***Synopsis***

**Published by Gray & Associates, LC 19 March 2020**

**Editor: Ellen Altman Milhiser**

**Twitter: @CongSynopsis**

**FDA Approves COVID treatments**

*Presidential press conference*

This morning’s White House press conference on the ongoing coronavirus crisis focused on the emergence of possible new treatments.

***Dr. Birx*** announced that ten counties across three states account for half of the country’s cases. She praised those states and localities for ramping up their responses.

FDA Commissioner ***Dr. Stephen Hahn*** stressed the importance of innovators in the US health care system, and promised that everyone at the FDA is focused on finding new treatments and therapies. The agency is working to provide innovators with regulatory flexibility to decrease the timeline for creating new treatments.

Hahn said the FDA has criteria and “very speedy approval” for compassionate use of experimental drugs. When those drugs are used, the FDA then collects data on their use, which is important to future treatment decisions. Although the President continues to push the importance of “right to try,” Hahn did not mention that this has actually been used in response to the current crisis. The drug Remdesivir, which is currently in clinical trials, has specifically been cleared for compassionate use approval to treat COVID patients. Hahn told reporters that FDA has already created protocols with the manufacturer to make the drug rapidly available to physicians through compassionate use and to collect data on its use, if anyone requests it. The drug is already being tested in China for treating coronavirus patients.

In the short term, the FDA is looking to use drugs already approved for other purposes to treat coronavirus patients. There are some promising candidates. However, Hahn stressed, it is crucial to identify not only the right drugs, but also the right dosages.

The drug chloroquine is already approved for treating malaria and arthritis. Hahn said the President has instructed that the FDA investigate expanding its use. The agency wants to create a large clinical trial to determine how and if it should be used to treat COVID.

Hahn said a “pretty exciting area” of investigation is convalescent plasma. The US is working with other countries in examining whether blood taken from those who have recovered from COVID can be turned into a treatment for new patients. Hahn said this can be a bridge to other therapies that could take three to six months to develop.

A possible vaccine started a phase 1 trial early this week. Hahn warned it will still probably take at least 12 months to gain approval, much less manufacture and distribute the final product.

***Other developments***

The Vice President thanked the country’s construction companies for contributing their N-95 industrial masks to health care systems and providers. Using the expanded liability coverage in the second supplemental bill (signed into law Wednesday), a wider variety of N-95 masks can be used by health care providers. The Vice President says this has “greatly expanded” the supply of masks, and the manufacturers have ramped up their production. Apparently, the 3M company told the Vice President they increased production in January, and the new legislation makes all of those additional masks available to health care providers immediately.

***Surgeon General Adams*** called upon all Americans who can to donate blood.

The President assured reporters that “we’re looking…very specifically” at ensuring hospitals receive the money and new equipment they need.

The President also said that Carnival cruise lines is ready to dock ships in New York City to provide more room for patients, in addition to the Navy hospital ship that is supposed to head there when it’s out of maintenance. Upon further questioning, it became clear the company has approached the government with this idea, but no plans have been made to take them up on it. The President apparently did speak directly with the cruise line’s chief executive.

The President expects to be able to garner wide bipartisan support for corporate bailouts, noting the impact of a large company going bankrupt on its thousands of employees and suppliers.

“We will be helping small businesses,” the President said several times, in addition to the large companies targeted for bailouts in the third supplemental bill.