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EMERGENCY USE AUTHORIZATION (EUA): BE AWARE, BE PREPARED

Emergency Use Authorization (EUA):

- **What is EUA:**
  - **A temporary and expedited pathway—as an alternative to 510(k) clearance or Premarket Approval (PMA)—that FDA employs in times of emergency to introduce certain medical products into interstate commerce:**
    - By approving an unapproved medical product; or
    - By approving an unapproved (off-label) use of an approved medical product
  - **How expedited: Hours/Days vs. Years**
- **Emergency Pathways Before EUA:**
  - **Investigational New Drug (IND)**
  - **Investigational Device Exemptions (IDE)**

The EUA Statute: Section 564, Food Drug and Cosmetics Act ("FD&C Act") (21 U.S.C. § 360bbb-3)

- **".. the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use")." § 360bbb-3(a)(1)**
- **Approval status: § 360bbb-3(a)(1)**
  - The use of an unapproved (unlicensed/uncleared) medical product
  - An unapproved (off-label) use of an approved (licensed/cleared) medical product
- **Declaration of emergency or threat justifying emergency authorized use. § 360bbb-3(b)**

Past EUAs:

- Anthrax (2005): 3 EUA (Anthrax Vaccine)
- H1N1 (2010): 4 EUAs
- MERS-CoV (Middle East Respiratory Syndrome Coronavirus) (2013): 2 EUAs
- Ebola (2015): 3 EUAs
- Zika Virus (2016-2017): 6 EUAs
- COVID-19 EUAs: More than 400 EUAs to date

COVID-19 EUAs:

- **First EUA**
  - Issued on February 4, 2020, the same day of HHS Declaration of emergency;
  - 2019-nCoV Real-Time RT-PCR Diagnostic Panel
- **Vaccines: all COVID-19 vaccines**
- **Drugs and Biological therapeutic products**
- **Medical Devices**
  - ventilators,
  - PPEs,
  - *in vitro* diagnostics,
  - respiratory assist devices,
  - blood purification devices,
  - renal replacement therapy and hemodialysis devices,
  - infusion pumps,
  - wearable monitoring devices, other devices)

Notable COVID-19 EUAs:

- **Hydroxychloroquine and Chloroquine**
  - Issued on March 28, 2020; Revoked June 15, 2020
- **Remdesivir (Veklury®) for Certain Hospitalized COVID-19 Patients**
  - Issued on May 1, 2020; Revised twice to expend usage;
  - PMA obtained on Oct. 22, 2020; EUA revoked same day.
- **COVID vaccines: Pfizer-BioNTech; Moderna; Janssen**

Criteria for Issuance of EUA: 21 USC § 360bbb-3(c)

- A life-threatening condition or disease exists;
- Based on the totality of scientific evidence available to the Secretary… it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing such disease or condition;
- The known and potential benefits outweigh the known and potential risks of the product;
- There is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition.

Request for Consideration For An EUA:

- **Section 564 does not address the precise processes and data requirements for an EUA request;**
- **FDA guidance document (not legally binding, recommended but not required):**
  - Request to be submitted by government agencies (CDC, DoD) or private entities;
  - Data submission:
    - Description of the product and its intended uses;
    - Rationale behind the product's use under an EUA;
    - Available safety and efficacy data;
    - Proposed labeling and instructions for the product's use.

Duration of EUA:

- **Duration: § 360bbb-3(f)**
  - Effective until termination of the declared emergency;
  - Effective until revocation
  - Continued use after termination is allowed on patient when use begins before termination.
- **Review and revocation:**
  - The Secretary shall periodically review the circumstances and appropriateness of the authorization;
  - The Secretary may revise or revoke the authorization if –
    - Emergency not longer exists
    - Criteria for issuance of EUA are no longer met
    - Other circumstances make revision or revocation appropriate

After Termination of EUA:

- **Product must be disposed of: § 360bbb-3(2)(B)**
  - The Secretary shall consult with the manufacturer with respect to the appropriate.
  - The Secretary shall provide advance notice of the termination. The period of advanced notice shall provide:
    - A sufficient period for disposition of the product;
    - A sufficient period for the disposition of the labeling
- **Revocation: Not addressed in Section 564**
  - FDA intends to communicate with manufacturers

Liability Protection: The PREP Act

- **Immunity under Public Readiness and Emergency Preparedness Act of 2005 (the "PREP Act") (42 U.S.C. § § 247d-6d, 247d-6e):**
  - "Qualified pandemic products are immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure."
  - Persons covered: manufacturers, distributors, program planners, qualified persons who prescribe, administer, or dispense countermeasures;
  - Activities covered: development, manufacture, testing, distribution, administration, and use of countermeasures;
  - Countermeasures covered: vaccines, drugs, medical devices
  - Claims covered: tort liability except for **willful misconduct**.

Liability Protection: The PREP Act

- **Definition of "qualified pandemic or epidemic product," 42 USC § 247d-6d(i)(7)**
  - A drug, biological product, or device … that is approved or cleared under the FD&C Act, subject to **exemption** under the FD&C Act, or is authorized for emergency use under the FD&C Act.
- **Definition of "willful misconduct," 42 USC § 247d-6d(c-d):**
  - Intentionally to achieve a wrongful purpose;
  - Knowingly without legal or factual justification; and
  - In disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.
  - Plaintiff bears the burden of proof by clear and convincing evidence.

Willful Misconduct vs. EUA Revocation:

- **Definition of "willful misconduct," 42 USC § 247d-6d(c-d):**
  - Initiation of an enforcement action by the federal government that resulted in a "covered remedy;" Id. at (c)(5);
- **Definition of an "enforcement action:" Id. at (c)(5)(B)(i)**
  - Injunction,
  - Mandatory recall,
  - A revocation based on willful misconduct, of an authorization under section 564 of such Act.
- **Definition of "covered remedy:"**
  - A revocation of an authority under section 564. Id. at (c)(5)(B)(i)(I).

Willful Misconduct vs. EUA Revocation:

- **A revocation of EUA may constitute willful misconduct;**
- **Revocation standard vs. willful misconduct standard:**
  - **Revocation:**
    - Emergency no longer exists;
    - Criteria no longer met;
    - Alternatives available;
    - Other circumstances (risk outweighs benefits, etc.)
  - **Willful misconduct:**
    - Intentionally to achieve a wrongful purpose;
    - Knowingly without legal or factual justification; and
    - In disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.
    - Plaintiff bears the burden of proof by clear and convincing evidence.

Litigation After EUA Revocation:

- **No product liability suits filed.**
- **Two subsequent lawsuits to force FDA to approve hydroxychloroquine:**
  - Ass'n of Am. Physicians & Surgeons v. FDA, 479 F. Supp. 3d 570 (W.D. Mich. 2020)
    - AAPS sued FDA for impeding the ability of President Trump to make hydroxychloroquine available to the public;
    - Case dismissed for lack of standing: hydroxychloroquine is still commercially available and physicians are free to prescribe them to patients for treating COVID-19. FDA does not intend to interfere with the practice of medicine.
  - Goico v. United States FDA, 2020 U.S. Dist. LEXIS 173415 (D. Kan. Sep. 22, 2020)
    - Individual plaintiff sued FDA alleging that the revocation of hydroxychloroquine held him and his father under illegal house arrest by withholding medication preventing COVID-19; seeking TRO;
    - Case dismissed for failure to show irreparable harm.
- **Nursing home investigation on unconsented administration of hydroxychloroquine without state authorization**

Start Taking Actions to Prepare for EUA Termination/Revocation:

- Keep close monitoring of FDA's EUA List;
- Engage in communication with FDA as early as possible;
- Keep clear labeling and complete documentation of EUA authorized products;
- Track shipments and distributions;
- Start formulating recall strategy;
- Consider alternatives to product destruction;
- Start the traditional pathways application process.

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