

Department of Health and Human Services (HHS)  
Public Health Emergency Medical Countermeasures Enterprise (PHEMCE)

## Pediatric Medical Countermeasure Roundtable for National Health Security

### Meeting Report

October 13-14, 2010  
Orlando, Florida



Convened by the HHS Office of the Assistant Secretary for Preparedness & Response (ASPR)  
Office of Policy and Planning  
Division of Medical Countermeasure Strategy & Requirements

Roundtable support provided by the Keystone Center

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## HOW TO USE THIS DOCUMENT

This document is intended to capture the proceedings from the Pediatric Medical Countermeasure (MCM) Roundtable for National Health Security, convened by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) on behalf of the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE). This Roundtable was designed to provide a forum for in-depth, solution-oriented discussions among expert stakeholders from diverse sectors, disciplines, and geographical regions to inform federal policy regarding pediatric MCM needs in the event of a disaster, such as an intentional chemical, biological, radiological, or nuclear (CBRN) event, or an influenza pandemic. The methodology supporting this two-day meeting included plenary sessions and small, topic-specific breakout groups led by professional facilitators and memorialized through simultaneous note-taking during the not-for-attribution discussions.

In framing objectives and procedures, the meeting format was designed to respect the opinions and knowledge of the diverse subject matter experts (SME) who constituted the participant group. The diversity of expertise was further capitalized upon by ensuring a balanced mix of knowledge experts at each breakout session. Every attempt was made to document questions, answers, and the spirit of dialogue on critical issues associated with ensuring the availability of MCMs for pediatric populations in a public health emergency.

This document is intended for those who attended the meeting, as well as for interested stakeholders from all sectors. Roundtable discussion is summarized here rather than presented in verbatim or near-verbatim form. This report does not attribute statements to individuals. Roundtable participants were given the opportunity to review the final draft report prior to its clearance by HHS; all participants' comments were addressed in this report.

Five breakout sessions were conducted throughout the course of the meeting (two concurrent on Day 1, and three concurrent on Day 2). These sessions, focusing on pediatric MCM dispensing and response issues for specific threat types and pediatric MCM development opportunities, were customized to meet the needs of the discussion topics and participants. Thus, the summaries of those breakout sessions take different forms in this report. As expected, many sessions overlapped in topics addressed and in suggested solutions.

Presentations with PowerPoint slides or other visual aids are not summarized here; hard copies were provided to participants at the time of the meeting, and electronic files are available upon request from Alla Rutstein Bobbitt at [Alla.Bobbitt@hhs.gov](mailto>Alla.Bobbitt@hhs.gov). This report does capture the discussions immediately following presentations, as well as some of the discussions that occurred during presentations. The meeting agenda is included as Appendix A, and the participant list is included as Appendix B.

This summary should not be construed as a scientific report or an attempt to rigorously sample opinions. The document serves as part of a larger and ongoing effort to inform MCM activities in order to best serve the American people.

During review for formal clearance of this report, HHS determined that specific comments on some of the suggested solutions developed during the Roundtable were necessary. Each post-Roundtable comment has been inserted into the report in brackets just below the suggested solution it addresses.

## Executive Summary

The Pediatric Medical Countermeasure (MCM) Roundtable for National Health Security was convened on October 13-14, 2010, by the Office of the Assistant Secretary for Preparedness & Response (ASPR) at the U.S. Department of Health and Human Services (HHS), on behalf of the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).

The Roundtable was conceived to provide a forum for pediatric subject matter experts (SMEs) from the public and private sectors to engage in solution-based discussions regarding pediatric MCM requirements, preparedness, and response issues raised by the *National Commission on Children and Disasters 2010 Report to the President and Congress* and the *ASPR Pediatric Preparedness and Response in Public Health Emergencies and Disasters Workshop in October 2009*. The Roundtable aimed to guide PHEMCE policymakers in ensuring that children's unique needs in regards to MCMs are successfully met in emergency preparedness planning, disaster response, and recovery efforts. Real-life experiences from the 2009 H1N1 pandemic provided an important backdrop for discussions.

Two days of active discussions among participating stakeholders yielded the following key themes and suggested solutions:

➤ **Address Regulatory Challenges:** Many participants voiced concerns regarding the current regulatory standards for obtaining pediatric indications for MCMs. As it stands, the Food and Drug Administration (FDA) requires that safety and dosing studies for all populations be conducted in Institutional Review Board (IRB)-approved clinical trials, which is often not ethical or feasible for pediatric MCMs. Likewise, the development of pediatric animal models presents significant challenges. Suggested solutions included:

- Ease FDA regulatory standards to allow 1) the pediatric use of CBRN MCMs in a public health emergency, and 2) the stockpiling of those MCMs for that purpose.
- Amend the Animal Rule to allow extrapolation to pediatric populations from testing in adult animals, along with use of animals for safety and pharmacokinetic studies when clinical alternatives are not feasible.

[Post-Roundtable Comment from FDA: Appropriate juvenile animal models should be explored, including non-human primates. FDA may, on a case by case basis, extrapolate from adult animal efficacy for pediatric use. However, safety data, if not obtainable in children, may need to come from adult human studies or studies of the drug in children in another indication. The FDA has experience with pharmacometric modeling (e.g., estimating the response of pediatric patients to a drug based on adult pharmacokinetic (PK) data and information from similar drugs used in the pediatric population) to develop drug dosing recommendations in the pediatric population.]

- Allow use of both historical and foreign data that fulfill our criteria for sound science to support pediatric Emergency Use Authorizations (EUAs) and other appropriate authorizations

[Post-Roundtable Comment from FDA: FDA will consider these data sources for EUAs and approvals, provided the data were obtained under adequate protections for humans involved in research, and are applicable to the U.S. population.]

- In the absence of sufficient pediatric data for submission of a pre-EUA package, provide clinicians with dosing and use guidance derived from the best available data and experience with the given MCM and/or similar drugs, with caveat that this guidance could only be applied for use in an emergency (of note, this cannot be “officially” done under current laws/regulations, which may need to be revisited)

[Post-Roundtable Comment from FDA: FDA is not aware of current laws or regulations that would prevent it from providing dosing and use guidance from the best available data and experience with the given MCM or similar drug, should the emergency require it. FDA used available scientific data when it issued the 2009 EUA for oseltamivir to provide dosing guidance for pediatric patients less than one year of age. No pre-EUA package on oseltamivir dosing for children less than one year of age was submitted prior to the H1N1 public health emergency.]

- Institute an expert chemical, biological, radiological, and nuclear (CBRN) MCM advisory group for FDA, to include pediatric experts.

- **Facilitate data collection on pediatric use of MCMs in an emergency:** It is important to be able to take advantage of opportunities to gather pediatric data in affected children if there is a natural or intentional release or outbreak of a CBRN agent. However this would be extremely challenging due to the need for post-event local institutional IRB approval of proposed protocols (resulting in loss of precious time for data collection). Suggested solutions included:

- Institute pre-approved data collection protocols prior to an event, both domestically and, if at all possible, internationally
- Stand up a specialized “national” IRB that would be responsible for assessing pediatric and other MCM study protocols in emergencies (and would vet such studies pre-event to the degree possible)

- **Reduce barriers to pediatric MCM development:** Industry is not incentivized to invest in pediatric MCM development due to inherent risks, complexities of data collection, and the limitation of the U.S. government being the only customer. Suggested solutions to these problems included:

- Boost industry incentives for pediatric MCM development (e.g., longer patent exclusivity, priority reviews, financial rewards).
- To facilitate pediatric MCM data collection, leverage the resources and expertise of, and provide increased support to, organizations such as the *Pediatric Emergency Care Applied Research Network* (PECARN).
- Encourage the HHS Biomedical Advanced Research & Development Authority (BARDA) to fund advanced development of pediatric MCMs if industry sponsors cannot be found.

**[Post-Roundtable Comment from BARDA and FDA:** If an industry sponsor is not willing or able to perform studies toward advanced development of pediatric MCMs, BARDA and the National Institutes of Health (NIH) have a mechanism by which they can collaborate and allow BARDA to sponsor such studies.]

- Explore opportunities for concurrent development of MCMs for both adults and pediatrics, along with options for developing “universal” formulations/products that could be used for everyone.
- **Improve local dispensing and medical response capabilities to adequately address the needs of pediatric populations:** Existing state and local resource, staff, and training challenges for effective MCM dispensing and administration are compounded for serving pediatric populations. Liability concerns and lack of information about existing MCMs are another complicating factor. Suggested solutions included:
  - Provide information/education to the response community regarding liability protections for use of available pediatric MCMs in an emergency.
  - Extend the Public Readiness and Emergency Preparedness (PREP) Act to cover state-owned MCM stockpiles.
  - Provide easily accessible training opportunities for medical personnel on using stockpiled and other assets to adequately address pediatric MCM needs in an emergency (e.g., online resources, leaflets, locally offered seminars).
  - Encourage and advance pediatric MCM response planning and coordination through private-public partnerships and leveraging of local SME resources (e.g., work with pediatric emergency departments and schools).
  - Conduct MCM-related public information campaigns and forums to foster pre-event “buy-in” and preparedness by local civic and professional communities; medical groups could be leveraged as important partners.
  - Encourage and provide resources for personal/family disaster planning.
- **Establish a multi-stakeholder pediatric MCM working group to advise HHS on pediatric MCM emergency preparedness:** Such a group would provide suggestions and guidance for addressing the challenges identified in the current Roundtable as well as others that emerge over time. The group should be structured to enable inclusion of pediatric SMEs from diverse sectors, including local, state, tribal, and territorial planners and responders, industry representatives, researchers/academicians, medical professionals, and federal officials.

Representatives of ASPR and the PHEMCE who were present indicated that they will actively follow up on the suggested solutions from the Roundtable, and will continue working with public and private stakeholders to advance pediatric MCM preparedness.

## I. INTRODUCTION

This report captures the major themes and key observations that emerged from discussions at the Pediatric Medical Countermeasure (MCM) Roundtable for National Health Security on October 13-14, 2010 in Orlando, Florida.

The Pediatric Medical Countermeasure Roundtable for National Health Security was convened by the Office of the Assistant Secretary for Preparedness and Response (ASPR) at the U.S. Department of Health and Human Services (HHS), on behalf of the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE).<sup>1</sup>

ASPR, within the framework of the PHEMCE, and in partnership with other HHS and interagency partners, oversees the advanced development and acquisition of MCMs (e.g. drugs, vaccines, diagnostics) to protect the civilian population against the adverse health effects of chemical, biological, radiological, and nuclear (CBRN) agents, as well as pandemic influenza and other emerging infectious disease emergencies. The MCM requirements developed by the PHEMCE and approved by the Enterprise Senior Council establish the qualitative and quantitative characteristics of the MCMs that HHS may seek to procure for the Strategic National Stockpile (SNS) and ensure that these products are available and usable when needed.

This Roundtable was conceived to provide a forum for pediatric MCM and emergency response experts from the public and private sectors to engage in solution-based discussions regarding pediatric MCM requirements, preparedness, and response issues raised by the *National Commission on Children and Disasters 2010 Report to the President and Congress* and the *ASPR Pediatric Preparedness and Response in Public Health Emergencies and Disasters Workshop* in October 2009. The Roundtable aimed to guide PHEMCE policymakers in ensuring that children's unique needs in regards to MCMs are successfully met in emergency preparedness planning, disaster response, and recovery efforts. Real-life experiences from the 2009 H1N1 pandemic provided an important backdrop for discussions.

Participants in the Roundtable were drawn from federal, state, and local government agencies, industry, professional associations, academia, and the medical and emergency response communities, and they represented a diverse set of fields including pediatrics, emergency medicine, pharmacology, developmental health, drug development and review, public health emergency preparedness and response, and counterterrorism.

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<sup>1</sup> The PHEMCE is a coordinated HHS inter-agency effort among the ASPR, the National Institutes of Health (NIH), the Food & Drug Administration (FDA), and the Centers for Disease Control and Prevention (CDC) that sets MCM requirements and guides the research, development, procurement, deployment, and utilization policies for MCMs targeted at CBRN and naturally emerging disease threats (including pandemic influenza) being procured for or already held in the SNS. The Departments of Defense, Homeland Security, Agriculture and Veterans Affairs are also members of the PHEMCE.

The Roundtable sought to inform federal understanding of the following issues:

- Considerations for mass dispensing and administration of MCMs to children in a mass casualty emergency, including protocols for using MCMs that do not have a pediatric indication.
- Ethical issues surrounding pediatric MCM dispensing and administration (e.g., MCM triage and prioritization, and decision making in the absence of parents or guardians).
- Regulatory challenges and opportunities, including addressing the lack of FDA approval for pediatric use of the majority of MCMs currently in the SNS.

**[Post-Roundtable Comment from FDA:** From FDA's perspective, the majority of MCMs currently in the SNS do have some pediatric labeling, although it may not cover all pediatric age groups. It should be noted, however, that there are MCMs in the SNS that have some or full pediatric labeling but are not approved for counterterrorism indications in any age group.]

- Local/state capabilities and planning pertaining to addressing pediatric MCM needs during an emergency response.
- Desired product characteristics for pediatric MCMs addressing major intentional threats, including acceptable risk-benefit profile in an emergency.
- Needs and challenges in the development of novel pediatric MCMs.
- Challenges and opportunities for extending label indications of existing MCMs for pediatric use.
- Promising strategies for creating incentives for and removing barriers to pediatric MCM development.

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## DAY ONE

### II. OPENING SESSION

#### Opening Remarks

Dr. Lisa Kaplowitz, Deputy Assistant Secretary of Health and Human Services for Preparedness and Response and Director, ASPR Office of Policy and Planning (OPP), opened the meeting by welcoming participants and stressing the importance of the Roundtable's objectives. Edward Gabriel, Director, Global Crisis Management and Business Continuity for The Walt Disney Company, welcomed participants on behalf of Disney and the local community.

Facilitators from The Keystone Center reiterated the meeting purpose and reviewed the agenda and ground rules.

## **Medical Countermeasure Policy, Strategic Planning, and Requirement-Setting at the Federal Level**

Dr. Monique K. Mansoura, Director, Division of Medical Countermeasure Strategy and Requirements (MCSR) at ASPR/OPP, provided an overview of the MCM requirement-setting process within the government and highlighted PHEMCE's current efforts to address pediatric MCM needs.

Observations by Dr. Mansoura included the following:

- The federal government has the unique responsibility of improving the nation's public health emergency preparedness. This task includes enhancing the response and recovery capabilities for pediatric populations, including developing and acquiring MCMs and ensuring their effectiveness.
- Although much of the discussion at the Roundtable will be focused on MCM response to CBRN threats, it is important to also leverage lessons learned from infectious disease outbreaks such as H1N1, as well as natural disasters.
- OPP is responsible for high-level strategic policy and planning to support domestic and international public health emergency preparedness and response activities within ASPR, HHS, and the federal government.
- ASPR manages the PHEMCE, which collectively oversees MCM research and development (NIH), advanced development (ASPR/BARDA), regulation (FDA), acquisition (BARDA and the Centers for Disease Control and Prevention [CDC]), storage and maintenance (CDC), and deployment and utilization (CDC and ASPR's Office of Preparedness and Emergency Operations [OPEO]).
- Key questions considered in setting MCM requirements are who will get what, when, and how.
- MCMs and the planning considerations that go along with them involve a complex array of evolving threats.
- MCM development is time-intensive and expensive.
- MCM development and response are further challenged by the diverse populations being served in an emergency, including pediatric populations, immunocompromised individuals, the elderly, and others.
- Stockpiled MCMs are part of the public health emergency preparedness assets intended to address threats such as anthrax, smallpox, botulism, bacterial threats, radiological and nuclear threats, chemical threats, and influenza.

Dr. Mansoura stated that she hoped this group would help to further identify and prioritize outstanding needs related to responses for a CBRN event, with a focus on MCMs for pediatric populations.

**Comment:** A participant suggested that it would be helpful to understand the federal government's plans and capabilities better before attempting to help identify gaps.

**Answer:** The fact that there are questions about this represents a gap in itself. While the locations of the stockpiles are secret, the plans and general capabilities are not, and the stakeholders participating in the meeting should ideally be well-informed. If they are not, there is a communication breakdown that needs to be addressed.

**Comment:** A participant suggested that the federal government needs to provide the appropriate incentives to companies that develop MCMs. It is difficult to motivate innovation and development in cases where the government is likely to be the sole client.

**Answer:** One strategy might be to build capacity around ongoing needs such as vaccine for seasonal influenza. Other strategies are being explored as well, and will be one of the topics of discussion at this meeting.

**Question:** How can partnerships be leveraged at the local level with schools and other entities?

**Answer:** It works best when state and local governments already have established good working relationships with schools prior to an emergency situation. To the extent that schools are active partners, this is invaluable. Further leveraging and partnering with the private sector can also be beneficial.

**Comment:** The fact that pediatric MCMs cannot ethically be tested in children using conventional methods and standards presents a significant challenge in both developing such drugs and securing FDA approval.

**Answer:** Agreed. Presently, MCM efficacy must be tested on animal surrogates and then extrapolated to humans, including pediatric populations if appropriate models exist. Safety and dosing studies are traditionally done in clinical trials, which can present a challenge in children. FDA will be covering these issues in more depth in its upcoming presentation.

**Question:** The federal government seems to be trying to walk a middle road with its elaborate response system, trying to allow people outside the chain of command to have flexibility in the midst of an intervention. What has and hasn't worked in other countries that lack such an elaborate system? Can lessons be learned from experiences in Iraq, Israel, and East Asia?

**Answer:** The U.S. needs to learn from whatever best practices are available. ASPR does work closely with the Department of Defense (DOD) as well as foreign partners to understand military and non-U.S. experiences. A fundamental difference is that military entities are primarily focused on ensuring the safety of their personnel before they go into harm's way (i.e., MCM protection before entry into a high-risk environment), rather than in a post-exposure setting. HHS is primarily focused on post-incident response in regard to the dispensing of MCMs. However, the President's recent Executive Order is causing a shift toward timely availability of MCMs. An example is the model of using the United States Postal Service (USPS) as a method of rapid strike distribution. Significant international dialogue is underway, but the U.S. is often the envy of other countries for its degree of and infrastructure for preparedness.

**Question:** To what extent can the federal government make available “best practices” and “lessons learned” from other countries, DoD, and other parties?

**Answer 1:** In terms of making this information publicly available, there is no agreement at the federal level about the appropriate level of information to share with professionals or with the public.

**Answer 2:** Public engagement is a cornerstone of our mission. Public buy-in and willingness to trust the MCMs and the supporting system can be as important as the interventions themselves.

**Comment:** Is there sufficient focus on the medical devices needed to deliver vaccines and other MCMs to children?

**Answer:** FDA and NIH are working together to give increased attention and funding to pediatric device development.

**Comment:** It is essential to think outside the box regarding what the U.S. has—and allows—in the SNS. We tend to insist on a burden of evidence that is rarely available. In the course of a regular pediatric practitioner’s day and especially in the course of responding to a major disaster, the majority of decisions that have to be made do not fall into the realm of what is officially approved by regulation. About 70% of the medications administered in hospital settings are used “off label” (i.e., do not have pediatric indications) using the provider’s best judgment and experience. We need to avoid the “regulatory checkmate” and find a path forward to ensure that regulatory standards for stockpiling MCMs for pediatric use are not overly restrictive, since MCMs used to treat pediatric patients in the context of an emergency are very likely to be investigational and/or without a pediatric indication.

### III. BREAKOUT SESSIONS: PEDIATRIC MCM DISPENSING AND MEDICAL RESPONSE

Participants divided into two concurrent discussion groups to consider different scenarios (involving biological and chemical attacks) with implications for a pediatric response.

Within the context of those scenarios, each group explored the following:

- Considerations for mass dispensing and administration of MCMs to children in a mass casualty emergency—including protocols for using MCMs that do not have a pediatric indication.
- Ethical issues surrounding pediatric MCM dispensing and administration (e.g., MCM triage and prioritization, decision-making in the absence of parents).
- Local and state capabilities and planning pertaining to pediatric MCM needs during an emergency response.
- Desired product characteristics for pediatric MCMs addressing the threat in question, including acceptable risk-benefit profile in an emergency.

## **Group A: Chemical attack**

In this breakout, the group considered a hypothetical nerve agent scenario at an amusement park, involving a number of pediatric cases. The group sought to identify likely response gaps, potential actions to address these gaps, and whether the gaps could be addressed in the near, mid, or long-term.

**Gap:** Participants indicated that communication will likely break down during the initial response. Information capabilities may be overwhelmed and misinformation may be extensive.

**Potential action:** Find ways to test and improve communication networks and coordination. Pay particular attention on how to link with federal-level assistance and expertise.

**Timeframe:** Ongoing effort that could be addressed in the mid-term.

**Gap:** Responders anticipate they are unlikely to get accurate, actionable information about the type and intensity of the CBRN event.

**Potential action:** Improve CBRN event detection capabilities that can help to guide EMS personnel in a response.

**Timeframe:** Ongoing effort that could be addressed in the mid-term.

**Gap:** Participants noted that pediatric dosing of MCMs that have multiple dosing levels for children of different ages and weights, and that are different from adult dosing, is likely to be confusing and overwhelming in a mass casualty event.

**Potential action:** Inventory dissimilar dosing frameworks between MCMs and move toward a standard framework that color codes different doses based on weight and size of the individual. It may be easier to have the standard dose be a pediatric dose and to increase (e.g., double or triple) it for adult doses.

**Timeframe:** Mid-term.

**Gap:** Participants noted that no clinical guidelines exist for formulating pediatric doses from MCMs currently in the SNS. Clinicians will use their best judgment in an emergency, but it would be preferable to have actual clinical guidance regarding dosing and altered standards of care for MCM administration and utilization for pediatric populations.

**Potential action:** Clinicians suggested that guidelines be developed in advance of a disaster. To the extent possible, an easy to use algorithm should be developed that indicates how to adjust dosing for pediatric populations.

**Timeframe:** Mid-term.

**Gap:** Participants indicated that not being able to include children in scientific studies is problematic in developing effective MCMs for pediatric populations.

**Potential action:** Participants suggested that conducting small dose de-escalation studies could be beneficial and yield important data. Regardless of strategy, finding a way to collect data that informs pediatric MCM dosing is essential.

**Timeframe:** Long-term.

**Gap:** Participants indicated that in a mass casualty event involving pediatrics, there may be difficulties and confusion regarding informed consent issues, particularly if parents are separated from children.

**Potential action:** Participants suggested creating a training program and exercises for a pediatric-focused CBRN event.

**Timeframe:** Mid-term.

**Gap:** Participants felt constrained by the emergency use guidelines. While well-intentioned, participants noted that the current guidelines can inhibit the ability to dispense MCMs in the event of a disaster. For example, products in CHEMPACKS are under the Shelf-Life Extension Program and so may require an Emergency Use Authorization (EUA). It was noted that emergency responders are worried about liability issues pertaining to MCM distribution in general, and especially to pediatric populations, if a response is necessary before an emergency is officially declared (which is likely).

**Potential action:** Enable a pre-event EUA that is inclusive of any necessary provisions for pediatrics.

**Timeframe:** Mid-term.

**Gap:** Participants noted that it is important to align regulatory status with utilization policy.

**Potential action:** Participants suggested establishment of a working group focused on MCMs for pediatric populations to ensure that the regulatory environment facilitates availability of the best possible care of pediatric populations during a CBRN event.

**Timeframe:** Mid-term.

**Gap:** Participants discussed the liquid potassium iodide (KI) example, where a pediatric MCM was developed and offered for free to states and locals. The MCM was rejected by state and local officials because the “free” MCM would come with hidden costs and financial burdens. For example, states would need to find suitable storage conditions, and replace the KI once it expires.

**Potential action:** Participants suggested that the federal government could develop and support a “total care” approach where funding and resources include storage, maintenance, and replacement of expired MCM stockpiles, similar to the CHEMPACK concept. State and local officials should be an integral part of developing this “total care” systems approach.

**Timeframe:** Long-term.

**Gap:** Participants suggested that health disparities issues must always be addressed within the context of pediatric MCMs and utilization policies and guidance.

**Potential action:** Participants recommended that the federal government convene a conversation about health disparities related to pediatric populations.

**Timeframe:** Long-term.

## **Group B: Biological Attack**

Participants in this breakout group were introduced to a scenario in which:

- A covert ground-based release of aerosolized anthrax spores occurs upwind of a major amusement park.
- Suspects are identified and contacted by law enforcement during the release.
- Anthrax is suspected but not confirmed.
- 25,000 visitors, workers, and neighbors are potentially exposed, 15,000 of whom are under the age of 18.
- The release is leaked to the press, followed by a massive surge to medical facilities.
- State and national public health emergencies are declared.

Later in the breakout session, participants were also asked to consider a scenario in which a large metropolitan anthrax release was detected by either BioWatch, or, in a worst-case scenario, via clinical detection (which would cause major delays in post-exposure prophylaxis [PEP]).

For both of these scenarios, participants were asked 1) to consider what happens next from the standpoint of PEP and treatment for pediatric populations; 2) to help identify the gaps, rate limiting factors, ethical issues and “I told you so’s” for addressing the MCM needs of pediatric populations (and whether some are more critical than others); and 3) what the solutions might be to address these challenges, either in the short-, mid- or long-term.

### ***Scenario response***

The group offered the following observations about the likely elements of response:

- Decontamination will take place quickly because responders have been trained to execute it immediately.
- Possible containment of the exposed population (pending PEP) may take place, but regardless, communication with potentially exposed persons will happen quickly. However, controlling the message will be critical, as set forth below.
- SNS “Push Packages” should be delivered within 12 hours of the decision to deploy; however, local cache breakdowns should be expected. (Other SNS assets may be delivered either on a similar timeline or following the Push Packages.)
- Incident command and public relations need to be coordinated to ameliorate the panic and help promote the response needed. The response may be broader than medically needed, depending on how well communications are coordinated.
- Authorities will need to confirm that the substance is anthrax and if so, the characteristics of that anthrax (strain, concentration, etc.).

- Parents will add an additional component to the need for information and treatment. Families will need to be treated as families; triaging kids first is unlikely to be a viable option.
- Unaccompanied minors will also be present, and a policy should be set in advance for how to treat and accommodate them.
- In terms of triage, life-years versus lives saved may be considered. Some of the triage protocols used in Haiti may be a good model.

### ***Communications***

Participants stressed the importance of communications in the immediate response to an event, and suggested the following:

- Media will need to be contacted quickly, given accurate information, and a spokesperson (likely a state or federal government official) identified.
- The spokesperson should be identified in planning efforts, and trained in advance of an event.
- One chain of command for media responses should be coordinated with the overall response process.
- Communications planning needs to recognize that the system will be dynamic, with many stakeholders and interested parties. The more advance planning, the better.

### ***MCMs***

With respect to the distribution and dispensation of MCMs, participants recommended the following:

- More pediatric suspensions could be considered for the stockpile; however, tablet crushing is also completely acceptable, and has numerous positive benefits for storage, dispensing and dosing considerations when compared to a liquid preparation. Crushing would also be much more practical and efficient in a mass casualty emergency setting. But clear and tested instructions would have to be provided to families.
- Responders will look to local facilities, such as children's hospitals and pharmacies, to address pediatric needs.
- The lack of pre-EUAs for pediatric indications of many stockpiled MCMs are a problem. If regulatory hurdles are the obstacle, guidance needs to be provided to clinicians for the emergency use of these MCMs (especially ones with which they are unfamiliar, such as anthrax antitoxin) in children, based on best available data.
- Vaccination may be a consideration for children in the event of a large scale anthrax event, though current vaccine (which requires 3 doses, takes 21 days to take effect, and has not been tested in pediatric populations) would not be a good candidate.

Next-generation vaccines with faster activity and one-time administration may be an option worth pursuing.

### ***Challenges and Potential Solutions***

The facilitator asked participants to identify challenges associated with a response to this scenario, and then to suggest solutions to those challenges. Discussion yielded the following points:

**Challenge:** MCMs that must be quickly administered to many people and require weight- or height-based dosing for children will be challenging for responders/medical providers and are likely to cause confusion and delays.

**Potential Solution:** Dose-banding (e.g., on syringes), pre-provided measuring devices, and/or age- and weight-based dose cards.

**Challenge:** Personnel resources will always be a limitation, especially those with knowledge of/specialty in pediatrics.

**Potential Solution:** Training (pre-event) and resources, including proper use of available MCMs to address pediatric needs, to equip local response efforts to adequately respond and be prepared to competently handle children's needs in an event.

**Challenge:** Palatability of the suspension and crushed tablets for ciprofloxacin

**Potential Solution:** Research on alternative formulations, e.g., microencapsulated granules with improved stability and taste (if mixed in with food/liquid).

**Challenge:** Compliance issues associated with lengthy 60-day regimen of currently stockpiled PEP antibiotics and corresponding adverse events, such as diarrhea, which will be especially challenging for parents trying to give the meds daily for two months to (often increasingly resistant) children; difficulty of determining and communicating the risks vs. benefits of taking a complete course.

**Potential Solution:** Compliance aids such as dosing charts and calendars, automatic email/text reminders, treatment "cards" with easy-to-follow instructions for users, and effective public communication about the importance of completing a full 60-day course and suggestions for parents.

**Challenge:** Liability issues associated with state-owned and locally available MCMs (i.e., those not covered by the Public Readiness and Emergency Preparedness [PREP] Act, which only applies to federally stockpiled assets).

**Potential Solution:** Inclusion of state caches under the PREP Act and improved communication regarding both state and federal liability protections in an emergency.

**Challenge:** Caring for children with special needs (e.g., allergies).

**Potential Solution:** Organize database/registry systems to coordinate response efforts to children listed as having special needs and establishing linkages to existing systems. Also, actively engage children's hospitals in developing protocols for special needs children.

**Challenge:** Limited capabilities of local PEP dispensation in a mass casualty situation.

**Potential Solution:** Pre-position antimicrobials in schools in coordination with local public health officials and consider other pre-positioning and quick deployment strategies (e.g., MedKits and USPS, provided clear instructions for pediatric dosing are included).

**Challenge:** Medical care for treatment of symptomatic patients is complex (e.g., blood needs, screening, IV lines, medical monitoring, respirators), and will be even more so in children, while both trained personnel and information on pediatric MCM use will be scarce. If there is no such information, physicians will have to guess at dosing and treatment guidelines, since they will not hesitate to use these MCMs in life-or-death situation.

**Potential Solution:** If pediatric dosing/use guidelines are not included in the MCM label or under a pre-EUA, the best available data should be used (or additional data collected as feasible) to provide guidelines to physicians for emergency pediatric use and dosing of these MCMs, especially those unfamiliar to physicians (such as anthrax antitoxin). Planning for availability of needed supportive care resources and provision of appropriate pre-event staff training is also critical.

**Challenge:** Lack of leadership for the citizen's role in a response—the “who's in charge” and “whom do I trust” syndrome. There is a lack of a sense of personal responsibility for being prepared in the event of an attack. For children's needs, parents will be the ones most needing guidance, support, and trustworthy sources of information.

**Potential Solution:** Establish a campaign to change the public's attitude toward preparedness and do it ASAP, prior to an event, including special information and resources provided to parents. Engage local/state governments, community organizations, medical associations, schools, parent groups, private partners, and others in planning and executing the messaging to maximize its effectiveness and reach. Citizens *must* become part of the response by assuming some degree of accountability; in the case of parents, for both themselves and their children.

**Challenge:** Difficult triage decisions in the face of challenging conditions (e.g., patient surge, panic, uncertainty, resource scarcity), especially ethical decisions involving children (e.g., prioritization of treatment vs. adults, treating them without parents present, etc.).

**Potential Solution:** Consider life-years versus lives saved for triage planning, convene SME working groups to develop advance guidelines for children's care in scarce-resource situations, and disseminate key information to the public both before and during an event. Triage protocols and corresponding ethical considerations established by U.S. teams in Haiti could serve as a good model.

**Challenge:** Parallel coordinated communication during a response.

**Potential Solution:** Identify how response processes, with specialized information for addressing pediatric needs, can be automated for greater throughput (e.g., web-based, mobile-based, kiosk-based information) to help conserve staffing and maximize dissemination of knowledge and response effectiveness. Vet external guidance on use of existing MCMs in children with medical organizations or societies, and/or recruit them as partners in establishing message content and communication channels. Establish

communication and coordination plans ahead of time among both private and public local, state, and federal entities likely to be involved in a response, with pre-selected spokespeople for the public.

### ***Cross-Cutting Solutions***

In addition to the solutions that address specific challenges captured above, participants suggested the following measures:

- Eliminate the need for FDA-approved pediatric indication and/or submitted pre-EUA for pediatric MCM acquisition in the SNS (or develop specialized, eased regulatory standards to enable pediatric use of stockpiled MCMs, in context of the changed risk-benefit considerations in an emergency).

**[Post-Roundtable Comment from FDA:** There is no regulatory requirement that MCMs have FDA-approved pediatric indications to be acquired by the SNS. However, there is a requirement that a legal mechanism (IND, pre-EUA, approved indication) be in place to deploy a stockpiled drug during a public health emergency.]

- Develop visual disaster instructions for mass PEP.
- Involve pediatric and pediatric emergency medicine experts in local, state, and regional disaster plan formulations and exercises.
- Develop an online educational program for hospitals to offer guidance in meeting a high pediatric surge.
- Encourage and provide resources for the development of personal/family disaster plans, leveraging resources such as the Federal Emergency Management Agency's (FEMA) [www.ready.gov](http://www.ready.gov) website.
- Provide transportation for transient populations.
- Ensure that community medical practitioners are able to bill insurance for preparedness activities, or otherwise get reimbursed.

## **IV. OVERVIEW OF DISNEY'S PREPAREDNESS SYSTEM**

Edward Gabriel, Director, Global Crisis Management and Business Continuity, The Walt Disney Company, presented an overview of Disney's emergency preparedness and global crisis management structure. Broad topic areas included local authority for individual parks, organizational structure and culture, special accommodations for children and families, cooperative agreements, and cross-sector partnerships.

Participants then received a tour of Walt Disney World's Emergency Operations Center, with a focus on the Center, emergency management, and security.

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## DAY TWO

### V. PLENARY DISCUSSION ON DISNEY MODEL

Participants began the day by reflecting upon the previous day's field experience.

Observations about the relevance of Disney's approach to other sectors included the following:

- Corporations such as Disney enjoy a clear line of command/hierarchical structure, whereas multiple "silos" exist in municipalities and other state/local jurisdictions (e.g., local and state public health departments, fire and police departments, hospital systems, etc.). Several participants expressed doubt that the public sector could achieve the same degree of shared purpose and cohesive communication in the foreseeable future. However, participants agreed that this is a model we can pull from and potentially modify for the public sector.
- ASPR is the right government entity to break down barriers and serve as the single coordinator, but needs to be given the authority.
- The federal government's executive structure does not lend itself to a top-down command system (i.e., many parallel branches/agencies). Moreover, state and local jurisdictions generally operate independently of the federal government, with their own lines of authority. Therefore, the enterprise of MCM distribution and dispensing may need to rely on bottom-up leadership, which must include everyone coming together in advance to negotiate roles and set expectations. Government cannot function like a business, but can focus on building workable partnerships.
- State and local government entities have more limited resources than most private sector organizations do, and must negotiate priorities among various uses for those resources. Such resource constraints make it difficult to achieve as sophisticated an emergency response system as Disney and other corporations.
- The private sector cannot serve as the "gold standard" for preparedness without being willing to share information more extensively with other parties (thereby exposing brands to added potential risk).
- State and local governments have important messages to deliver about preparedness and response, but generally do a poor job at communicating those messages and at protecting their own "brands" (reputation with community, successful public engagement, etc).

### VI. MEDICAL COUNTERMEASURES FOR PEDIATRIC USE: ETHICAL AND REGULATORY CHALLENGES/OPPORTUNITIES

Rosemary Roberts, Director of the FDA's Office of Counter-Terrorism and Emergency Coordination at the Center for Drug Evaluation and Research (CDER), presented scientific and ethical considerations for the development of pediatric MCMs.

In her presentation, Dr. Roberts stressed the need to protect children through research. Adequate data are needed to support the safe and effective use of drugs, devices, and biological products in infants, children, and adolescents, in addition to adults. However, obtaining these data is non-trivial from both an animal research and ethical human research perspective. According to existing regulations, children may only be enrolled in research that is scientifically necessary and ethically sound, which can be a difficult standard to meet when it comes to CBRN MCMs.

Dr. Roberts noted that per current regulations, the selection of an appropriate dose and the assessment of pediatric safety should *not* be extrapolated from animals. Additional protections for children in research should include: appropriate balance of risks and benefits, scientific necessity, parental consent, and child assent. Risk can be minimized further by eliminating any scientific procedures that do not contribute to the scientific objective (i.e., that are not solely related to the investigational product).

The discussion following her presentation is summarized below, with answers and at times comments supplied by various representatives of FDA and other federal agencies.

**Question:** How do we get a product that has labeling indications for children into a device? There may be a temptation to use an auto-injector for kids just as we would for adults, but specialized pediatric auto-injectors would be needed. How can we provide the appropriate incentives to manufacturers to develop such devices?

**Answer:** Currently only one company in the U.S. manufactures auto-injectors. Government needs to provide a contractual incentive to manufacture auto-injectors for pralidoxime now that it has been approved for pediatric use.

**Question:** Has a pediatric plan been put in place for key existing MCMs? Will it include safety and dosing information?

**Answer:** Incoming applications for drugs and biologics should state their intent. Waivers and deferrals may be issued depending on the product. Development plans for pediatric populations are typically submitted by sponsors to fulfill a post-marketing commitment. FDA is generally initially engaged in licensing products for the adult population, since it is usually the indication/formulation that is developed first. Reviewers usually ask what will be done to accommodate pediatric and other special population needs, and requirements for such studies are often included in approvals as post-marketing commitments.

**General Comments:**

- Sequential development of MCMs from adult to pediatric populations is the industry standard due to the complexities of pediatric drug development. Every BARDA contract includes an option for extending the age ranges to pediatric and geriatric populations. Often, CBRN MCMs simply cannot be tested on children due to ethical constraints.
- FDA must seek opportunities to use investigational and new products to get data from children and gain direct benefit. With some threats (spontaneous outbreaks of

plague, for example), there may be opportunities in other parts of the world to test products in children while safety and efficacy concerns are part of the research initiative. In order to accomplish this, FDA needs to establish clear and appropriate research protocols in advance of such efforts.

- If a CBRN agent is released in the U.S., sites where data could be collected under research protocols associated with an Investigational New Drug (IND) application would need to be established.
- It needs to be determined what IRB to use in such circumstances, since a local IRB may trump any other. The most effective way to persuade an IRB of the appropriateness of such an approach is to demonstrate that the MCM has been studied sufficiently in adults without serious adverse events and that the product was efficacious. It would be important to establish confidence that children would not be exposed to more than a minor increase over minimal risk with a pediatric application of the investigational MCM. The IRB would need to agree that the investigation proposed can provide benefit to the health and welfare of children, in addition to agreeing with the protocol. This communication would need to take place in advance of an emergency event whenever possible.

**Comment:** Participants recommended that BARDA contracts be changed from including label extensions to pediatric age groups as contract options following licensure in adults, to incorporating requirements for such studies into the core contracts, whether to be done simultaneously with or following licensure in adults.

**Comment:** The system may not be ready for a 6-7 auto-injector (for dosing of diverse ages/weights) plan for response. It is a struggle for first responders even to maintain competency to use conventional Mark 1 kits. The sense of urgency that prevailed following the terrorist attacks of September 11, 2001 has lapsed somewhat. The government should be cautious about any likelihood of developing and putting forward a set of products that the market is not ready to absorb (i.e., that end-users are not prepared or inclined to use). Participants suggested re-evaluating the auto-injectors available and which populations they treat. Potential replacement of the current auto-injector schema with 2 or 3 “new” auto-injectors that can be used across adult and pediatric populations might be preferable to simply adding multiple pediatric auto-injectors to the stockpile.

**Question:** Is there an advantage to giving certain MCMs to healthy children, assuming that parents are willing?

**Answer/Comment:** It is enormously difficult to successfully conduct prospective pediatric studies to test safety and efficacy of interventions prior to an event, with the ethical obstacles of testing novel MCMs (such as anthrax antitoxin) in healthy children being a significant limiting factor. However, under current regulations, pivotal safety and dosing data cannot be extrapolated from animals and must be obtained from clinical trials. Efficacy, on the other hand, can be tested in animal models under the animal rule.

## VII. BREAKOUT SESSIONS: DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR PEDIATRIC USE

Three concurrent breakout groups addressed each of the following three issues:

- Development of novel pediatric MCMs (regulatory and market challenges, animal models).
- Challenges and opportunities for extending label indications of existing MCMs for pediatric use (including off-patent drugs available as generics).
- Creating incentives for and removing barriers to pediatric MCM development.

Since each breakout session focused on somewhat different challenges and emphasized different (although generally complementary) solutions, highlights of each group's discussion are outlined separately below.

### Group A

#### **Removing barriers to pediatric MCM development and extending label indications**

*Government should clearly signal its commitment to MCM development.* Participants felt the government needs to signal a stronger commitment to building a robust stockpile of MCMs relevant to pediatric populations. Extending Project BioShield, which currently sunsets in 2013, would be helpful, as would continuing to link to national security funds and interests. Additionally, the government should clearly indicate that the programs and MCM development are for pediatric as well as adult populations.

*Indicate a clear regulatory pathway for novel MCMs with pediatric applicability.* The MCM regulatory pathway is even more difficult for pediatric than for adult applications. There is an initial hurdle of extrapolating from animal models to adults, then an additional step of extrapolating from adults to children. Achieving clear consensus from a diversity of stakeholders regarding acceptable best practices in extrapolating from animal models to both adults and children could potentially be a first step. Stakeholders in such a discussion should include scientists, ethicists, and representatives of federal agencies, industry, and medical associations.

*Develop consensus on MCMs already included in the SNS and how those might be applied to pediatric populations in an emergency.* Participants suggested to first start with the MCMs that have been approved for adult use and then convene a diversity of stakeholders from the American Academy of Pediatrics (AAP), the American Medical Association (AMA), pharmacists, and others to assess how to apply what is currently in the stockpile to pediatric populations under emergency circumstances.

### Incentives

*Liability protection.* Liability protection exists during an officially declared public health emergency due to a CBRN incident, but not at any time prior to the incident. Industry could

be further incentivized if such protections were in place during studies and other pre-event activities.

*Long-term contracting and exclusivity.* Longer-term contracts and commitments are needed for MCM development and manufacturing. While short-term contracting makes sense in many areas of government procurement, it is a clear disincentive from the standpoint of MCM development. Precedent exists in DoD contracting for products important to national security, and this model should be explored for MCM development and procurement.

*Transferable Priority Review.* Establishing a regulatory mechanism to enable priority review status to be transferable to similar products or classes of products would be a real incentive for industry. Ability for “exclusivity transfer” might also provide an incentive.

## **Group B**

### **Challenges in the development and availability of novel MCMs**

Participants observed that extrapolation to low-weight for exposure is difficult, and that the gap increases with younger children. Obtaining low-weight dosing information is difficult for the duration of a treatment. With the lack of any official guidance, the decision is presently in the hands of doctors.

Also, no mandate, justification, or regulatory impetus currently exists for seeking pediatric approval before adult approval.

### **Possible Solutions**

Participants identified the following possible short-term and long-term solutions to assist in the availability of pediatric MCMs:

- In the short-term, fact sheets regarding use of certain MCMs in children could be used in instances when there is a high certainty of a low probability of adverse effects. However, the regulatory and legal implications of creating such fact sheets for off-label and/or non-EUA uses are unclear (it is illegal for sponsors to develop such fact sheets; they would not be condoned by FDA, and development by medical societies could have liability implications).
- MCMs could be provided in several pre-packaged doses, based on body weight.
- Delivery systems other than auto-injectors may work well, such as rectal and intranasal treatments (with the exception of chemical MCMs).
- Detailed modeling of the impact on and needs of children in various types of emergencies can help address some of the challenges of developing new MCMs for pediatric use.
- A PHEMCE review of optimal incentives for industry could be helpful in identifying priorities and targeting strategic investments.

- A system somewhat like the hospital credentialing process—which allows for emergency exemptions for off-label pediatric use of MCMs with information on exceptions—might help move development forward.
- A national IRB needs to be stood up and maintained (pre-event/in near future) with a standing protocol to allow quick data collection during an emergency. Such an IRB might also allow for or encourage data collection during small-scale events. Poison Control Centers and the Agency for Toxic Substances and Disease Registry may also be able to play a role.
- In the case of an event, access trumps research. Lessons learned include building in access to data collection for at least some patients up front, and working in advance with organizations treating children.
- ICUs and pediatric emergency care services provide some helpful examples of pediatric practitioners using their best judgment and experience for pediatric use of products not approved in children. Their practices should be leveraged for developing optimal strategies for pediatric MCM use in a CBRN emergency.
- *The Pediatric Emergency Care Applied Research Network (PECARN)*, which is funded by the Health Resources and Services Administration (HRSA) as well as outside grants, is an ideal resource for advancing pediatric MCM drug development. Collaboration with and funding for PECARN by the PHEMCE and private partners could greatly help in filling pediatric MCM data gaps.
- Systems for long-term follow up of pediatric (and other) patients following an emergency will be necessary to assist with data collection (e.g., tracking those exposed in the Tokyo sarin attack). Without such systems in place pre-event, tracking patients and estimating level of exposure and received treatments is extremely challenging.

### **Priority MCMs for Pediatrics**

Participants were asked to identify the highest priority areas for development of pediatric MCMs. Suggestions included the following:

- Focusing on essential basics of life-saving treatments as a priority is appropriate.
- Appropriate use of anthrax PEP antibiotics for children (dosing, compliance) is challenging for non-medical professionals/the general public and diverse populations. More research is needed on comprehension of instructions for appropriate administration. (It was noted that BARDA is conducting a study, and broader research may be forthcoming that includes children's hospitals.)
- Guidance regarding dosing and administration of anthrax antitoxin for emergency treatment of sick children in a hospital setting is a high priority.
- Chemical event MCMs are a high priority, as is personal protective equipment for chemical agents.

- It was suggested that ASPR prioritize development based on the most likely events, to the degree that intelligence allows.
- End-users are generally least familiar with MCMs and treatment for radiological and nuclear threats, an issue that would be magnified when it comes to children. Much more education and information for the response community are needed.
- Diagnostics are also a priority, especially for children, as MCMs have side effects and should not be used in those who do not truly need them.

## Group C

### **Development of novel MCMs**

Discussion focused on the regulatory challenges surrounding pediatric approvals, resulting in slow approval processes and inadequate attention to pediatric needs. Several participants voiced concern that pediatric use of a novel MCM is simply an option rather than a mandatory consideration in development, and observed that the current “trickle-down approach” (i.e., centering on adults first and then considering use by children) in a biodefense context means that the pediatric application is delayed or never arrives.

Many participants (from different sectors) voiced strong support for the following strategies:

- Development of a cross-sector stakeholder working group to identify gaps and needs in pediatric MCM development. Participants should be drawn from federal agencies (e.g., FDA, BARDA, DOD, CDC, the National Library of Medicine); state, local, tribal and territorial governments; the private sector; and key areas of subject matter expertise.
- Multi-stakeholder advocacy with the U.S. Congress and at the FDA commissioner level to enable use of historical data from other countries to support EUAs and/or product approvals when analogous U.S. data is neither available nor obtainable. Current restrictions on doing so foster redundancy and inefficiency in the U.S., and such a mechanism may be especially useful for supporting pediatric indications for CBRN products that cannot be ethically tested in children outside of an event.

Individual participants also offered the following recommendations:

- FDA should revisit the animal rule to adjust guidelines for such models.
- Development efforts should focus on formulations that are universally accepted across all subsets of the pediatric population.
- BARDA should develop a consortium of pediatric expertise to support clinical trials to ensure collection of the necessary data.
- BARDA should ensure that all its product reviews are informed by pediatric expertise.

- FDA should work with its European counterparts to utilize existing models for global harmonization, in order to align standards and procedures relevant to novel MCM development for pediatrics.

### **Challenges and opportunities for extending label indications of existing MCMs for pediatric use**

Participants generally agreed that overly restrictive regulations limit the availability and use of MCMs for pediatric use. Regulatory changes are needed to allow for the stockpiling (SNS, state, and local) of products for use in children that have not received an FDA pediatric approval or do not have a vetted pre-EUA for pediatric use. To enable this change, several participants suggested the formation of a sanctioned panel of stakeholder experts to review existing MCMs and identify those that should be considered appropriate for pediatric use in emergency situations.

**[Post-Roundtable Comment from FDA:** The SNS has stockpiled products for use in children without these products having FDA approval or a pre-EUA for some or all pediatric age groups. The SNS has also stockpiled products that are not FDA-approved at this time. However, there is a requirement that a legal mechanism (IND, pre-EUA, approved indication) be in place to deploy a stockpiled drug during a public health emergency.]

### **Creating incentives for and removing barriers to pediatric MCM development**

Stakeholders from various sectors noted the challenge of insufficient incentives for the private sector to invest in pediatric MCM development, especially in cases where the government constitutes the sole client.

Participants suggested the following strategies to either increase the level of incentives for business or compensate for the lack of such incentives:

- Extend patent protection.
- Encourage BARDA to sponsor any research and development effort that industry declines.

**[Post-Roundtable Comment from BARDA and FDA:** If an industry sponsor is not willing or able to perform studies toward advanced development of pediatric MCMs, BARDA and NIH have a mechanism by which they can collaborate and allow BARDA to sponsor such studies.]

- Encourage industry to provide information and coordination to another party that actually conducts the research.

## VIII. PLENARY DISCUSSION ON DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR PEDIATRIC USE

Following reports from the preceding breakout sessions, participants highlighted several recommended measures to augment the development and availability of pediatric MCMs.

Several individuals emphasized the need to enhance industry incentives through steps such as long-term contracting, expanded liability protection, extended patent exclusivity, support from government up-front and throughout the early stages of MCM development, and collaborative data-sharing to inform research conducted by other parties.

Other suggestions included:

- Amending the animal rule, recognizing that in many cases adult animal models could potentially be extrapolated to pediatric populations, and that some interventions (such as for symptomatic anthrax) can never be tested using human subjects.
- Developing protocols to streamline FDA interaction with developers (while making FDA leadership aware of the present struggles).
- Allowing FDA to use data that is historical or from other countries.

**[Post-Roundtable Comment from FDA:** FDA will consider these data sources for EUAs and approvals, provided the data were obtained under adequate protections for humans involved in research, and are applicable to the US population.]

- Encourage BARDA to fund advanced development of pediatric MCMs if industry sponsors cannot be found.

**[Post-Roundtable Comment from BARDA and FDA:** If an industry sponsor is not willing or able to perform studies toward advanced development of pediatric MCMs, BARDA and NIH have a mechanism by which they can collaborate and allow BARDA to sponsor such studies.]

The group discussed the merits and feasibility of increased stakeholder involvement through establishment of both an SME working group to support FDA in approval decisions, and a panel of leading experts (drawn from various non-governmental sectors) to make recommendations regarding potential pediatric use of products that do not currently have a pediatric indication or pre-EUA.

Participants acknowledged the difficulties experienced by FDA in accessing the perspectives of SMEs due to increasingly restrictive rules regarding conflicts of interest. Individuals suggested utilizing existing networks such as the PECARN to help in data-gathering and refinement of strategies. FDA was advised to draw upon SMEs from various disciplines who are less likely to bring up conflict-of-interest concerns (e.g., toxicologists, emergency pediatricians), and to work with AAP and other professional organizations to identify appropriate experts. Academic centers within the armed forces can be another source of SMEs for consultation, advisory committees, and panels.

## IX. CLOSING REMARKS

Each participant was asked to highlight the top-priority action they hoped the PHEMCE would undertake going forward and (if possible and appropriate) a supporting action they themselves are able and willing to undertake.

Suggested priorities for PHEMCE to consider included the following:

- Ease or eliminate regulations restricting what goes into the SNS for use in children.

**[Post-Roundtable Comment from FDA:** The SNS has stockpiled products for use in children, without these products having FDA approval for some or all pediatric age groups or pre-EUAs in place. The SNS also has stockpiled products that are not FDA-approved at this time. However, there is a requirement that a legal mechanism (IND, pre-EUA, approved indication) be in place to deploy a stockpiled drug during a public health emergency.]
- Create a PHEMCE pediatric MCM working group comprising stakeholders from both the public and private sectors (federal, state, local government, academia, physicians, advocacy groups, industry, etc.) to provide guidance on pediatric MCM development and stockpiling.
- Set high ambitions, work with a sense of urgency, and avoid letting the perfect be the enemy of the good. Define the “dream MCM” and set to work trying to develop it, but also figure out how to use the resources currently available to save lives.
- Develop guidance—including algorithms—for pediatric MCM use for clinicians, including for those MCMs that are not approved or with pre-EUA for pediatrics (based on best-available data).
- Track off-label use of potential and existing MCMs by pediatricians in order to obtain use data.
- Develop a partnership among professional associations to collect needed pediatric pharmacokinetic and other data.
- Pursue a less complicated pediatric regulatory process, including providing industry with better clarity regarding what it needs to provide to FDA. Pursue global regulatory harmonization and data-sharing.
- Ensure horizontal integration from federal to local levels, so that plans and information are consistent.
- Provide clear advice on pediatric use of CHEMPACKs.
- Ensure pediatric considerations at all levels of MCM development (including within FDA and DoD).
- Pursue legislative amendments to allow the national security enterprise to sponsor and fund needed pediatric research.
- Articulate and then broadly disseminate a framework for triage of pediatric MCMs in case of limited resources.

It was also suggested that pediatric advocacy groups generally set CBRN MCMs as a top priority for their own research and advocacy.

Several participants voiced willingness to help PHEMCE and one another with developing pediatric MCM use guidance (including algorithms), advocating for needed regulatory changes, advocating for needed funding (e.g., for development of pediatric MCM applications), building partnerships, and mobilizing expertise for one or more working groups.

Prior to adjourning the meeting, Dr. Monique Mansoura (Director, MCSR/OPP/ASPR) identified several early priorities for PHEMCE based on participant input. Highlights included:

1. Providing clinical guidance for pediatric use of existing assets in the SNS.
2. Involving stakeholders early and often in MCM design.
3. Identifying partners to assist in “branding” the MCM enterprise, communicating broadly about MCMs, and advocating for preparedness.
4. Fostering increased public engagement. (“How do we rally our neighbors?”).
5. Asking local partners: What is your assessment of pediatric capability gaps?

Dr. Mansoura thanked participants for their contributions to the discussion, and stressed that ASPR will continue to engage actively with planners, end-users, and other stakeholders to enhance pediatric MCM preparedness going forward.

## APPENDIX A: Agenda



**U.S. Department of Health and Human Services  
Office of the Assistant Secretary for  
Preparedness & Response (ASPR)**

### **Pediatric Medical Countermeasure Roundtable for National Health Security October 13-14, 2010**

#### **Agenda**

**OBJECTIVE:** To provide a forum for pediatric subject matter experts from the public and private sectors to engage in solution-based discussions regarding pediatric medical countermeasure requirements, preparedness, and response issues raised by the *National Commission on Children and Disasters 2010 Report to the President and Congress* and the *ASPR Pediatric Preparedness and Response in Public Health Emergencies and Disasters Workshop* in October 2009. The roundtable will aim to guide PHEMCE policymakers to ensure that children's unique needs in regards to medical countermeasures are successfully met in both emergency preparedness planning, and disaster recovery and response efforts. Real-life experiences from the 2009 H1N1 pandemic will provide an important backdrop for discussions.

#### **October 13, 2010**

**7:30    Continental Breakfast in Meeting Room**

**8:30    Opening Comments and Introductions**

##### ***Federal Welcome***

Lisa Kaplowitz, Deputy Assistant Secretary of Health and Human Services for Preparedness and Response; Director, Office of Policy and Planning (OPP)

##### ***Local Welcome***

Edward Gabriel, Director, Global Crisis Management and Business Continuity, The Walt Disney Company

##### ***Introductions***

We ask that participants share their positions and affiliations, and the role they play in ensuring pediatric medical countermeasure (MCM) preparedness for, and/or effective response to, a CBRN public health emergency.

##### ***Review of Meeting Purpose, Agenda Review, and Ground Rules***

The Keystone Center

- 9:30 Medical Countermeasure Policy, Strategic Planning, and Requirement-Setting for at the Federal Level**  
*Monique K. Mansoura, Director, Division of Medical Countermeasure Strategy and Requirements (MCSR), Office of Policy and Planning (OPP), Office of the Assistant Secretary for Preparedness and Response (ASPR)*  
*This session will provide an overview of the requirements-setting process within the government, and showcase current PHEMCE efforts to address pediatric MCM needs.*

**9:50 Plenary Q&A and Discussion**

**10:15 Break**

- 10:30 Breakout Sessions: Pediatric MCM Dispensing and Medical Response**  
*Two breakout sessions based on scenarios (bio, chem) will walk through a CBRN scenario that has implications for a pediatric response. Within the context of that scenario, each group will seek to address the following issues:*
- Considerations/guidelines for mass dispensing/administration of MCMs to children in a mass casualty emergency, including protocols for using MCMs that do not have a pediatric indication
  - Ethical issues surrounding pediatric MCM dispensing and administration (MCM triage and prioritization, decision-making in the absence of parents)
  - Local/state capabilities and planning pertaining to addressing pediatric MCM needs during an emergency response; and
  - Desired product characteristics for pediatric MCMs addressing the threat in question, including acceptable risk-benefit profile in an emergency

**12:30 Lunch**

**1:00 Overview of Disney's emergency preparedness and global crisis management structure**  
Edward Gabriel, Director, Global Crisis Management and Business Continuity, The Walt Disney Company

**1:45 Depart for Walt Disney World's Emergency Operations Center field experience**  
*The field experience will focus on the Walt Disney World's Emergency Operations Center (EOC), emergency management and security.*

**4:30 Adjourn for the day**

**5:30 Cocktails (optional)**

**6:00 Group Dinner at Disney**  
*Arrangements will be made at a local restaurant.*

## October 14, 2010

**8:00 Continental Breakfast in Meeting Room**

**9:00 Plenary Discussion**

*This session will reflect upon the previous day's break-out sessions and field experience*

**9:30 Medical Countermeasures for Pediatric Use: Ethical and Regulatory Challenges/Opportunities (Presentation and Q&A)**  
*Rosemary Roberts. Director, Office of Counter-Terrorism and Emergency Coordination, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA)*

**10:15 Break**

**10:30 Breakout Sessions: MCM Development**

*Three breakout groups. Each will address all of these issues:*

- Development of novel pediatric MCMs (regulatory and market challenges, animal models)
- Challenges and opportunities for extending label indications of existing MCMs for pediatric use (including off-patent drugs available as generics)
- Creating incentives for and removing barriers to pediatric MCM development

**12:30 Lunch**

**1:00 Plenary discussion**

*Report outs and reflections from the morning break-out sessions*

**1:30 How to make it all happen**

*Full group discussion will focus on how to increase the priority and visibility for the development and acquisition of pediatric MCMs within the U.S. Government.*

**2:30 Break**

**2:45 Final impressions, questions, brainstorming**

*Emphasis on what have we missed?*

- What has not yet been discussed that could affect the design of emergency medical countermeasures for effective pediatric use?
- Are there other things you would like ASPR to know or keep in mind as we generate medical countermeasure requirements, or special factors we need to consider?
- If similar events were held in the future, what should be the focus?

**3:30 Closing Comments**

Monique K. Mansoura, Director, MCSR/OPP/ASPR

**4:00 Adjourn**

## **APPENDIX B: Participant List**

### **HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Pediatric Medical Countermeasure Roundtable for National Health Security**

**Orlando, FL October 13-14, 2010**

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