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FAST BREAK:

CHANGES IN WASHINGTON – IMPACT ON FDA AND MEDICAL DEVICES

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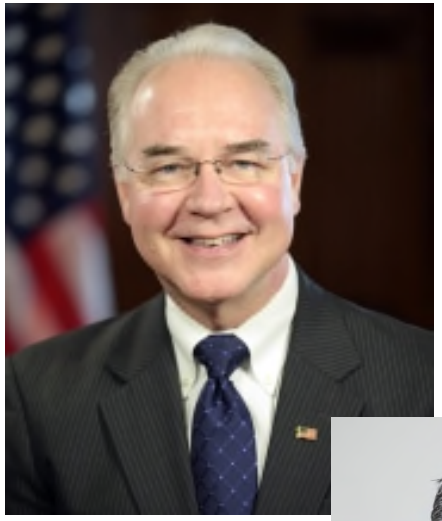
May 23, 2017

Changes in Washington

- Leadership transition
- New administration efforts on regulatory and agency reform
- Changes directly impacting FDA/HHS
- Medical device update

Leadership Changes

- HHS Secretary Tom Price confirmed and sworn in Feb. 10, 2017



- FDA Commissioner
  - Robert Califf resigned on Jan. 20
  - Scott Gottlieb sworn in as FDA Commissioner May 11, 2017

SECTION 01

NEW ADMINISTRATION EFFORTS ON REGULATORY REDUCTION AND REFORM

Broad Efforts for Regulatory Reform

- Executive Orders and Memos
  - Presidential Memorandum for the Heads of Executive Departments and Agencies: Regulatory Freeze Pending Review (Jan. 20)
  - Presidential Memorandum Regarding the Hiring Freeze (Jan. 23) (lifted Apr. 12)
  - Executive Order on Reducing Regulation and Controlling Regulatory Costs (Jan. 30)
  - Executive Order on Enforcing the Regulatory Reform Agenda (Feb. 24)
  - Executive Order on a Comprehensive Plan for Reorganizing the Executive Branch (Mar. 13)

Regulatory Freeze

- Requires agencies to put a hold on issuing new regulations until President Trump appoints a new department or agency head
- Includes final rules, ANPR, NPR, notices of inquiry, and guidance documents
- OMB Director can allow exemptions for "emergency situations or urgent circumstances related to health, safety, financial, or national security matters or otherwise."

Hiring Freeze

- Applies to hiring of all "Federal civilian employees across the board in the executive branch"
  - OMB to "recommend a long-term plan *to reduce the size of the Federal Government's workforce through attrition*"
  - Hiring freeze to remain in effect until implementation of the OMB plan
- Agency heads may exempt positions deemed "to meet national security or public safety responsibilities"
- OMB Director also can grant exemptions
- Not clear whether FDA will get exemptions based on:
  - Public health and safety reasons
  - User fee funding for new personnel
- Lifted on April 12; OMB produced a report outlining a plan for reduction in the civilian workforce.

Regulatory Reduction - "1 in, 2 out"

- Executive Order 13771
- No new regulations will be promulgated unless two are repealed
- "Regulation" is broadly defined and appears to include guidance documents
- Applies only to "significant regulatory actions"
- OMB Director can grant exemptions

Enforcing Regulatory Reform Agenda

- Executive Order 13777
- Requires head of each agency to designate an agency official as its Regulatory Reform Officer
- RRO will oversee implementation of regulatory reforms, including EO 13771
- Establishes a Regulatory Reform Task Force at each agency, chaired by the RRO, which shall:
  - Evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification
  - Provide reports to the agency head on implementation of regulatory reform initiatives and identifying regulations for repeal, replacement or modification

Comprehensive Plan for Reorganizing the Executive Branch

- Executive Order 13781
- Directs OMB Director to "propose a plan to reorganize governmental functions and eliminate unnecessary agencies. . ., components of agencies, and agency programs."
- Requires the head of each agency to submit a proposed reorganization plan to OMB Director within 180 days
- OMB Director also to request public comments via Federal Register notice
- OMB Director to submit plan to the President within 180 days after closing of comment period

SECTION 02

CHANGES DIRECTLY IMPACTING FDA/HHS

Changes Directly Impacting FDA/HHS

- 21st Century Cures
- User Fee Legislation
- White House Budget
- American Health Care Act

21st Century Cures

- 21st Century Cures
  - New funding for research
  - Expedited review pathways
  - Larger role for patient experience data and real world evidence
  - Reduced regulatory burdens in certain areas (e.g., medical-related software, dissemination of health care economic information, combination products)

FDARA and User Fee Legislation

- FDA Reauthorization Act of 2017 (FDARA) (S. 934)
  - Includes User Fee Legislation
    - User fees are set to expire at the end of September 2017
    - New user fees for *de novo* applications
  - FDA and industry continue to support the agreements
  - Senate HELP Committee passed FDARA May 11 and sent to the Senate floor
    - The draft includes language requiring risk-based inspections of medical device facilities, regulatory changes regarding contrast agents used with imaging systems, and the OTC sale of certain hearing aids.
    - The current discussion draft did not include language addressing lab-developed tests.
  - House Energy and Commerce Health Subcommittee passed similar FDARA/user fee language May 18

AHCA and White House Budget

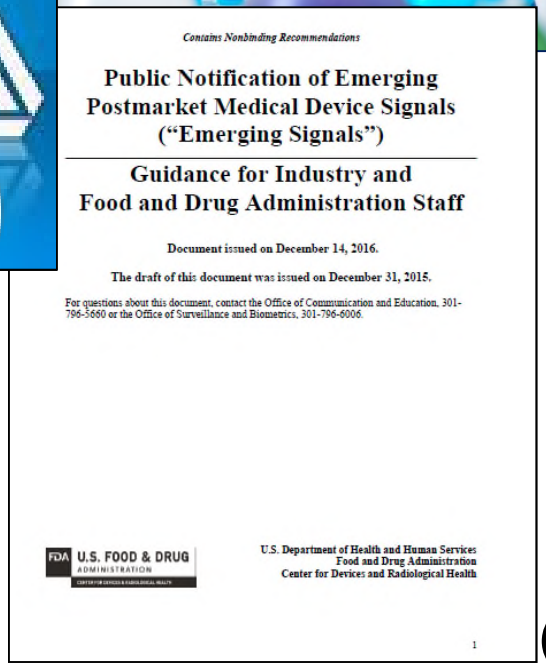
- White House Budget
  - Further emphasizes plan for a "major reorganization of the Executive Branch"
  - Decreases funding to HHS by $12.6 billion or 16.2%
  - Doubles FDA's medical product user fees to over $2 billion for 2018
  - Reduces NIH spending by $5.8 billion to $25.9 billion
  - Includes funds to implement the 21st Century Cures Act
- American Health Care Act
  - No direct provisions impacting FDA
  - Includes repeal of OTC medication tax, medical device excise tax, tax on Rx medications
  - Passed by the House of Representatives on May 4

SECTION 03

MEDICAL DEVICE UPDATE

Recent Developments – Medical Devices

- Laboratory Developed Tests
- Exemptions from 510(k) requirements
- Emerging Signals



Contains Nonbinding Recommendations

Public Notification of Emerging Postmarket Medical Device Signals ("Emerging Signals")

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 14, 2016.

The draft of this document was issued on December 31, 2015.

For questions about this document, contact the Office of Communication and Education, 301-796-5660 or the Office of Surveillance and Biometrics, 301-796-6006.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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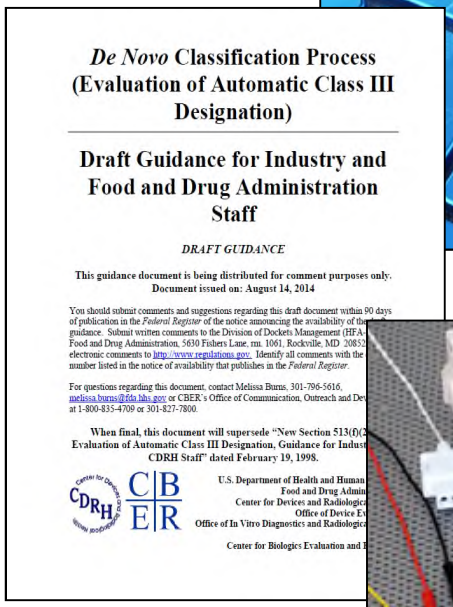
Recent Developments – Medical Devices

- Cybersecurity
- De Novo Requests
- Medical Device Accessories



De Novo Classification Process (Evaluation of Automatic Class III Designation)

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: August 14, 2014

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Melissa Burns, 301-796-5616, melissa.burns@fda.hhs.gov or CBER's Office of Communication, Outreach and Development at 1-800-833-4709 or 301-827-7800.

When final, this document will supersede "New Section 513(f)(3) Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff" dated February 19, 1998.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Office of In Vitro Diagnostics and Radiological Health
Center for Biologics Evaluation and Research

Thanks!

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Please join us for next month's webinar:

"Security Breach Crisis Response"
Best Practices for Defending against
New Cyber Threats
Featuring Reece Hirsch

- Thursday June 9, 2017 3:00 PM (EST)

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