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April 13, 2011

Testimony of
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On behalf of the
American Academy of Pediatrics

Before the
**Subcommittee on Emergency Preparedness, Response, and
Communications of the Homeland Security Committee**

“Taking Measure of Countermeasures (Part 1)”

Chairman Bilirakis and Ranking Member Richardson, thank you for holding today's hearing on such an important topic, medical countermeasures. My name is Dan Fagbuyi, 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 in crisis situations.

I am currently the Medical Director of Disaster Preparedness and Emergency Management at Children's National Medical Center in Washington, DC. I am an Assistant Professor of Pediatrics and Emergency Medicine at The George Washington University School of Medicine with board certification in both Pediatrics and Pediatric Emergency Medicine. I have the distinct honor of recently being appointed by the U.S. Secretary of Health and Human Services, Kathleen Sebelius, to serve on the National Biodefense Science Board. As a Major in US Army, I was involved in combat and civil military operations, serving as a battalion surgeon on the front lines and caring for more than 800 soldiers while deployed for Operation Iraqi Freedom with the US Army's 101st Airborne Division.

Recent events in Japan make today's hearing especially timely and critical. The Academy strongly supports the federal government's response to the Japanese government and its people. We have been in touch with our pediatrician colleagues through the Japan Pediatric Society to offer the Academy's assistance and, as of today, we have raised \$51,519 in gifts and pledges for Disaster Relief for Japan through the AAP Friends of Children Disaster Relief Fund.

The recovery and relief efforts 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 citizens, children, may present several unique challenges and it is important that we as Americans look within our own borders to assess whether our planning and exercises our government and communities engage in, our medical capabilities, the training of our first responders, and the preparedness of our nation's hospitals, federal, state and local governments, and families, adequately account for the needs of children should a disaster strike.

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 reality.

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 countermeasures and disaster preparedness?

- 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 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.

- 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. In a 2008 survey of hospital preparedness by the Centers for Disease Control and Prevention (CDC), only 42.6 percent of hospitals had a tracking system for accompanied and unaccompanied children, about 34 percent of hospitals had plans for reunification of children with families, and 31.1 percent for protocols to identify and protect displaced children.^v

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.^{vi} 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.^{vii}

This Committee is no doubt familiar with ED overcrowding as a day-to-day reality. Imagine layering on top of the current situation, a widespread mass care or mass casualty event involving children, including children with special healthcare needs. The experience is much like what my institution saw with H1N1.^{viii} Large volumes of patients and their families seeking medical care;

having to educate pharmacies on how to constitute Oseltamivir for the pediatric population with cherry syrup; creating innovative strategies to address the surge of patients on top of the baseline patients; engaging the community and demystifying vaccine concerns; ensuring that media message was consistent and accurate and medically sound, ensuring infection control and so on. Fortunately for all of us, the overall morbidity of H1N1 was less than expected, though children were disproportionately impacted by the pandemic.

The science of ED surge remains relatively undeveloped^{ix}. What we do know is that when it comes to pediatrics, less than one-third (32.4 percent) of hospitals have guidelines for increasing pediatric surge capacity. 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 and 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.

Children with special health care needs^x are the fastest growing subset of children, representing 15 to 20% of the pediatric population.^{xi} 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.

Emergency Medical Services for Children

The Emergency Medical Services for Children (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 21 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 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, some of whom are testifying at today's hearing. 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 given the subject of today's hearing, the Commission recommended that Congress, HHS, and DHS/FEMA 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^{xii}. The Commission offers 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 this recommendation.

I am saddened to report that the Commission officially terminated on April 4, pursuant to the statute that established it. The Academy opposes the termination of the Commission and will continue to urge Congress to move quickly to reconstitute the Commission. I had the pleasure of partaking in the discussions of the medical care subcommittee of the Commission and the achievements this Commission made with its federal partners, professional organizations, and the public have been tremendous.

The Academy supported the creation of the Commission and we are committed to helping carry on the work of implementing the Commission's outstanding recommendations. 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 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.

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 (EMA). 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 with BARDA and their industry partners to improve pediatric labeling for medical countermeasure. There are opportunities for collaborations with the National Institutes of Health (NIH) as well. Within the last week, 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 reauthorize and strengthen BPCA and PREA, two laws that have done so much to improve children's health.

Medical Countermeasures for Children

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. 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/BARDA needs 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.^{xiii} 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.

Other 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.
- The *Pandemic and All-Hazards Preparedness Act* should be amended to require that the Secretary, acting through BARDA, prioritize children.
- Children must be distinguished as a separate population from the broader “at-risk” individuals’ category and the HHS Secretary should create an Office of Preparedness and Response for Children to be headed by a Director who reports to the Secretary.
- 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 and child care facilities 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 teenagers. 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 countermeasures. America’s children represent the future of our

nation, our most precious national resource. They must not be an afterthought in medical countermeasures and disaster planning. 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 conducted 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 better prepared with the medical countermeasures to keep our children healthy and ensure they have the opportunity to achieve optimal health outcomes. As a pediatrician and a father of three, I look forward to your questions and to working with you to address the preparedness needs of all children.

ⁱ Committee on Environmental Health and Committee on Infectious Disease. Chemical-Biological Terrorism and Its Impact on Children: A Subject Review. *Pediatrics*, Vol. 105 No. 3 March 2000. (update scheduled for publication in *Pediatrics* September 2006.)

ⁱⁱ American Academy of Pediatrics. Children, Terrorism & Disasters Toolkit. The Youngest Victims: Disaster Preparedness to Meet Children's Needs. <http://www.aap.org/terrorism/topics/PhysiciansSheet.pdf>

ⁱⁱⁱ American Academy of Pediatrics. Children, Terrorism & Disasters Toolkit. The Youngest Victims: Disaster Preparedness to Meet Children's Needs. <http://www.aap.org/terrorism/topics/PhysiciansSheet.pdf>

^{iv} Hagan, J and the Committee on Psychosocial Aspects of Child and Family Health and the Task Force on Terrorism. Psychosocial Implications of Disaster or Terrorism on Children: A Guide for the Pediatrician. *Pediatrics*, Vol. 116, No. 3, September 2005.

^v Niska R and Shimizu I. Hospital Preparedness for Emergency Response: United States, 2008. *National Health Statistics Reports*, No. 37, March 24, 2011.

^{vi} Markenson D, Reynolds S, Committee on Pediatric Emergency and Medicine and Task Force on Terrorism. The Pediatrician and Disaster Preparedness. *Pediatrics*, Vol. 117 No. 2 February 2006.

^{vii} Gausche-Hill M, Schmitz C, Lewis RJ. Pediatric preparedness of United States emergency departments: a 2003 survey. *Pediatrics*. 2007;120(6):1229-1237

^{viii} Fagbuyi DB, et al. A Rapid Medical Screening Process Improves Emergency Department Patient Flow During Surge Associated With Novel H1N1 Influenza Virus. *Annals of Emergency Medicine*, Vol. 57, No. 1, January 2011.

^{ix} Nager AL, Khanna K. Emergency department surge: models and practical implications. *J Trauma*. 2009;67(2 Suppl):S96-99

^x MacPherson M et.al. A New Definition of Children with Special Health Care Needs. *Pediatrics*, Vol. 102, No. 1, July 1998.

^{xi} Van Dyck P et.al. Prevalence and Characteristics of Children With Special Health Care Needs. *Arch Pediatr Adolesc Med*, Vol. 158, No. 9, September 2004.

^{xii} National Commission on Children and Disasters. *2010 Report to the President and Congress*. AHRQ Publication No. 10-M037. Rockville, MD: Agency for Healthcare Research and Quality. October 2010.

^{xiii} Committee on Environmental Health. Radiation Disasters and Children. *Pediatrics*, Vol. 111, No. 6, June 2003.