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Emergency Funds for Pharmaceuticals under the CARES Act

Background

The FDA has come under a great deal of criticism from the President on down for not moving with more alacrity on issues which affect the country's ability to deal with this pandemic. The FDA has been tasked to work directly with the CDC and the Vice Presidential task force with the mission to move diagnostic, treatment and person protective equipment products into the market much quicker that will assist in identifying those infected with the virus, provide treatment options for patients and protect the health care providers responsible for those patient's care.

FDA response

Hydroxycholorquine

On March 30, 2020 the FDA approved drugs within the chloroquine family of drugs, specifically Hydroxycholorquine, for a secondary indication for use, which is to be used to treat confirmed COVID 19 patients. This was done through an Emergency Use Authorization. This authorization is not as broad as one would think. The agency authorized use for hospitalized patients as appropriate but only when a clinical trial is not available or feasible. As part of the use, a fact sheet of the known risks and drug interactions must be made available to physicians. In part this was done because the chloroquine family of drugs has fairly severe side effects and cardiac patients; patients with anemia and others should not take these drugs. This family of drugs also has documented uptake issues and therefore higher allowable dosing may be prescribed to account for the uptake issue. The other issue with the chloroquine family of drugs is that it is well known that the human body, when the drugs were used to combat malaria, developed drug resistance to this family of drugs, rendering them less than effective. This EUA was based in large part on a small study done in France where some positive responses by COVID 19 patients were noted when given the Hydroxychloroquine. It is worth noting that in a small clinical trial was commenced in Brazil to monitor the efficacy of the use of Hydroxychloroquine in treating the COVID 19 virus, that such severe safety issues of a cardiovascular nature occurred with the use of the drug, that the clinical trial was halted.

Emergency Use Authorization

The EUA is a regulatory mechanism which under Section 564 of the FD&C Act allows unapproved products or unapproved uses for medical products to be used to an emergency to diagnose, treat or prevent serious or life threatening diseases caused by a chemical, biological, radiological and nuclear threat (CBRN) when there is a threat to public health or a public health emergency. The declaration on February 4, 2020 by the Secretary of Health and Human Services (HHS) declaring a public health emergency set the stage for use of the EUA.

Guidance for Testing

Also in February after the HHS declaration, the FDA issued a guidance for diagnostic testing regarding the diagnostic tests for the Coronavirus without public comment (something that would normally occur before the guidance is implemented). It was put in place to help accelerate the availability of novel diagnostic tests for the coronavirus.

Testing for antibodies

Diagnostic testing has been at the center of the pandemic. The FDA has received information from approximately 230 test developers indicating that they are working on diagnostic testing which would accurately diagnose the COVIS 19 virus. FDA has granted 20 authorizations for use of diagnostic testing. However, the majority if not all of these are the nasal or throat swab which will only demonstrate whether or not the patient has an active infection. The second generation of the diagnostics is the use of antibody testing to not only detect infections but whether the person has been infected in the past. Identifying the proteins or antibodies in the patients blood may assist researchers in understanding why some recover from the virus faster and easier than others. To date only one company has received EUA for its antibody diagnostic (April 1,2020).

Hand Sanitizers

On March 20, 2020, the FDA issued two guidance documents on alcohol based hand sanitizers. These two documents are temporary policies as to the FDA's position on hand sanitizers. It recognizes that there is an insufficient supply on the market. The first temporary policy allows for compounding pharmacies to make hand sanitizers on a more general basis, foregoing the need for a patient prescription from a treating physician. The second temporary policy indicates that the FDA will not undertake enforcement action against manufacturers of alcohol for use as an active ingredient in hand sanitizer provided that the manufacturer registers with the FDA under its Registration and Listing System and the alcohol itself meets eight other criteria.

Personal Protective Equipment

In order to accommodate the shortage of Personal Protective Equipment, the FDA has relaxed it enforcement for masks, respirators, gowns and gloves.

Additional FDA funding

As part of the $2 trillion dollar emergency relief bill, the FDA will receive $80 million in additional funding to continue its response efforts, including the development of vaccines and promoting the manufacturing of medical products. It also included language modernizing the over the counter drug approval systems which effects products such as hand sanitizers which is at the forefront of the pandemic as well as other medical products.

HHS Call for Submissions to BARDA

Separate and apart from the FDA itself, HHS as the overall entity responsible for US healthcare, on March 6, 2020 issued a statement (later expanded on March 11th) soliciting proposals for the development of medical products for the treatment and care of patients with COVID 19. The solicitation called for submissions to the

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Biomedical Advanced Research and Development Authority (BARDA) department of HHS. (*See*, BAA-18-100-SOL-00003).

– The call was specifically for submissions for vaccines, medicines (both therapeutic and anti-virals) and diagnostics, respiratory protective devices and ventilators. As part of this, BARDA has already granted $561,330 to a company to support further development of a diagnostic test. BARDA has set up an online portal for submissions for companies to submit brief descriptions of their diagnostics, therapeutics, vaccines and other products applicable to addressing COVID19. BARDA's budget for 2020 prior to the declaration of a pandemic was **$1.3 billion**. The portal for submissions was originally to be open through early April, however, there is discussion of leaving it open longer due to the continuing rise in the incidence of disease.

Additional funds were added in after the pandemic

FDA Funds

$80 million in additional funding for the FDA "to prevent, prepare for, and respond to coronavirus, domestically or internationally." FDA describes this as: "…$80 million in funding to continue the Agency's COVID-19 response efforts, including the development of medical countermeasures and vaccines, promoting the advanced manufacturing of medical products and monitoring of the medical product supply chain."

Public Health and Social Services Emergency Fund

$27 billion in additional funding to the "Public Health and Social Services Emergency Fund" for development and purchase of products to "prevent and prepare for, and respond to the coronavirus domestically or internationally."

– **$3.5 billion** funding to Biomedical Advanced Research and Development Authority (BARDA) for expenses concerning the manufacturing and production of vaccines and small molecule active ingredients. Specifically, "manufacturing, production, and purchase of vaccines, therapeutics, diagnostics, and small molecule active pharmaceutical ingredients, including the development, translation, and demonstration at scale of innovations in manufacturing platforms."

– $16B of the $27B is earmarked for obtaining PPE and ventilators, etc. And $250M is for grants to hospitals.

– The Coronavirus Preparedness and Response Supplemental Authority Act, 2020, enacted on March 6, 2020, provided **$3.1 billion** for similar categories of emergency funding as authorized in the CARES Act to prepare for and respond to COVID-19, that also includes the manufacture and purchase of vaccines and necessary medical supplies. This funding is in addition to the authorized funding in the CARES Act.

For more information

Jonathan P. O'Brien, Ph.D.
Chair, Intellectual Property Department
jobrien@honigman.com
T: 269.337.7704

Diane J. Romza-Kutz
dromza-kutz@honigman.com
312.701.9325

Kathryn D. Doyle
kdoyle@honigman.com
269.337.7836