Good afternoon, Mr. Chairman and Senators –

My name is Marcia Witte, and I am here representing the Idaho Department of Health and Welfare. I am an internist by training and work part-time in the Department's Division of Public Health and part-time at St Luke's McCall.

I am here to talk to you about outpatient therapeutics for COVID-19 and the Department's role in their distribution.

The good news is that we have more therapeutic options now to prevent and treat COVID-19 than we have had at any other time during this pandemic.

The unfortunate news is that these therapeutics are in extremely limited supply, especially with the emergence of the Omicron variant.

Today, I will briefly review the various therapeutic options currently authorized to prevent or treat COVID-19.
Then, I will explain how these therapeutics are currently being distributed.
Finally, I will review how the information is being shared with providers and the public.

Currently, there are 3 different categories of therapeutics for the outpatient prevention and treatment of COVID-19.

The **first category** is long-acting monoclonal antibodies authorized for pre-exposure prophylaxis (or prevention) of COVID-19. The only product in this category is a product called Evusheld, and it just received FDA authorization in early December. Evusheld is authorized for use in individuals 12 years of age and older weighing at least 40 kg who are ***not*** currently infected with SARS-CoV-2 and who have ***not*** had a recent exposure to an individual with SARS-CoV-2 infection AND <u>either</u>:

- Have a compromised immune system and may not mount an adequate immune response to the COVID-19 vaccination **or**;
- Vaccination with any available COVID-19 vaccines is not recommended due to a history of a severe adverse reaction to a COVID-19 vaccine or components of those vaccines.

In one clinical trial, Evusheld reduced the risk of symptomatic infection by 77% compared to placebo.

The **second category** of therapeutics is the monoclonal antibodies authorized for post-exposure prophylaxis (in some cases) and treatment of mild-to-moderate COVID-19. There are three products in this category that have received FDA authorization and are currently available:

- One is the combination of casirivimab and imdevimab – or the Regeneron product
- Another is the combination of bamlanivimab and etesevimab
- And the third is a product called Sotrovimab

Unfortunately, the first two products, which were available during the Delta surge, are not thought to retain activity against the Omicron variant. That leaves us with just sotrovimab which is authorized for the treatment of lab-confirmed mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) who are at high risk of progressing to severe COVID-19, including hospitalization or death.

In clinical trials, sotrovimab reduced the risk of hospitalization or death by 79% compared to placebo.

Finally, the **third category** of therapeutics is the oral antiviral medications, Paxlovid and molnupiravir. These two medications just received FDA authorization in late December. They are authorized for the treatment of lab-confirmed mild-to-moderate COVID-19 in individuals at high risk for progressing to severe disease. Paxlovid is authorized for patients 12 years of age and older weighing at least 40 kg; Molnupiravir is authorized for use in adults only. Both medications must be given within 5 days of symptom onset.

In clinical trials, Paxlovid reduced the risk of hospitalization and deaths by 88% compared to placebo, and molnupiravir reduced the risk of hospitalization and deaths by 30% compared to placebo.

Now, I want to discuss the Department's role in the distribution of these therapeutics. The U.S. Government has purchased these therapeutics, and the U.S. Department of Health and Human Services coordinates their distribution. In mid-September, HHS transitioned from a direct ordering system to a system in

which distribution is coordinated by the states and territories. Currently, every week Idaho receives an allocation of the monoclonal antibodies, and every other week, Idaho receives an allocation of the oral antiviral medications.

All of these therapeutics are in extremely short supply nationally. As an example (and this is a slight uptick compared to previous weeks), this week Idaho was allocated:

360 doses of Evusheld and
102 doses of sotrovimab…for the entire state

Last week, we received our 2-week allocation of the oral antivirals, and these quantities were:

400 doses of Paxlovid
1600 doses of molnupiravir…again, for the entire state

Suballocation to sites around Idaho has been challenging given the limited supply. When casirivimab/imdevimab and bamlanivimab/etesevimab were effective against the circulating variants, we had sufficient supply to fulfill most requests for product from facilities. During that time, at the direction of the Governor, we also established four monoclonal administration sites around the state that are supported with state funds – one in N Idaho, one in Idaho Falls, one in Boise, and one in Nampa.

Given their lack of effectiveness against the Omicron variant, we are now transitioning away from the use of casirivimab/imdevimab and bamlanivimab/etesevimab, and you can tell from the numbers I provided that we have insufficient supply of the other therapeutics to meet the demand. Our strategies for allocation have basically been as follows:

- For **Evusheld**, we have followed HHS guidance and worked with cancer centers around the state since they are likely to treat the majority of highly immunocompromised individuals. We will broaden the types of locations receiving Evusheld as supply increases.
- For **sotrovimab**, we have tried to support broad geographic distribution and provided a small quantity of product to multiple sites around Idaho. We have recommended that sites reserve sotrovimab for their highest risk patients.
- For the **oral antivirals**, we are distributing to a limited number of pharmacies around the state that are part of the federal retail pharmacy

partnership program. There is at least one of these pharmacies in each of the seven public health districts.

In addition, we have emphasized that these therapeutics should be reserved for the highest risk patients and have pointed providers and facilities to the NIH Treatment Guidelines that outline "Patient Prioritization Strategies When There are Logistical or Supply Constraints."

Finally, we have shared this information with providers and the public in a number of ways:

- We have sent out multiple messages to providers via the public health districts through the Health Alert Network messaging system regarding the availability of these therapeutics
- Public health districts have sent out their own messages to providers and also assisted in dissemination of information about the state-supported monoclonal antibody administration sites to providers and the public
- We contacted oncologists directly via email about the availability of Evusheld
- Information about the different therapeutics is posted on the Idaho coronavirus website, including a map produced and maintained by HHS that shows the locations and availability of the newer therapeutics
- The therapeutics have been mentioned in multiple press briefings and during a recent continuing education talk to medical providers by Dr. Hahn

In conclusion, we have multiple therapeutic options available for use, but unfortunately they are currently in limited supply. As supply increases, the Department will continue to quickly distribute these therapeutics as widely as possible. Patients should discuss with their medical providers the options that are most appropriate for them but should also continue to protect themselves from infection in other ways such as through vaccination and other preventive measures.

That concludes my remarks. Thank you for your time. Mr. Chairman - I'm happy to take questions.