
FISCAL UPDATE Article

Fiscal Services Division

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NCSL COVID-19 WEBINAR — THERAPIES AND VACCINES

Webinar Series. On April 17, 2020, the National Conference of State Legislatures (NCSL) held a webinar related to COVID-19 therapies and vaccines. The webinar will be posted on the NCSL's website in a few days.

Food and Drug Administration (FDA) Response. The U.S. FDA has implemented a [Coronavirus Treatment Acceleration Program](#) (CTAP) to use available methods to move new treatments to patients quickly while still maintaining patient safety. Through the CTAP, the FDA is working with companies to identify potential new treatments, with 284 clinical trials underway, along with 10 therapeutic agents in active trials and 15 more in the planning stages. For vaccine development, the FDA has been able to accelerate development timelines for entry into clinical trials with human subjects. Finally, last month representatives from the FDA and the European Medicines Agency jointly chaired a global regulators meeting to discuss strategies to facilitate development of COVID-19 vaccines.

Pharmaceutical Industry Response. Representatives from the pharmaceutical industry discussed the ways their members are working to combat COVID-19. Highlights from this segment of the presentation included a timeline for a COVID-19 vaccine development, stating:

- It will take a minimum of 18 to 24 months for potential FDA approval of a COVID-19 vaccine. This is much faster compared to previous new diseases. In 2003, it took 20 months from genetic sequencing of the Severe Acute Respiratory Syndrome virus to conducting a human study of a vaccine. For COVID-19, this process took less than four months.
- Speed and impact can be scaled higher with knowledge of the virus's genetic sequence, allowing scaling, production, and use of adjuvants to increase effectiveness of a potential vaccine.
- The failure rate will be high, as only 5.0% to 10.0% of industry tests will succeed.

The presentation also highlighted the following other important aspects of the pharmaceutical industry's role in the health care system:

- Ensuring continuity in drug chain supply by submitting data on potential shortages to the FDA.
- Providing the Medicine Assistance Tool (MAT) through [mat.org](#) to help patients, caregivers, and health care providers learn more about resources available to assist in accessing affordable medicines. Information that can be accessed includes a medicine's list price, average patient out-of-pocket costs, and materials to provide context for costs of medicines.
- A partnership with Healthcare Ready to facilitate financial support and in-kind donations of personal protective equipment (PPE), medicines, and critical medical supplies. Healthcare Ready also has programs to provide information for patients regarding open and closed pharmacies ([Rx Open](#)), cards for patients to document prescriptions and other important medical information ([Rx on the Run](#)), and a [COVID-19 Resource Hub](#).

Generics and Biosimilars Industry Response. This part of the presentation highlighted that although the global pharmaceutical supply chain is straining under the stress and demand of the COVID-19 outbreak, the manufacturers in this space are still working to supply 9 out of 10 prescriptions filled in the U.S. The presentation focused on production changes and donations in response to the COVID-19

outbreak. There were also two infographics that discussed how generic medicines reach patients through the supply chain, arriving at two primary destinations:

- At the pharmacy counter.
- At hospitals or through administrative medicine.

Additional Information. Additional information is available from the LSA upon request and from the following sources:

- Iowa COVID-19: coronavirus.iowa.gov/
- Department of Public Health COVID-19: idph.iowa.gov/Emerging-Health-Issues/Novel-Coronavirus
- LSA COVID-19: www.legis.iowa.gov/publications/information/covid19Resources
- NCSL COVID-19: www.ncsl.org/research/health/ncsl-coronavirus-covid-19-resources.aspx
- FDA: www.fda.gov/emergency-preparedness-and-response/counterterrorism-and-emerging-threats/coronavirus-disease-2019-covid-19

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