Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/the-drug-report/fdas-fight-against-the-novel-coronavirus/11284/

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FDA's Fight Against the Novel Coronavirus

Announcer:
You're listening to *The Drug Report* on ReachMD, hosted by Linda Bernstein, Pharm.D., Clinical Professor on the Volunteer Faculty of the School of Pharmacy, University of California, San Francisco.

Dr. Bernstein:
Welcome to *The Drug Report*. I'm Dr. Linda Bernstein.

As cases of the Novel Coronavirus continue to rise, the FDA just announced key actions to further the development of Novel Coronavirus medical countermeasures. The FDA wants to collaborate with interagency and international partners, product developers, and global regulators with the goal of speeding up the development and availability of medical products needed to diagnose, treat, mitigate and prevent such outbreaks.

According to FDA Commissioner Stephen M. Hahn, M.D., "We have a vital mission to protect and promote public health and the FDA is closely collaborating with our domestic and international public health partners to mitigate the impact of the novel coronavirus that emerged in Wuhan, China." He goes on to say, "We are actively leveraging the vast breadth of the FDA's expertise and have begun employing the full range of our public health authorities to facilitate the development and availability of investigational medical products to help address this urgent public health situation."

The FDA has an ongoing commitment to prepare and respond to infectious disease emergencies such as viral outbreaks. The FDA is sharing updates on processes in place to help developers understand the pathways, including Emergency Use Authorization (EUA) to expedite medical countermeasures against this virus, including diagnostic tests. The FDA is also launching a landing page that provide key information for the public, including product developers to help support this effort.

FDA Deputy Commissioner of Policy Legislation and International Affairs Anna Abram, stated, "We are committed to keeping the American people informed as we prepare and respond to emerging public health threats, including the novel coronavirus. The agency is committed to ensuring safe and effective medical countermeasures are available as quickly as possible to protect public health."

Quick and accurate diagnosis of infected patients is an essential step in the process to help patients realize they need care and prevent the spread of the virus to others. There are currently no commercially available products that are authorized to detect novel coronavirus, but the FDA is diligently working to pave the way for the development and availability of diagnostics that can detect this virus. The FDA is collaborating with public health partners to advance and share reference materials needed to facilitate diagnostic development.

The FDA is inviting diagnostic test sponsors interested in potential Emergency Use Authorization for tests to detect 2019-nCoV to contact them at CDRH-EUA-Templates@fda.hhs.gov for further information and templates.

Similarly, therapeutic developers are urged to submit information and questions via the FDA's Pre-IND Consultation program.

Here is some important information about the Pre-IND Consultation Program:
Established in 1988, the Office of Antimicrobial Products (OAP) Pre-Investigational New Drug Application (Pre-IND) Consultation Program is designed to facilitate and foster early communications between the divisions of OAP and potential sponsors of new therapeutics (drugs, monoclonal antibodies, and therapeutic proteins) for the treatment of bacterial, fungal, and viral infections, opportunistic infections, emerging infections (including naturally emerging diseases and potential biothreat agents), topical microbicides directed at prevention of HIV transmission, and transplant rejection.

Pre-IND advice may be requested for issues related to data needed to support the rationale for testing a drug in humans; the design of nonclinical pharmacology, toxicology, and drug activity studies, including design and potential uses of any proposed treatment studies in animal models; data requirements for an Investigational New Drug (IND) application; initial drug development plans, and regulatory requirements for demonstrating safety and efficacy.

The FDA encourages all potential drug sponsors or investigators to examine the information available from this site and to initiate contact with them as early in the drug development process as possible, so that they will have the opportunity to consider their recommendations in planning preclinical and clinical development programs.

The Division of Antiviral Products (DAVP) is responsible for:

- HIV, AIDS and prevention of HIV transmission
- Viral hepatitis
- Herpes viruses
- Topical microbicides
- Emerging viral infections (including but not limited to respiratory viruses, zoonoses, and potential biologic threat agents)
- Other non-life-threatening and life-threatening viral infections

For *The Drug Report*, I'm Pharmacist, Dr. Linda Bernstein.

Announcer:
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