- Good afternoon. I'm Devon Andres, Biologist and Project Officer within the Chemical Medical Countermeasures branch of the CBRN division of BARDA. ASPR Mission is to protect Americans from health security threats, not just terrorism, but public health emergencies, like the COVID pandemic and hurricanes. Within ASPR, BARDA has the mission of developing medical countermeasures to address these public health emergencies through partnerships with industry, academia and other federal agencies. And finally, our mission in the chemical medical countermeasure program is to improve the health outcomes of all victims of a chemical exposure, no matter how they were exposed.

Now, why are we interested in chemical defense? Well, because of this little girl here in this picture and those like her. Because chemical attacks do happen. Chemical incidents can occur by accidental release or by intentional use as weapons. This world map shows the partial list of sites of intentional use of chemicals since World War I. The circled incidents are those intentional uses that have occurred since 2013, indicating an increased use worldwide.

These incidents include the use of opioids in the Moscow theater, multiple uses of different chemicals in the Syrian Civil War and in assassination attempts using nerve agents and Novichok with Kim Jong Nam, in Salisbury incident and the Russian opposition leader, Alexi Navalny. Now the increased use of chemicals as weapons has created a real problem that needs attention.

Now, there are more than 200 chemicals on the DHS chemical terrorism risk assessment list. Obviously, we can't develop or deploy specific antidotes for all 200 chemicals, nor could we have them on hand where and when they are needed.

So we developed the approach of treat the injury, not the agent. We are interested in the five primary injury categories or toxidromes listed here, that can result from exposure to most chemical agents. They include neurological, pulmonary, respiratory, metabolic and vesicating injuries. Advantages of treat the injury approach include having a multifunctional pipeline that allows the use of normal practice of emergency medicine, where clinicians treat what they see and it's agnostic because we are not concerned so much with what caused the injury, but the injury itself.

This also allows the clinicians to use drugs they know, and already have on hand, reducing the need for stockpiling and complex deployment strategies. To reach our goal of ensuring medical countermeasures are available when and where they are needed, we have three objectives. First to develop a threat agnostic pipeline to treat the injury, not the agent.
We would like to use drugs that hospitals and first responders already have access to and familiarity with. We also like to engage with the end user to make sure that we provide solutions that they can use in emergency situations. We have several successes with our treat the injury approach. First is the FDA approval of Argentum’s Silverlon. It is a commercially available wound dressing, that in 2019 received FDA 510(k) clearance with BARDA support to treat sulfur mustard skin injuries.

This is the first ever US approved treatment for sulfur mustard injuries in over 100 years of its use as a chemical agent. Second is the FDA approval of Seizalam. This was in collaboration with the DoD and NIH for a formulation or intermuscular formulation for injection of Midazolam. Its indication was approved to treat all seizures, whether they arise from epilepsy or whether they are a result of nerve agent or organic phosphate pesticide poisoning.

So far, I have discussed our development strategy. Here’s our three-pronged plan to develop more medical countermeasures for injuries due to chemical exposure. First is the identification of candidates by finding a common pathway and drugs to treat them. Second is to screen these candidates in animal models of chemical injury, through internal BARDA resources, our non-clinical network or through the redirect program.

We also provide program support to develop these drugs. If the drug has already been approved clinically, then we provide support through label expansion. If it is not already approved, then we co-develop the drug for clinical indication alongside the chemical indication. I would like to close by talking about our current portfolio and FY22 priorities. As shown here, we have efforts directed to all our priority agent areas, including enabling technologies.

Our partners range from academia and small biotech companies to some of the largest pharma companies in the world. It is important for our products we support to have both a real world use or clinical indication and not just a chemical indication. This is a list of, or sampling of our portfolio that contains both the threat and the clinical indications that they’re being developed for. Of note are the products under development to address both the use of opioids in terrorism, as well as our terrible opioid pandemic or epidemic.

First is the intra-nasal formulation of Nalmefene which is very similar to Narcan, but with potentially better suited to treat overdoses or poisoning by fentanyl and other long-acting opioids. There’s also the ENA-001 with Enalare, which is a true agnostic treatment for drug induced respiratory depression, not just opioids.

This is important because recent statistics show that greater than 50% of overdoses contain a mixture of opioids and other drugs, making it necessary for drugs like ENA-0001 for treatment of these overdoses. Now the last three items on this list are part of our redirect initiative. Which you can hear more about at 3:15. Now there are several avenues to work with, the chemical program in FY22. First is the EZ-BAA, where we are looking for projects to develop medical countermeasures to prevent or treat acute and chronic efforts, effects of chemical threats.
With our treat the injury approach and our need to put the drugs into the hands of our first responders as soon as possible, we will prioritize proposals that have relevant commercial indications that are similar or identical to symptoms of the chemical injuries and those proposals that include label expansion of already approved and authorized drugs.

Another avenue of funding is the BAA, the EZ-BAA. This is in collaboration between the Chem MCM program and DRIVe. It supports our repurposing efforts by providing seed money to obtain proof of concept or preliminary data necessary for entry into the Chem core program. But for their information attend the DRIVe redirect session or the ARDS breakout session at 3:15. Now the Chem program has had to establish, or we have established our FY22 priorities based on gap analysis.

They include repurposing of approved and late stage drugs to treat chlorine induced lung injury, opioid induced respiratory depression, and sulfur mustard ocular and inhalational injuries. If you have proof of concept data, please see and apply to our BAA. If you need preliminary data for chemical indication, please see the EZ-BAA for the DRIVe redirect program. Now the success of the Chem program wouldn't be possible without our great team that consists of eight government employees and multiple subject matter experts to support you.

A big thank you to them and all the work they do to support our partnerships and the missions within ASPR, BARDA and the Chem program. Now I have provided a lot of information here, but if you have further questions, please reach out to myself, Devon Andrus or our branch chief, Judy Laney. Our email addresses are provided here for your easy access. Thank you. Now it's time for Shannon.