Mrs. CAPPS. That would even be better.

Ms. LURIE. Yes.

Mrs. CAPPS. You know, just in one general area, potassium iodide tablets have been available to my community members in the surrounding region, but since we saw the markers of mild considered exposed in Japan to have increased dramatically. That is one question that I think is certainly in the minds of my constituents as they will also look forward to the results of your study and hope that it will be completed at the earliest possible time.

Ms. LURIE. Right.

Mrs. CAPPS. There is another related but not necessarily just confined to nuclear exposure but surge capacity is another topic that is very much on my mind. I have a background in healthcare and that, of course, is the ability to respond in case of a mass casualty event, whether that be a tornado, a bombing, an outbreak of an infectious disease. The ability of any community to respond to a massive influx of casualties' capacity depends on care across the system, including ambulatory care, hospital care, critical care, trauma and emergency care. Some mass casualty events takes weeks or months to develop such as a pandemic flu or a biologic attack, but many events provide no such warning, as you know.

After a terrorist bomb explosion or a natural disaster such as an earthquake, hospitals and the community would have to be able to respond without any assistance in the immediate minutes and hours without any assistance from State or Federal authorities. Such assistance cannot arrive in time, and that is why I believe surge capacity is so critical to response capabilities.

So there is not enough time to go into this in depth, but could you talk a little bit about the Hospital Preparedness Program and anything else you want to bring up?

Ms. LURIE. Sure. No, thank you. So the Hospital Preparedness Program has been central to getting hospitals prepared to surge in case of emergencies. We also recognize two things that are really important. It is not about only the individual hospital. It is about all the entities in the community being able to do this. And at the end of the day, if we are going to be able to have the surge capacity we need, it has to be built on the back of strong day-to-day systems, especially for those no-notice events you talk about.

So dealing with issues like emergency department boarding and crowding, which I know this committee has had hearings on in the past, central issue here, getting people to the next-lowest level of safe and appropriate care in an emergency, something else that is really central. So as we are moving with the next generation of the HPP program, that set of issues about surge capacity is front and center, being sure that we have the ability to work within the HPP program to innovate and be flexible and test some new models, and that is also really critical.

Mrs. CAPPS. Thank you. And Mr. Chairman, if I could just beg for one follow-up that anything you could do to help our communities just as you had an evaluation or training of facilities, I think our communities would like to train and go through some preparations to be prepared.

Ms. LURIE. That is a great comment and in the program we do continue to support training and exercising all the time.

I would make one last comment. As I have looked at the no-notice disasters that have struck this country since I have been in this, there are many times when States and communities have not needed to call the National Disaster Medical System to provide medical care. They surged and handled it on their own. And I continue to hear it was the Hospital Preparedness Program that got us ready. It was that training and exercising that I really didn't want to do but we did anyone and it really helped.

Most recently in Joplin, you know, we saw them be able to stand up a temporary hospital extremely rapidly after a disaster. And that was done with a lot of support as a result of the kinds of things that HPP does. Similarly, with a lot of the flooding events and others that have happened. So in all of the major events that I have been here to see, I hear from emergency doctors, hospital administrators, State and local public health about this very issue. We did it because.

Mrs. CAPPS. Excellent. Thank you very much. Thank you, Mr. Chairman.

Mr. PITTS. Thank you. The chair thanks the gentlelady and recognizes the gentleman from Michigan, Mr. Rogers, for 5 minutes for questions.

Mr. ROGERS. Thank you, Dr. Lurie, and thanks for working with us on this piece of legislation. Hopefully, we can continue to work together to perfect it in a way that we can here in Congress if there is such a thing.

And I just want to follow up on Mrs. Capps' line of questioning. There is a point of issue that I hope you can help us with is during

an emergency from a terrorist attack or, as we saw with H1N1, it is critical that there is a point person, somebody that makes the decision, somebody that is absolutely in charge. It is not CDC, it is not NIH, it is not the FDA or anyone else. It is you.

Ms. LURIE. That is right.

Mr. ROGERS. How can we improve the functions at HHS to ensure that you are, in fact, in charge of the preparedness efforts? And we understand HHS does work on a consensus model brought by peer review and other things, but in this particular case, I think it is incredibly important that there is a person in charge or it takes longer, as you know. How can we help you clarify that?

Ms. LURIE. Thank you. And I very much appreciate the question. The original intent of the legislation was to do just that. And I have found through this experience that indeed I have the authorities that I need to be in charge. We have strengthened our policy coordination and our preparedness planning with all of the entities involved. So, you know, being in charge during a response also requires sort of being in charge and providing that policy direction in all of the preparations so that when the balloon goes up, you are really ready.

Mr. ROGERS. And do you find you have that?

Ms. LURIE. And I find that the collaboration with the sister agencies and HHS, I don't think it has ever been better. We are working extremely closely together. I think they recognize and respect the fact that we provide policy direction and are in charge. And I think all of the efforts that we have undertaken to coordinate across HHS have done that.

You know, during response, you know, it is really the secretary's operations center run by the Office of Preparedness and Emergency Operations in my office that is the bellybutton for those activities, the central coordinating point for our operational response, and it is my office as well that is the central coordinating point for the strategic and policy response. And that has all become increasingly recognized with each of the events that we have dealt with this year. And I very much understand that I am in charge that I am accountable and I think I have the authorities that I need to do that.

Mr. ROGERS. Well, I am not so interested if you know you are in charge because I think you do. It is the other folks at the table I want to understand that you are——

Ms. LURIE. Right. Right. Right. I appreciate that.

Mr. ROGERS. Yes, thank you. I am going to move to the FDA here for a minute. Last year the HHS conducted a comprehensive medical countermeasure review. In that review you identified the need to improve regulatory science at the FDA to ensure medical countermeasures are given a priority. Specifically, you said the FDA needs "to work with sponsors to identify and help resolve scientific issues as early and efficiently as possible." And I couldn't agree more with that statement. And I think that is absolutely critical. Countermeasures are different than the next generation of—you know, they are different from Viagra. They are different from—clearly. And so having the FDA involved early, to me, is incredibly important.

Can you explain why improving regulatory science at the FDA is so important in your view?

Ms. LURIE. Sure.

Mr. ROGERS. And why early intervention may be different and is important in countermeasures as it is different from other drugs?

Ms. LURIE. Let me do the early intervention part first if I can because I think it will help explain better the regulatory science piece.

You know, if a company is developing a product and gets either hung up scientifically or has a pathway to regulation that is not as clear as it could be, it is really hard for that company to go forward. We have—as I think you know or have heard—really transformed the way in which we work with companies so that now, at the beginning, at the get-go, we do what I affectionately as a primary-care doctor call "case management." We sit down with scientists from FDA, NIH, CDC, BARDA. We look at what the plan is, we provide scientific input and expertise and then now on a very regular basis, we sit down, review the process and the progress with those companies and try to troubleshoot. And FDA is now at the table and a very active participant. It has been very welcomed by companies and I get feedback about that all the time.

Now, if in fact you are moving along on a plan to develop a product and to get it approved or authorized by the FDA and, for example, you don't have the tests necessary to know how effective it is going to be, the time to develop those tests isn't when the company is ready to submit a dossier to the FDA. The time is very early on in the development process. A great example of that has been, you know, the sterility testing for a flu vaccine, which hadn't changed for 30 or 40 years. Now, you know, we are doing things early on to work with FDA and companies to change that process.

So what you need are the tools. You need the scientific tools to evaluate whether a product is going to be safe and effective, and the science has changed so rapidly that we need to be able and we have to ask FDA to use new science, not antiquated science, to do its job. That means that it has to be at least at the pace of or a step or two ahead of where all of these companies are so that when the companies are ready to have their products evaluated, the science is there to do that.

Animal models are another great example. We are working hand-in-glove with NIH and FDA on developing those kinds of animal models so that at the end of the day if an animal model is an appropriate way to move forward, we could do it. So regulatory science becomes central to being able to get a product approved and to clarifying and I think speeding up a regulatory pathway.

Mr. ROGERS. And early intervention with those folks is——

Ms. LURIE. Much earlier intervention. And we have been doing that, as I said, since the secretary's countermeasure review. It seems to be working quite well. In that early intervention, we sort of make a plan. On the vaccine front, we have moved forward with also working on some timelines so that we and the BARDA, the sponsor, FDA agree on the plan, agree on timelines, and we manage to those.

Mr. ROGERS. Good. Thank you.

Mr. PITTS. The chair thanks the gentleman and recognizes the gentleman from Louisiana, Dr. Cassidy, for 5 minutes for questions.

Mr. CASSIDY. I thought I was third in line.

So Dr. Koh, I appreciate the anti-tobacco efforts, but let me just be a contrarian for a second. We just raised taxes tremendously on tobacco. Do we know that the effects of this taskforce, which I am sure consume a fair amount of resources—are they responsible for our decrease in tobacco usage or would it just be the fact that we are taxing the heck out of it and that it making it less affordable for people to smoke?

Mr. KOH. Well, there are many parts to tobacco control, Congressman, and the plan that we have put together really accomplishes a multi-pronged approach. So you mentioned one, which is raising the price and just about every State has done that in the last 10-plus years.

Mr. CASSIDY. So let me ask you, has there been any sort of, for example, regression and analysis to see if there is a secular trend that is just continuing downward usage as we increase taxes versus this kind of significant commitment of Federal resources which, frankly, I like, but I am wondering could we redirect those resources if taxes are doing it all for us?

Mr. KOH. Well, Congressman, this is one area in public health that we have tremendous science; we have tremendous data. We know what works. We know raising the price works. We know that community-based interventions work. We know that quit lines work. We know that providing cessation services to smokers who want to quit is extremely helpful. So the challenge is to put it all together so that we can have a country where we are reducing the suffering here. We do know that tobacco usage, which was declining for many years has stalled over the last 7 or 8 years, and that is actually why the secretary asked me to convene this group. And so we hope we can——

Mr. CASSIDY. Well, let me ask you because, again, I think as part of the CHIP reauthorization last year, there was a dollar a pack placed. Now, was there any sort of downtick in tobacco usage with that dollar-a-pack tax? And did that precede the efforts of your interagency——

Mr. KOH. It preceded the efforts of our group. And the economics of raising tobacco prices has been extremely well studied. In fact, we know that raising the price about 10 percent decreases consumption 4 percent for adults and even higher for children. So that was a Federal effort from several years ago. I think you are referring also to State efforts. And each governor of both parties actually in just about every State has raised taxes over the last decade or so.

But I do want to stress again, Congressman, that is an important and well studied intervention, but it is only one intervention.

Mr. CASSIDY. I guess but what I am wondering is does that overwhelm the efficacy of all the others?

Mr. KOH. We need all the efforts. I am a physician. I——

Mr. CASSIDY. No, I accept that, but I am just wondering, again, as we have scarce resources, I guess I am asking is there a secular trend whereby all others pale in significance. Sure, if taxes are not

raised, then we need the others, but if taxes are raised, the others are obviated?

Mr. KOH. The price can increase can help to some degree and I have presented the numbers to you, but we also know that tobacco addiction is a really tough addiction. I know you know that as a health professional, Congressman. And so do I. I am a physician who has cared for patients for over 30 years. So when you see people who are hooked and they want to quit and they haven't been able to, you need every resource and you also need additional resources to prevent the next generation from taking up——

Mr. CASSIDY. I am just asking is there statistical data to show that these other interventions help over and above——

Mr. KOH. Absolutely.

Mr. CASSIDY [continuing]. But I am also out of time, so let me just kind of try——

Mr. KOH. Yes, and let me just say, Congressman, this area has been extremely well studied. I would be glad to provide you more materials, but we need many approaches here to tackle this problem.

Mr. CASSIDY. That would be good if you could. And again, I am not saying we shouldn't do it. I am just saying if we have got limited resources, where do we spend it sort of thing.

Let me ask you also, just broadly, as long as I have you—and either of you can answer—but I am struck that sometimes it seems—as perhaps you know, I am a doctor that treats diseases of the liver——

Mr. KOH. Right.

Mr. CASSIDY [continuing]. And societal and economic impact is tremendous, and yet the amount of funding from the Federal Government kind of pales in significant to some other illnesses which, arguably, don't cost more if you will. Is there any sort of metric as we do funding for Federal activities that I can imagine a metric named morbidity, mortality, years of life lost, potential—because smallpox clearly doesn't kill anybody now but the potential death is tremendous—is there any sort of metric applied to this or is it more or less historical funding moving forward?

Mr. KOH. I can start and, Congressman, I really appreciate your support of the Viral Hepatitis Strategic Plan. I remember when you testified and presented in front of our congressional briefing, and I know you have spent much of your career caring for patients with hepatitis, so we really appreciate that.

And you all know that if you intervene on hepatitis, you can prevent liver cancer and prevent liver transplant, all of which drives up healthcare costs in this country.

So with respect to your question, obviously, these are very challenging budget times. We have launched this plan to address a rising public health need. We do need to bring in as many resources on the table from many parts of our——

Mr. CASSIDY. Well, let me ask you because I am frankly out of time but I am asking do we have any sort of metric by which Federal funding for addressing illnesses applied or it historical funding that kind of continues for it? Is it active politicians determining how we spend our dollars or is there a metric that is applied that

scientifically says we should put X number of dollars here, Y there, and Z here?

Mr. KOH. Well, those metrics have been well defined for tobacco. For hepatitis less so.

Mr. CASSIDY. Well, I am just saying globally. OK, we have this death rate from HIV, this from breast cancer, this from prostate, this from hepatitis, this from smallpox——

Mr. KOH. Right.

Mr. CASSIDY. And do we have a metric that then determines how we do our spending?

Mr. KOH. Again, they are State-by-State guidelines for spending on tobacco that are very well defined from scientific data but on hepatitis there is less so.

Mr. CASSIDY. OK. I yield back. I think I know what the answer is.

Mr. PITTS. The chair thanks the gentleman and recognizes the gentleman from Georgia, Dr. Gingrey, for 5 minutes for questions.

Mr. GINGREY. Mr. Chairman, thank you so very much. And I was going to direct my question to Dr. Koh, but as usual, my good friend and colleague from Louisiana stole all my thunder and I will have to then direct my question—I will let you take a breath, Dr. Koh, and I will direct mine to Dr. Lurie.

Dr. Lurie, you mentioned in your testimony about the Emergency Medical Countermeasures Enterprise Review, MCM Review in August of last year that articulated "a vision for a nimble, flexible infrastructure to produce MCMs rapidly in the face of an attack or threat, including a novel, previously unrecognized naturally occurring emerging infectious disease"—that terrorists or hostile governments might use a drug-resistant form of bacteria or other infectious disease as a weapon against us, against the United States?

Ms. LURIE. Well, one of the great things is that the scientific methods and tools to do all kinds of things we call synthetic biology has progressed tremendously. One of the very scary things is it has become a lot more automated and a lot easier—I don't know if you have seen these articles about the DIY, the do-it-yourself, you know, garage manufacturing of——

Mr. GINGREY. Yes, we actually heard a little bit about that activity from our first witness, our colleague, Charlie Dent, in regard to some of these——

Ms. LURIE. Good point.

Mr. GINGREY [continuing]. Synthetic drugs——

Ms. LURIE. And so, you know, the technology to genetically engineer all kinds of deadly organisms is there. It is available. It is becoming more available and we have to be very prepared for those kinds of things.

Mr. GINGREY. So a real threat.

Ms. LURIE. Yes, it is a real threat.

Mr. GINGREY. Well, look, let me ask you this, then. If we ever meet these emerging threats, we need more novel antibiotics, yet our current development is not as robust as it needs to be. And you mentioned in your testimony that MCM Review had identified choke points where product development was—and I will quote you—"stalling or failing."

Ms. LURIE. Yes.

Mr. GINGREY. Can you take a moment and describe some of these choke points and disincentives in the current antibiotic development pipeline? Because I think you know I had some real interest in this area.

Ms. LURIE. Right. No, I appreciate that and I am glad you have interest in this area because antimicrobial resistance is terribly, terribly important.

In the medical countermeasure arena, we focus on antimicrobial resistance for two reasons. One is because of the genetically engineered set of issues. The other, quite honestly is because antimicrobial resistance complicates our ability to treat and save lives from trauma, from H1N1 where something like 40 percent of kids died from methicillin-resistant staph complicating their H1N1 infection, et cetera. So if we are going to meet our mission in the countermeasure arena and in the preparedness arena, we have to have novel antibiotics. Now, to the sets of issues about the choke points——

Mr. GINGREY. It might be little off the subject matter of the day, but I mean it would be true, too, in cancer to chemotherapy patients, you know, whose immune system is beaten down, they have no platelets, they have no T-cell lymphocytes and then all of a sudden their own enteric bacteria is a tremendous threat to them and they need more than just the usual off-the-shelf, third-generation wonder drugs.

Ms. LURIE. But one of the things that I think is not as appreciated about this whole medical countermeasure enterprise that we are embarked on is that an awful lot of the developments that are coming through this pipeline, whether it is novel antimicrobials or a next-generation ventilator, actually have benefits to a broader population in this country even if we are never attacked, for example, or don't have a new kind of threat. And a goal is for us to do those multi-use and dual-use things as much as we can.

Mr. GINGREY. Sure. Absolutely.

Ms. LURIE. Our primary mission is to meet our counterterrorism and biological——

Mr. GINGREY. I have got 30 seconds left so I am going to shift just for a second. Mr. Shimkus was asking you a little bit about our preparedness for a disaster of any kind. And I am thinking Katrina because I remember jumping on a plane. I had been out of the practice of medicine for a couple of 3 years and flying down to Louisiana and just say here I am, I have got my white coat, my stethoscope, and here is my medical license. It is still active. Let me help out. I don't think the Red Cross had any way, shape, or form of checking on me to see if anything had been suspended or whether I truly was an OB/GYN or maybe somebody with a criminal background indeed.

But in any regard, I think what he was trying to get at was at the Federal level—you said the States and I think the States are indeed doing a good job in regard to that, hopefully all of them will—but we need to get that data, don't you think, at the Federal level where somebody on the ground when the next—Mrs. Capps talked about if another—obviously, we all know another disaster is going to occur in some shape or form, be it an earthquake or what-

ever. But we need that information and if you could just comment very quickly.

Mr. Chairman, if you will let her do that and then I will yield back.

Ms. LURIE. First, I just want to comment that when Katrina hit and people came here, I walked into the armory with a stethoscope around my neck. They said are you a doctor? I said yes, and they set me loose. I didn't even show a license. So I do think that we have to protect people and let them know—you know, be sure that they are who they say they are and they are really qualified to practice whatever their profession is.

I do think we need a national system to be able to rapidly look at somebody's credentials and give them the OK. You know, we also have a set of challenges that we continue to face because State by State, you know, there is not license reciprocity across all States. So a governor can, you know, use their—I think we talked about it in another meeting—the metric smoke stick and say in an emergency, you know, situation I will accept licensed providers from another State and do that, but everybody needs, then, that mechanism to know are they licensed providers and to have that work in a hurry.

On a Federal level, we credential everybody you know in advance through the National Disaster Medical System and we have been working very aggressively since the Haiti earthquake to be able to credential people in other specialties, particularly in the critical care area and some of the specialty surgical areas and trauma areas where we don't necessarily have a full cadre of people on each team so that when a disaster happens, we can pull those volunteers from anywhere in the country and put them to work joining our NDMS teams. And that is actively underway.

Mr. PITTS. The chair thanks the gentleman and recognizes the gentlelady from North Carolina, Mrs. Myrick, for 5 minutes for questions.

Mrs. MYRICK. Thank you. I appreciate it. And thank you both for being here. I am sorry I have to leave for a few minutes. I understand that there are like 44 million doses of the first-generation anthrax vaccine for the Strategic National Stockpile for civilian use. Is that roughly about right?

Ms. LURIE. I would have to check on exactly what the number of doses in the stockpile is now but we are continuing to add to it.

Mrs. MYRICK. Well, I know that is a lot of the budget obviously.

Ms. LURIE. Yes. Right.

Mrs. MYRICK. And I know back in 2004, HHS issued a requirement to purchase 75 million doses of a second-generation anthrax vaccine. How are you going to move forward on that? Do you know? I mean is that something you have looked into?

Ms. LURIE. Well, so issuing the requirement, you know, really means that we have a public health and preparedness need for that.

Mrs. MYRICK. Um-hum.

Ms. LURIE. Sometimes when we issue a requirement, there is something kind of off the shelf already licensed that we can go buy. Sometimes when we issue a requirement, that product doesn't exist

and we have to make it. That is what the advanced development piece is really about.

Mrs. MYRICK. Um-hum.

Ms. LURIE. And so we have invested in the advanced development of a next-generation anthrax vaccine largely because the current vaccine, you know, really takes multiple doses——

Mrs. MYRICK. Yes.

Ms. LURIE [continuing]. To develop immunity and isn't ideal from the perspective of needing to respond to a public health emergency involving millions of people.

Mrs. MYRICK. But a second generation that is being developed, is that——

Ms. LURIE. We are seeking next-generation vaccines that would, you know, when they are developed—and the requirements is that they have to meet certain, you know, specifications so that ideally we would like something, you know, that is one shot and works quickly. We are not there yet in the development process. This is a great example of where science is hard. The development process is cumbersome and it takes really all the best scientific minds and the creativity of many of our industry partners to do that.

Mrs. MYRICK. Well, is this another area where you have to have investors that are willing to do this? I mean I know all of this, if you produce these countermeasures, is very expensive. What kind of tools do you have at your disposal?

Ms. LURIE. It is a great question. So right now we use advanced research and development funds to be able to do that. And as you probably recall, PAHPA gave us the authority to spend money on these advanced research and develop purposes, and that is what we need to do.

The strategic investor seeks to do two other things that are really important to think about. One is that, you know, some of these companies have great scientific ideas but not a lot of business expertise and so fail not for scientific reasons but for business reasons. And so the strategic investor, first of all, seeks to help them with those business issues. And secondly, it seeks to identify companies that might be working on something for a commercial application. They don't want to work on anthrax because there is not a good market for it, but they could say you have got a really great idea and something innovative. And we are going to take us in our venture-capital-like state, we are going to sort of take a risk, invest in you, and working with us say we want you to take this platform, this idea and apply it to the anthrax problem. That is exactly what it is intended to do.

Mrs. MYRICK. Yes, you have answered some of this while I was gone, I apologize. I can always look at your testimony. But the strategic investor is actually working with HHS or for HHS? Is that what I understand?

Ms. LURIE. The strategic investor, as I explained to Mr. Rogers and I am happy to again would be a private, nonprofit entity that exists outside of government.

Mrs. MYRICK. OK.

Ms. LURIE. But what we have to do is say here are the kinds of things that we need you to invest in. We have a requirement for a next-generation vaccine whether it is for anthrax or purple spots

and please, you know, go stimulate the development of those things through the ways in which you work as a strategic investor.

Mrs. MYRICK. And maybe he asked the same question, but about the strategic investor——

Ms. LURIE. Yes.

Mrs. MYRICK [continuing]. Is that someone that is actually like a consultant to HHS or something? Is that——

Ms. LURIE. No, it is not.

Mrs. MYRICK. It is a volunteer or a——

Ms. LURIE. No, I think it would be a private, not-for-profit company ideally, and it would act in many ways like venture capital companies act——

Mrs. MYRICK. Right.

Ms. LURIE [continuing]. But also act to invest strategically. So one of the things I explained is that the intelligence community does that now. NASA has done that in the past.

Mrs. MYRICK. Right.

Ms. LURIE. There are a number of examples across government where that has been very successful. We didn't dream it up ourselves.

Mrs. MYRICK. Is that the type of thing that you would be looking at, then, on the——

Ms. LURIE. Yes. We are looking for the authority to start a strategic investor so that we can use this additional tool to get the kinds of products we need.

Mrs. MYRICK. Thank you very much.

Ms. LURIE. Yes.

Mrs. MYRICK. Thank you, Mr. Chairman.

Mr. BURGESS. [Presiding] The gentlelady yields back.

The gentlelady from Washington State is recognized for 5 minutes for the purposes of questions.

Mrs. MCMORRIS RODGERS. Thank you, Mr. Chairman.

My questions relate to the Enhancing Disease Coordination Activities Act of 2011, and I wanted to ask how the committees for specific diseases and conditions will be established and then how the bill changes the current process.

Mr. KOH. Well, first of all, Congresswoman, thank you for your interest in the support of public health. I know you have been a leader in many areas, and we appreciate that. In my testimony, I did review a number of areas where we have strategic plans and implementation efforts and then also did review that we have actually many advisory committees up and running. So the proposed legislation supports that general theme, which we applaud. And in fact the mission of my office, the Secretary for Health's office is to advance that coordination on behalf of the Department and the country.

The provisions in the proposed legislation that require a strategic plan update every 2 years might hold us to a level where we are perhaps spending too much time on that effort and not enough on implementation. So that current status that we have offers us more flexibility.

And then I did review and mention that the unintended consequences of a legislation like this might be to drive up cost because putting together committees and running them adds to our

budget issues. So those are some of the areas that we reviewed for you.

Mrs. MCMORRIS RODGERS. In our experience in developing a strategic plan for Down syndrome, the patient advocacy organizations and private research foundations provide critical insight into what is needed to move a research agenda forward. And for example, as we speak, the Down syndrome community is in the process of working with the National Institute of Child Health and Human Development to establish a consortium that includes patient advocacy organizations and researchers. This interaction is critical to furthering one agenda. And I have a little bit of a concern that the draft bill we are discussing today keeps too much authority with the Federal agencies with respect to the development of a research strategy, possibly to the detriment of the collective goal of finding a cure or treatment. And I just wanted to ask you to comment and could the legislation be strengthened by including a role for stakeholders?

Mr. KOH. Well, thank you for raising attention to that particular issue. And we are pleased to report the evolution of that consortium as you just mentioned, and there is a very concerted effort at NIH to have a cross-trans-NIH coordinating committee on Down syndrome, which I understand is up and running and moving very, very well. In all these efforts, current and proposed, we make special efforts to bring in the best experts in the country so that we can do our work really informed by people who are learned and have spent their career studying these issues. And then we want the portfolio and the public health areas addressed to focus not just on research but on services and public health dimensions in the broadest sense. So that is what we try to do. Currently, I think the proposed legislation really resonates with that theme as well.

Mrs. MCMORRIS RODGERS. OK. Thank you. I appreciate you answering those questions.

Mr. KOH. Thank you.

Mr. BURGESS. I am sorry. I didn't see you. You came in so quietly.

The chair now recognizes Mr. Green from Texas for the purposes of questions.

Mr. GREEN. Thank you, Mr. Chairman, and I know it is unusual for a Texan to sit quietly but I want to thank each of you for being here. This is my first term in Congress at least on the Energy and Commerce Committee. I haven't been on the Health Subcommittee and I appreciate the opportunity to weigh in on the hearing on H.R. 2405 introduced by both Congressman Rogers, a number of members, and myself. I am an original cosponsor of the legislation. I am pleased it is a bipartisan piece of legislation. It appears there are a few issues germane that need to be worked about before this bill moves to subcommittee markup. I know there is an interest in the sharing special considerations given to children during national emergencies, and I hope we will resolve this issue before the markup.

The University of Texas Medical Branch's Galveston National Lab is one of the two national biocontainment labs constructed under grants awarded by the National Institute of Allergy and Infectious Disease and the National Institute of Health and I am

proud much of this research is literally performed in the backyard of my district in Houston. And I was happy during Hurricane Ike that there was lots of damage but the lab was very safe.

At this BSL–4 lab research is conducted to develop therapies and vaccines and tests for diseases like anthrax, Avian flu, the bubonic plague, hemorrhagic fever such as Ebola, typhus, West Nile virus, influenza, and drug-resistant tuberculosis.

I have a personal interest in this legislation because my daughter was actually at UTMB during her fellowship and did some work there in studies at the BSL lab, and believe me, when you talk about my concern from our colleague from Georgia, Dr. Gingrey, about—I was at the Astrodome when we evacuated a quarter of a million people from New Orleans, and you are right, Doctor, there were folks running around everywhere because the medical community in Houston literally came together, and I was amazed at what happened. And as we know, medical facilities, nonprofits, and profits sometimes compete with each other and their neighbors, but I watched them that doing such a great job on triaging these folks who literally were picked up in New Orleans and had no medication, no medical records unless they were veterans. In those cases we were very lucky.

But my concern today is that Texas A&M, University of Texas, and Baylor College of Medicine, along with Texas Children's Hospital in Houston, along with GlaxoSmithKline, along with many other distinguished partners in a newly established and developed National Center for Innovation and Advanced Development and Manufacturing in Texas. The purpose of the center will be to develop medical countermeasures to ensure domestic vaccine manufacturing serve capacity for emerging and infectious diseases, pandemic, influenza, and other threats during public health emergencies utilizing flexible and multi-product technologies. These public and private partnerships along with academic research institutions are vitally important both in the Federal Government and the private companies as we work to develop novel bioterrorism measures. Solicitations for these efforts were issued by HHS on March 30 of 2011.

My first question is can you discuss the Center for Innovation and Advanced Development and Manufacturing and the process going forward for these important institutions, Dr. Lurie? And I believe these centers will be at the forefront of developing medical countermeasures needed by our country in the event of a bioterrorism event.

Ms. LURIE. Thanks so much for your question and for your recognition of Advanced Development and Manufacturing facilities. You know, they were another critical piece of the recommendations of the secretary's Medical Countermeasure Review, and they are intended to provide technical expertise and core services to the small companies that get into the countermeasures space and need help. You are right, we did issue the request for proposals, and the deadline for proposals is today. We are receiving applications and we are very excited about that. And we will be reviewing those applications over the course of the year working to be sure that we can identify the very best entities to do that job and then after that hope to make one or more awards.

Mr. GREEN. One of the concerns I have is BARDA has issued contracts that are fulfilled by international companies with production facilities in Europe. This leaves open the question of supply security and job creation in our own country. Is BARDA committed to allowing contract modifications for pandemic flu vaccine development that will bring some of those jobs back to the U.S. so you can supply us with these contract modifications?

Ms. LURIE. We are very focused on domestic manufacturing of our critical countermeasures, including pandemic vaccines. And that has been the focus of much of our work.

Mr. GREEN. OK.

Ms. LURIE. And I think certainly what happened in the pandemic very much showed us the criticality of domestic manufacturing.

Mr. GREEN. OK. Thank you.

Mr. Chairman, thank you.

Mr. PITTS. The chair thanks the gentleman. That concludes our first round of questioning. We will go to one follow-up on each side. Dr. Burgess is recognized for a follow-up.

Mr. BURGESS. Thank you, Mr. Chairman.

Dr. Lurie, Representative Markey of this committee amended the Public Health Security and Bioterrorism Preparedness Response Act in 2002 to make potassium iodide available to State and local governments to meet the needs of all persons living within a 20-mile radius of a nuclear power plant. However, the Nuclear Regulatory Commission in both the previous administration and in this administration has not enforced this provision. Have there been any studies done on the health effects of the difference on health effects done at different differences and will we have a large enough supply of potassium iodide to provide for us in a 20-mile radius?

Ms. LURIE. Thank you for that question and I think it is a question that has been on everybody's minds since Fukushima. And certainly planning for a radiologic disaster is part of our all-hazards preparedness. You know, that disaster has caused us to go back and try to look at what all of our public health gaps are and to try to look at, you know, should there be a requirement for potassium iodide, particularly for children in the stockpile? And then how much should we stockpile? How much should that be? So because we in public health like to apply the best available science that we can, you know, going back we have been reviewing all that. We are doing a lot of modeling right now to determine is there a requirement and how big it should be so that we can protect children. It is fair to say, I think, that Fukushima sort of challenged a number of our assumptions about an event.

Mr. BURGESS. Sure, well, let me ask you this. I mean apparently it is my understanding that you have the authority to purchase the potassium iodide. Is that correct?

Ms. LURIE. We have the authority.

Mr. BURGESS. And you have the money? The money has been appropriated in previous Congresses. Is that correct?

Ms. LURIE. That is right.

Mr. BURGESS. But the money has not been spent.

Ms. LURIE. So right now we are in the process of figuring out—so we had pediatric potassium iodide in the stockpile, you know,

and that is now set to expire over the next year or two. And so what we need to figure out right now is how much do we need to have in the stockpile to adequately protect the American people? And that is what we are doing right now. And once we figure that out, assuming that we agree that there needs to be potassium iodide in the stockpile, I think that we will act on that requirement.

Mr. BURGESS. Are you looking at larger radiuses than a 20-mile radius as was outlined in Mr. Markey's amendment? Has the experience in Japan taught us anything there?

Ms. LURIE. You know, I think what we are doing is, you know, taking all of the science into account and taking what we have learned from the recent event and trying to figure out what does it best take to protect the population, whether it is going to be what the exact radius is that we are going to settle on, you know, I think that is going to really depend on what the science shows us.

Mr. BURGESS. The potassium iodide itself is a relatively stable compound. Does it really go bad?

Ms. LURIE. You know, we just had that discussion as we looked at shelf-life extension for the pediatric potassium iodide that is in the stockpile. And FDA was really a terrific partner with us in rapidly testing the liquid to try to look at its stability over time. I think the stability of the liquid version and the tablet version are different but we do need to sort out what the shelf life of it is and when it is, you know, safe to do the shelf-life extension. It sort of highlights the need for some of the shelf-life extension authorities potentially.

Mr. BURGESS. Well, I remember in my district in the H1N1 crisis the FDA released all kinds of outdated antiviral medication and I was assured by Dr. Hamburg that it was just as good as the day it was minted and that they were revising some of those shelf-life expiration dates on a much more complex molecule than potassium iodide, which is relatively straightforward.

Let me just ask you a question. Do you have any concern about the availability of potassium iodide? As I understand it, it is the only treatment that is currently available for prevention of uptake of radioactive iodine by the thyroid and particularly in young populations. Are you concerned about the availability of potassium iodide?

Ms. LURIE. Well, I think what one of the things that we said during the Fukushima event was this incredible epidemic of fear in the United States and there was a huge run on the companies. And so people bought up short-term the available——

Mr. BURGESS. Yes, that is kind of the point.

Ms. LURIE [continuing]. Supply.

Mr. BURGESS. That is kind of the point.

Ms. LURIE. Yes.

Mr. BURGESS. We assure people that we have——

Ms. LURIE. What we need to do is be sure that we have it where we need it, that it is stockpiled where we need it. You know, there have been plans to stockpile it around nuclear power plants. It is exercised differently in different States. That is one of the things that we looked at.

Mr. BURGESS. My understanding is that Janet Napolitano just today released information that was gathered in the Osama bin Laden compound about al-Qaeda's desiring to infiltrate nuclear power plants in this country and reek some sort of damage. So this is not just a theoretic concern. If the Secretary of Homeland Security is out there talking about this, then our National Strategic Stockpile should reflect that level of concern. And really I urge you to spend some energy on doing that.

Ms. LURIE. No, I appreciate that. And I think we all very much appreciate the concern and that is why we are in the midst, I think, almost a closure on coming up with, you know, the recommendations about how much we should stockpile. I don't think any of us has any question that this is a concern and I don't think any of us have any question that we need to protect the American people in this way.

Mr. BURGESS. Thanks, Mr. Chairman. I will yield back.

Mr. PITTS. The chair thanks the gentleman and yields to Mr. Pallone for follow-up.

Mr. PALLONE. Thank you, Mr. Chairman.

Dr. Lurie, I was going to ask you this before so I didn't have a chance. I wanted to ask about our current efforts on biosurveillance. As you know, in many cases of bioterrorism or natural disease outbreaks the first clue is that people seek medical care for their condition. And sometimes the condition may appear like other common conditions and could be missed unless there is a system to detect unique features of an outbreak. And biosurveillance is the ability of our system to detect these ongoing outbreaks whether natural or manmade. I am concerned because there was a recent GAO report in December that suggests that HHS should be doing more to provide a strategic plan for situational awareness.

So I have two questions. I will mention both. In your professional opinion, do we have adequate capabilities for biosurveillance and what are we doing to enhance these capabilities? And can you tell us how the public health infrastructure relates to the biosurveillance infrastructure?

Ms. LURIE. Sure. Great questions and issues that I think are very much on my mind all the time. I appreciate that.

You know, surveillance and recognition of outbreaks is most often something that happens locally. Sometimes it happens through an astute clinician who happens to see something more than once. Sometimes it happens through other surveillance systems that are in place in health departments and hospitals throughout the country. At the end of the day, our preparedness in this country, particularly in this area is built on the back of strong day-to-day systems. We see around the country right now, because of the economic situation, real threats to public heath, an erosion of public health capabilities. So something like 40,000 jobs in the State and local level in public health have been compromised over the past couple of years. They have either been lost or been cut back drastically.

Mr. PALLONE. They lost their jobs, then.

Ms. LURIE. So people have lost their jobs, they are working part-time, and right now it is often only money that is coming through a public health preparedness vehicle that is holding that surveil-

lance capability together at the State and local level. So when you say do we have biosurveillance capability and how good is it? We know the techniques, we have the tools, and we know what to do, but we have to make it work and be sure it works day to day on a State and local level and doesn't get eroded as we are falling on hard times because this erosion at the end of the day compromises our national security.

Mr. PALLONE. I mean it is true, you know, I mean it is a long time since I was a councilman, but I was at one time, and I remember going over the budget and it was often the case that, you know, somebody that would say let us cut back on, you know, the health department because, you know, nobody really knew what they did and also, you know, if you are talking about something that may happen in the future, it is easy to say, well, I don't know if that is going to happen so why should I deal with the preparedness? I mean I see that that is a significant problem.

But Chairman Pitts and I were talking about how important this hearing is and how interesting it was because, you know, you can't take that attitude. You have to take the attitude that, you know, we need to prepare. But it is hard. It is hard from a political point of view because people, you know, they don't want to prepare for contingencies that may never occur and it is easy to think that they never will occur.

And, you know, this is of course after the fact, but one of the things that we have in my district is we have one of the 9/11 clinics, you know, mostly first responders who sustained all kinds of health problems from 9/11. And, you know, I talk to the people that are in charge of the clinic from time to time and even today, you know, they are still coming up with diseases and disorders that, you know, are unforeseen or that, you know, manifest themselves years later. So it is just so important. But it is difficult, you know, to deal with this issue and to be prepared. I mean I am only looking at it after the fact but obviously when you talk about it before the fact, I think it is even more difficult.

Ms. LURIE. And, you know, I think this reluctance of people to always want to think about the unthinkable even though it has happened an awful lot since I have been here is in part human nature and it is part something we have to work against. But it also, I think, shows us the importance of being sure that the day-to-day systems are really strong so that the systems that detect your foodborne outbreaks, the systems that detect seasonal flu, the systems that do these other things and function in the background day-to-day to prevent us from infectious diseases and do that kind of surveillance have to be strong if we are going to be able to detect a bioterror event or a new emerging disease. We are working, you know, again through BARDA on the diagnostics end of this, but there is that whole local infrastructure that has to be on the ground to make this work.

Mr. PALLONE. Thank you. Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman, also thanks the witnesses. Excellent panel, great testimony. Thank you very much for answering our questions.

In conclusion, I would like to thank the witnesses and the members for participating in today's hearing. I remind members that

they have 10 business days to submit questions for the record, and I ask the witnesses to respond promptly to the questions. Members should submit their questions by the close of business on August 4.

This subcommittee is adjourned.

[Whereupon, at 12:06 p.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

Opening Statement of the Honorable Joe Barton
Chairman Emeritus, Committee on Energy and Commerce
Subcommittee on Health
"Legislative Hearing to Address Bioterrorism, Controlled Substances, and Public Health Issues"
July 21, 2011

Thank you, Mr. Chairman, for holding this hearing to examine these important pieces of legislation. As we discuss the provisions in these bills, I hope we can work together in a bi-partisan fashion so that we may improve the health, safety, and wellbeing of all American citizens.

Each of these bills represents important steps we must take to ensure that our agencies are well equipped to adapt and respond quickly to a changing environment with a common goal. As science and technology advance, we must be prepared to take these steps to protect our citizens.

Congressman Dent's bill, The Synthetic Drug Control Act, addresses an issue that did not exist only a few years ago. Today, in many states, you can buy synthetic chemical substances designed to simulate drugs such as cocaine and marijuana. These powerful and dangerous drugs are not approved for medical use by the FDA, but because of a loophole in the law, they are not illegal.

H.R. 2405, the Pandemic and All-Hazards Preparedness Act of 2011, will also address new and changing threats to our citizens. This legislation will improve the Nation's public health and medical preparedness and response capabilities for emergencies. I worked closely with the Senate on this bill in 2006, and I look forward to working with my colleagues again this year to move this important piece of legislation.

I thank the Chairman for holding this hearing and I look forward to hearing from our witnesses today. I yield back.

Statement from Representative John D. Dingell
House Committee on Energy and Commerce
Subcommittee on Health
"Legislative Hearing to Address Bioterrorism, Controlled Substances and Public Health Issues"
July 21, 2011

Thank you Mr. Chairman for holding today's hearing.

I like meetings like this. This meeting is an example of what can be accomplished when we truly legislate effectively in the manner our forefathers envisioned: members on each side of the aisle come together to draft legislation that will have a strong and positive impact on the health of the American public.

I want to voice my support for the bills before us today. H.R. 2405, the Pandemic and All-Hazards Preparedness Act of 2011, will reauthorize two pieces of biodefense legislation – Project Bioshield and the Pandemic and All-Hazards Preparedness Act of 2006. Reauthorizing these technical, but critical programs will help to boost our public health emergency response capabilities so that we can best ensure our communities are prepared in the event of an infectious disease outbreak or act of bioterrorism.

I also support H.R. 1254, the Synthetic Drug Control Act, which would ban dangerous synthetic drug substitutes that mirror stimulant properties similar to marijuana or cocaine. Like many parents, I worry about children being able to purchase these substances legally for ill-informed and dangerous recreational use. I do not make a decision to ban materials lightly, but I believe in this instance it is necessary and just to protect today's children from synthetic drug abuse.

Lastly I also lend my support to the discussion draft entitled Enhancing Disease Coordination Activities Act. We have seen under the Combating Autism Act the good work that can be done when government agencies, such as HHS, are able to form interagency committees to coordinate research and collaborate on treatment proposals. Such collaboration helps to prevent duplication and ~~to~~ advances research and treatment. This is a simple and effective solution to curbing government waste and encouraging development of cures for diseases that impact American families.

I hope that today's hearing will help the bipartisan discussion continue and progress the work being done on these pieces of legislation, and I wish to continue working with my colleagues as we move forward.

112TH CONGRESS
1ST SESSION

H. R. _____

To improve the coordination of research and other activities conducted or supported by the Department of Health and Human Services that are specific to a disease or condition, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

M__. _____ introduced the following bill; which was referred to the Committee on _____

A BILL

To improve the coordination of research and other activities conducted or supported by the Department of Health and Human Services that are specific to a disease or condition, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Enhancing Disease Coordination Activities Act of 2011".

SEC. 2. COORDINATION OF RESEARCH AND OTHER ACTIVITIES SPECIFIC TO A DISEASE OR CONDITION.

Part B of title II of the Public Health Service Act (42 U.S.C. 238 et seq.) is amended by adding at the end the following:

"SEC. 249. COORDINATION OF RESEARCH AND OTHER ACTIVITIES SPECIFIC TO A DISEASE OR CONDITION.

"(a) ESTABLISHMENT.—The Secretary may establish committees, to be known as coordination committees, to coordinate research and other activities conducted or supported by the Department of Health and Human Services that are specific to one or more diseases or conditions.

"(b) RESPONSIBILITIES.—Each coordination committee established under subsection (a) shall—

"(1) develop and update every two years a summary of advances in research related to causes, prevention, treatment, early screening, diagnosis or rule out, intervention, and access to services and supports for individuals with any of the diseases or conditions involved;

"(2) monitor Federal activities with respect to each disease or condition involved;

"(3) make recommendations to the Secretary regarding any appropriate changes to such activities,

including recommendations to the Director of the National Institutes of Health;

"(4) make recommendations to the Secretary regarding public participation in decisions related to each disease or condition involved; and

"(5) develop and update every two years a strategic plan under subsection (c).

"(c) STRATEGIC PLANNING.—

"(1) SUBMISSION.—Not later than 2 years after the date of the establishment of a coordination committee under subsection (a), and every 2 years thereafter, the committee shall submit to the Secretary an up-to-date strategic plan for the conduct and support by the Department of Health and Human Services of research and other activities relating to each disease or condition involved. The Secretary shall submit each such strategic plan to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

"(2) CONTENTS.—Each strategic plan under paragraph (1) shall address—

"(A) the summary of advances in research under subsection (b)(1);

"(B) any appropriate changes to research activities, including recommendations to improve the research portfolio of the National Institutes of Health, taking into account private research activities;

"(C) how scientifically based strategic planning is implemented in support of research priorities, including key research questions, methodologies, and knowledge gaps, that impact research activities relating to the disease or condition;

"(D) innovative approaches to study emerging scientific opportunities or eliminate knowledge gaps in research to improve the research portfolio;

"(E) how best to coordinate the activities of the National Institutes of Health and other Federal departments and agencies to avoid unnecessary duplication of effort;

"(F) expansion of the number of research proposals that involve collaboration between 2 or more national research institutes or national centers of the National Institutes of Health, including proposals for use of funds reserved

under section 402A(c)(1) for the Common Fund;

"(G) ensuring the participation of patient advocacy and community organizations;

"(H) how best to disseminate information on research progress; and

"(I) how to expand partnerships between public entities, including Federal agencies, and private entities.

"(3) RECOMMENDATIONS.—Each strategic plan under paragraph (1) shall include—

"(A) a summary of the research and other activities conducted or supported by the Department of Health and Human Services relating to each disease or condition involved, including with respect to diagnosis, prevention, and treatment; and

"(B) recommendations for enhancing and coordinating such activities.

"(d) MEMBERSHIP.—

"(1) IN GENERAL.—Each coordination committee established under subsection (a) shall be composed of the following members:

"(A) The Assistant Secretary for Planning and Evaluation, who shall serve as chair of the coordination committee.

"(B) The Director of the National Institutes of Health, and the directors of such national research institutes and national centers of the National Institutes of Health as the Secretary determines appropriate.

"(C) Such other department or agency heads (or the designees thereof) as the Secretary may appoint or invite, as appropriate, to serve on the coordination committee.

"(D) Such individuals who are not Federal officials or employees as the Secretary may appoint, of which—

"(i) at least one shall be an individual with one of the specific diseases or conditions involved;

"(ii) at least one shall be a parent or legal guardian of an individual with one of the specific diseases or conditions involved; and

"(iii) at least one shall be a representative of research, advocacy, and service or-

ganizations for individuals with one of the specific diseases or conditions involved.

"(2) REPRESENTATION OF NON-FEDERAL MEMBERS.—Of the members serving on any coordination committee established under subsection (a), the Secretary shall ensure that not fewer than 6, or at least 1/3, whichever is greater, are members appointed under paragraph (1)(D).

"(e) PAY; EXPENSES.—

"(1) IN GENERAL.—Except as provided in paragraphs (2) and (3), members of a coordination committee established under subsection (a) shall serve without pay.

"(2) FEDERAL EMPLOYEES.—Members of a coordination committee established under subsection (a) who are full-time officers or employees of the United States may not receive additional pay, allowances, or benefits by reason of their service on the committee.

"(3) TRAVEL EXPENSES.—Each member of a coordination committee established under subsection (a) shall receive travel expenses, including per diem in lieu of subsistence, in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code.

"(f) ADMINISTRATIVE SUPPORT.—A coordination committee established under subsection (a) shall receive necessary and appropriate administrative support from the Secretary.

"(g) MEETINGS.—A coordination committee established under subsection (a) shall meet at the call of the committee's chair or upon the request of the Secretary. The committee shall meet at least once each year.

"(h) FUNDING.—The funds made available to carry out this section shall be derived exclusively from the funds made available under section 241(a).".

SEC. 3. REVIEW OF AND AUTHORITY TO ABOLISH COMMITTEES.

Part B of title II of the Public Health Service Act (42 U.S.C. 238 et seq.) is further amended by inserting after section 249, as added by section 2, the following:

"SEC. 249A. REVIEW OF AND AUTHORITY TO ABOLISH COMMITTEES.

"(a) REVIEW OF COMMITTEES.—The Secretary shall—

"(1) identify each committee that is established in, or is utilized by, the Department of Health and Human Services for the purpose of providing advice or recommendations specific to one or more diseases or conditions;

"(2) determine the status of each such committee;

"(3) determine the benefits of maintaining each such committee;

"(4) formulate recommendations on whether each such committee should be maintained or abolished; and

"(5) not later than 6 months after the date of the enactment of this section, and every 2 years thereafter, submit a report to the Congress containing—

"(A) the list of committees identified pursuant to subparagraph (A); and

"(B) the determinations and recommendations made pursuant to subparagraphs (B), (C), and (D).

"(b) AUTHORITY TO ABOLISH COMMITTEES.—Notwithstanding any other provision of law, the Secretary may abolish any committee that—

"(1) is subject to the Federal Advisory Committee Act; and

"(2) is established in the Department of Health and Human Services for the purpose of providing advice or recommendations specific to one or more diseases or conditions.

"(c) DEFINITION.—In this section, the term 'committee' means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof, which is established by statute or reorganization plan, by the President, or by the Department.".

I

112TH CONGRESS
1ST SESSION

H. R. 1254

To amend the Controlled Substances Act to place synthetic drugs in Schedule I.

IN THE HOUSE OF REPRESENTATIVES

MARCH 30, 2011

Mr. DENT (for himself, Mr. MEEHAN, Mr. MARINO, Mr. PLATTS, Mr. BARLETTA, Mr. CUELLAR, Mrs. EMERSON, Mrs. BIGGERT, Mr. LATOURETTE, Mr. GIBSON, Mr. STIVERS, and Mr. REED) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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A BILL

To amend the Controlled Substances Act to place synthetic drugs in Schedule I.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Synthetic Drug Control Act of 2011".

SEC. 2. ADDITION OF SYNTHETIC DRUGS TO SCHEDULE I OF THE CONTROLLED SUBSTANCES ACT.

(a) CANNABIMIMETIC AGENTS.—Schedule I, as set forth in section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended by adding at the end the following:

"(d)(1) Unless specifically exempted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of cannabimimetic agents, or which contains their salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation.

"(2) In paragraph (1), the term 'cannabimimetic agents'—

"(A) means any substance that is a cannabinoid receptor type 1 (CB1 receptor) agonist as demonstrated by binding studies and functional assays within the following structural classes:

"(i) 2-(3-hydroxycyclohexyl)phenol with substitution at the 5-position of the phenolic ring by alkyl or alkenyl, whether or not substituted on the cyclohexyl ring to any extent.

"(ii) 3-(1-naphthoyl)indole or 3-(1-naphthyl)indole by substitution at the nitrogen atom of the indole ring, whether or not further

substituted on the indole ring to any extent, whether or not substituted on the naphthoyl or naphthyl ring to any extent.

"(iii) 3-(1-naphthoyl)pyrrole by substitution at the nitrogen atom of the pyrrole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the naphthoyl ring to any extent.

"(iv) 1-(1-naphthylmethyl)indene by substitution of the 3-position of the indene ring, whether or not further substituted in the indene ring to any extent, whether or not substituted on the naphthyl ring to any extent.

"(v) 3-phenylacetylindole or 3-benzoylindole by substitution at the nitrogen atom of the indole ring, whether or not further substituted in the indole ring to any extent, whether or not substituted on the phenyl ring to any extent.; and

"(B) includes—

"(i) 5-(1,1-dimethylheptyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (CP-47,497);

"(ii) 5-(1,1-dimethyloctyl)-2-[(1R,3S)-3-hydroxycyclohexyl]-phenol (cannabicyclohexanol or CP-47,497 C8-homolog);

"(iii) 1-pentyl-3-(1-naphthoyl)indole (JWH-018 and AM678);

"(iv) 1-butyl-3-(1-naphthoyl)indole (JWH-073);

"(v) 1-hexyl-3-(1-naphthoyl)indole (JWH-019);

"(vi) 1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl)indole (JWH-200);

"(vii) 1-pentyl-3-(2-methoxyphenylacetyl)indole (JWH-250);

"(viii) 1-pentyl-3-[1-(4-methoxynaphthoyl)]indole (JWH-081);

"(ix) 1-pentyl-3-(4-methyl-1-naphthoyl)indole (JWH-122);

"(x) 1-pentyl-3-(4-chloro-1-naphthoyl)indole (JWH-398);

"(xi) 1-(5-fluoropentyl)-3-(1-naphthoyl)indole (AM2201);

"(xii) 1-(5-fluoropentyl)-3-(2-iodobenzoyl)indole (AM694);

"(xiii) 1-pentyl-3-[(4-methoxy)-benzoyl]indole (SR-19 and RCS-4);

"(xiv) 1-cyclohexylethyl-3-(2-methoxyphenylacetyl)indole (SR-18 and RCS-8); and

"(xv) 1-pentyl-3-(2-chlorophenylacetyl)indole (JWH-203).".

(b) OTHER DRUGS.—Schedule I of section 202(c) of the Controlled Substances Act (21 U.S.C. 812(c)) is amended in subsection (c) by adding at the end the following:

"(18) 4-methylmethcathinone (Mephedrone).

"(19) 3,4-methylenedioxypyrovalerone (MDPV).

"(20) 3,4-methylenedioxymethcathinone (methylone).

"(21) Naphthylpyrovalerone (naphyrone).

"(22) 4-fluoromethcathinone (flephedrone).

"(23) 4-methoxymethcathinone (methedrone; Bk-PMMA).

"(24) Ethcathinone.

"(25) 3,4-methylenedioxyethcathinone (ethylone).

"(26) Beta-keto-N-methyl-3,4-benzodioxyolybutanamine (butylone).

"(27) N,N-dimethylcathinone (metamfepramone).

"(28) Alpha-pyrrolidinopropiophenone (alpha-PPP).

"(29) 4-methoxy-alpha-pyrrolidinopropiophenone (MOPPP).

"(30) 3,4-methylenedioxy-alpha-pyrrolidinopropiophenone (MDPPP).

"(31) Alpha-pyrrolidinovalerophenone (alpha-PVP).

"(32) 6,7-dihydro-5H-indeno(5,6-d)-1,3-dioxal-6-amine) (MDAI).".

SEC. 3. TEMPORARY SCHEDULING TO AVOID IMMINENT HAZARDS TO PUBLIC SAFETY EXPANSION.

Section 201(h)(2) of the Controlled Substances Act (21 U.S.C. 811(h)(2)) is amended—

(1) by striking "one year" and inserting "2 years"; and

(2) by striking "six months" and inserting "1 year".

○

I

112TH CONGRESS
1ST SESSION

H. R. 2405

To reauthorize certain provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act relating to public health preparedness and countermeasure development, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JUNE 28, 2011

Mr. ROGERS of Michigan (for himself, Mrs. MYRICK, and Mr. GENE GREEN of Texas) introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To reauthorize certain provisions of the Public Health Service Act and the Federal Food, Drug, and Cosmetic Act relating to public health preparedness and countermeasure development, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Pandemic and All-Hazards Preparedness Reauthorization Act of 2011".

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. REAUTHORIZATION OF CERTAIN PROVISIONS RELATING TO PUBLIC HEALTH PREPAREDNESS.

(a) VACCINE TRACKING AND DISTRIBUTION.—Subsection (e) of section 319A of the Public Health Service Act (42 U.S.C. 247d–1) is amended by striking "such sums for each of fiscal years 2007 through 2011" and inserting "$30,800,000 for each of fiscal years 2012 through 2016".

(b) IMPROVING STATE AND LOCAL PUBLIC HEALTH SECURITY.—Effective on October 1, 2011, section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a) is amended—

(1) in subsection (f)—

(A) in paragraph (2), by inserting "and" at the end;

(B) in paragraph (3), by striking "; and" and inserting a period; and

(C) by striking paragraph (4);

(2) by striking subsection (h); and

(3) in subsection (i)—

(A) in paragraph (1)—

(i) by amending subparagraph (A) to read as follows:

"(A) IN GENERAL.—For the purpose of carrying out this section, there is authorized to be appropriated $632,900,000 for each of fiscal years 2012 through 2016."; and

(ii) by striking subparagraph (B); and

(B) in subparagraphs (C) and (D) of paragraph (3), by striking "(1)(A)(i)(I)" each place it appears and inserting "(1)(A)".

(c) PARTNERSHIPS FOR STATE AND REGIONAL HOSPITAL PREPAREDNESS TO IMPROVE SURGE CAPACITY.—Paragraph (1) of section 319C–2(j) of the Public Health Service Act (42 U.S.C. 247d–3b(j)) is amended to read as follows:

"(1) IN GENERAL.—For purposes of carrying out this section, there is authorized to be appropriated $378,000,000 for each of fiscal years 2012 through 2016.".

(d) CDC PROGRAMS FOR COMBATING PUBLIC HEALTH THREATS.—Section 319D of the Public Health Service Act (42 U.S.C. 247d–4) is amended—

(1) by striking subsection (c); and

(2) in subsection (g), by striking "such sums as may be necessary in each of fiscal years 2007

through 2011" and inserting "$160,121,000 for each of fiscal years 2012 through 2016".

(e) DENTAL EMERGENCY RESPONDERS: PUBLIC HEALTH AND MEDICAL RESPONSE.—

(1) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL RESPONSE CURRICULA AND TRAINING.—Section 319F(a)(5)(B) of the Public Health Service Act (42 U.S.C. 247d–6(a)(5)(B)) is amended by striking "public health or medical" and inserting "public health, medical, or dental".

(2) NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(3) of the Public Health Service Act (42 U.S.C. 300hh–1(b)(3)) is amended—

(A) in the matter preceding subparagraph (A), by inserting "and which may include dental health facilities" after "mental health facilities"; and

(B) in subparagraph (D), by inserting "(which may include such dental health assets)" after "medical assets".

(f) PROCUREMENT OF COUNTERMEASURES.—

(1) CONTRACT TERMS.—Clause (ii) of section 319F–2(c)(7)(C) of the Public Health Service Act (42 U.S.C. 247d–6b(c)(7)(C)) is amended by adding at the end the following:

"(X) GOVERNMENT PURPOSE.—The contract shall provide a clear statement of defined Government purpose limited to uses related to a security countermeasure, as defined in paragraph (1)(B).".

(2) REAUTHORIZATION OF THE SPECIAL RESERVE FUND.—Section 319F–2 of the Public Health Service Act (42 U.S.C. 247d–6b) is amended—

(A) in subsection (c)—

(i) by striking "special reserve fund under paragraph (10)" each place it appears and inserting "special reserve fund as defined in subsection (g)(5)"; and

(ii) by striking paragraphs (9) and (10); and

(B) by adding at the end the following:

"(g) SPECIAL RESERVE FUND.—

"(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to amounts appropriated to the special reserve fund prior to the date of the enactment of this subsection, there is authorized to be appropriated, for the procurement of security countermeasures under subsection (c) and for carrying out section 319L (relating to the Biomedical Advanced Research

and Development Authority), $2,800,000,000 for the period of fiscal years 2014 through 2018. Amounts appropriated pursuant to the preceding sentence are authorized to remain available until September 30, 2019.

"(2) NOTICE OF INSUFFICIENT FUNDS.—Not later than 15 days after any date on which the Secretary determines that the amount of funds in the special reserve fund available for procurement is less than $1,500,000,000, the Secretary shall submit to the relevant committees of Congress a report detailing the amount of such funds available for procurement and the impact such funding will have—

"(A) in meeting the security countermeasure needs identified under this section; and

"(B) on the annual Public Health Emergency Medical Countermeasure Enterprise Implementation Plan under section 319F–5(b).

"(3) USE OF SPECIAL RESERVE FUND FOR ADVANCED RESEARCH AND DEVELOPMENT.—The Secretary, acting through the Director of the Biomedical Advanced Research and Development Authority, may utilize not more than 30 percent of the amounts authorized to be appropriated under paragraph (1) to carry out section 319L (related to the

Biomedical Advanced Research and Development Authority). Amounts authorized to be appropriated under this subsection to carry out section 319L are in addition to amounts otherwise authorized to be appropriated to carry out such section.

"(4) RESTRICTIONS ON USE OF FUNDS.—Amounts in the special reserve fund shall not be used to pay—

"(A) costs other than payments made by the Secretary to a vendor for advanced research and development or procurement of a security countermeasure under subsection (c)(7); and

"(B) any administrative expenses, including salaries.

"(5) DEFINITION.—In this section, the term 'special reserve fund' means the 'Biodefense Countermeasures' appropriations account, any appropriation made available pursuant to section 521(a) of the Homeland Security Act of 2002, and any appropriation made available pursuant to paragraph (1) of this paragraph.".

(g) BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY.—

(1) TRANSACTION AUTHORITIES.—Section 319L(c)(5) of the Public Health Service Act (42

U.S.C. 247d–7e(e)(5)) is amended by adding at the end the following:

"(G) GOVERNMENT PURPOSE.—In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.".

(2) BIODEFENSE MEDICAL COUNTERMEASURE DEVELOPMENT FUND.—Paragraph (2) of section 319L(d) of the Public Health Service Act (42 U.S.C. 247d–7e(d)) is amended to read as follows:

"(2) FUNDING.—To carry out the purposes of this section, there is authorized to be appropriated to the Fund $415,000,000 for each of fiscal years 2012 through 2016, the amounts to remain available until expended.".

(3) CONTINUED INAPPLICABILITY OF CERTAIN PROVISIONS.—Section 319L(e)(1)(C) of the Public Health Service Act (42 U.S.C. 247d–7e(e)(1)(C)) is amended by striking "7 years" and inserting "10 years".

(h) NATIONAL DISASTER MEDICAL SYSTEM.—Section 2812 of the Public Health Service Act (42 U.S.C. 300hh–11) is amended—

(1) in subsection (a)(3), by adding at the end the following:

"(D) ADMINISTRATION.—The Secretary may determine and pay claims for reimbursement for services under subparagraph (A) directly or by contract providing for payment in advance or by way of reimbursement."; and

(2) in subsection (g), by striking "such sums as may be necessary for each of the fiscal years 2007 through 2011" and inserting "$56,000,000 for each of fiscal years 2012 through 2016".

(i) EXTENSION OF LIMITED ANTITRUST EXEMPTION.—Section 405(b) of the Pandemic and All-Hazard Preparedness Act (42 U.S.C. 247d–6a note) is amended by striking "6-year" and inserting "10-year".

SEC. 3. COORDINATION BY ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE.

(a) IN GENERAL.—Section 2811 of the Public Health Service Act (42 U.S.C. 300hh–10) is amended—

(1) in subsection (b)(3)—

(A) by inserting "stockpiling, distribution," before "and procurement"; and

(B) by inserting ", security measures (as defined in section 319F–2," after "qualified countermeasures (as defined in section 319F–1)";

(2) in subsection (b)(4), by adding at the end the following:

"(D) IDENTIFICATION OF INEFFICIENCIES.—Identify gaps, duplication, and other inefficiencies in public health preparedness activities and the actions necessary to overcome these obstacles.

"(E) DEVELOPMENT OF COUNTERMEASURE IMPLEMENTATION PLAN.—Lead the development of a coordinated Countermeasure Implementation Plan under subsection (d).

"(F) COUNTERMEASURES BUDGET ANALYSIS.—Oversee, in consultation with the Director of the Office of Management and Budget, the development of a comprehensive, cross-cutting 5-year budget analysis with respect to activities described in paragraph (3)—

"(i) to inform prioritization of resources; and

"(ii) to ensure that challenges are adequately addressed.

"(G) GRANT PROGRAMS FOR MEDICAL AND PUBLIC HEALTH PREPAREDNESS CAPABILITIES.—Coordinate, in consultation with the Secretary of Homeland Security, grant programs of the Department of Health and Human Services relating to medical and public health preparedness capabilities and the ability of local communities to respond to public health emergencies, including by—

"(i) coordinating the program requirements, timelines, and measurable goals of such grant programs; and

"(ii) establishing a system for gathering and disseminating best practices among grant recipients.";

(3) by amending subsection (c) to read as follows:

"(c) FUNCTIONS.—The Assistant Secretary for Preparedness and Response shall—

"(1) have authority over and responsibility for—

"(A) the National Disaster Medical System (in accordance with section 301 of the Pandemic and All-Hazards Preparedness Act);

"(B) the Hospital Preparedness Cooperative Agreement Program pursuant to section 319C–2;

"(C) the Biomedical Advanced Research and Development Authority under section 319L;

"(D) the Medical Reserve Corps pursuant to section 2813;

"(E) the Emergency System for Advance Registration of Volunteer Health Professionals pursuant to section 319I;

"(F) the Strategic National Stockpile; and

"(G) the Cities Readiness Initiative; and

"(2) assume other duties as determined appropriate by the Secretary."; and

(4) by adding at the end the following:

"(d) COUNTERMEASURE IMPLEMENTATION PLAN.—Not later than 6 months after the date of enactment of this subsection, and annually thereafter, the Assistant Secretary for Preparedness and Response shall submit to the Secretary and relevant congressional committees a Countermeasure Implementation Plan that—

"(1) describes the chemical, biological, radiological, and nuclear threats facing the Nation and the corresponding efforts to develop qualified coun-

termeasures (as defined in section 319F–1), secured countermeasures (as defined in section 319F–2), or qualified pandemic or epidemic products (as defined in section 319F–3) for each threat;

"(2) evaluates the progress of all activities with respect to such countermeasures or products, including research, advanced research, development, procurement, stockpiling, deployment, and utilization;

"(3) identifies and prioritizes near-, mid-, and long-term needs with respect to such countermeasures or products to address chemical, biological, radiological, and nuclear threats;

"(4) identifies, with respect to each category of threat, a summary of all advanced development and procurement awards, including the time elapsed from the issuance of the initial solicitation or request for a proposal to the adjudication (such as the award, denial of award, or solicitation termination), and including—

"(A) projected timelines for development and procurement of such countermeasures or products;

"(B) clearly defined goals, benchmarks, and milestones for each countermeasure or product, including information on the number

of doses required, the intended use of the countermeasure or product, and the required countermeasure or product characteristics; and

"(C) projected needs with regard to the replenishment of the Strategic National Stockpile;

"(5) evaluates progress made in meeting the goals, benchmarks, and milestones identified under paragraph (4);

"(6) reports on the amount of funds available for procurement in the special reserve fund as defined in section 319F–2(g)(5) and the impact this funding will have on meeting the requirements under section 319F–2; and

"(7) incorporates input from Federal, State, local, and tribal stakeholders.".

(b) CONSULTATION IN AUTHORIZING MEDICAL PRODUCTS FOR USE IN EMERGENCIES.—Subsection (e) of section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) is amended by striking "consultation with the Director of the National Institutes of Health" and inserting "consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health,".

SEC. 4. ELIMINATING DUPLICATIVE PROJECT BIOSHIELD REPORTS.

Section 5 of the Project Bioshield Act of 2004 (42 U.S.C. 247d–6c) is repealed.

SEC. 5. ACCELERATE COUNTERMEASURE DEVELOPMENT BY STRENGTHENING FDA'S ROLE IN REVIEWING PRODUCTS FOR NATIONAL SECURITY PRIORITIES.

(a) IN GENERAL.—Section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4) is amended to read as follows:

"SEC. 565. COUNTERMEASURE DEVELOPMENT AND REVIEW.

"(a) COUNTERMEASURES AND PRODUCTS.—The countermeasures and products referred to in this subsection are—

"(1) qualified countermeasures (as defined in section 319F–1 of the Public Health Service Act);

"(2) security countermeasures (as defined in section 319F–2 of such Act); and

"(3) qualified pandemic or epidemic products (as defined in section 319F–3 of such Act).

"(b) IN GENERAL.—

"(1) INVOLVEMENT OF FDA PERSONNEL IN INTERAGENCY ACTIVITIES.—The Secretary shall accelerate the development, stockpiling, approval, and

licensure of countermeasures and products referred to in subsection (a) by expanding the involvement of Food and Drug Administration personnel in interagency activities with the Biomedical Advanced Research and Development Authority, the Centers for Disease Control and Prevention, the National Institutes of Health, and the Department of Defense.

"(2) TECHNICAL ASSISTANCE.—The Secretary shall establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of countermeasures and products referred to in subsection (a).

"(e) AGENCY INTERACTION WITH SECURITY COUNTERMEASURE SPONSORS.—

"(1) COUNTERMEASURE DEVELOPMENT PROGRAM.—

"(A) IN GENERAL.—For each security countermeasure (as defined in section 319F–2 of the Public Health Service Act) that is procured under such section 319F–2, the Secretary shall initiate, in consultation with the security countermeasure sponsor (referred to in this sec-

tion as the 'countermeasure sponsor'), a program of frequent scientific feedback and interactions regarding the process of developing such countermeasure, including—

"(i) regular meetings between appropriate Food and Drug Administration personnel and the countermeasure sponsor during the process of developing the countermeasure, to be scheduled within 45 days after attainment of each milestone identified pursuant to subparagraph (B)(iv)(I) in the regulatory management plan for the countermeasure;

"(ii) written feedback from the Food and Drug Administration within 30 days after submission of a request for feedback pursuant to subparagraph (B)(iv)(II) in the regulatory management plan for the countermeasure;

"(iii) written feedback from the Food and Drug Administration within 30 days after submission by the countermeasure sponsor of a study report that is considered to be complete pursuant to subpara-

graph (B)(iv)(III) in the regulatory management plan for the countermeasure;

"(iv) at the request of the Director of the Biomedical Advanced Research and Development Authority, participation in meetings of such Authority on the development of the countermeasure; and

"(v) other meetings, including on-site meetings, as appropriate.

"(B) REGULATORY MANAGEMENT PLAN.—In carrying out the program under subparagraph (A), the Secretary shall, in consultation with the countermeasure sponsor, develop a written regulatory management plan for each security countermeasure (as defined in section 319F–2 of the Public Health Service Act) that is procured under such section 319F–2. The regulatory management plan shall be completed within 60 days of issuance of a contract for the countermeasure under such section 319F–2 or, for a countermeasure that was procured under such section 319F–2 before the date of the enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011, within 60 days after such date of enactment. The reg-

ulatory management plan for a security countermeasure shall include—

"(i) an assessment of the current regulatory status, an assessment of known scientific gaps, and a proposed pathway to approval or licensure of the countermeasure;

"(ii) guidance by the Food and Drug Administration regarding the data required to support delivery of the countermeasure to the Strategic National Stockpile;

"(iii) guidance by the Food and Drug Administration regarding data required to support submission of a proposed agreement on the design and size of clinical trials for review under section 505(b)(5)(B); and

"(iv) an agreement between the Food and Drug Administration and the countermeasure sponsor to identify—

"(I) developmental milestones that will trigger meetings between the Administration and the sponsor;

"(II) the process for requesting and receiving written or oral feedback from the Administration; and

"(III) the type study reports that will be considered by the Administration to be complete.

"(C) APPLICABILITY TO CERTAIN QUALIFIED PANDEMIC OR EPIDEMIC PRODUCTS.—The Secretary may, with respect to qualified pandemic or epidemic products (as defined in section 319F–3 of the Public Health Service Act) for which a contract for advanced research and development is entered into under section 319L of such Act, choose to apply the provisions of subparagraphs (A) and (B) to the same extent and in the same manner as such provisions apply with respect to security countermeasures.

"(d) FINAL GUIDANCE ON DEVELOPMENT OF ANIMAL MODELS.—Not later than 180 days after the date of the enactment of the Pandemic and All-Hazards Preparedness Reauthorization Act of 2011, the Secretary shall provide final guidance to industry regarding the development of animal models to support approval or licensure of countermeasures and products referred to in sub-

section (a) when human efficacy studies are not ethical or feasible.

"(e) ANNUAL REPORT.—Not later than January 1, 2012, and every January 1 thereafter, the Secretary shall submit a report to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate that, with respect to the preceding fiscal year, includes—

"(1) the number of full-time equivalent employees of the Food and Drug Administration who directly support the review of countermeasures and products referred to in subsection (a);

"(2) estimates of funds obligated by the Food and Drug Administration for development of such countermeasures and products;

"(3) the number of regulatory teams at the Food and Drug Administration specific to such countermeasures and products and, for each such team, the assigned products, classes of products, or technologies;

"(4) the length of time between each request by the sponsor of such a countermeasure or product for information and the provision of such information by the Food and Drug Administration;

"(5) the number, type, and frequency of official interactions between the Food and Drug Administration and—

"(A) sponsors of a countermeasure or product referred to in subsection (a); or

"(B) another agency engaged in development or management of portfolios for such countermeasures or products, including the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the appropriate agencies of the Department of Defense;

"(6) any other measure to determine the efficiency of the regulatory teams described in paragraph (3); and

"(7) the regulatory science priorities which the Food and Drug Administration is addressing and the progress made on these priorities.".

(b) DISCUSSIONS BETWEEN FDA AND SPONSOR ON DESIGN AND SIZE OF ANIMAL AND CLINICAL TRIALS INTENDED TO FORM THE PRIMARY BASIS OF AN EFFECTIVENESS CLAIM WHEN HUMAN EFFICACY STUDIES ARE NOT ETHICAL OR FEASIBLE.—Subparagraph (B) of sec-

tion 505(b)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)) is amended to read as follows:

"(B)(i) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of—

"(I) clinical trials intended to form the primary basis of an effectiveness claim; or

"(II) animal and clinical trials intended to form the primary basis of an effectiveness claim when human efficacy studies are not ethical or feasible.

"(ii) The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.".

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