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Testimony of
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On behalf of the
American Academy of Pediatrics

Before the
U.S. Senate Committee on Health, Education, Labor & Pensions

"A Nation Prepared: Strengthening Medical and Public Health Preparedness and Response"

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Chairman Harkin and Ranking Member Enzi, thank you for holding today's hearing on such an important topic, strengthening our medical and public health preparedness and response. My name is Mike Anderson, MD FAAP, and I am representing the American Academy of Pediatrics, a non-profit professional organization of more than 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. For more than a decade, the Academy has engaged in a broad range of activities related to disaster preparedness, including policy statements on clinical care and tools for pediatricians before, during, and after disaster situations.

I am Vice President and Associate Chief Medical Officer at University Hospitals Case Medical Center and Associate Professor of Pediatrics at the Case Western Reserve School of Medicine in Cleveland, OH. I am also a practicing pediatric critical care specialist at Rainbow Babies & Children's Hospital. In my capacity as a practicing clinician, I have been active at the local, state, and national level in pediatric disaster readiness and response. In 2008, I was appointed by President George W. Bush to the National Commission on Children and Disasters (the Commission) which was created by Congress under the strong leadership of Chairman Harkin, former Senator Chris Dodd, and many others. I had the distinct honor of serving as the Commission's Vice Chair until its termination in early April 2011.

Recent events in Alabama, Mississippi, and in the Chairman's home state of Iowa make today's hearing especially timely and critical. These events and the tragedy in Japan are a stark reminder that disasters can and do strike, and oftentimes without warning. Therefore, as a nation and as individuals and families, we must plan ahead and we must be prepared.

The recovery and relief efforts here in the U.S. from tornadoes and flooding and from the earthquake and tsunami in Japan will take time and for countless families, especially those who lost loved ones, life will never be the same. Recovery for the most vulnerable of our population, children, may present several unique challenges and it is important that we as Americans assess whether the planning and exercises our government and communities engage in; whether our medical capabilities and the training of our first responders; and whether the preparedness of our nation's hospitals, federal, state and local governments, and families, adequately account for the needs of children and other populations in the event of a disaster.

Unfortunately, today, the reality is that none of those systems are fully prepared to address the needs of nearly 25 percent of the population, children. We need to work to change this realty. The Academy supports the efforts of this Committee to reauthorize the *Pandemic and All-Hazards Preparedness Act (PAHPA)* and urges the Committee to use the reauthorization bill as an opportunity to redouble our efforts at the federal level to prioritize the needs of children, including children with special heath care needs.

The most significant step Congress could take to achieve this goal would be to remove children from the broader at-risk population category and designate an office with the authority and funding necessary to adequately meet the needs of children during a disaster. This is especially

critical now that the National Commission on Children and Disasters has terminated. The Commission provided the needed, and previously lacking, focus and attention to children's needs in disaster planning and preparedness within Federal agencies. Additionally, removing children from the broader at-risk population category would allow Federal agencies to better direct resources and attention to populations such as individuals with disabilities, senior citizens, and pregnant women.

Children Are More Vulnerable Than Adults

You've heard the saying that children are not little adults. Why is that and, more importantly, why does that matter when it comes to medical and public health preparedness and response?

- Children are particularly vulnerable to aerosolized biological or chemical agents because they normally breathe more times per minute than do adults, meaning they would be exposed to larger doses of an aerosolized substance in the same period of time. Also, because such agents (e.g. sarin and chlorine) are heavier than air, they accumulate close to the ground – right in the breathing zone of children.
- Children are also much more vulnerable to agents that act on or are absorbed through the skin because their skin is thinner and they have a much larger skin surface-to-body mass ratio than adults.
- Children are more vulnerable to the effects of agents that produce vomiting or diarrhea because they have smaller body fluid reserves than adults, increasing the risk of rapid progression to dehydration or shock.[i]
- Children have much smaller circulating blood volumes than adults, so without timely intervention, relatively small amounts of blood loss can quickly tip the physiological scale from reversible shock to profound, irreversible shock or death. An infant or small child can literally bleed to death from a large scalp laceration.
- Children have significant developmental vulnerabilities not shared by adults. Infants, toddlers and young children may not have the motor skills to escape from the site of a hazard or disaster. Even if they are able to walk, young children may not have the cognitive ability to know when to flee from danger, or when to follow directions from strangers such as in an evacuation, or to cooperate with decontamination.[ii] As we all learned from Hurricane Katrina, children are also notably vulnerable when they are separated from their parents or guardians.
- Children have immature immune systems that make them more susceptible to biological, chemical, radiological agents.
- Children are also more vulnerable to radiological agents due to their more rapid metabolic and cellular growth rates.

Children Have Unique Treatment Needs

When children are critically ill or injured, their bodies respond differently than adults exposed to similar insults. Consequently, pediatric treatment needs are unique in a number of ways:

- Children need different dosages and formulations of medicine than adults – not only because they are smaller, but also because certain drugs and biological agents may have adverse effects in developing children that are not of concern for adults.
- Children need different sized equipment and other medical devices than adults. In fact, our day-to-day emergency readiness requires the presence of many different sizes of key resuscitation equipment for infants, pre-school and school-aged children, and adolescents. From needles and tubing, to oxygen masks and ventilators, to imaging equipment and laboratory technology, children need equipment that has been specifically designed for their size.
- Children demand special consideration during decontamination efforts. Because children lose body heat more quickly than adults, mass decontamination systems that may be safe for adults can cause hypothermia in young children unless special heating precautions or other warming equipment is provided.[iii] Hypothermia can have a profoundly detrimental impact on a child's survival from illness or injury. Additionally, a first responder wearing a Hazmat suit can be scary for a child so decontamination systems should ideally be designed so that parents can remain with their children and help them through the decontamination process.
- Children display unique developmental and psychological responses to acute illness and injury, as well as to mass casualty events. Compared to adults, children appear to be at greater risk for acute- and post-traumatic stress disorders. The identification and optimal management of these disorders in children requires professionals with expertise in pediatric mental health.[iv] When disaster strikes and these professionals are not readily available, it may fall to the responsibility of first responders who need to be adequately prepared, trained and equipped for children.
- Children may be developmentally unable to communicate their needs with health care providers. The medical treatment of children is optimized with the presence of parents and/or family members. Timely reunification of children with parents and family-centered care should be a priority for all levels of emergency care.

Children Need Care From Providers Trained to Meet Their Unique Needs

Because children respond differently than adults in a medical crisis, it is critical that all health care workers be able to recognize the unique signs and symptoms in children that may indicate a life-threatening situation, and then possess the experience and skill to intervene accordingly.[v] As already noted, a child's condition can rapidly deteriorate from stable to life-threatening as they have less blood and fluid reserves, are more sensitive to changes in body temperature, and have faster metabolisms. Once cardio-pulmonary arrest has occurred, the prognosis is particularly dismal in children, with less than 20% surviving the event, and with 75% of the survivors sustaining permanent disability.

Therefore, the goal in pediatric emergency care is to recognize pre-cardiopulmonary arrest conditions and intervene before they occur. While children represent 25 to 30% of all emergency department visits in the U.S., and 5 to 10% of all EMS ambulance patients, the

number of these children who require this advanced level of emergency and critical care, and use of the associated cognitive and technical abilities, is quite small. This creates a special problem for pre-hospital and hospital-based emergency care providers, as they have limited exposure and opportunities to maintain their pediatric assessment and resuscitation skills. Fifty percent of U.S. Emergency Departments (EDs) provide care for fewer than 10 children per day.[vi] The Academy, jointly with the American College of Emergency Physicians, and the Emergency Nurses Association, issued guidelines to help hospitals with identifying and training a pediatric advocate within their institutions to implement certain protocols and help improve hospital preparedness.[vii]

Children with special health care needs represent 13.9 percent of U.S. children, and 21.8 percent of households with children include at least one child with a special health care need.[viii] Children with chronic medical conditions, including children with special health care needs, rely on multiple medications, medical devices, and complex management plans, which can cause them to be at increased risk of acute deterioration, medical errors, and suboptimal outcomes, especially in emergency situations.[ix] These children pose unique emergency and disaster care challenges well beyond those of otherwise healthy children. Our emergency medical services systems and our disaster response plans must consider and meet the needs of this group of children.

Clinicians' Role Before, During, and After a Disaster

Clinicians, including pediatricians, play an integral role in disaster preparedness. From my personal experience, families view pediatricians as their expert and trusted source of information. As part of the network of health responders, pediatricians need to be able to answer concerns of patients and families, recognize signs of possible exposure to a weapon of terror, understand first-line response to such attacks, and sufficiently participate in disaster planning to ensure that the unique needs of children are addressed satisfactorily in the overall process.[x] However, the challenges that face pediatricians and other clinicians in their daily practices are heightened during a disaster situation.

It is important to point out that more than 95 percent of office-based pediatricians practice in settings defined as 'small businesses' by the U.S. Small Business Administration. Fifty percent of private office-based pediatricians work in practices of 3 or fewer physicians with 8 or fewer non-physician staff; 70 percent work in practices of no more than 5 physicians and no more than 15 non-physician staff. Children live in every part of the country and, as such, pediatricians are part of the recovery effort in all communities after a disaster. When disaster strikes, pediatricians may become displaced, losing their workplaces and/or their homes. During the immediate aftermath of a disaster, they may be unable to practice, leaving children without access to care within their medical home. Every effort should be made at the federal, state, and local level to help pediatricians with assistance relocating or rebuilding within their communities.

Many clinicians, myself included, are volunteers with the National Disaster Medical System (NDMS). The NDMS plays a vital role in our nation's preparedness but the NDMS and the

Volunteer Medical Reserve Corps (MRC) need more clinicians. Thought should be given to how we might make it easier on clinicians to volunteer and how we might tailor pre-certification or training programs to reach clinicians on a broader scale. Special attention should be paid to the recruitment of clinicians for specific populations such as geriatrics, pediatrics, and individuals with disabilities or chronic medical conditions.

Disaster preparedness starts at home with one's own preparedness. The Academy has provided guidance to pediatricians about preparedness in their own offices and communities.[xi] For clinicians, there may be great value in reviewing what type of education, if any, they are receiving during medical school and subsequent training around disaster preparedness. A core curriculum around disaster preparedness, including at-risk population such as children, may be helpful.

Hospital Preparedness for Children

This Committee is no doubt familiar with ED overcrowding as a day-to-day reality for many, if not most, hospitals. Imagine layering on top of the current situation, a widespread mass care or mass casualty event involving children. This scenario played out in hospitals across the country in 2009 during the H1N1 pandemic. Large volumes of patients and their families sought medical care; pharmacies had to be educated on how to constitute Oseltamivir for the pediatric populations; hospitals had to create innovative strategies to address the surge of patients on top of the baseline patients; physicians and other health care providers worked to engage their communities and demystify vaccine safety concerns; physician groups like the AAP partnered with the government to ensure that media messages were consistent and accurate with medically sound and timely information. While children were disproportionately affected by this strain of influenza virus, fortunately the overall morbidity of this strain was less than expected.

The experience of H1N1 taught us many lessons. Among them is the fact that the science of ED surge remains relatively undeveloped[xii]. In a 2008 survey of hospital preparedness by the Centers for Disease Control and Prevention (CDC), less than one-third (32.4 percent) of hospitals had guidelines for increasing pediatric surge capacity. About one-third (34 percent) of hospitals had plans for reunification of children with families, and only 42.6 percent of hospitals had a tracking system for accompanied and unaccompanied children.[xiii]

In the face of a disaster, all hospitals will need to increase their capacity. The vital clinical ability to recognize and respond to the needs of an ill or injured child must be present at all levels of care – from the pre-hospital setting, to emergency department care, to definitive inpatient medical and surgical care. The outcome for the most severely ill or injured children, and for the rapidly growing number of special needs children with chronic medical conditions, is optimized in centers that offer pediatric critical care and trauma services as well as pediatric medical and surgical subspecialty care. As it is not feasible to provide this level of expertise in all hospital settings, existing emergency and trauma care systems and state and federal disaster plans need to address regionalization of pediatric emergency and critical care within and across state lines,

leveraging inter-facility transport as a means to maximize the outcome of the most severely ill and injured children.

This Committee has helped hospitals make notable progress with their disaster preparedness upon the creation of the Hospital Preparedness Program, formerly the National Bioterrorism Hospital Preparedness Program, under PAHPA. The Assistant Secretary for Preparedness and Response (ASPR) at the Department of Health and Human Services recently announced that more than 76 percent of hospitals participating in the National Hospital Preparedness Program (HPP) met 90 percent or more of all program measures for all-hazards preparedness in 2009.[xiv] Without question, the leadership of the ASPR and the congressional support through appropriations for the Hospital Preparedness Program has made our nation better prepared.

The disparity between the CDC's 2008 data on hospital preparedness and ASPR's recent announcement is striking. As Congress looks ahead to the reauthorization of PAHPA and the ASPR develops grant guidance for the HPP program for FY 2012, attention should be paid to what criteria hospitals are being asked to meet for children, including children with special health care needs, through the Hospital Preparedness Program. A "Whole Community" approach to the HPP program and other grant programs may be very beneficial for children and other at-risk populations. The AAP commends the HPP program for prioritizing the "Needs of At-Risk Populations," including children, as one of four overarching requirements that must be incorporated into the development and maintenance of all program sub-capabilities but we feel that specific requirements and performance measures pertaining to pediatric preparedness in the HPP program are currently lacking and should be included in the future.

To ensure the needs of children, including children with special health care needs, are integrated into hospital planning, the AAP recommends the following:

- All hospital emergency departments should stand ready to care for ill or injured children through the adoption of the AAP's Joint Guidelines for Care of Children in the Emergency Department.[xv]
- All health care professionals who may treat children during an emergency should have adequate pediatric disaster clinical and psychosocial support training and equipment.
- The creation of guidelines for addressing pediatric surge capacity and a formal regionalized pediatric system of care including written transfer protocols and memoranda of understanding (MOUs) with other hospitals.
- The needs of children should be specifically addressed in exercises and drills including the National Level Exercise.
- The inclusion of a focus on mental and behavioral health for children in disaster planning activities and the enhancement of pre-disaster preparedness and just-in-time training in pediatric disaster mental and behavioral health, including psychological first aid, and bereavement support.
- The creation of tracking systems for accompanied and unaccompanied children and establishment of plans for reunification of children with families and protocols to identify and protect displaced children.

Emergency Medical Services for Children

The Academy commends the work of the HELP Committee to reauthorize the Emergency Medical Services for Children (EMSC) program in the *Patient Protection and Affordable Care Act* and urges Congress to fully fund the EMSC program at its authorized level of $27,562,500 in FY 2012. It is fitting that this hearing is being held one day before national EMSC Day. The EMSC program has played a crucial role in driving significant improvements in pediatric emergency care, including disaster preparedness. Despite a modest appropriation of slightly more than $20 million, EMSC has managed to effect these changes despite the lack of pediatric emphasis in other related government programs. EMSC has funded pediatric emergency care improvement initiatives in every state, territory and the District of Columbia, as well as national improvement programs. These include the development of equipment lists for ambulances, guidelines for hospital emergency preparedness, pediatric treatment protocols, and handbooks for school nurses and other providers that would be critical in the event of an emergency. EMSC supports training for emergency medical technicians and paramedics who often have little background in caring for children, and has underwritten the development of vital educational materials and treatment guidelines. In the 27 years since the program was established, child injury death rates have dropped by 40 percent.

National Commission on Children and Disasters

Recognizing how far children lagged behind in disaster preparedness, response, and recovery, Congress, led by this committee, saw fit to create the National Commission on Children and Disasters in 2008. The Commission produced two reports, the most recent in October 2010, in which it makes comprehensive recommendations aimed at the Federal government and policymakers. The Commission also called on the President to develop and present to Congress a National Strategy on Children and Disasters. Such a national strategy from the President would serve as a clarion call to government, the private sector, communities and families to engage one another in setting and achieving goals and priorities for children.
Of note to this committee, the Commission recommended that Congress, HHS, and the Department of Homeland Security/Federal Emergency Management Agency should ensure availability of and access to pediatric medical countermeasures at the Federal, State, and local levels for chemical, biological, radiological, nuclear, and explosive threats[xvi]. The Commission offered several proposals to carry out this recommendation which include amendments to the Emergency Use Authorization authority to allow the FDA to authorize pediatric indications of medical countermeasures for emergency use before an emergency is known or imminent as well as funding and grant guidance for the development, acquisition, and stockpiling of medical countermeasures for children. The Academy strongly supports these recommendations.

The Commission, through the leadership of its Chair Mark Shriver and my fellow Commissioners, made great progress within the Federal agencies to improve our nation's preparedness for children. The Commission also raised public awareness of the many gaps that exist for children. Despite the efforts of many on this committee, the Commission terminated

last month as was required by the authorizing language that created it. The Academy opposes the termination of the Commission and urges Congress to move quickly to reconstitute it. It is unacceptable to us, and it should be to Congress as well, to allow the Commission's recommendations to simply sit on a shelf and gather dust.

Medical Products for Children

In 1977, AAP experts first published a policy statement saying that not only was it ethical to study drugs in children, it was unethical not to. Since that time, the Academy has advocated strongly that children deserve the same standards of therapeutic evidence as adults.
The first step forward in public policy solutions to the lack of pediatric drug research came in 1997 when Congress, under this Committee's leadership, passed the Food and Drug Administration Modernization Act. This law contained the first authorization of pediatric exclusivity, an incentive to study drugs in children. This program was reauthorized as the Best Pharmaceuticals for Children Act (BPCA) in 2002. In 2003, the Pediatric Research Equity Act (PREA), a requirement for pediatric studies, was passed after the Pediatric Rule was struck down. Finally in 2007, BPCA and PREA were reauthorized together, creating an integrated system for pediatric research incentives and requirements. These vital programs for children will expire on September 30, 2012 and the AAP looks forward to working with the Committee to reauthorize them.

The uniqueness of pediatric therapeutics has been proven over and over again by surprising and unexpected results. BPCA and PREA studies have revealed safety issues, altered dosing, led to new indications, and have shown some drugs to lack efficacy in children. In total, nearly 400 drugs have been labeled for children as a result of BPCA and PREA. These laws have also served as a model for international advances in pediatric therapeutics, including the development of a parallel pediatric program used by the European Medicines Agency (EMEA). We can say unequivocally that BPCA and PREA have dramatically improved pediatric practice.

There are real opportunities to harness the experience of these programs and the strong leadership of the Food and Drug Administration (FDA) with Biomedical Advanced Research and Development Authority (BARDA) and their industry partners to improve pediatric labeling for medical countermeasures. There are opportunities for collaborations with the National Institutes of Health (NIH) as well. Within the last month, NIH released the 2011 BPCA Priority List of Needs in Pediatric Therapeutics and among the drugs identified by the NIH are several in the biodefense arena. The Academy looks forward to working with Congress to maximize the potential of BPCA and PREA in the medical countermeasures enterprise.

Medical Countermeasures for At-Risk Populations

Progress has been made to improve the availability of pediatric countermeasures but much more work needs to be done. Most recently, pediatric labeling was added to pralidoxime for the treatment of nerve agent poisoning meaning it can now be stockpiled for that indication in

children. However, that labeling took seven years during which time no new data was presented. It is hard to understand why it took that long. Pediatric labeling was the first step. HHS and BARDA need to support the manufacture and purchase of a child-specific auto-injector so that pralidoxime can be forward deployed and administered in the field.

In the event of a radioactive release much like we saw in Japan, children must be administered potassium iodide as quickly as possible, ideally within two hours, and in an appropriate form and dosage to prevent long-term health effects.[xvii] The liquid formulation of potassium iodide exists and is safe and effective but if federal and state governments do not purchase it to be stockpiled in the event of radiation exposure and in sufficient quantities to treat all of our nation's children, how secure are we really?

The Academy looks forward to the approval of pediatric labeling for midazolam to treat nerve gas exposure. Those studies are well underway at NIH and the Academy hopes that NIH and FDA are closely coordinating their efforts in order to expedite the approval of pediatric labeling.

Additional Policy Recommendations

The American Academy of Pediatrics has specific recommendations for all policymakers regarding children and medical countermeasures:

- The medical countermeasure enterprise, led by the federal government, should set a goal to achieve parity between adult and child medical countermeasures developed and included in the Strategic National Stockpile (SNS) and all other federally-funded caches.
- PAHPA should be amended to require that the Secretary, acting through BARDA, prioritize children.
- The federal government should conduct a comprehensive review of the contents of the SNS and all other federally-funded caches to assess how many products have pediatric labeling and, for those that don't, the government should create a plan by which pediatric labeling can be added.
- The Emergency Use Authorization process should be amended to allow the FDA to authorize pediatric indications of medical countermeasures for emergency use before an emergency is known or imminent.
- The federal government must give guidance to states that ensures they purchase adequate supplies of countermeasures for children, especially liquid potassium iodide in states with or near nuclear facilities. And, there must be accountability for states' plans for maintenance and distribution of medical countermeasures for children.
- Prepositioning of medical countermeasures is critical. All prepositioning strategies must include locations where children gather, e.g. schools,, child care facilities, and camps, and they must include plans for children with special healthcare needs.
- Because "children" encompass individuals from birth through adolescence, it is often insufficient to have a single size device to serve all children. In the case of respiratory masks, for example, different sizes are needed for infants, young children, and

adolescents. Both individual facilities and the SNS must take this into account and provide for these needs. Similarly, drugs must be available in appropriate formulations and dosages for children. Infants cannot be expected to take pills. Needles must be provided in smaller sizes. In many cases, dosages for children should be determined not by age but by weight.

- Utilize pediatric subject matter expertise in identifying gaps, setting priorities, planning, and exercising all-hazard disaster response capabilities.
- Federal agencies such as FDA, BARDA, and NIH must coordinate their efforts with the goal of prioritizing pediatric medical countermeasures.

CONCLUSION

The American Academy of Pediatrics thanks the Committee for this opportunity to testify on the important issue of medical and public health preparedness and response. America's children represent the future of our nation, our most precious national resource. Children must not be an afterthought in disaster planning and medical countermeasures. The Academy looks forward to working with you to protect and promote the health and well-being of all children, especially in emergency and disaster preparedness. We would like to offer the children and disasters website of the Academy as a resource to you as you work on disaster preparedness issues. It can be found at www.aap.org/disasters.

Finally, we would like to leave you with the findings of recent public opinion polling released by the AAP in partnership with Children's Health Fund on the use of resources related to disaster planning and response specific to children's issues. The poll found:

- 76% of Americans agree that if resources are limited, children should be given a higher priority for life-saving treatments;
- 75% believe that if tough decisions must be made, life-saving treatments should be provided to children rather than adults with the same medical condition; and
- 92% agree that if there were a terrorist attack, our country should have the same medical treatments readily available for children as are now available for adults

You represent fathers, mothers, grandparents, uncles and aunts, our children deserve better. When disaster strikes, we as a nation must be adequately prepared so that our children will be protected and can achieve their full potential. As a pediatrician and a father, I look forward to your questions and to working with you to address the preparedness needs of all children.

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