The Potential Life Sciences Implications of the Election

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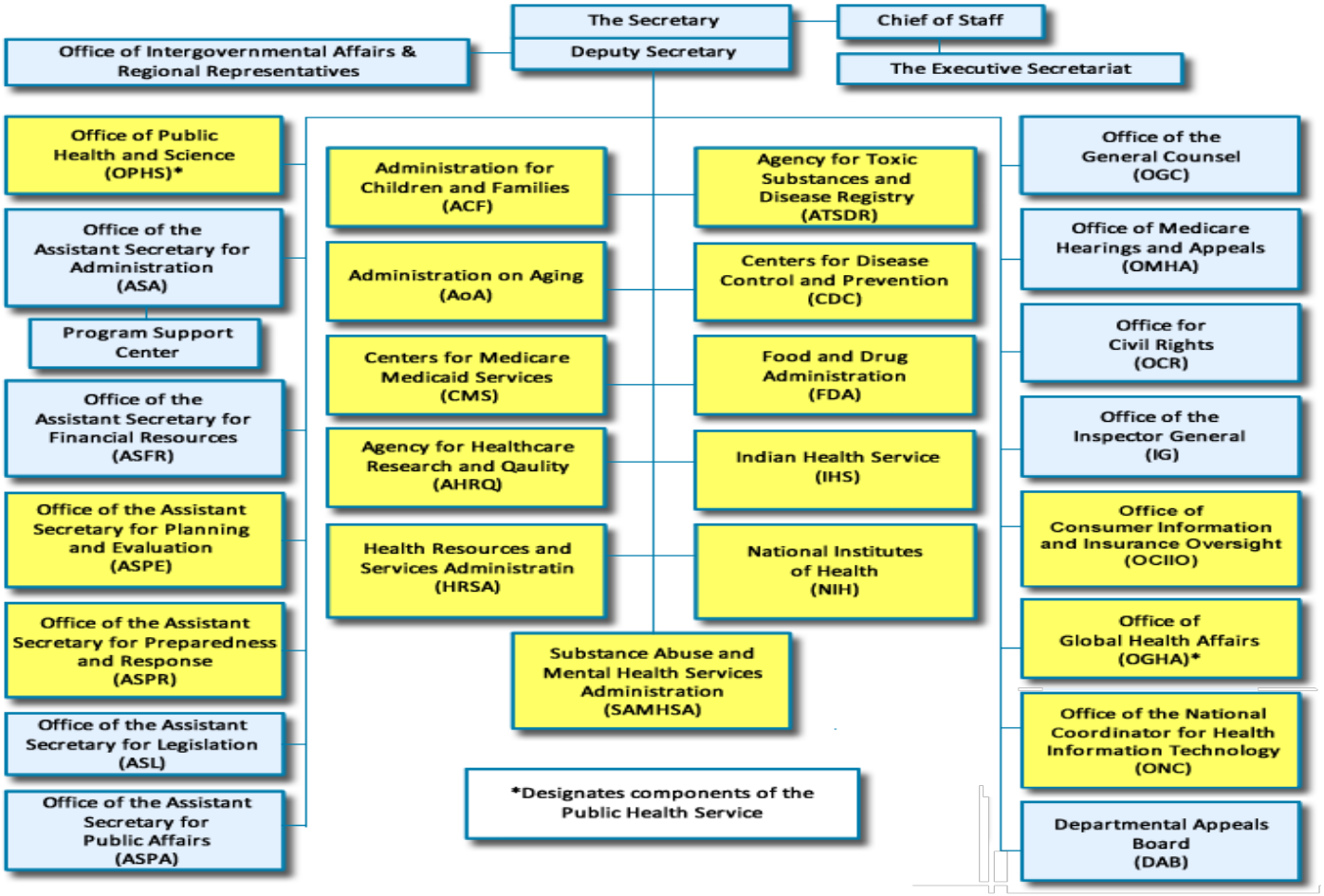
How should we think about politics and FDA?

- Political appointees
- Bureaucratic structure
- Statutory / regulatory mission
- Congress – party philosophy
- Administration – party philosophy

What is a political appointee?

- According to the United States Office of Government Ethics, a **political appointee** is "any employee who is appointed by the President, the Vice President, or agency head."
- As of 2016, there are around **4,000 political appointment positions** which an incoming administration needs to review, and fill or confirm, of which about **1,200 require Senate confirmation**.

FDA is an operating division in HHS



HHS Secretary supervises FDA

- HHS Secretary is politically appointed
- So is FDA Commissioner
- They set priorities at a high level

Current Secretary (non-pandemic) priorities:

- Opioid crisis
- Health insurance reform
- Drug pricing
- Value-based care (e.g, health IT, price/quality transparency, reduced regulation)

"For Biden's potential HHS pick, priorities include…."

- Public option
- Increased antitrust enforcement of hospital mergers and acquisitions (M&A)
- Price negotiations with hospitals (cost control)

https://www.hfma.org/topics/news/2020/09/for-biden-s-potential-hhs-pick--priorities-include-public-option.html

Secretary Leavitt (GW Bush) claimed accomplishments

- Implementing the Medicare prescription drug benefit
- Finally seeing health information technology standards developing
- Tangible progress toward transparency of price and quality
- Developing a new national strategy for safety of imported products
- Globalizing the efforts of the FDA
- Mobilizing the nation's pandemic preparedness and retooling the nation's medical emergency plans

HHS Political Appointees

- *'A mass exodus': HHS staffers jumping ship amid pandemic, fears of Trump loss*
  - "At least 27 political appointees have exited the embattled Health and Human Services department since the start of the Covid-19 crisis in February, according to a POLITICO review, and senior leaders are bracing for dozens more officials to depart swiftly if President Donald Trump loses re-election."
  - "'There will be a mass exodus should the election go the other way' against Trump, predicted a senior department official …."

  -- Politico 10/26/20
- But political appointees *must* leave when the other party takes over (may be temporary holdovers for continuity)

FDA has many fewer politically appointed

- FDA Commissioner - yes
- Principal Deputy Commissioner - yes
- Chief Counsel - yes
- Others?

Example of HHS overruling FDA

- **HHS chief overrode FDA officials to ease testing rules -** *Alex Azar took matters into his own hands, overriding objections from FDA chief Stephen Hahn. (Politico, 9/2020)*
- "Overriding objections from FDA chief Stephen Hahn, Azar revoked the agency's ability to check the quality of tests developed by individual labs for their own use, according to seven current and former administration officials with knowledge of the decision."
- "Azar's decision is the latest example of Trump administration appointees overruling experts at public health agencies."

Example of HHS overruling FDA

- "At some points the dispute was so intense that it boiled over into screaming matches between Azar and Hahn, four of the sources said. And FDA's device chief, Jeff Shuren, was cut out of crucial HHS meetings leading up the policy shift."
- "The FDA's own website, meanwhile, still insists that it has the power to regulate all manner of lab-developed coronavirus tests."

Wildcard?

- **"Trump Issues Executive Order Making Some Civil Servants Easier to Hire and Fire" – WSJ 10/22/2020**
- EXECUTIVE ORDER: "Separating employees who cannot or will not meet required performance standards is important, and it is particularly important with regard to employees in confidential, policy-determining, policy-making, or policy-advocating positions. High performance by such employees can meaningfully enhance agency operations, while poor performance can significantly hinder them."

  https://www.whitehouse.gov/presidential-actions/executive-order-creating-schedule-f-excepted-service/

Wildcard?

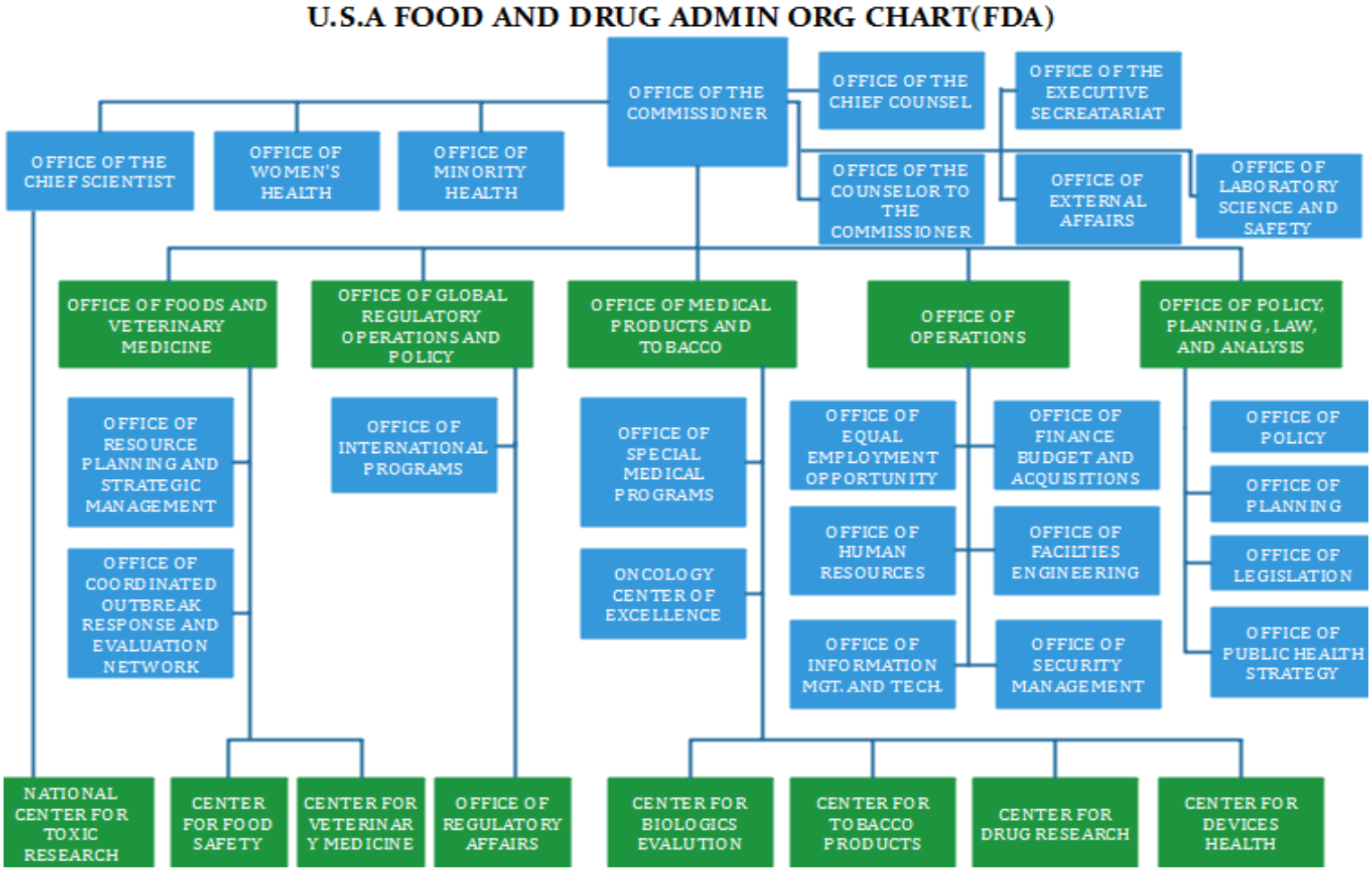
"Schedule F. Positions of a confidential, policy-determining, policy-making, or policy-advocating character not normally subject to change as a result of a Presidential transition shall be listed in Schedule F. In appointing an individual to a position in Schedule F, each agency shall follow the principle of veteran preference as far as administratively feasible.

(ii) 5 CFR 6.4 is amended to read:
"Except as required by statute, the Civil Service Rules and Regulations shall not apply to removals from positions listed in Schedules A, C, D, E, or F,

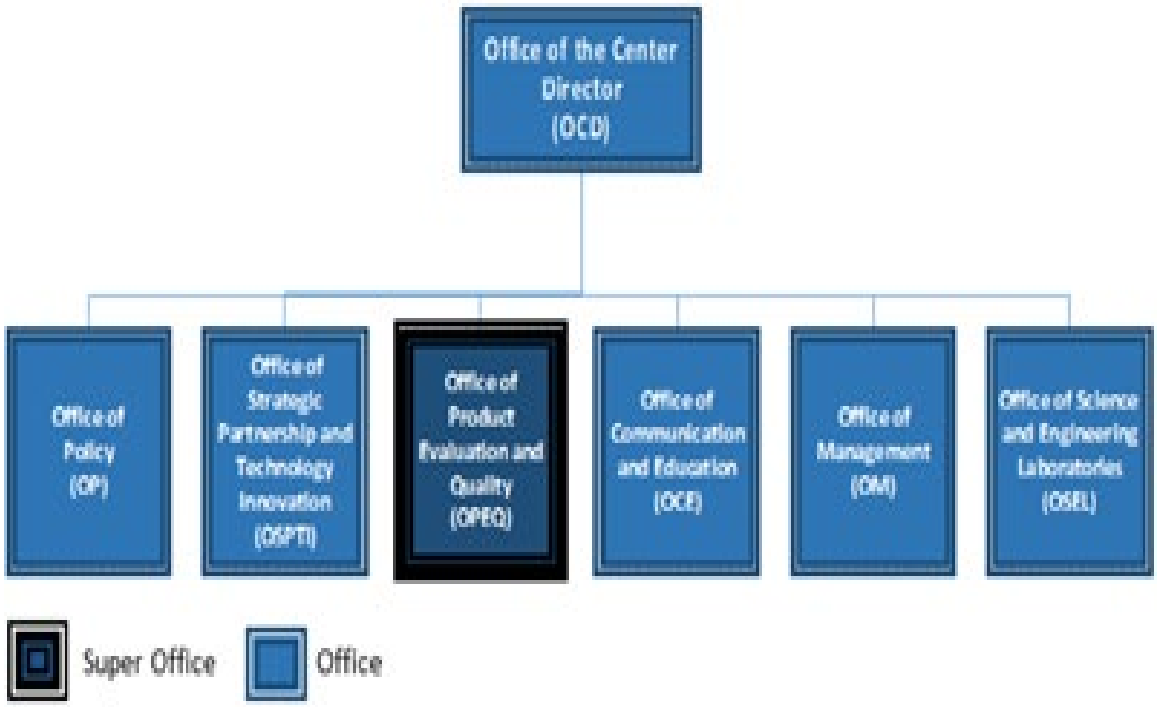
This would likely be rescinded in a Biden administration

- Federal work force unions have already announced opposition
- Democrats tend to view federal bureaucracy as their constituency
- Republicans (conservatives) view this measure as “opening a valve to drain the swamp”

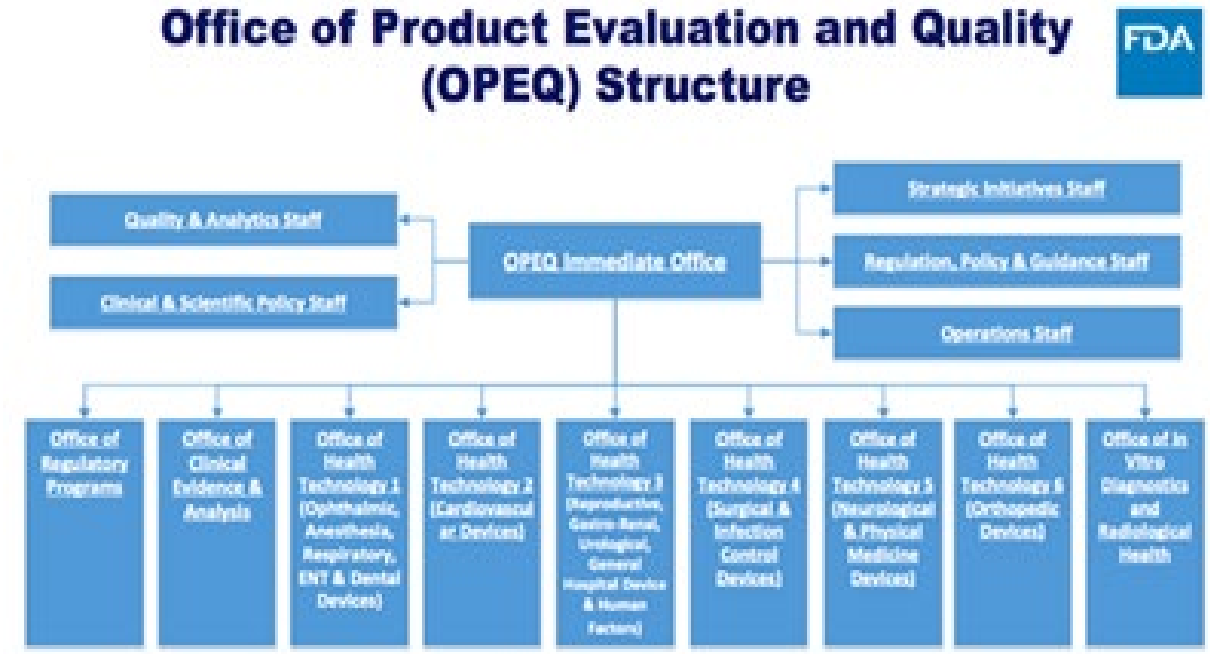
FDA Org Chart -- where's CDRH?



CDRH Organization



OPEQ Organization



The regulatory work is well below the offices with political comings and goings

- HHS directs FDA
- FDA commissioner's office directs the Centers and ORA (field offices)
- Center and ORA management directs the actual regulatory reviews and inspections – and these activities are largely fixed by law (discussed below)

CDRH implements law-based regulation of medical devices

- Laws / Statutes
- Regulations
- Guidance Documents

FDA "reform" popular on both sides of the aisle – with different emphasis

- 1976 Medical Device Amendments
- Safe Medical Devices Act of 1990
- Mammography Quality Standards Act of 1992
- Food and Drug Modernization Act of 1997
- Medical Device User Fee and Modernization Act of 2002
- Food and Drug Administration Amendments Act of 2007
- Patient Protection and Affordable Care Act – 2010 (excise tax)
- FDA Safety and Innovation Act of 2012
- 21st Century Cures Act – 2016

FDA "reform" popular on both sides of the aisle – with different emphasis

- On March 27, 2020, the President signed into law H.R. 748, the "Coronavirus Aid, Relief, and Economic Security Act" (CARES Act)
- The CARES Act includes an important legislative initiative that reforms and modernizes the way OTC monograph drugs are regulated in the United States
- It's been needed for decades and somehow it snuck on the back of pandemic relief legislation - bipartisan

Key Device Regulations

- 21 CFR Part 801 (labeling)
- 21 CFR Part 803 (MDR)
- 21 CFR Part 806 (correction/removal reporting)
- 21 CFR Part 806 (registration/listing/510(k))
- 21 CFR Part 812 (IDE)
- 21 CFR Part 814 (PMA)
- 21 CFR Part 820 (QSR)

Key Device Regulations

- 21 CFR Part 821 (tracking)
- 21 CFR Part 822 (surveillance)
- 21 CFR Part 830 (UDI)
- 21 CFR Part 860 (classification procedures)
- 21 CFR Parts 862-892 (classification regulations)
- 21 CFR Part 895 (banned devices)
- 21 CFR Parts 1000-1050 (radiological health)

Tracking deregulation in the Trump era (Brookings, 10/2020)

- An emergency notice permitting the use of certain medical devices (EUAs) (effective)
- A rule clarifying the definition of "biological products" to reduce uncertainty (effective)
- A rule allowing minimal risk clinical investigations to bypass or alter certain informed consent requirements (effective)
- A rule expanding the definition of "tobacco products" for the purposes of FDA regulation (Deeming Rule) (delayed)
- Repealing the requirement for irradiated drugs to obtain an FDA-approved NDA or ANDA for marketing (effective)
- A rule redefining the standard for evaluating "intended uses" of products regulated by the FDA (proposed)

Examples of Pending Proposed Rules

- Medical Devices; Amendments to Medical Device Classification Regulations That Exclude Software Functions In Accordance With the 21st Century Cures Act
- Medical Device De Novo Classification Process
- General and Plastic Surgery Devices: Restricted Sale, Distribution, and Use of Sunlamp Products

Bottom line

- Shifting priorities may affect premarket review and postmarket inspection/compliance at the margins
- For the most part, though, these activities implement statutes and regulations that do not rapidly respond to elections
- FDA's bread and butter work is so technical, and s/e so highly valued, that political system involvement generally remains high level
  - Exception are when FDA or industry request statutory fixes to technical problems (e.g., de novo – 1997 and 2012)

GOP Platform 2016 **and** 2020

- "The United States has led life sciences and medical **innovation** for decades, bringing millions of high-paying jobs to our country and helping Americans and people around the world live longer, healthier lives. Unfortunately, the continuously **increasing burden of governmental regulation and red tape** is taking its toll on our innovative companies, and their pipeline of new life-saving devices and drugs to our nation's patients is slowing and diminishing. The FDA has slowly but relentlessly changed into an agency that more and more puts the public health at risk by **delaying, chilling, and killing the development of new devices, drugs and biologics** that can promote our lives and our health. The FDA needs leadership that can reform the agency for our century and fix the **lack of predictability, consistency, transparency and efficiency** at the agency. The FDA needs to return to its traditional emphasis on hard science and approving new breakthrough medicines, rather than divert its attention and consume its resources trying to overregulate electronic health records or vaping."
- Democrat platforms do not address FDA at all (at least back to 2012)

Pandemic has brought about most political scrutiny of FDA in decades

- **Vaccine: "White House lifts block on FDA's stricter vaccine requirements "**The agency's decision to hold vaccine developers to the stricter criteria will likely push any vaccine authorization beyond Election Day." *** "The FDA on Tuesday told coronavirus vaccine developers that it will hold them to strict standards for emergency authorization, releasing new guidelines that the White House had fought against for weeks. The agency guidelines were released Tuesday afternoon after being held up at the White House budget office for review." (Politico, 10/20)
- WH eventually caved – because the safety/effectiveness issues are too technical yet momentous for the political system to overrule FDA

Pandemic has brought about most political scrutiny of FDA in decades

- Testing: In early January, Chinese scientists published the genetic sequence of the new coronavirus, which allowed laboratories to start designing tests.
  - FDA approved CDC test quickly
  - FDA placed burdens on non-CDC organizations
  - CDC test only one available in February 2020 but they botched it – did not work
- Effectively nation flew blind for a critical month

ALL THAT SAID, WHAT MIGHT THE ELECTION BRING?

Recent Congressional Democrat proposals and statements

- Democrats introduce legislation to revise FDA requirements for LGBT blood donors (9/2020)
- Democrat pushes FDA to act after 'forever chemicals' found in bottled water (7/2019)
- Senate Democrats question if FDA's digital health pre-certification will 'compromise public safety' (7/2017)

Recent Congressional Republican proposals and statements

- 20 Republican Senators Petition the FDA to Ban the Abortion Pill (Sept. 2020)
- H.R.19, the Lower Cost, More Cures Act (incentivize competition in the market to drive prices down / expand generic and biosimilar drugs)

NPR: Trump Vs. Biden On Health Care, Prescription Drugs, Medicare (Oct 2020)

- Biden's proposal … lower prescription drug prices within Medicare, create an independent commission to oversee and regulate the price of new drugs, and get rid of the tax breaks given to pharmaceutical corporations on advertising….
- Trump has attempted to usher through prescription drug reforms via a series of executive orders signed in July and September. . . . A notable order would lower drug prices for those on Medicare parts B and D to comparable costs seen internationally.

Final Predictions

- **After the election, no matter who wins, there will be a look-back at FDA's actions during pandemic**
- There will be three main questions
  - What did FDA do wrong (e.g., testing) (bipartisan)
  - Was there political interference esp. re vaccine (Ds only)
  - What lessons can be drawn to improve normal FDA operations (Rs and maybe Ds)
- **These inquiries will lead to bipartisan statutory changes in FDCA, no matter who wins**

FDA is already thinking about lessons learned

- Jeff Shuren says the US Food and Drug Administration's device center has been tallying up lessons learned from the coronavirus pandemic.
- "COVID-19 has presented challenges for the world, our country and the FDA," the director of the Center for Devices and Radiological Health (CDRH) said on 15 September at RAPS Convergence 2020, hosted by the Regulatory Affairs Professionals Society.
- "The greatest tragedy of the pandemic would be if we did not learn from it, and not just how we can be better prepared for the next outbreak, but how we can take the lessons learned to better serve patients at all times," Shuren said.

QUESTIONS?

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