



Presidential Commission
for the Study of Bioethical Issues

TRANSCRIPT

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DR. WAGNER: Let me invite our next session, experts forward, Bruce Lockwood, Dr. Benjamin.

While they're getting set, let me set the stage for this next session, which is on countermeasures distribution. And, our speakers will address policies and programs for medical countermeasures distribution in the United States. Dr. Georges Benjamin is Executive Director of the American Public Health Association. Served previously as secretary of the Maryland Department of Health and Mental Hygiene, and as Deputy Secretary of the Maryland Public Health Services. Board Certified in Internal Medicine and a Fellow of the American College of Physicians, a Fellow of the National Academy of Public Administration, a Fellow Emeritus of the American College of Emergency Physicians and an Honorary Fellow of the World Society of Public Health. He is extremely well published with scientific articles and book chapters and brings great expertise to us. Dr. Benjamin, thank you for joining us. The floor is yours.

DR. BENJAMIN: Good morning, thank you very much. Let me just start by, um, you can go to the next slide. Thank you. Again, I just want to thank you very much for the opportunity for being here today. Just to remind you, I'm here in my capacity – my capacity at the American Public Health Association not in my capacity as National Biodefense Science Board or any other federal capacity, that I might have.

And, I want to talk about medical countermeasures and for the purposes of today, these are, therapeutics, prevention mechanisms used, uh for weapons of mass destruction, for emerging infectious diseases with really high casualty potential. So we're not going to talk about the common cold. And they include medicines, devices and other medical interventions in particular.

We often talk about high priority threats. This is the list that most people use, when they're talking about high priority threats. I know that you're very much focused on the anthrax today, but this just gives you a feel for what the list of threat concerns that people usually have when they're talking about medical countermeasures.

There is a national strategy that HHS has. This is a plan that was put out in, originally, 2007 and it's usually updated every five years. So, the 2012 plan, is the most current one. This is the Public Health Emergency Medical Countermeasures Enterprise Strategy. It has really four real important goals. One, to identify and create and develop and manufacture these various countermeasures. Two, establish and communicate clear regulatory pathways to actually get these countermeasures developed and used.

To look at the logistics and operational aspects of these countermeasures. And of course to look for gaps in the population, which includes children, seniors, underserved populations, etcetera.

So they look at implementation, there is an implementation plan, as well, that really has three overarching focus areas. One to address those – address those that are of most significance. Two to try to look at this in a holistic manner. If there is anything that we can do in terms of our medical countermeasures to address multiple threats that will be very helpful. And, of course to

look at these in the real world. They actually operationalize these, because there are lots of things we've learned, um, about theory and fact and actually delivering countermeasures, that we've learned over a series of public health threats both, the terrorist act in 911, including the anthrax letters. And, naturally occurring, events like the H1N1 or SARS.

Our central challenge, of course is distribution. Certainly every state has a distribution plan for medical countermeasures, as a component of their overarching and overall public health preparedness plans. I will point out that the first response is always local. We just saw that with Hurricane Sandy. The same with H1N1. We saw that with the anthrax letters. All the first response is local, and then, of course the federal response, is rapid.

Most states plan for in essence to be on their own for 72 hours, although the Strategic National Stockpile, is targeted to get there within 12 hours, and is prepositioned to be able to do that. We can talk about how complicated that really is.

The national central asset is the Strategic National Stockpile, which is a large, cache of, which is prepositioned, again, designed to get there within 12 hours. It includes pharmaceuticals, vaccines, antiviral drugs, a range of equipment including things like ventilators.

It really has two components. It is a – it manages things that are directly managed by the Strategic National Stockpile, and then, a series of vendors that they have that are contracted to get things to you in a “just in time” manner. But this was a big cache. This is not a little box that someone brings to you. This is a truck. This is a -- You think about a C130 aircraft coming in with just huge pallets of materials. So, it's not something that, you can put in your Jeep and drive up and pick it up, and take it where you need to go. It is a big deal, to get one of these, stockpiles, opened, delivered and, distributed to you.

There's a series of strategies that the people have been looking at over the years, um, led by a really massive national discussion. Certainly, you know, if something happens, you know, you can go to your doctor or the federal authorities or the local authorities can say, you know, this is happened. Go to your doctor and get a prescription. Your doctor can dispense. Your pharmacy can dispense, based on a prescription for some of the pharmaceuticals, cipro, tetracycline and things like that, some antiviral drugs.

Some of the health department either serving as a primary care or emergency provider, um, can do that as well. The Strategic National Stockpile, being a primary mechanism of getting things to people, there is another mechanism we call cached, medical countermeasures. These are smaller stockpiles in a pharmacy or in a school or in a warehouse, where you can tell people to go, to pickup medications. But, they're, pre-deployed and setup to distribute, pharmaceuticals.

They are, there is a, uh, there's been a pilot that has been done to actually, allow people to have, countermeasures in a little packet at home. So, everybody has one on the shelf at home. Um, there's some challenges with that. One of the – one of the concerns, of course, is are people going to open those up and use them every time they get a cold?

There are issues around, expiration of, of, of the pack. There issues around, them being inappropriately used for variety of members of the household.

And then, of course, a very public, discussion has been occurring and a trial has been run using the US Postal Service, as a primary deliverer of pharmaceuticals. The fact that they can get to every home in the nation within a defined period of time, there is a model which has been tried, and it seems to have been fairly successful to actually do that. But, again that was for primarily Cipro or an antibiotic model.

If you think about it, how complex it is to simply in a normal routine health system to distribute pharmaceuticals. It is very complex. You've got to authorize the person to get it. You've got to fill the therapeutic, particularly if it is in a vile or a multi-dose vial. Someone's got to draw it up, label it, make sure that the person that's going to get it is the right person that's supposed to get it.

If you're going to do this in large volume, it can be – it can be quite challenging doing H1N1. We had health departments, that took people through basically, drive-by centers where you stuck your arm out the window and you got your shot. There were places where people, you know, lined up for, for hours, just like you were voting, to go up, put your arm up and get your shot. So large volume dispensing is a big deal.

Of course, you've got to document this. You've got to have some mechanism to do, surveillance around adverse events. And, of course, ensuring compliance is a big issue particularly, when you have to give pills over a long period of time. We know that during the anthrax letter event that we did not have great compliance among people for a variety of reasons. I don't remember exactly the numbers but there was a huge variance in compliance amongst people that got that.

And, of course, this is the important one, specific challenges for children. We've been talking earlier about the parental consent and custody issues. Well, what do you do about someone with dual custody? What do you do about the kids that are in foster care?

The issue about the event occurs here, the parents are at work, the child is over here, and the parents are over here. Um, um, school issues, childcare issues.

The big issue around dosage variances from a lot of these medicines for kids. Um, will we even have enough of it – of the child dose? The range of, of, of, adverse events including allergies, making sure, that we've adjusted for that.

And, you know, Emergency Use Authorization and off label use for kids is one of those things, of course, that's part of the debate we're having today, and, actually, the fact that we often don't get the kids included in our response exercises. We do a lot of great exercises. We do tabletops. We bring folks in but, we really don't do a lot of great exercises with the kids.

So, a lot of this stuff really hasn't been tested on how you actually do this. Um, um, broad enough to have some confidence that we can do this on a repeated basis – on a repeated basis. With that I'll stop and be happy to take any questions that you might have.

DR. WAGNER: I think what we'll do is hold questions, until we hear from both of you.

DR. BENJAMIN: Perfect.

DR. WAGNER: If you don't mind. And, I'm sure you're going to have quite a few. Um, although we're going to hear next from Bruce Lockwood. He will present views from the first responder community. Mr. Lockwood is the Deputy Director of Emergency Management for the town of New Hartford, New Hartford, Connecticut, and is the first vice president of the International Association of Emergency Managers, US Council. Previously, he served as the director of Emergency Management and fire marshal for the town of Canton and, as an Emergency Response Coordinator for the Bristol Burlington, Burlington Health District. Mr. Lockwood is the founding member, a founding member and served as the first president of the Connecticut Emergency Management Association. He co-chairs the Connecticut Child Safety and Crisis Response Committee. Also, on the Public Health Preparedness Advisory Committee for the Connecticut, uh, the Connecticut Department of Public Health, and a member of the National Commission on Children in Disasters. Welcome, Mr. Lockwood. Eager to hear from you.

MR. LOCKWOOD: Thank you. Just to be clear, I'm a former commissioner of the National Commission on Children in Disasters but that's okay. They insist that you have to make sure you put the word former in there.

DR. WAGNER: Well, we're pleased you have that experience.

MR. LOCKWOOD: I understand the seat you're seating in. Uh, I apologize. I'm going to be reading from my notes. This last week, obviously has already been discussed, Sandy hit the east coast. So, my notes are what I have to run off of today.

Distinguished members of the commission, thank you for – for inviting me to speak to you. The topic you are currently reviewing is critically important, as it relates to our ability to meet the unique needs of 25% of our nation's population, children.

My name is Bruce Lockwood. I'm a Certified Emergency Manager. I'm the first vice president of the US Council of the National Association of Emergency Managers, a non-profit educational organization with more than 5,000 members worldwide, dedicated to promoting the principles of emergency management and representing those professionals whose goals – whose goals are saving lives and protecting property and the environment during disasters and emergencies.

I'm also representing the Emergency Services Coalition for Medical Preparedness, which was formed to lead the develop of a national strategy to provide, to protect providers in the event of a large scale biological event. The coalition draws support from all emergency services, associations and over three million providers.

I believe my background positions me to have a unique perspective related to the issues before you. I'm in my 22nd year as a career firefighter, a licensed paramedic and a member of the Regional Hazardous Materials Response Team. I've been an emergency manager for two

communities in Connecticut and currently, I am the Emergency Response Coordinator for the Bristol Burlington Health District with a population for mass dispensing of 70,000.

I've been a member of the regional planning team, specifically under the city's ready initiative for a population of 1.3 million. I serve as the co-chair for the Connecticut Children's Emergency Preparedness Committee, and I'm a member of the Connecticut Health Preparedness Advisory Committee, and served, obviously, from 2008 to 2011, as a commissioner on the national, uh, congressionally chartered, National Commission on Children Disasters.

Before we continue, let me clear. I am not a subject matter expert in the sciences or the current protocols related to the testing requirements of FDA.

In this post-September 11 era, our planning for incidents, both natural and manmade, manmade have broadened to include responses specific to health outbreaks, which include those that may be related to chemical, biological, radiological, nuclear and explosive events. Our members have grown beyond the traditional emergency managers. Now, including public health, public works, law enforcement and hospitals. The whole of the community approach to being prepared for our communities and our nation requires us to communicate, collaborate and coordinate to ensure we meet the needs of our individually diverse communities.

For several years, our communities have been developing plans specifically addressing the public health response to an anthrax event. Planning has been focused in the delivery of mass prophylaxis. This program is funded by preparedness grants through Health and Human Services. The basis of our planning is done using the guidance from the target capabilities published by the Department of Homeland Security in 2007, and the Public Health Preparedness Capabilities published by the Centers for Disease Control and Prevention, Office of Public Health Preparedness and Response in March of two-thousand, uh, eleven.

The critical task assigned to this mission is the delivery of antimicrobial, antimicrobials drugs within 48 hours. As you're aware these drugs are most effective when administered prior to the onset of symptoms. The challenge facing us is that it may be hours or even days before the release is detected and will most likely depend on clinical diagnosis after people begin to seek medical treatment for symptoms, significantly decreasing the timeline for delivery of medications.

The discussion today is specific to the AVA vaccine and children. However, we must acknowledge that AVA is not currently licensed for post-exposure use that it currently requires authorization by FDA, under the Emergency Use Authorization during an emergency declared by the Secretary of, um, Health and Human Services, justifying such authorization for those 18 years of age and older.

Today, children can only receive the vaccine under an investigational new drug protocol. Antimicrobials are only a treatment. So, prolonged exposure, repeat, repeated exposure will require repeated treatment, prolonged treatment, which raises additional concerns.

As I stated in my introduction, I served on the National Commission for Children in Disasters, where I was a member – where I was a member of the Pediatric Medical Subcommittee. In our 2010 report to the President and Congress, Recommendation 3.1 stated,

Congress, HHS, DHS and FEMA should ensure the availability of and access to pediatric medical countermeasures at the federal, state and local level for chemical, biological, radiological and nuclear and explosive threats.

We cited in our report, the summary report of a February 2010 workshop sponsored by Public Health Emergency Medical Countermeasures Enterprise, which reemphasized the need for certain populations, um, especially children to have immediate access to medical countermeasures. The workshop report discussed how incentives to develop pediatric medical countermeasures are impeded by the obstacles involved in conducting clinical trials of medical countermeasures on children.

The impact of not addressing this critical issue has a potential for a ripple effect in meeting the needs of our community. There is strong and consistent evidence that we cannot assume emergency services providers are competent in their ability to serve in a number of large scale events, most notably biological protect, uh, biological events.

The single most frequently cited reason for hesitating to report is lack of family protection. In no professional category can emergency providers be guaranteed to report for duty. In cases where they might infect family members, less than half might report. The Emergency

Services Coalition for Medical Preparedness has provided this research and testimony numerous occasions to the FDA and Congressional Oversight Staff and Committees.

Absent the security of prepositioned antibiotics in-home, pre-event vaccines, an increased awareness about the need for simultaneously protect – uh, to protect first, uh, responders in their household, there is a distinct possibility for degraded emergency services.

The potential for this cascading effect keeps me awake at night. It also underscores the necessity for the development of a pathway for licensing vaccines including AVA for children.

In September, 2012, Assistant Secretary Garza testified in response to questions from ranking member, Richardson, of the US House Homeland Security Subcommittee on Emergency Preparedness, Response and Communications that the federal government was planning to start a pilot program, uh, for pre-event vaccination of first responders. Press reports suggest the pilot program might be conducted in two states and two federal departments. Other details about the pilot including how the program will be, um, assessed and, which emergency services providers will be included have not yet been publicly announced.

The Department of Homeland Security and other federal departments have announced plans for funding employee biological protection programs presuming – presumably including antibiotics and vaccines.

My assessment is that the employees of the department will like other emergency services providers expect, want and need provisions for similar protections for their family. This puts an onus on us having the wherewithal to develop these protections for the entire population including our next generation currently aged less than 18.

It is my firm belief, as a former commissioner and advocate for children as an emergency manager that children of this country will be better served in an event of an anthrax attack, if a

small pre-event study on the efficacy of AVA has already been completed. While this conclusion obviously carries with it the heavy burden and many logistical challenges, children have too often been therapeutic orphans and deserve the full support of the scientific community, as we face the threat of an anthrax attack.

I look forward to hearing your deliberations, the testimony of your witnesses and your report, because it is vital – because it is vital to find a way to protect our children and youth from the same scourges we are currently planning to protect emergency services providers against.

The children need protection. Emergency Services Personnel will perform better knowing their loved ones are fully provided for in these extreme circumstances. We should expect nothing less.

DR. WAGNER: Thank you, sir. Barbara, you had the first question.

DR. ATKINSON: I do. I'm interested. We've heard about getting community input on either the protocols or on, on whether or not to do it. I'm interested in, in how you do that in terms of what you already do in your practice sessions but, also, just what questions should the community ask? How should, how should scientists go about asking for community input? What specific questions should they be actually dealing with and how do you do the community input piece is I guess what I'm really asking?

MR. LOCKWOOD: I can tell you that, in our planning process, we're actually required to have a, a planning committee, which must be diverse. It must include the whole of the community. So, faith based, uh, all the different organizations, agencies, and etcetera that must come to the table as a part of our planning process.

So they have input into the process but, I, I think that even the reality of the medical countermeasures, those are predefined for us, as what we're going to be able to, provide. It's, it's how we're going to be able to provide them, and I will tell you that even though we have the plans in place, if you look at the magnitude of what we're going to have to do in the timeframe, we have to do it in, I'm still not convinced that we are – on paper, a lot of times, I think that we, we meet – we can meet the need. But, I'm not sure that in implementation, we're actually going to be able to meet that need.

DR. BENJAMIN: Yeah, the Institute of Medicine, just actually, did some of this with vaccines, and I think the way to do it, of course is through using focus groups, pulling together balanced focus – focus groups, geographically, with some geographic variability, small towns, large towns, big cities, um, that kind of thing. Making sure you have, under representative groups, men and women involved. You know, what I want to know as a parent? I want to know if it's safe. I want to know how would I get it? You know, is there any, preservative in here that has mercury in it for example because of some of the concerns about mercury in vaccines. So, the preservatives would be a big issue. you know, do I need it once or twice? Is it, um, am I

protected for life? I mean, some of the really common sense things. I think, you know, we as human beings are not very good at measuring risk. So, I'm not sure we can answer the safety question per se, but we can define the relative risk, both of the vaccine, if I get it, and the relative risk of what would happen if I didn't take it, and I was exposed to a particular, um, threat.

MR. LOCKWOOD: Can I just add to that is if you look back at our H1N1 response, the issues of, you know, uh, what preservatives were in um, the vaccine were an issue, as we, uh, were trying to process and move forward with the parameters we were given. Um, but I will also tell you what I found was, and I would say near the end but, it really wasn't near the end when you looked at the total number we actually, provided vaccine to was, when we didn't have it, everybody wanted it. And, as soon as we had it, it was almost like nobody wanted it.

DR. ATKINSON: Interesting. Can I ask a follow-up?

DR. WAGNER: Sure, go ahead.

DR. ATKINSON: Did you actually really get meaningful input from the community that helped you make decisions about things?

MR. LOCKWOOD: Yeah, we, actually developed an After Action Report specifically related to the H1N1 response. It drove some of our planning. One of the things that, we came to a great realization on was that the majority of our planning for medical countermeasures has been using, and the name keeps changing but, the head of household form or the point of distribution form. That doesn't work when it is

So, we've had to create two models of how we'll mass dispense. One is using head of household, scenario and the other is when we have to perform an invasive procedure, i.e., giving the vaccine, where the individual actually has to be present to do that. It was significant, and then, the other issue we had to deal with and we built into our plans, now is how to deal with the issues related to, questions when they arise, specific to the preservatives because that was never in our plan.

DR. WAGNER: I've got, Anita, Nita, John, Dan and Nelson. Anita.

DR. ALLEN: Thank you, I really appreciate your very pragmatic perspectives. We've been talking all morning about the difference between plausibility and risk and about risk. How do you measure it? How do you know it when you see it? And, I had a question for both of you. It troubles me a lot.

So, we're focusing very intently on the possibility of a particular kind of bioterrorist, problem, and also we're talking about a kind of pathogen that does occur in nature. But, I, I'm wondering, how do we think about the question of risk? In a world in which the next big thing

might be anthrax but, it also might be a cyber security attack or it might be a power grid attack. You know? So, how do we know – how do we think about the risk involved with anthrax, when we have to also worry about the risk involved with other generically different sorts of events. Not only the kind of natural disaster we just had with Sandy, weather, earthquake or with flu but, with the possibility that evil people might do things. Not as they did in 2001/2002 with anthrax in, you know, envelopes. But they might attack the power grid or attack, attack the um, the um, the internet. I'm just wondering, does this – does this kind of question, comparative risk and plausibility, fit into your thinking about what we should be doing right now, as a practical matter to protect Americans?

DR. BENJAMIN: Sure, let me, let me, – I think, I think like anything else, you have to look at the most likely things that are going to happen. I mean the most likely risk is someone is going to blow something up. I mean, of all the threats, the most likely threat is an explosion.

Having said that – because it's easy to get the stuff. It's easy to do. However, I remember, I, I spent most of my life as a high school, you know, as a science nerd, and, uh, I just, I've watched the evolution of people's ability to take a biological agents, um, and literally grow them in your kitchen. And in medical school, you know, as an internist, of course, I learned about anthrax and, you know, I trained in Texas, and I wasn't going to – at least, initially, I wasn't going to practice in Texas. Thought I might go back there but, I never thought I'd ever have to worry about anthrax, at all, um, except in a single individual who might have been exposed, you know, on the farm. And low and behold in Maryland, you know, right next to Washington DC, somebody did it. And we used to think that they couldn't make the good stuff. Well, he did, and, was quite efficient. We used to think that, if you, you know, the less – the information we were giving people at the time was if someone had a powder, and if it was anthrax that they really couldn't make the good stuff. All you got to do is take a cloth or something, cover it up, go wash your hands, no big deal. But this was a major, this was a major event. And, what made it a major event was not just the fact that it was the good stuff, and a few died, as you know, tragically, but it was the fact that, the mass hysteria involved with it.

I mean, we were testing the powder on donuts, on materials that were on desks. I mean this nation was literally paralyzed. 9-11 aside, which was a terrible, terrible event but, we spent months and months and months, um, with my good colleagues here, folks, responding to every event, and, uh, it didn't matter how sophisticated it was. I remember one of our EMS users, users responding, to one of our very well-known sophisticated teaching hospitals in Maryland, because of what turned out to be Creamora on the table. But my lab had to test it. And, people – and we had to record these people in a registry, and we had to decide whether or not they needed to have Cipro prophylactically. I mean, it was that much of a big deal.

So, the fact that, at least with anthrax, we've seen it, we know it exists. We know that someone could do it. And, just, just today you wouldn't even need to – you just need to take a bunch of – if you just want to create the hysteria, you wouldn't have to have the really good stuff, the fine powdered milk anthrax to cause hysteria. You just have to get a bunch of anthrax,

grow it up, grind it down, put it in so that it shows up as anthrax, and our, our systems would, you know, would go whacky. And so that's the challenge we have. I, I, think as we measure the relative risk, we do have to rely on our security forces to, to help us define what those risks are, give us some good information about what the risk are, and then, we have to have a system in place.

But, the best way for us to be prepared, as a nation is to be, as prepared for any, you know for everything in a holistic manner, and, have at least, the resources on the shelf, to be able to quickly respond.

And, I, again, just in closing, the evidence that this nation has the capacity to do that was both SARS and H1N1, when we rapidly identified a new disease, we created ways of testing for it, and with H1N1 for example, we ended up with a vaccine. So, this nation does have a capacity to do that. It needs to be accelerated some but, we can respond.

MR. LOCKWOOD: I want to follow-up with that, too. Thank you for asking that question. I mean we deal with threat versus vulnerability every day. We have to try and make decisions for our community based on weather events. I mean, if you had said that that, uh, storm coming up the east coast would become a hybrid and we would be dealing with the significant damage we're dealing with in the New England states, we would probably all tell you that, there's no way that would happen, and it clearly did.

So there are a couple of things I want to say. One is the threat is real in the sense of, um, if you ask those people who were impacted in early 2000, uh, we actually had one of the fatalities in Connecticut, Ali Lungren. Our mobile hospital is actually named after her. That threat is very real.

To the point of, you just need to take some of the, the, not so good anthrax, grind it up and in a test it comes back. I will tell you that, if you've been watching the news, this year with letters coming out of Dallas, I believe it was, we've been responding to threats that appeared or potentially could be anthrax. So, while it may not have ended up being anthrax, we are on a daily basis responding to those types of calls, and, and we see peaks and valleys. And, and over this early part of this year, we were around this country, responding to those calls on a regular basis.

Our hazmat team was deploying on a regular basis simply to go out with, the Connecticut State Police and the FBI to deal with those specific events.

DR. GARZA: Hey, Jim, can I just interject one, one thing. An indirect answer to Anita's question, which is, yes, the federal government does do an integrated threat matrix to take a look at cyber, CBRN, conventional terrorism across the board. So, the answer to your question is yes.

DR. FARAHANY: So, thank you. This has, been incredibly helpful to think about both the risk concerned with the threat but also the alternatives that we might be considering for an anthrax vaccine. So, I want to explore a little bit some of the comments that you made about

antibiotics, and problems and deployment post-event of antibiotics because of limitations for example, and personnel being able to get to individuals who would need it. To be able to continue the follow-up that would be needed for antibiotics. But, then, also the alternative of it potentially being in homes and whether or not, the first time there's a common cold in the home, it's broken out and used for that instead.

So, I was hoping both of you could expand a little bit about this possibility, which is, if we think that there is, antibiotics, which could be an effective, at least short-term alternative, which would enable something like post-event testing for a vaccine. How realistic would it be to have those antibiotics in the home. How likely is it that somebody could actually use it for the purpose that it's intended for?

MR. LOCKWOOD: So, the US Postal Service has already piloted that, and, it's one of the things we referenced in my testimony today is the fact that there's actually data that shows that there was, um, significant compliance, uh that they found very few packets were actually opened. Uh, packets were either – the few that were opened or some, where just, in the middle of a move, somebody had misplaced it and just could not put their hands on it.

From the first responder community that's actually what we've been asking for is to try and preposition them, so that if, example, if I'm at home and I'm being recalled to work, I can be given the, I can be given a phone call telling me it's time to open the pack, take based on the instructions the medications, and also, work with my family to give them their, medications. As well as, if I'm at work, you know, and, and making sure that my family's, uh, got it at home and they can start taking it before I arrive.

One of the greatest fears, uh, most of us in the first response community have is bringing it home. I will tell you I'm in my 22nd year, and for the last 15 years of my career, I do not wear my uniform to or from work. I do not wear my boots. Anything I wear at work, stays at work. I have been extremely concerned, especially in this post-911 era, and I wouldn't say like obsessed with it but, just I, I acknowledge the fact that if I take care of it that way, I limit my risk to my family but, the risks still, uh, remains. So, I think that, those are real possibilities.

One thing that is in the target capabilities is a requirement. So, we should talk about – we have to pre-deploy – we have to be able to dispense those medications in that 48-hour period. Part of it also says that we must be able to pre – we must be able to pre-dispense or dispense prior to that to our, first responders and our workers in our mass dispensing centers.

So, there's a complication to the fact that we – we've had the event. We have to now try and get our medications, the antibiotics into the hands of our first responders, and that includes public health and the other individuals who will be dealing with it. And then, to get it to our families, the communities hands. You know, I think that really does create, um, a real resource issue and the one thing I continually remind people is that when this happens, as soon as it becomes public, there will be a level of hysteria that will take place. Our call volume will go through the roof, and when I tell you that, I tell you that because there will be an impact in that arena and we will be potentially deploying people in to the field who may not have the protections, um, in that process. So, I think that it's a holistic look we're trying to take a look at.

DR. BENJAMIN: Let, let, let me say that, I don't believe that the, at least in the terms of anthrax, the current antibiotics we have are, on alternative as the sole therapy for, for that. I'm, obviously a fan of also vaccination and mostly because the anthrax spores can hang around for so long. You have to take the antibiotic for a long period of time. Anyone who's ever taken Cipro, for, a week, five days, it is not fun and, so compliance falls off pretty quickly, for a variety reasons, even tetracycline. Milder on the stomach, but one of the reasons some of you may know that it was picked, Cipro was picked over tetracycline, originally, even though, both of the – the spores at those times were pretty confident, they were sensitive that was because of the photosensitivity, and also using tetracycline in kids also poses a hazard. So, from a – from a therapeutic perspective, simply using it as an antibiotic in my, in my view is not only an option.

The second part is the whole issue about repositioning of antibiotics. I, I do think there are classes of folks for which that will work very well. I, I'm not yet confident that that's a strategy for the whole nation. I do believe that, um, recognizing the experience we had with the anthrax letters, how quickly Cipro disappeared off the shelves, in the Washington DC metropolitan region, argues strongly for first providers and those that we know will be put in harm's way to have immediate access.

But I think the evidence for whether or not, uh, one should do this on a, on a large scale basis is just go and look at your own medicine cabinet and see how many expired medications that you have there. The process of trying to, as a nation, make sure that everybody has their kit and that their expiration date is intact is a major logistical nightmare and, I don't quite think that that would, would work for everybody.

DR. WAGNER: We're pushing the time with lots of people who want to ask questions. So, John, very quickly.

DR. ARRAS: Yeah, thanks very much. I think it's fair to say that this is, this qualifies as a hot button issue. Whatever our, commission decides, whatever the 407 committee decides, whatever Secretary Sebelius decides, a firestorm of criticism is going to come down on our respective heads. And that's clear from the letters we're getting already from the public. Right? On both sides of the question.

So, there's, there's the American Academy of Pediatrics, and there's also a lot of, very, alarmed or alarmist letters, you know, coming from physicians who say that they've dealt with lots of cases and they've seen big damage from this, this vaccine.

So, so, I guess my question would be given the fact that it's not simply a matter of getting all the nuts and bolts into, into place, as Mr. Lockwood is rightly worried about. There's the question of the reception by the community of decisions of this nature. And, I'm wondering what you think we still need to do, you know, by virtue of making overtures to the larger community, bringing them in on the decision making to guarantee better uptake and acceptance of whatever is decided.

DR. BENJAMIN: Yeah, I think you've really got to get out into the broad community, and not, rely solely on people who are – who are activist who, who think about this stuff all the time, and I value very, very much their opinion but, that's what they do. It's what I do. You know, and so, I think, if you want to get the, the soul of a nation, you've got to go out and hear from the soul of the nation.

I mean, there's two ways. There's another way of looking at this. We can either experiment with this now, or we can experiment with this during a disaster. Because I can tell you they're going to be – people are going to be clamoring for the vaccine in a disaster, and you're going to have to make this, you know, we going to, as a, as a corporate “we”, we are going have to make those decisions, in the middle of making a lot of other life-threatening quick decisions. And I've always been a fan that it's not, you know, the time to exchange business cards is not during the middle of a disaster. You want to do it in a thoughtful, you know, organized manner, even if you decide that we ought not do the – do the research. We ought to get this right, and we ought to engage as many people as we possibly can and do, in the sum, what we think is in the best interest of our children.

MR. LOCKWOOD: Just, just one quick follow-up and that is that, addressing the whole of our community, one of the things we found is perception versus reality. If we're able to get out in front of it and provide solid, realistic information to our individuals in our community, we tend to get a much better outcome, um, and I think that's part of what you're asking is, I don't know what, what, vehicle you would use to do that, but there has to be a way that if this going to move forward that, the community is informed in a very, simplistic and realistic manner. I think that the other thing we've learned is if we complicate the message, uh, the message sometimes gets lost.

DR. WAGNER: Dan.

DR. SULMASY: I very much appreciate the emphasis on, logistics given the fact that I was working at St. Vincent's Hospital in Manhattan when 400, highly, strung NBC employees descended on our emergency room within an hour. It gets very difficult.

But, I wanted to ask question – actually, on a different focus and that's on the question of justice. And I wondered whether you could, uh, tell us whether you think there are any particular populations that either, would be vulnerable to having, difficulty in accessing, countermeasures that would be a problem in and of itself. Or that would make them a particularly, vulnerable population for recruiting for research.

DR. BENJAMIN: Yes, clearly, the uninsured, underinsured, our immigrant population, those who speak, languages other than English, absolutely. And, you might find, well, let me stop with those populations for right now.

MR. LOCKWOOD: So, I would just say that our current, at risk populations are at risk populations no matter what category, no matter what we're looking at, whether it's vaccine or medical countermeasures or simply the deployment of some of our disaster materials.

I think if you're asking about who those potential individuals are that, and I don't remember what word you use but, potential candidates for, the threat. My way of looking at it is and we've already acknowledged that fact that the military has been vaccinated, if you look at those individuals who the adults are already being vaccinated, I guess my question is, if they're being vaccinated, we should be looking at what the impact to their family is. And, in that process, whether it be the first responders, whether it be the military, individuals who are working in labs, etcetera, I think that those are a category of individuals who, those parents may already have the ability to understand the vaccine process, be informed about the vaccine and what the true threat is to them. And, it may be an area where, um, there's an opportunity.

I can speak on the holistic standpoint but, I can only tell you it from that standpoint because that's a very personal individual decision once it gets down to that level, no matter whether it's an individual of a first responder or military or whatever, and it's a family decision. So, I think that that's an area where it would work.

DR. WAGNER: We will hope you two will hang around for just a few minutes. We have a break, uh, coming up and maybe those with remaining questions can corner you. We do have – but let's end this session on a question from the audience. We have a Dr. King [Krug] who is Chair of the Disaster Preparedness Advisory Council who is asking about lessons learned and thoughts about the future.

Lessons learned from the data, from the Antimicrobial Agent Compliance among those exposed to anthrax during the postal service event. Did we learn much from that?

And, also from concerns that we might have for pediatric compliance with, the ability even to stomach the very unpalatable, crushed Cipro. Are we, are we, do we imagine that those should be factors that should be taken into account for the very specific, case of anthrax, when we imagine that, when we consider whether or not pre-event testing, uh, should be considered. And, I see, Dr. Benjamin's hand.

DR. BENJAMIN: Yeah, clearly, you know, when you, when you take an adult medication and you've got to figure out how to give it to kids, it becomes more challenging. Even when it's properly formulated, it becomes – it becomes a big issue. So, I think, I think dosing strategies, accessibility, supply, all make, and the tolerance of a medication, all make it very difficult.

DR. WAGNER: Did we learn anything from the antimicrobial postal service event?

DR. BENJAMIN: I'm going to pass it over to my friend. Although, I think we learned a fair amount but, I don't have –

MR. LOCKWOOD: I was actually going to say that, I didn't come into public health until 2005. So, I can't answer that question. But, I do know that, um, the issue with our ability to, dispense medications to children, um, it's actually a focus in, in this year's review. We do a thing called the technical assistance review, of our mass dispensing plans. And one of the focuses last year was to highlight that we knew that we were going to be dealing with this year making sure that we had the ability to, meet the needs of children related to the current tools that are provided to us.

And we're looking at that but, there are obviously issues with suspension. What types, you know, if we, if we have to go to crushing, which ones. I believe one of them can't be at all and the other one can be. Because we're just starting that process now within where I work but, I think it's critically important to know that as we do that, um, if we just look at H1N1, with the issue of compliance and etcetera, I mean, I actually, I actually have one story and that is that we had a nurse that was bit trying to give the nasal, uh, mist. And the mother had insisted on, uh, she would have preferred the actual, injection. Lesson learned, if we had probably just given the vaccine the way she'd asked for it, our staff person would not have been, bitten by the individual.

So, I think compliance is going to be an issue but, I think it really comes down to the parent. If they truly believe there's a threat and, are concerned that compliance would be more regimented. If it's not, then it won't be.

DR. WAGNER: Mr. Lockwood and Dr. Benjamin, thank you so much for being with us today, and please, do hang around. We've got a break and in a perfect world it would be a really swift one. We would get back here in about five minutes, if we can make it work. Thank you all very much.