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SA Military Medical Industry Day

REGULATORY STRATEGY – IMPORTANCE OF FDA INTERACTIONS

AGENDA

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- Welcome to VelocityTX
  - BexarBio pitch competition
  - Military Medical Industry Day
- Panel Introductions and discussion

MMID

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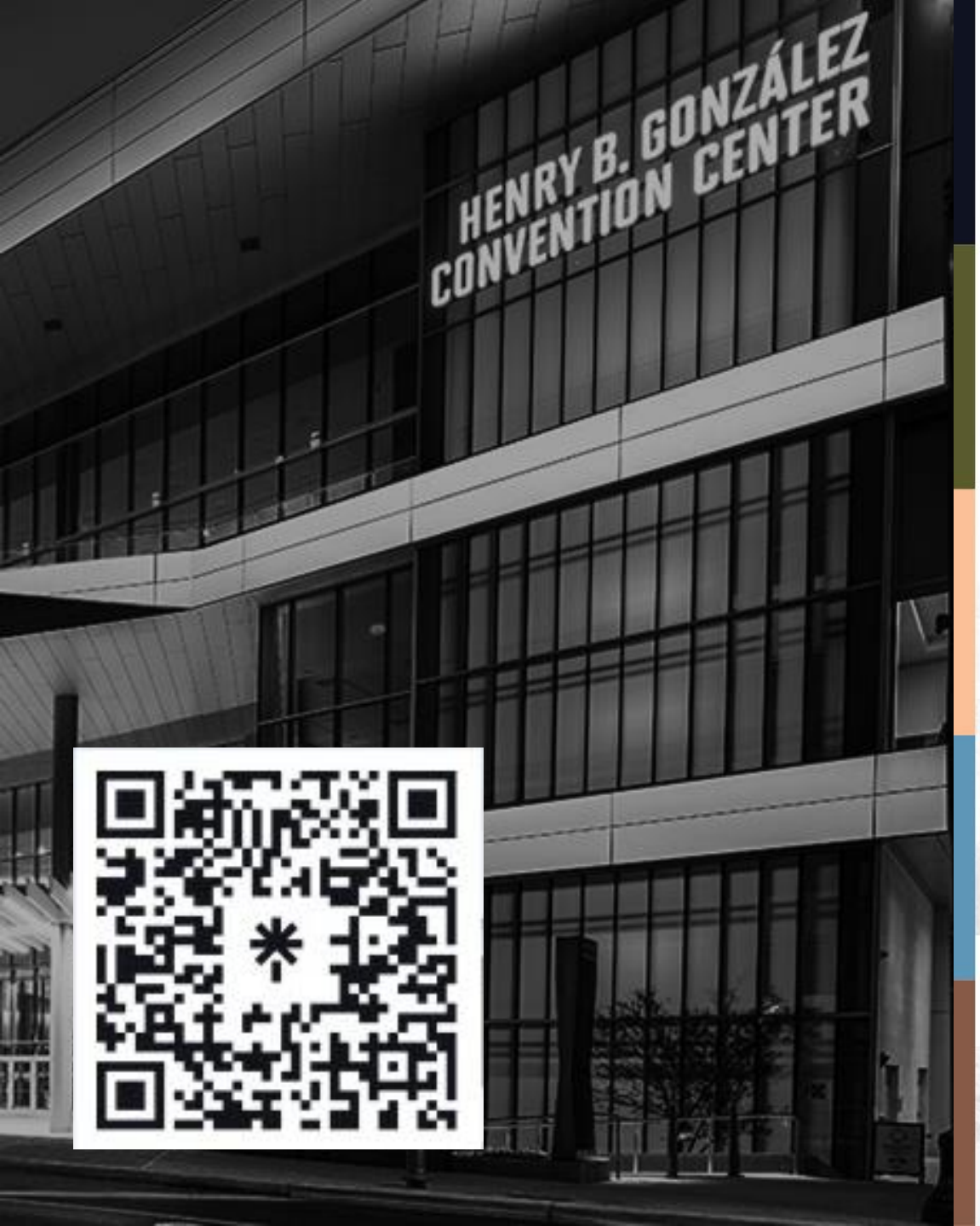
A **premier networking and collaboration** event in **Military City USA**:

- **50+ companies**
- **3 pre-event symposiums**
- **1 Full-Day Conference**
- **335+ Attendees**



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CITY OF SAN ANTONIO TEXAS

FREE FOR .MIL

MILITARY MEDICAL INDUSTRY DAY

MAY 2, 2023

HENRY B. GONZALEZ CONVENTION CENTER, SAN ANTONIO, TX

REGISTRATION NOW OPEN*

San Antonio's premier networking and collaboration event for the armed services and private sector in support of the military's medical mission.

STAY & PLAY, ARRIVE EARLY TO ATTEND BEXARBIO PITCH COMPETITION, MAY 1

BEXARBIO

VELOCITY.TX

A **pitch competition showcasing San Antonio's key assets with 150+ attendees and $100k in cash prizes, using a proven method to give companies access to the San Antonio ecosystem.**

BEXAR COUNTY & VELOCITYTX PRESENT

BEXARBIO

PITCH COMPETITION

$100K*

NON-DILUTIVE FUNDING

DOORS 5:30P, EVENT 6P-8P

MAY 1, 2023

2023

* Finalist prize winner required to maintain a company presence (office or remote employee) within Bexar County for a minimum of 6 months after prize money award date.

PANELISTS

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MODERATOR: **Scott Walter, Ph.D. (US Air Force 59th Medical Wing (MDW))**

PANELISTS:

- **Dr. Heather Agler** (Sr. Science Health Advisor, US Food & Drug Administration (FDA))
- **Eddie Webb** (Director Advanced Development, Air Force Medical Readiness Agency (AFMRA))
- **Rachel Hunnicutt** (Acting Chief, FDA Regulatory Law Division Office of the Staff Judge Advocate (JAG), U.S. Army Medical Research & Development Command (MRDC))
- **Ms. Carmen Maher** (Sr. Director Medical Regulatory JPEO-CBRN and DTRA JSTO)
- **Ms. Lisa Borek** (ORA Director/Senior Regulatory & Clinical Services Manager)

Regulatory Strategy: Importance of FDA Interactions and Public Law 115-92

A Presentation for:

VELOCITY TX and SA Military Medical Industry Day

Rachel K. Hunnicutt, J.D., M.S.
Acting Chief, FDA Regulatory Law Division
Office of the Staff Judge Advocate (JAG)
U.S. Army Medical Research & Development Command
Rachel.k.Hunnicutt.civ@health.mil

JAG Mission & Vision

MISSION:

Provide responsive, well-researched, candid legal support to our clients in order to bring exceptional medical solutions to our nation's warfighters

VISION:

MRDC'S and Fort Detrick's most well-respected, user friendly, and collegial team of professionals

OFFICE OF THE STAFF JUDGE ADVOCATE

P.L. 115-92 Background

- **OSD-led effort to expand the existing Emergency Use Authority (EUA) at Section 564 of the Federal Food, Drug and Cosmetic Act (FD&C Act) to apply beyond CBRN threats.**
  - Senate version of FY18 NDAA included Section 732, which would have given the Secretary of Defense the authority to issue an emergency use authorization under 564 of the FD&C Act; passed at Section 711.
- **Meeting between Dr. Terry Rauch (DoD) and FDA Commissioner Scott Gottlieb on October 27, 2017**
  - FDA objected to the DoD approach on the grounds it impeded FDA's statutory authority and questioned DoD's ability to make correct risk/benefit calculations.
  - DoD rejected FDA's offer of an expedited approval mechanism because the proposal did not also include an expansion of the EUA.
- **FY18 NDAA (HR 2810) included Section 711 (formerly 732) with OSD's approach to EUA expansion; became Public Law No: 115-91 on 12/12/17.**
- **With White House intervention, compromise between OSD and FDA reached in November 2017 to <u>both</u> expand the scope of the EUA and provide an expedited approval mechanism for DoD-medical priorities *via a concurrent legislative vehicle*, H.R. 4374**
- **H.R. 4374 became Public Law No. 115-92 on 12/12/17. Repealed NDAA language and the compromise became law.**

Summary of P.L. 115-92

- **Section 1(a):** expands the EUA beyond CBRN threats to cover "agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to the United States military forces."
- **Section 1(b)(1):** allows SecDef to request expedited approval of any regulatory application (investigational or pre-market approval).
- **Section 1(b)(2):** allows FDA to expedite development of any regulatory application subject of a SecDef request by taking any of the non-exhaustive steps in the statute.
- **Section 1(b)(3):** requires semi-annual review between DoD and FDA on DoD's portfolio and requires quarterly CBER/FDA-DoD meetings for CBER-regulated products.

Expansion of the EUA

- **Section 1.(a)**
  - "(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, United States Code, of attack with—

    "(i) a biological, chemical, radiological, or nuclear agent or agents; or

    "(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;"

Expedited Approval

- **Section (b)(1) allows SecDef to request FDA to take actions to "expedite the development of a medical product," review any medical application (investigational or pre-market approval)**:
  - if there is a military emergency, or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk
- **Section (b)(2) allows FDA to expedite review of an application using one or more of the following means (list not exhaustive):**
  - Meetings w/ review division;
  - Increased communication on clinical and non-clinical needs;
  - Involve senior FDA leadership;
  - Use of cross-disciplinary teams for review;
  - Advice on efficient trial designs;
  - Application of any other expedited approval program; and
  - Permission of expanded access.

Enhanced Collaboration

- **Section 1(b)(3)(A): requires semi-annual review between DoD and FDA on DoD's portfolio:**
  - "(A) the Food and Drug Administration shall meet with the Department of Defense and any other appropriate development partners, such as the Biomedical Advanced Research and Development Authority, on a semi-annual basis for the purposes of conducting a full review of the relevant products in the Department of Defense portfolio;"
- **Section 1(b)(3)(B): requires quarterly CBER/FDA-DoD meetings for CBER-regulated products.**
  - "(B) the Director of the Center for Biologics Evaluation and Research shall meet quarterly with the Department of Defense to discuss the development status of regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to the Department of Defense (which may include freeze dried plasma products and platelet alternatives)"

Other Provisions

- **Defines "medical product" broadly to include all medical product categories**
  - "(4) MEDICAL PRODUCT.—In this subsection, the term "medical product" means a drug (as defined in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321)), a device (as defined in such section 201), or a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262))."
- **Repeals Section 716 of the 2018 NDAA**
  - "(c) REPEAL.—Effective as of the enactment of the National Defense Authorization Act for Fiscal Year 2018, subsection (d) of section 1107a of title 10, United States Code, as added by section 716 of the National Defense Authorization Act for Fiscal Year 2018, is repealed."

P.L. 115-92 Implementation & Progress

- **DoD-FDA Memorandum of Understanding**
  - FDA-DoD MOU signed November 2018
  - Semi-Annual meetings between DoD and FDA Senior leadership, coordinated through the Office of the Commissioner
    - Semi-annual meetings have participation of the Directors of the Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER), and the Center for Devices and Radiological Health (CDRH)
  - Quarterly meetings with the Director of CBER, with other centers looped in as appropriate per Priority List products
  - Expanded EUA authority and DoD accelerated management mechanism.
  - Implements a “one voice” approach for the DoD enterprise re: the priority list

P.L. 115-92 Implementation & Progress

- **Where are we now?**
  - DoD Priority List initiated in March 2018 and revised annually
  - Priority List developed by the Medical Product Acceleration Committee (MPAC)
  - The MPAC is intended to serve as the DoD enterprise-wide forum for discussions on which products are identified as DoD MPPs for the Priority List. The MPAC aims to achieve a DoD "one voice" approach envisioned by the statute.
- **Impacts:**
  - Freeze Dried Plasma EUA (JUL18), Cold Stored Platelets FDA Waiver (AUG19)
  - FDA Approvals/Clearance:
    - Tafenoquine (JUL18); RAFA Atropine Auto-Injector (JUL18); RECELL® (SEP18) Sufentanil (NOV18); Intravenous Artesunate (MAY20), Laboratory Assay for Traumatic Brain Injury (JAN21); Tick-borne Encephalitis Vaccine (AUG21)
  - Rapid communication on emerging issues: COVID-19 testing, treatments, vaccines

PL 115-92 Sponsor Authorization Letter

Model Authorization Letter for FDA to Share Non-Public Information With DoD

Excerpt from example authorization letter, Exh. B to FDA and DoD MOU 225-19-001

On behalf of [*insert name of information owner*], I authorize the United States Food and Drug Administration (FDA) to share with DoD Partners, and with contractors to those Partners, all information concerning the above described product(s) that [*insert name of information owner*] has provided or will provide to FDA or to any other DoD Partner. I understand that those Partners have committed to use such information only for the purposes of the DoD and have committed or are otherwise legally required to maintain the confidentiality of such information (or both), and that contractors to DoD are bound by their contracts to maintain the confidentiality of the information. I understand that the information may contain confidential commercial or financial information or trade secrets within the meaning of 18 USC § 1905, 21 USC § 331(j), and 5 USC § 552(b)(4), that is exempt from public disclosure. I agree to hold FDA harmless for any injury caused by FDA's disclosure of this information.

Authorization is given to FDA to share this information without deleting confidential commercial or financial or trade secret information. This authorization shall remain valid unless revoked in writing. As indicated by my signature, I am authorized to provide this consent on behalf of [*insert name of information owner*] and my full name, title, address, telephone number, and facsimile number are set out below for verification.
Sincerely,

See https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001

Contact Us

Rachel K. Hunnicutt, J.D., M.S.
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U.S. Army Medical Research & Development Command (USAMRDC)
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Fort Detrick, MD 21702
Email: **Rachel.k.Hunnicutt.civ@health.mil**

U.S. FOOD & DRUG ADMINISTRATION

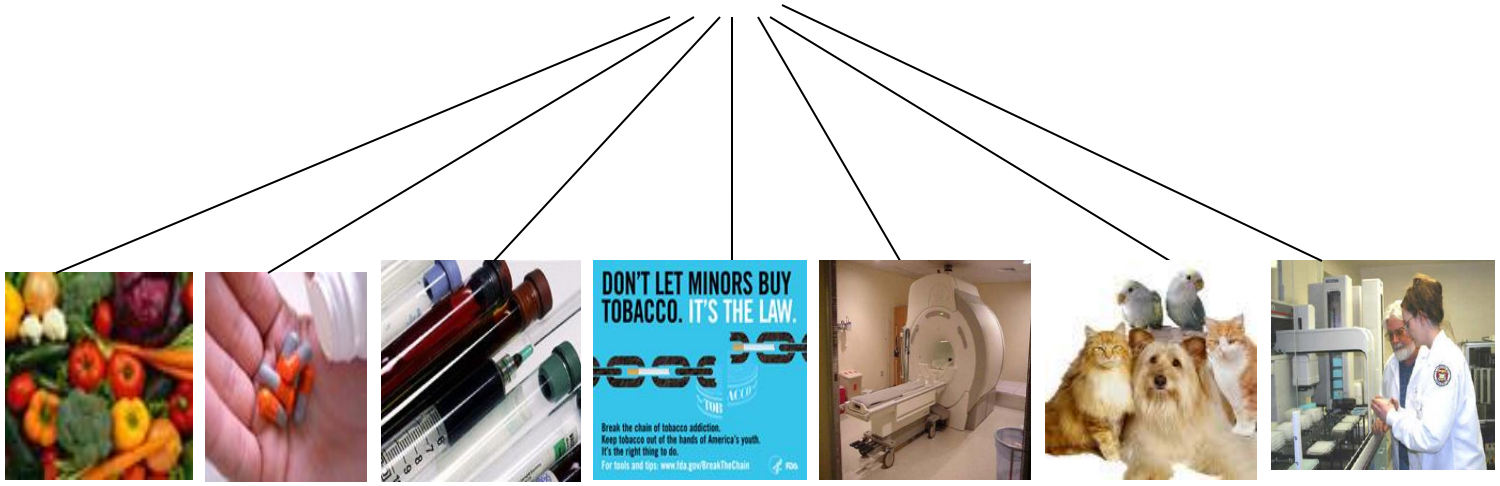
FDA and Military Medical Device Development

Heather Agler, PhD
Senior Science Health Advisor
Medical Countermeasure Innovation Program Lead
All-Hazards Readiness, Response, and Cybersecurity (ARC)
Office of Strategic Partnerships and Technology Innovation (OST)
CDRH/FDA

April 11, 2023

What Do You Need to Succeed?

- ✓ Don’t wait to think about the regulatory pathway.
- ✓ Don’t be afraid to talk to the FDA.
- ✓ Work with your military partner.



Center for Food Safety & Applied Nutrition

Center for Drug Evaluation & Research

Center for Biologics Evaluation & Research

Center for Tobacco Products

Center for Devices & Radiological Health (CDRH)

Center for Veterinary Medicine

National Center for Toxicological Research

Center for Devices and Radiological Health (CDRH)

- Responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices and in-vitro diagnostics for sale in the United States.
- Regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions

Medical devices encompass a wide range of technologies…

23

All-Hazards Readiness, Response and Cybersecurity (ARC) Innovation Program

Supports the development of new innovative medical countermeasure devices and new innovative devices to support the warfighter

- **MCM Devices**: A medical device used in the detection, prevention, and management of a CBRNE, emerging infectious disease, or natural disaster event.

- Work with our federal partners including the DoD, BARDA, CDC, and others to get new medical countermeasure devices cleared and approved.
  - Outreach
  - Education
  - Collaboration

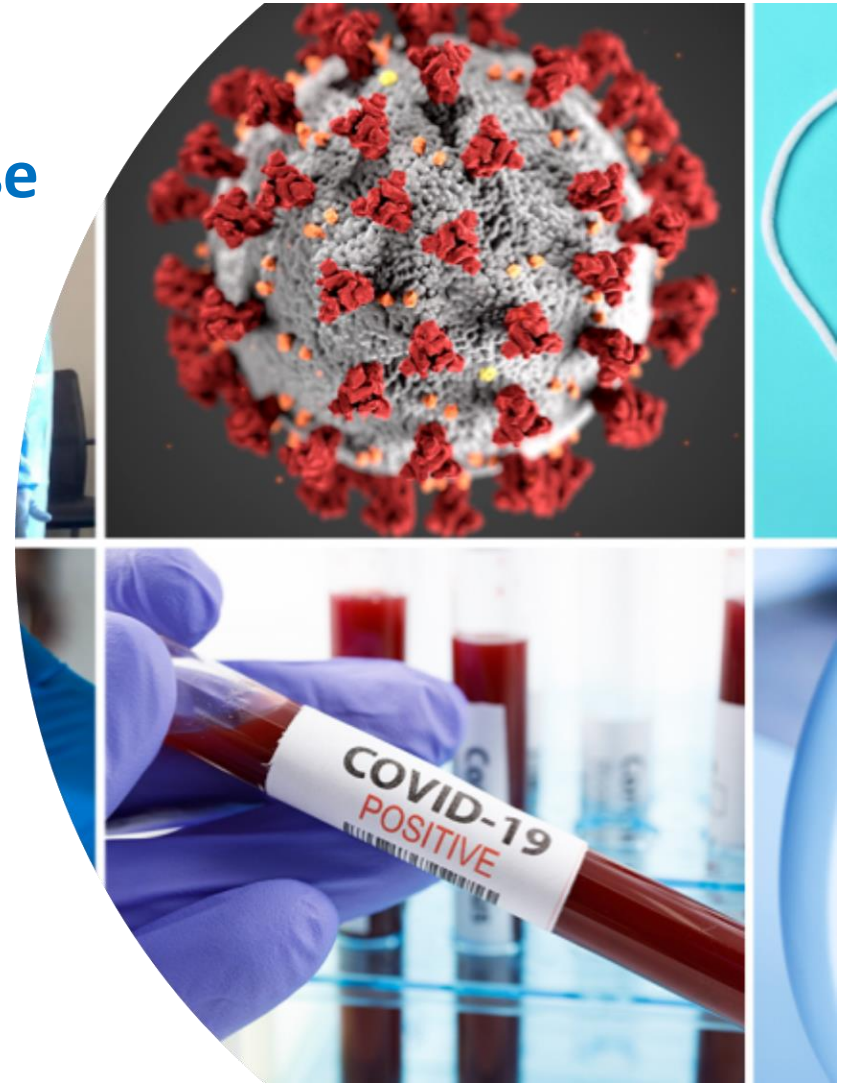
- **Our goal**: Shorten time it takes to development safe & effective MCM devices so they are available when needed.

Collaborations with DoD

- DARPA
  - Sepsis, TBI, Prosthetics, Wound Stasis System,
- ONR
  - Automated / Autonomous Critical Care
- ARMY/MRDC
  - TBI, closed-loop control technologies, wearables
- Air Force
  - Closed-loop control ventilation
- DTRA (Defense Threat Reduction Agency)
- Special Operations Command (SOCOM)

Collaboration with the DoD was Key During the COVID-19 Response

- Relationships with federal partners such as DHA, MRDC, JPEO Chem-Bio, and Air Force were already in place.
- FDA was already aware of devices that the DoD was developing that might be used in the COVID-19 response.
- Based on the device development work done before the pandemic, along with conversation with our federal partners including DoD during the pandemic, FDA quickly had an understanding of the technologies available that could help facilitate the availability of critical devices using
  - EUAs
  - Enforcement policies



Medical Countermeasure Devices Critical for COVID-19 Response

PPE

- Respirators
- Surgical Masks
- Gowns
- Gloves
- Decontamination Systems

Tests

- Serological
- Diagnostics
- Collection supplies (e.g. blood tubes, swabs)

Respiratory Devices

- Ventilators
- Ventilator accessories
- Diaphragmatic stimulators

Other Devices

- Extracorporeal membrane oxygenation (ECMO)
- Remote Monitoring
- Continuous Renal Replacement Therapy (CRRT)

Types of Interactions: Medical Device Manufacturers

- Work with small medical device companies that are developing needed medical devices for the warfighter.
  - Often have no prior experience with FDA and need help with understanding our processes and regulations.
  - Provide strategic help by educating companies on the various pathways available. (ex. Breakthrough Devices Program, HDE, De Novo…)
  - Provide information on the various resources FDA has available on our website

Provide a POC to ask questions!!

Classification System and Risk Categorization

Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Adulteration / Misbranding
- Premarket Notification [510(k)] (unless exempt)
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)

Special Controls (addressing Risk)
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)

Determining Classification and Regulatory Requirements

- Device Regulations
  - 21 CFR parts 800-898
- FDA Web site including
  - Product Classification Database (Classification DB)
  - 510(k) Clearance Database (510k)
  - Device Guidance Documents (Guidance)
- 513(g)
  - Written request for agency's views about the classification and regulatory requirements that may be applicable to your device
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm
  - 513(g) submissions are subject to user fees

Public Law 115-92 – Formalizing FDA and DoD Interactions

Public Law 115-92
December 12, 2017

Three Main Components

- **Expands Emergency Use Authorization (EUA) Authority**
  - Allows FDA to issue an EUA for a medical product for a disease/condition caused by an "agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces"
- **Encourages Enhanced Engagement on DoD's Top Priority Products**
  - Authorizes DoD to request and FDA to take actions to ***expedite development and review of medical products*** reasonably likely to diagnose, prevent, treat, or mitigate a specific and life-threatening risk to the U.S. military forces
- **DoD-FDA Required Meetings**
  - Semi-Annual, FDA-DoD to review portfolio & priorities
  - Quarterly, CBER-DoD to discuss CBER priority products

Expedite Development and Review of Military Products

Legislation states that expedited development and review may include the following as appropriate:

- Hold meetings with the sponsor and review team throughout the development of the medical product
- Timely advice and interactive communication to gather clinical and non-clinical information
- Involve senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review
- A cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor
- Take steps to ensure that the design of the clinical trials is as efficient as practicable
- Apply any applicable FDA program intended to expedite the development and review of a medical product
- In appropriate circumstances, permit expanded access to the medical product during the investigational phase.

FDA-DoD Joint Announcement
Jan 16, 2018

U.S. Department of Health and Human Services

FDA U.S. FOOD & DRUG ADMINISTRATION

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News & Events

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FDA News Release

FDA and DoD launch program to expedite availability of medical products for the emergency care of American military personnel

SHARE TWEET LINKEDIN PIN IT EMAIL PRINT

For Immediate Release January 16, 2018

Summary The U.S. Food and Drug Administration and the Department of Defense launch join program to prioritize the efficient development of safe and effective medical product intended to save the lives of American military personnel.

Release The U.S. Food and Drug Administration and the Department of Defense's (DoD) Office of Health Affairs announced today the launch of a joint program to prioritize the efficient development of safe and effective medical products intended to save the

- FDA: Blood and Blood Products
- DoD: Military Health System

- Establish a program to prioritize efficient development of medical products for military use
- Describes "partnership" between CBER and DoD, with CBER commitment to key actions
- FDA leadership commits to ensuring these commitments are applied to address aspects of DoD's portfolio in the other medical product centers

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592581.htm

DoD Priority List

- CDRH is treating devices on the DoD Priority List as if they are in the Breakthrough Devices Program
- For questions regarding the development of the DoD Priority List: https://mrdc.amedd.army.mil/index.cfm/about/jag/pl_115-92

Breakthrough Device Eligibility

Breakthrough devices go through a formal designation process which determines if the device meets the following eligibility criteria:

Subject to PMA, De Novo and 510(k) that:

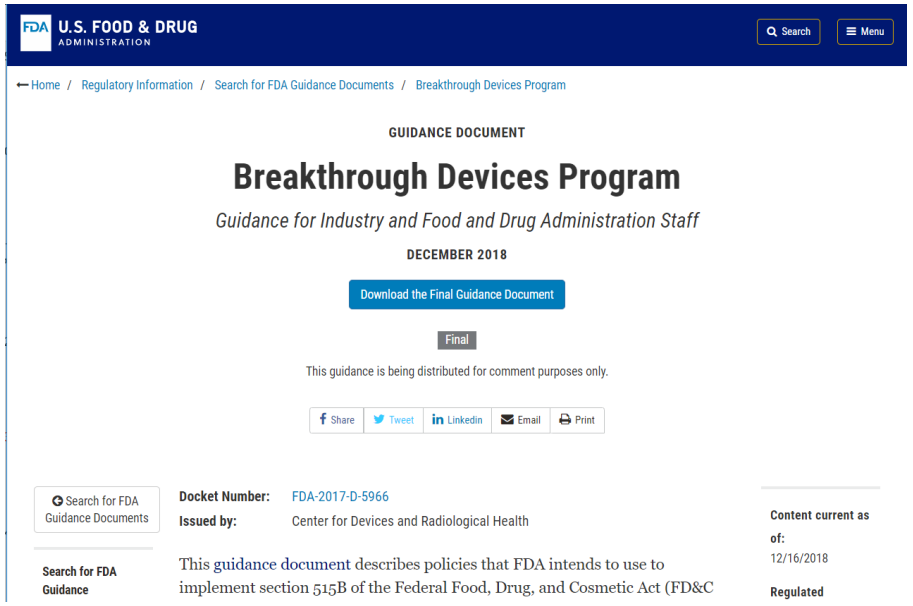
- 1: “provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; **and**

- 2A: that represent breakthrough technologies; or
- 2B: for which no approved or cleared alternatives exist; or
- 2C: that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients’ ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
- 2D: the availability of which is in the best interest of patients.”

Devices on the DoD Priority List are treated as if they have Breakthrough Status

Breakthrough Devices Program Resources

- Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download
- More information on the Breakthrough Devices Program: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program



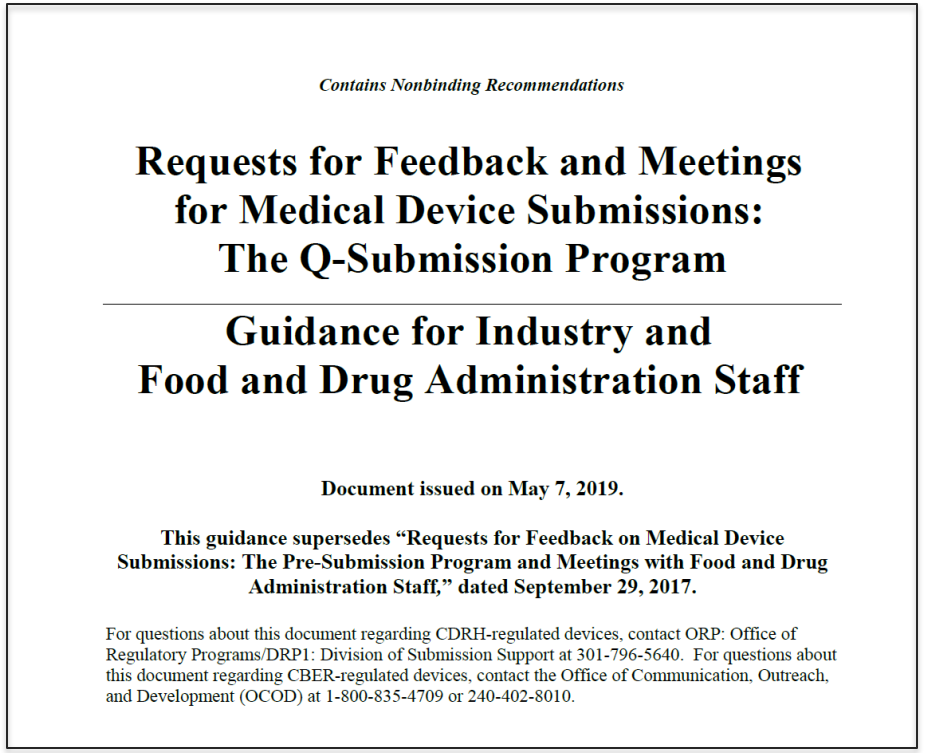
Total Product Life Cycle (TPLC) Advisory Program – *also called TAP*

- TAP will promote early, frequent, and strategic communications between the FDA and medical device sponsors to help spur more rapid development.
- Pilot program started in 2023.
  - Must be a part of the Breakthrough Devices Program
  - For FY23 FDA intends to enroll up to 15 devices in the Office of Health Technology 2 (OHT2): Office of Cardiovascular Devices
  - FDA intends to expand the TAP Pilot in subsequent years (see website for current plan)
- Goals:
  - Improving participants' experiences with the FDA by providing for more timely premarket interactions;
  - Enhancing the experience of all participants throughout the device development and review process, including FDA staff;
  - Facilitating improved strategic decision-making during device development, including earlier identification, assessment, and mitigation of device development risk;
  - Facilitating regular, solutions-focused engagement between FDA review teams, participants, and other stakeholders, such as patients, providers, and payers, beginning early in device development; and
  - Collaborating to better align expectations regarding evidence generation, improve submission quality, and improve the efficiency of the Premarket review process.

Please see the website for more information: https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap

Q-Submissions

- FDA released a new guidance document on the Q-Submission Program and Meetings with FDA Staff http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf



Contains Nonbinding Recommendations

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on May 7, 2019.

This guidance supersedes "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff," dated September 29, 2017.

For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs/DRP1: Division of Submission Support at 301-796-5640. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

Types of Q-submissions

Q-Sub Type	Method of Feedback	Timeframe for Sending Feedback or Scheduling Meeting (from receipt of submission)
Pre-Submission	Meeting (face-to-face or teleconference) with written feedback provided in advance	Written Feedback: 70 days or 5 days prior to scheduled meeting, whichever is sooner Meeting: Date based on mutual agreement (typically at 60-75 days)
	Written Feedback Only	70 days
Submission Issue Request (SIR)	Meeting or Written Feedback	If SIR is received within 60 days of FDA's marketing submission letter: 21 days as resources permit
		If SIR is received more than 60 days after FDA's marketing submission letter: 70 days as resources permit
Study Risk Determination	Formal Letter	90 days
Informational Meeting*	Meeting	90 days

*When used to track requests that do not meet the definition of a Q-Sub type, Informational Meeting timeframe and feedback mechanism can vary. Typically, informational meetings do not include FDA feedback

Involving FDA Early in the Process

- Early collaboration allows you and the reviewers to get on the same page. This in turn can shorten the timeline.

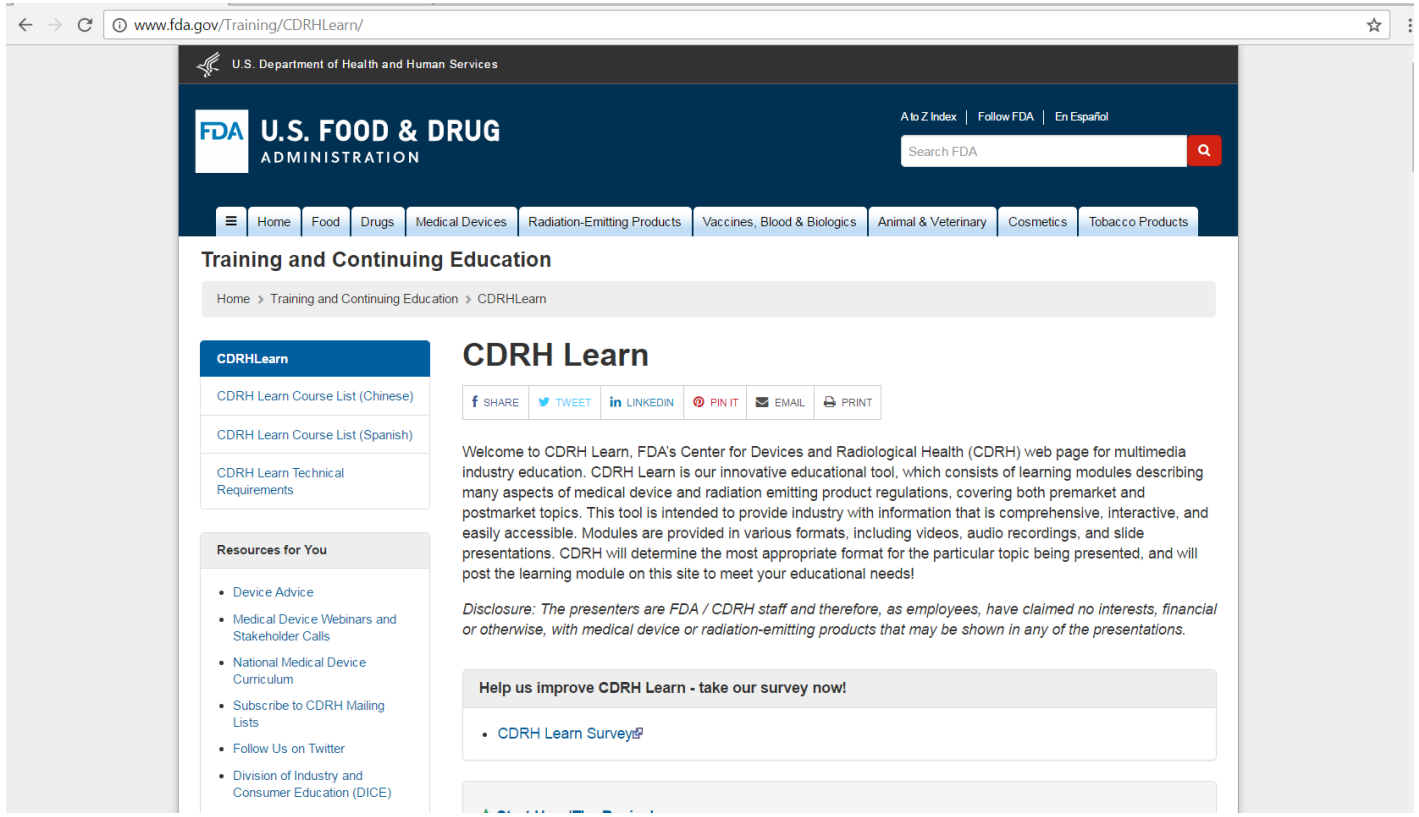
- Provides a way to get feedback early.
  - For example concerns over how an animal study is conducted can be discussed during the planning stage instead of afterwards so that a costly animal study isn't repeated.

- Identify intended patient population early and design appropriate studies to evaluate risk / benefit profiles
  - Usability Studies are becoming increasingly important

Providing Industry Education

CDRH Learn – Multi-Media Industry Education

- Over 80 modules – videos, audio recordings, power point presentations, software-based "how to" modules
- Accessible on your portable devices
  http://www.fda.gov/training/cdrhlearn/default.htm

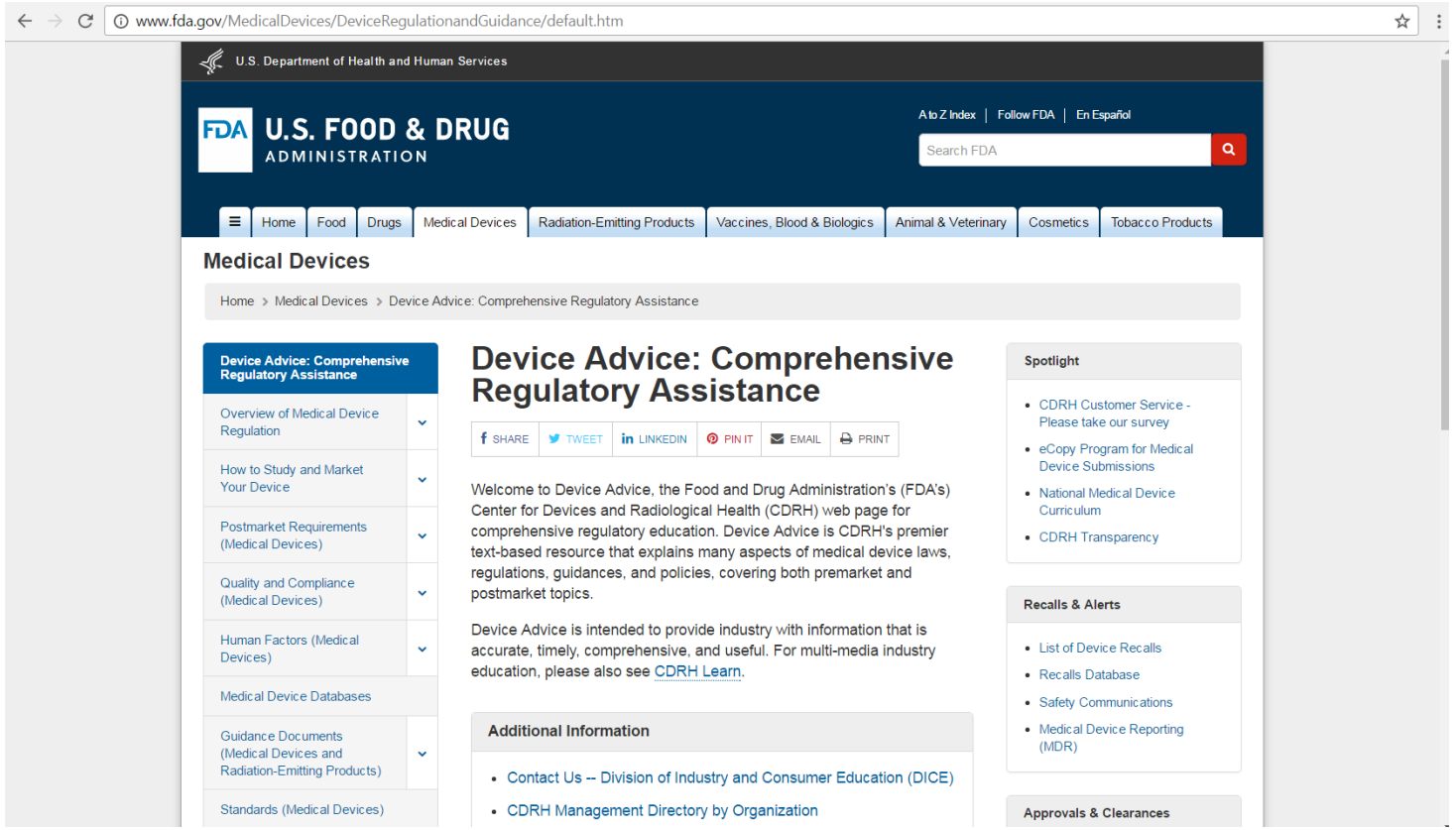


Providing Industry Education

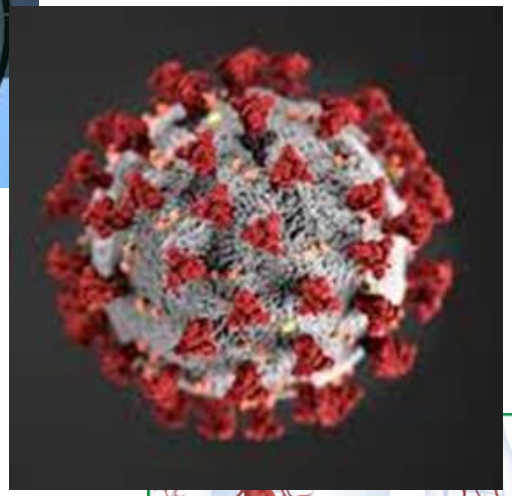
Device Advice – Text-Based Education

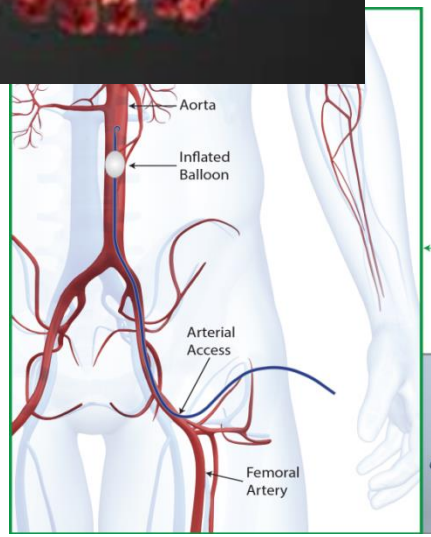
- Comprehensive regulatory information on premarket and post-market topics

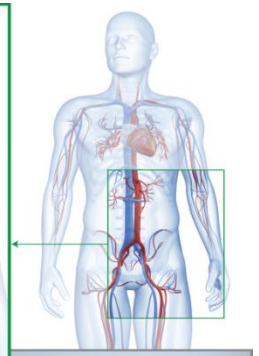
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm




MEDICAL SCOPES LINKED TO
SPREAD OF "SUPERBUG"




Aorta
Inflated Balloon
Arterial Access
Femoral Artery




ER-REBOA™ CATHETER


COMBAT READY CLAMP
(CRoC)
CLAMPING DOWN ON HEMORRHAGE

Where to go for help

General Questions:

- FDA Medical Device website (www.fda.gov/medicalDevices/)
  - Guidance Documents
  - Public information on cleared or approved devices
  - Regulations
- Heather.Agler@fda.hhs.gov

Division of Industry and Consumer Education (DICE)

- If you have a question – Email: DICE@fda.hhs.gov
- Phone 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30pm EST)

Web Homepage:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

Digital Health related questions

- DigitalHealth@fda.hhs.gov

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Thank you for your time and attention!

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