FEDERAL PUBLIC HEALTH AGENCIES FIGHT COVID-19

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COVID-19 information overload?

For those who are finding themselves overwhelmed by print and broadcast media, press conferences with a rotating cast of faces from an alphabet soup of government sources, "talking heads," and late-night comedians— maybe this will help.

The lead federal health agency is the **Department of Health & Human Services (DHHS**). Many of the leaders and experts that we have been hearing from (and about) are from agencies of DHHS. It is their mission to enhance and protect the health and well-being of all Americans by providing effective health and human services and fostering advances in medicine, public health and social services. This article describes just a few of the dozens of federal public health offices and agencies: NIH, CDC, FDA, Surgeon General, and CMS. It does not describe efforts by the departments of Defense, Homeland Security (FEMA), Labor, or State. https://www.hhs.gov/about/agencies/hhs-agencies-and-offices/index.html

National Institutes of Health (NIH) is the premier health research institution in the world. NIH supports biomedical and behavioral research within the United States and abroad, conducts research in its own laboratories and clinics, trains promising young researchers, and promotes collecting and sharing medical knowledge. NIH is made up of 27 different components (Institutes and Centers), each with its own specific research agenda, often focusing on particular diseases or body systems.

In NIH, the **National Institute of Allergy & Infectious Diseases (NIAID)** supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. It is comprised of 6 divisions, including Microbiology & Infectious Diseases, and a Vaccine Research Center. Research into prevention and treatment of coronaviruses and development of vaccines is/will be conducted by NIAID and also funded by contracts and grants to academic institutions and other agencies. https://www.nih.gov/about-nih/what-we-do/nih-almanac/national-institute-allergy-infectious-diseases-niaid

Centers for Disease Control & Prevention (CDC) protects the public health of the nation by providing leadership and direction in the prevention and control of diseases and other

preventable conditions and by responding to public health emergencies. CDC is our "boots on the ground." It provides lab and epidemiologic services, protocols, models, guidance, and on-site presence as needed. CDC often interacts directly with state departments of public health. We have heard from experts from the National Center for Immunization and Respiratory Diseases (NCIRD) whose mission is to prevent disease, disability, and death through immunization and by control of respiratory and related diseases. https://www.cdc.gov/ncird/

The **Food & Drug Administration (FDA)** is reputed to be the global "gold standard" for science-based regulation of our drug supply. FDA ensures that food is safe, pure, and wholesome; that human and animal drugs, biological products, and medical devices are safe and effective; and that electronic products that emit radiation are safe. American consumers benefit from having access to the safest and most advanced pharmaceutical system in the world. https://www.fda.gov/drugs/drug-information-consumers/protecting-americas-health-through-human-drugs

FDA is the only regulatory agency in our list, with law enforcement powers. It has *sole authority* to approve new human drugs, biologics, and medical devices and to assure compliance with the Food, Drug & Cosmetic Act (FD&C) post-marketing. The FDA regulates clinical studies that generate the scientific evidence of safety and effectiveness of drugs, biologics, and medical devices.

> **Center for Drugs Evaluation & Research (CDER)** regulates over-the-counter and prescription drugs, including biological therapeutics and generic drugs. In short-hand, drug products are often described as "small molecule" drugs meaning that they are chemically derived by isolation or design. A possible drug therapy for COVID-19 is the antiviral *remdesivir*; another is the immune response-muting drug *hydroxy-chloroquine*. Both would be reviewed and approved for this indication by CDER, based only on supportive clinical study results. *Chloroquine* and *hydroxy-chloroquine* have received Emergency Use Authorization by the FDA Commissioner. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#covidtherapeutics
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> CDER also regulates protein therapeutics such as monoclonal antibodies. The immune response-muting monoclonal *tocilizumab* is being tested in clinical studies for effect on COVID-19.
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> **Center for Biologics Evaluation & Research (CBER**) ensures the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies. Also part of the mission is seeking to protect the public against the threats of emerging infectious diseases and bioterrorism. In addition to enforcement under the FD&C Act (biologic products meet the definition as drugs), the Public Health Service Act gives additional authority over the manufacture of biologic products. CBER will review the development and clinical studies of new coronavirus vaccines and license as appropriate based on successful results for safety and effectiveness. Development

for treatment use of coronavirus hyperimmune globulin and convalescent plasma from patients who have recovered is regulated by CBER. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-coordinates-national-effort-develop-blood-related-therapies-covid-19

Center for Devices & Radiological Health (CDRH) assures the timely and continued access to safe, effective, and high-quality medical devices, provides science-based information about products, and facilitates medical device innovation. The **Office of In Vitro Diagnostics** is responsible setting quality standards for clinical laboratory testing that is used to indicate the course of treatment for patients. It determines policy and oversees the Clinical Laboratory Improvement Amendments (CLIA) program. The Division of Microbiology Devices develops rules and guidance for CLIA according to the complexity of the testing. CDRH has provided Emergency Use Authorizations in several instances to address the coronavirus pandemic including the use by health care systems of PPE previously approved for industrial use, the use of modified ventilators, and 25 (to-date) diagnostic testing kits and/or components. https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Within DHHS, the **Office of the Surgeon General** recommends health policy for the nation, supported by medical-epidemiologic studies and data. The Surgeon General Is the head of the **US Public Health Service Commissioned Corps**, a specialized branch of the Navy comprised of physicians, pharmacists, nurses and other professionals in health sciences. The Corps works in all the health agencies, providing service and expertise, and working side-by-side with the civil service workforce. Members of the Corps can be deployed on short notice in response to health and natural emergencies and to special areas of need. https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/fda-commissioned-corps-officers-front-line-covid-19-response

Centers for Medicare & Medicaid Services (CMS) combines the oversight of the Medicare program, the federal portion of the Medicaid program and State Children's Health Insurance Program, the Health Insurance Marketplace, and related quality assurance activities. CMS sets standards for reimbursement by Medicare. CMS regulates all laboratory testing (except research) performed on humans in the U.S. through CLIA. In total, CLIA covers approximately 260,000 laboratory entities.

Lastly, located outside the US, is the **World Health Organization (WHO),** an agency of the United Nations. The US supports the WHO with funding and other resources and participates in an advisory and collaborative capacity to address global health issues, especially in developing countries.

Coordinating our national response to COVID-19 is an ongoing challenge. NIH, FDA, CDC and other parts of DHHS are experienced in collaborating across agencies to meet well-defined goals.