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AAP News

How FDA is responding to COVID-19 pandemic

by from the Food and Drug Administration's Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health and Office of Pediatric Therapeutics

Editor's note:*For the latest news on coronavirus disease 2019, visithttps://www.aappublications.org/news/2020/01/28/coronavirus.*

As the coronavirus disease 2019 (COVID-19) pandemic has expanded across the globe, pediatric patients have been infected alongside adults. Our understanding of the natural history of this disease in children is limited. As the body of pediatric data is developed to better understand the impact of COVID-19 on pediatric subpopulations, specific needs for treatment, prevention and amelioration of symptoms will become clearer.

The Food and Drug Administration's (FDA's) efforts are multifaceted, focusing on:

- actively facilitating efforts to diagnose, treat and prevent the disease;
- surveilling medical product supply chains for shortages or disruptions; and
- leveraging the full breadth of our public health tools as we oversee the safety and quality of FDA-regulated products for American patients and consumers.

Medical products (MP) used for diagnosis, prevention and treatment of COVID-19 should be studied in well-designed clinical trials whenever possible. In global emergencies such as this, special processes exist to assist physicians.

The following Q&A addresses some of the relevant regulatory pathways.

Q: What are "medical countermeasures?"

A: Medical countermeasures (MCMs) are products regulated by the FDA, such as drugs, devices and biologics, which may be used in a public health emergency, such as an emerging pathogen or a terrorist attack. As of April 1, there are no FDA-approved MCMs for COVID-19.

Q: How can pediatricians gain access to investigational treatments for pediatric patients seriously ill with COVID-19?

A: There are several pathways to bring investigational treatments to pediatric patients:

- Clinical trials: Investigators or industry sponsors may initiate trials through submission of an Investigational New Drug (IND) application to the FDA. To find ongoing trials, visit https://clinicaltrials.gov. Expanded access: For patients with serious or immediately life-threatening diseases or conditions who are not eligible or who are unable to participate in randomized clinical trials, access may be available through participation of acute care facilities in an investigational expanded access protocol under an IND already in place. For example, the FDA has facilitated the development of a protocol to help provide convalescent plasma to physicians to treat patients with COVID-19 (https://www.uscovidplasma.org/).
- Expanded access programs allow patients with serious or immediately life-threatening diseases or conditions without therapeutic alternatives to receive investigational drugs through an agreement with the industry sponsor and submission of an expanded access request to the FDA (previously referred

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to as "compassionate use"). These programs can be established for individual patients, for intermediate-size patient populations or for widespread treatment use.

- Single-patient emergency use INDs: Emergency treatment may be requested for a single patient if 1) the investigational drug is urgently needed for a patient's serious or immediately life-threatening disease or condition, 2) there are no comparable or satisfactory alternatives, 3) the patient cannot access the investigational drug through another IND or 4) the probable risk from the investigational drug is not greater than the probable risk of the disease or condition.

Q: What is Emergency Use Authorization (EUA) authority and how does it help in caring for patients?

A: When a public health emergency has been declared, the FDA commissioner may allow unapproved medical products or unapproved uses of approved medical products to be used in an emergency to diagnose, treat or prevent serious or life-threatening diseases or conditions caused by chemical, biological, radiological and nuclear threat agents when there are no adequate, approved and available alternatives.

Q: How will the March 27 COVID-19 Emergency Relief Bill help the FDA deliver support and guidance to protect and promote public health during this pandemic?

A: The legislation provides an additional $80 million in funding to continue the agency's COVID-19 response efforts, such as developing MCMs and vaccines, promoting advanced manufacturing of medical products, and monitoring the medical product supply chain.

The bill also reforms and modernizes the regulation of certain over-the-counter (OTC) drugs, including OTC monograph products critical during the pandemic, such as hand sanitizers and acetaminophen. These regulatory tools will help the FDA respond more quickly to emerging safety concerns.

Parents should be reminded to keep hand sanitizer out of children's reach, as drinking even a small amount of hand sanitizer can cause alcohol poisoning in children.

Resources

- FDA actions related to COVID-19
- Pediatric medical countermeasures
- National Institutes of Health COVID-19 research
- Expanded Access Information for Physicians
- Information from the FDA on safe use of hand sanitizer
- FDA statement on signing of the COVID-19 emergency relief bill
- Additional FDA Update columns