Strategically Managing Health Care Policy

The Food and Drug Administration: Policy and Process

June 24, 2022

Presented by:

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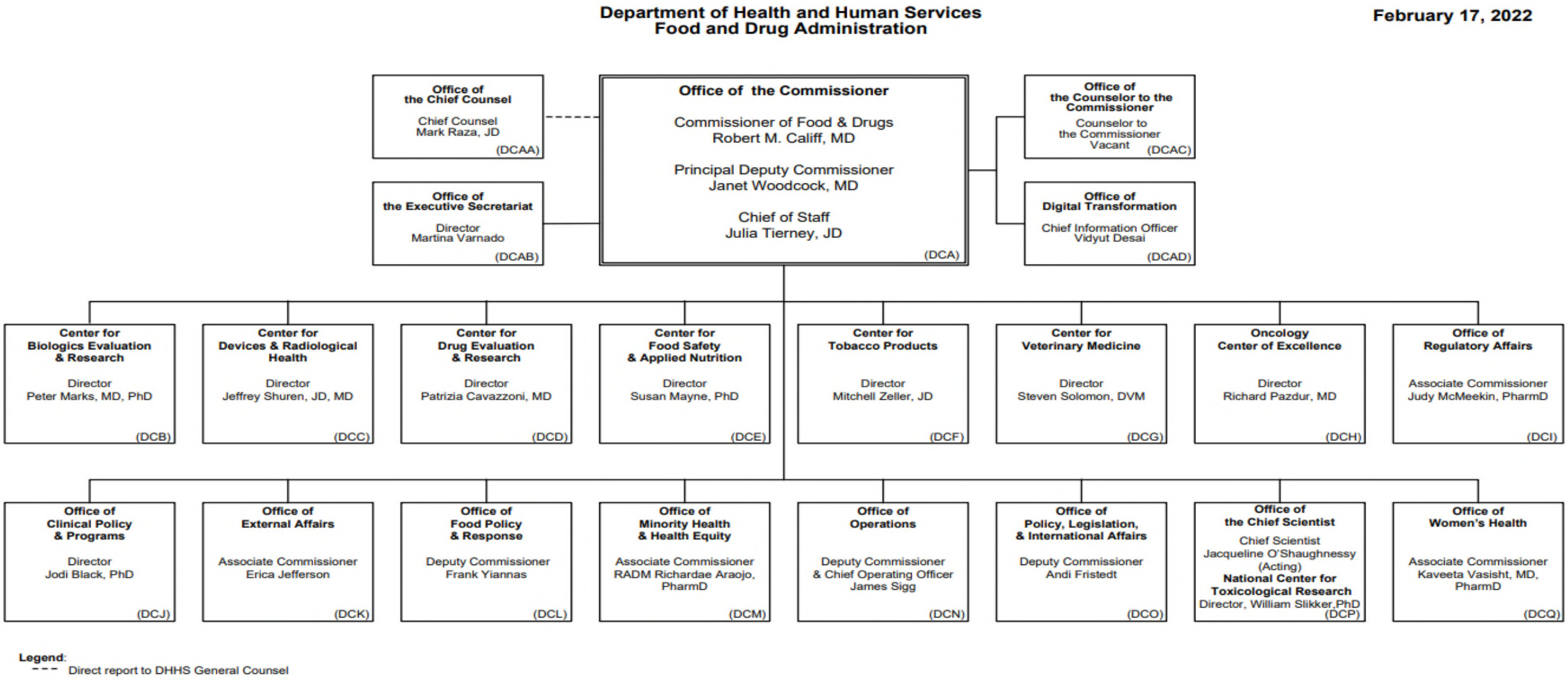
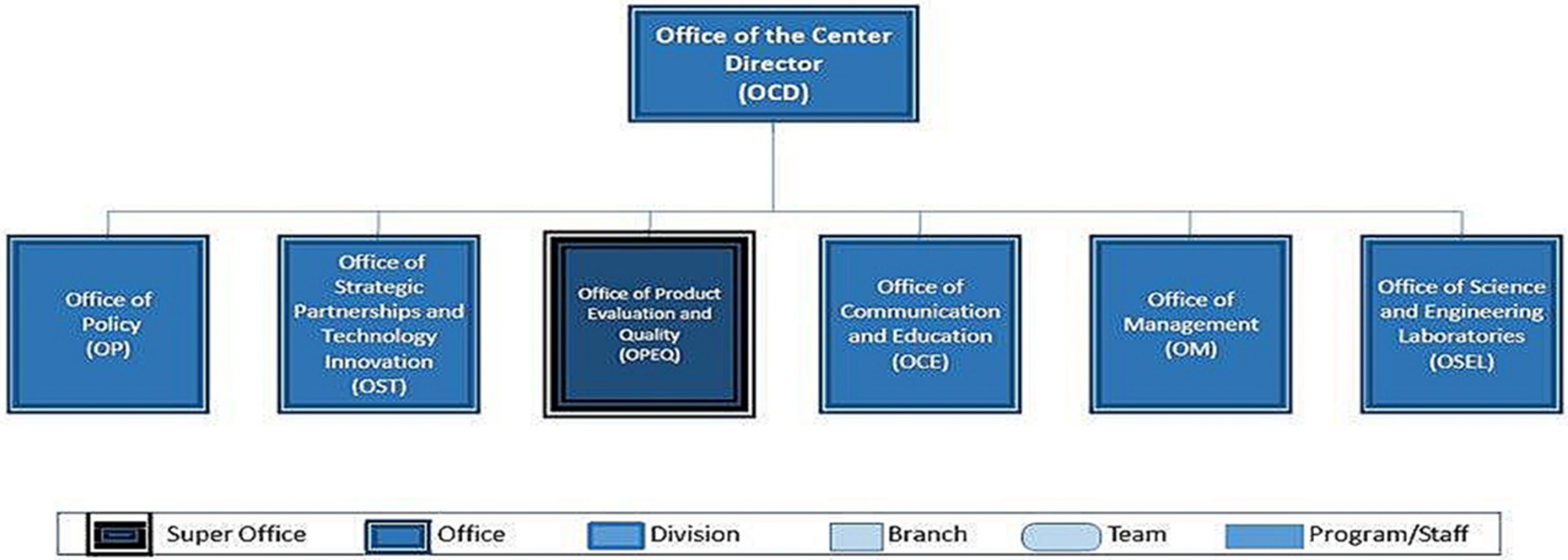
The FDA: The Organization



CDRH Overview

New CDRH Structure After Reorg Implementation



www.fda.gov

Is Your Product A Medical Device?

Medical Device Defined: Section 201(h) of the FDCA

A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

- *Recognized in the official national Formulary, or the United States Parmacopoeia, or any supplement to them*
- *Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or*
- *Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.*

Range from bed pans to implantable cardiac defibrillators and surgical robots.

Medical Device Amendments of 1976

The FDA's Risk Based Classification System is Established

- Class I (Low Risk): General Controls, exempt from pre-market review (e.g. stethoscope, bandages)
- Class II (Moderate Risk): General Controls and Special Controls
  - Pre-Market Notification, i.e. 510(k) submission and product clearance (e.g. blood glucose test strips, some insulin pumps, many orthopedic devices)
- Class III(Significant Risk): General Controls, Special Controls AND Pre-Market Approval + post-market requirements (e.g. pacemaker, cardiovascular stent)

Not Sure About Your Device Classification?

FDCA 513(g) Request for Information Process

Submit a Request

- Cover Letter
- Describe Device
- Describe Intended Use
- Provide proposed labeling or promotional material (plus for comparable products)

FDA Response:

- Within 60 days of receipt
- Device – yes or no – but maybe regulated by FDA elsewhere
- If yes, classification and regulatory requirements
- If combination product, then which Center has primary jurisdiction
- If not clear, then refer to Office of Combination Products

Class I Medical Devices

- Minimal risk of harm to the patient and provider
- Governed by General Controls
  - Establishment registration/device listing
  - Compliance with labeling regulation
  - GMP compliance (audited)
- Most Class I devices do not require pre-market submissions (i.e., exempt from 510(k) pre-market notification)
- Many Class I devices exempt from QSR other than record keeping an reporting requirements

Class II Medical Devices

"... general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device"

- General and Special Controls
  - Establishment registration/device listing
  - Compliance with labeling regulation
  - Compliance with quality system regulation (via audit)
  - FDA guidance (product specific; fewer than 10% require clinical data)
- Typically require pre-market notification submission (510(k) submission) to demonstrate substantial equivalence to legally marketed predicate device (FDA clearance)
  - Both have the same intended use and technological characteristics (or similar)
  - Comparison of critical performance criteria

Product Codes: 3 letter code to categorize device types (identify predicates)

Class III Medical Devices

- Subject to general and special controls and . . .
- Class III typically require:
  - PMA (Premarket Approval application) – provides reasonable assurance of safety and efficacy
  - Clinical trial data (Investigational Device Exemption (IDE) required)
  - Quality systems information part of the PMA submission
  - Pre-approval inspection (PAI)
  - Post-Approval requirements

Combination Products

- Product comprised of two or more regulated components (drug, biologic, device) that are physically, chemically or otherwise combined
  - Lead regulatory Center depends on “primary mode of action”
    - the means by which a product achieves its intended therapeutic effect or action
      - Drug + Device, Device + Biologic, etc.
- Several variations on the theme
  - One integrated product, e.g. drug eluting stent, advanced wound dressing
  - Co-packaged, e.g. pre-filled syringe
  - Cross-labeled, e.g. diagnostics + therapeutics

Regulatory Pathways to Market

Risk Classification Dictates Pathway

- Class I – no premarket application needed (510(k) exempt)
- Class II – premarket notification required (510(k))
- Class III – premarket approval required (PMA)

Class II – Traditional 510(k) Application

Legal Framework and Data Requirements

- Demonstrate substantial equivalence to marketed device- predicate
  - Same indications for use
  - Comparable technological characteristics
- Testing comparable to predicate
  - Benchtop versus clinical
  - Biocompatibility, electrical safety, software validation, cybersecurity, shelf life, sterilization, ship testing
- Timing: 90 days from submission
- Full Quality Management System 21 CFR 820; ISO 13485

Class III – Pre-Market Approval Applications

Legal Framework and Data Requirements

- Significant risk devices that:
  - Support sustain life
  - Implanted
  - Present potential unreasonable risk of illness or injury
- Examples – cardiac stents, pacemaker
- Premarket approval – PMA
  - Comprehensive data package clinical performance, manufacturing process, QMS inspection
- Formal clinical trials comparing to Gold Standard or SOC
- Investigational Device Exemption (IDE) needed to conduct trial
- Timing : 2-3 years

What About Cases of First Impression?

De Novo Pathway for Low to Moderate Risk Devices

- No predicate
- Risk-based strategy asking FDA to classify as Class I or II, due to low or moderate risk
- Testing requirements similar to traditional 510(k)
- Some clinical data

The Covid-19 Impact

- Triggers Additional Regulatory Pathway: Emergency Use Authorization
- Limited in Duration
- Limited in Scope
- Advantageous for Properly Aligned Innovators and Manufacturers

Emergency Use Authorization

- Statutory Authority
  - Project Bioshield Act of 2004 (Public Law 108-276) amended the FDCA
  - Rooted in a counterterrorism response to September 11, 2001
  - Before EUA can be utilized by FDA, HHS must declare an emergency exists

Emergency Use Authorization

- Types of Emergency Declarations
  - Domestic emergency or significant potential for a domestic emergency involving a heightened risk of attack with a CBRN agent(s) – declared by Secretary of Homeland Security
  - Military emergency or significant potential for a military emergency involving a heightened risk to the US military of attack with a CBRN agent(s) – declared by Secretary of Defense
  - Public health emergency or significant potential for public health emergency that affects or has a significant potential to affect national security or the health and security of US citizens living abroad and that involves a CBRN agent or agents or a disease or condition that may be attributable to such agents – declared by Secretary of HHS
  - Under the Public Health Service Act that there is a public health emergency or that a public health emergency is presented by a significant outbreak of infectious diseases or bioterrorist attacks – declared by the Secretary of Homeland Security

Emergency Use Authorization

- Limited in Duration
  - Termination of an EUA Declaration
    - Upon determination that underlying emergency no longer exists
    - Upon approval of a device such that EUA status is no longer needed

Emergency Use Authorization

- Limited in Scope
  - For products intended to be used to address the public health emergency
  - That are not cleared or approved for that intended use
    - COVID-19
      - Ventilators
      - PPE: Masks, Respirators, shields, gloves, gowns
      - Diagnostic tests
      - Treatments

Emergency Use Authorization

- Pros
  - PREP Act Protection
  - DPA Protection
  - Relaxed FDA standards
  - Speed to market

Emergency Use Authorization

- Cons
  - When the emergency ends, the EUA ends
  - Your product will be noncompliant
  - Risk of enforcement action by FDA

Questions?

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