FDA in the Headlines and the Impact to Your Communities

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Federal Agencies Within HHS

United States Department ... State

United States Department ... the Treasury

United States Environment... Protection A...

United States Department ... Justice

United States Department ... Homeland S...

United States Department ... Defense

United States Department ... Commerce

United States Department ... Energy

United States Department ... the Interior

United States Department ... Labor Office...

United States Department ... Health and ...

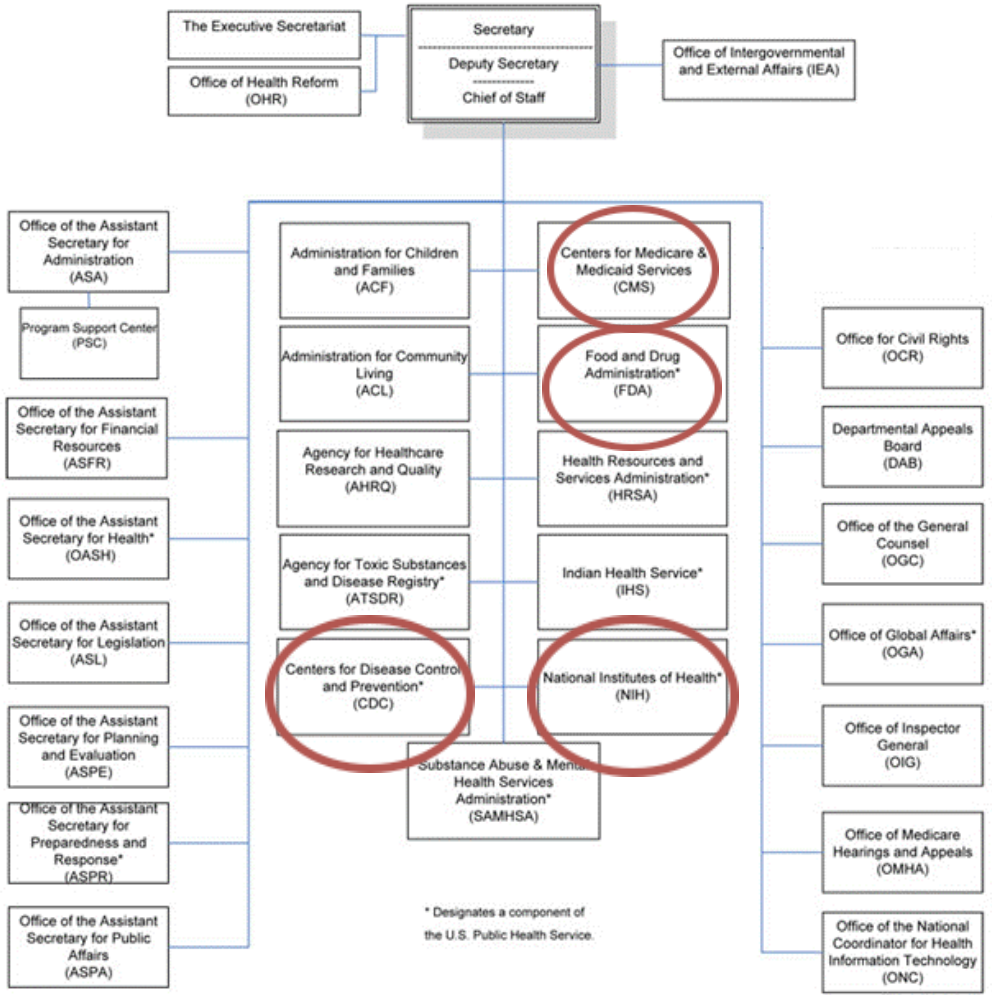
United States Department ... Housing and...

United States Department ... Veterans Aff...

U.S. Department ... Transportati...

United States Department ... Education

United States Department ... Agriculture



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Mission of HHS and FDA

- Protect the public health
- Advancing the public health
- Ensuring the safety, efficacy, development and security of human and veterinary drugs, biological products, and medical devices to address public health threats
  - Jurisdiction over
    - Biologics (Center for Biological Evaluation and Research CBER)
    - Brand and Generic Drugs (Center for Drug Evaluation and Research CDER)
    - Medical Devices (Center for Devices and Radiological Health CDRH)
- Regulatory authority over food, cosmetics, over-the counter drugs, tobacco products

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Role of FDA Leadership

- Secretary of HHS nominated by the president and confirmed by the Senate
  - Not independent of the president
  - Current HHS Secretary - Alex Azar
- Commissioners report to Secretary
  - Current Commissioner - Stephen M. Hahn, MD
- Within HHS, power given to secretary not Agency
  - HHS Secretary oversees FDA Commissioner has authority to make decisions on drugs and vaccines
  - Opportunity for HHS secretary to overstep, but generally deferential to the agency

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Congressional Committees of Jurisdiction and Appropriation

- Legislative Committees
  - House
    - House Committee on Energy and Commerce (E&C)
  - Senate
    - Senate Committee on Health, Education, Labor, and Pensions (HELP)
- Appropriation Subcommittees
  - House & Senate
    - Labor, Health and Huaman Services, Education, and Related Agencies
      - Oversees HHS direct budget, including NIH and CDC
    - Agriculture, Rual Development, Food and Drug Administration, and Related Agencies
      - FDA is under HHS operationally, but under subcommittee for appropriations

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Federal Agencies and Congress

- Oct 1: Federal Fiscal Year begins
- November: OMB analyzes budget requests considering presidential priorities, program performance, and budget constraints
- Late November: Pass back to agencies
- Dec-Jan: Agency submission
- January: Agencies prepare budget justifications for Congress
- First Monday in February: President submits budget to Congress

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Pressing Issues for the FDA

- COVID response - stewarding the development and authorization of tests, treatments and vaccines
- Reauthorizing agency user fees
- Regulation of diagnostic tests

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COVID Response

- White House Corona Virus Task Force
  - United States Department of State task force that oversees administration's efforts to combat the spread of COVID-19
    - HHS Secretary Azar first appointed then replaced by Vice President Pence
    - Dr. Peter Marks, FDA Director of the Center for Biologics Evaluation and Research, appointed May 15, 2020 but left shortly after
- Operation Warp Speed
  - Accelerate the development, manufacturing, and distribution of COVID-19 vaccines, therapeutics, and diagnostics
  - Goal is to produce and deliver 300 million doses of safe and effective vaccines with the initial doses available by January 2021
  - Operation Warp Speed is separate from FDA
    - May 20: Janet Woodcock, MD, and Peter Marks, MD, PhD named overseers for Operation Warp Speed and recuse themselves from FDA considerations about approving COVID-19 vaccine
    - May 22: Dr. Janet Woodcock steps away from CDER to focus on Operation Warp Speed, Dr. Marks leaves Operation Warp Speed and returns to CBER director

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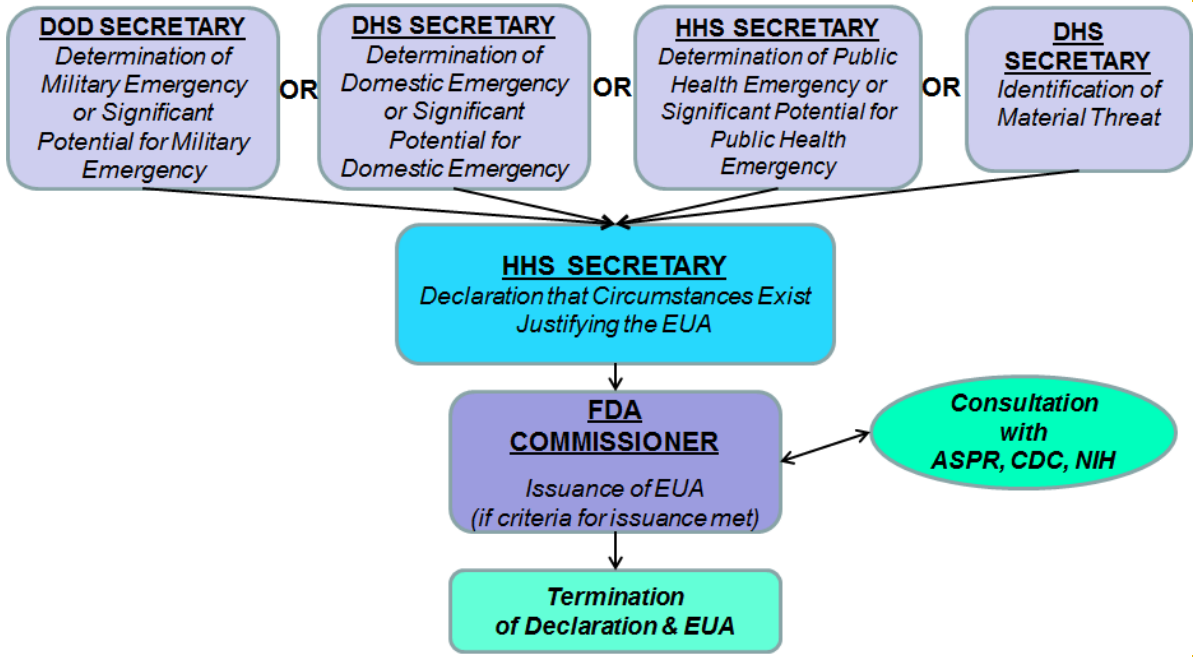
COVID Response Authorities

- Emergency Use Authorization
  - Evidence demonstrates that the product may be effective at treating a public health threat and those benefits outweigh the risks – considering the emergency and the lack of treatment options
  - Different standard than approval
  - FDA provides specific scope and conditions of use
- What happens next?
  - The FDA may revise or revoke EUAs
  - Products must be approved to stay on the market after a public health emergency
- FDA does not have authority over distribution or prioritization



The New York Times

Study Finds 'Single Largest Driver' of Coronavirus Misinformation: Trump

abc NEWS

FDA chief apologizes for overstating plasma effect on virus

POLITICO

An angry Azar floats plans to oust FDA's Hahn

Pink Sheet
Informa Pharma Intelligence

New York State To Conduct Its Own Review Of COVID-19 Vaccines In Another Blow To FDA's Reputation

"All the News That's Fit to Print" The New York Times EARLY EDITION

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U.S. DEATHS NEAR 100,000, AN INCALCULABLE LOSS

Bloomberg Law

Trump Says FDA Pulled 'Political Hit Job' With Vaccine Rules (1)

POLITICO

White House blocked FDA commissioner from testifying to House panel

STAT

Is it time for the FDA to be independent?

The Washington Post

Another casualty of the coronavirus pandemic: Trust in government science

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When was the Emergency Use Authorization (EUA) Pathway Established?

A. By a President Trump Executive Order in response to COVID-19
B. In the 21st Century Cures Act to stimulate the development of pandemic response products
C. By a President Obama Executive Order in response to H1N1
D. In the Project BioShield Act of 2004 in response to anthrax attacks

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COVID Response – Current EUAs

Drug	EUA Submitted	EUA Approval	EUA Revoked	FDA Approval
Hydroxychloroquine Sulfate (HCQ) and Chloroquine Phosphate (CQ)	Yes	March 20, 2020	June 15, 2020	N/A
Veklury (Remdesivir)	Yes	May 1, 2020	N/A	October 22, 2020
Convalescent Plasma	Yes	August 23, 2020	N/A	N/A
REGN-COV2	Yes			
LY-CoV555	Yes			

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FDA User Fees

- Prescription Drug, Generic Drug, Medical Device, and Biosimilar drug manufactures pay the FDA for review and oversight of their products
- Fees are authorized by Congress every five years (…2012, 2017, 2022...)
- Fee structures and “goals” are negotiated between FDA and industry
  - Referred to as the “goals letter”
  - Cannot make new policy or change the law
  - Occurs about 1.5-2 years prior to authorization
- Congress memorializes the goals letter, and passes legislation updating the fees
  - Cyclical opportunity to advance changes to policy or law

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Diagnostic Test Regulation

- Tests conducted by a single lab or lab network are regulated by the Clinical Laboratories Improvement Act (CLIA) for analytical validity
- Lab tests that are sold across labs are regulated by the FDA as medical devices for analytical *and* clinical validity
- HHS legal decision in October stripped the agency of authority over lab tests for COVID-19
- Ongoing efforts to sync, clarify, and improve the regulatory system for all tests
  - VALID Act in Congress

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Other Important Terms and Topics

- Accelerated Approval (AA)
  - Allows the FDA to approve drugs based on intermediate or surrogate information that predict a long-term benefit and requires post-market studies .
- Breakthrough Designation
  - Provides additional facilitation through development for products with early positive clinical data
- Regenerative Medicine Advanced Therapy (RMAT) Designation
  - Provides additional facilitation through development and post-market studies for cell, tissue, and gene therapy products with early positive clinical data
- Expanded Access
  - Potential pathway to gain access to an investigational medical product for treatment outside of clinical trials when there is no comparable or satisfactory alternative therapy.

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