U.S. FOOD & DRUG ADMINISTRATION

MEDICAL DEVICE CYBERSECURITY: Through The FDA Lens

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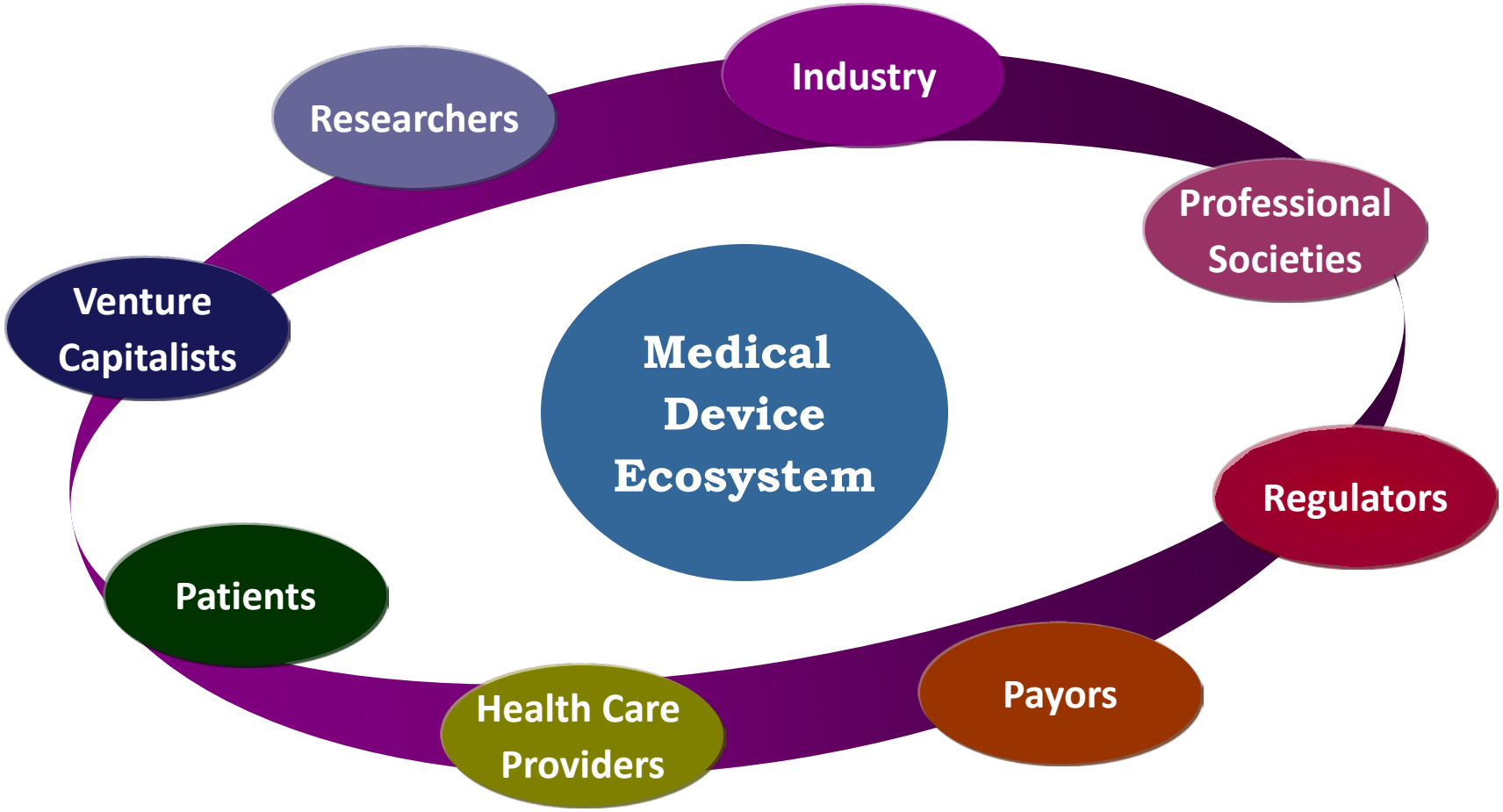
Framing the Issue: Environment

- The healthcare and public health (HPH) critical infrastructure sector represents a significantly large attack surface for national security today
  - Intrusions and breaches occur through weaknesses in the system architecture
- Connected medical devices, like all other computer systems, incorporate software that is vulnerable to threats
- Cybersecurity vulnerabilities and incidents that could directly impact medical devices or hospital network operations
- When medical device vulnerabilities are not addressed and remediated, they can serve as access points for entry into hospital/healthcare facility networks
  - May lead to compromise of data confidentiality, integrity, and availability
  - May lead to compromise of essential performance

Bottom Line Up Front (BLUF)

- *"Whole of community"* approach: Collaboration is key
- Security spans across the total product lifecycle
- Impact on critical infrastructure within and across sectors
- Shifting the mindset:
  - Consider scenarios beyond "intended use"
  - Integrate threat modeling
  - Beware of using probabilistic determinations—these can yield a false sense of security
- Foster culture and create incentives that encourage proactive behavior, *especially for information sharing*
- Major strides made AND acceleration necessary

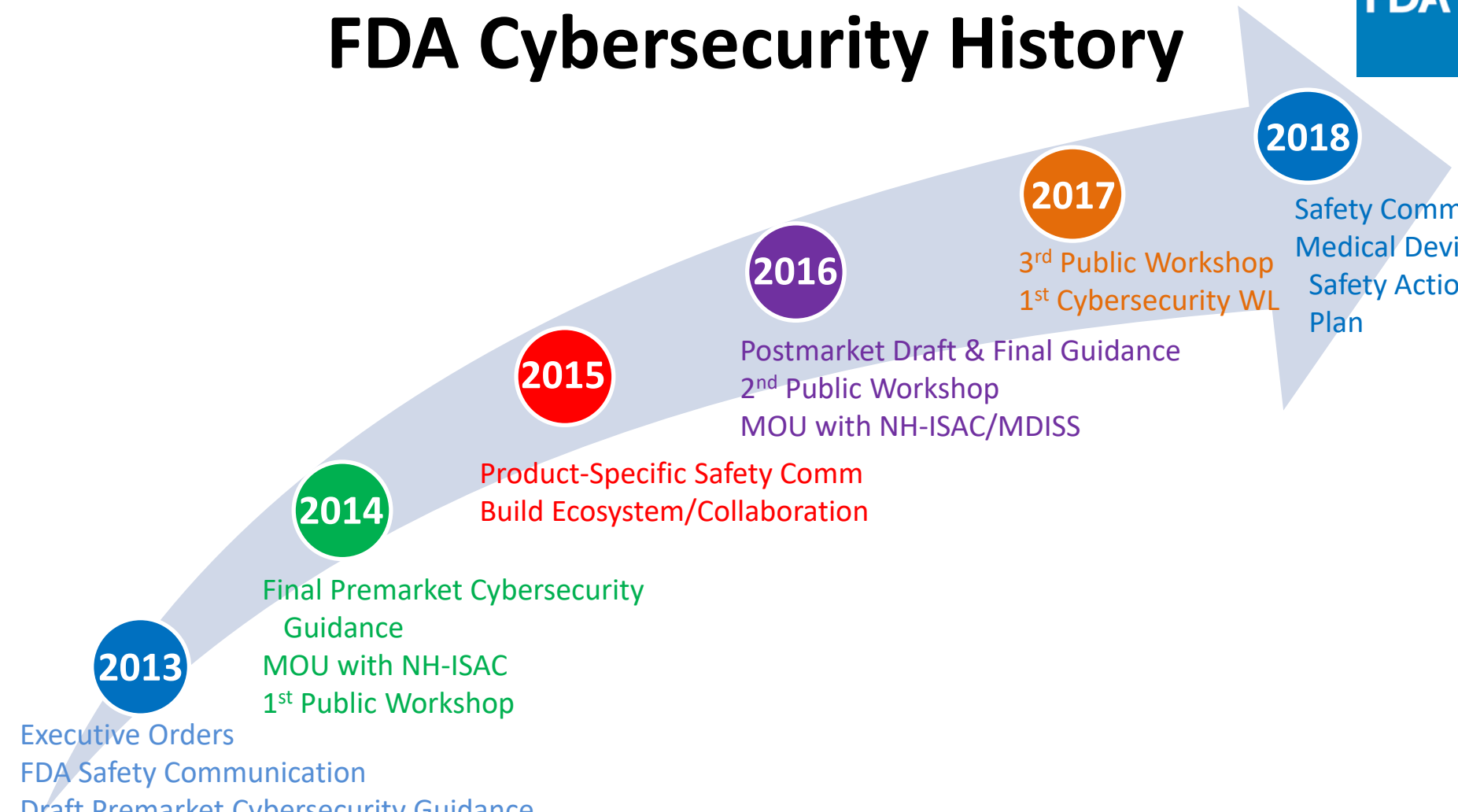
Ecosystem Stakeholders



Framework to Strengthen Cybersecurity and Critical Infrastructure

- Federal policy framework for cybersecurity and critical infrastructure resilience emphasizes a collaborative approach among government, industry and other stakeholders; establishment of Information Sharing and Analysis Organizations (ISAOs); and support for cybersecurity risk management efforts to protect critical infrastructure
  - Executive Order 13636, Improving Critical Infrastructure Cybersecurity (*"We can achieve these goals through a partnership with the owners and operators of critical infrastructure to improve cybersecurity information sharing and collaboratively develop and implement risk-based standards."*)
  - Presidential Policy Directive 21, Critical Infrastructure Security and Resilience
  - Executive Order 13691, Promoting Private Sector Cybersecurity Information Sharing (encouraging voluntary establishment of ISAOs as a mechanism for entities to share information related to cybersecurity risks and incidents and to respond collaboratively in as close to real time as possible)
  - Executive Order 13800, Strengthening the Cybersecurity of Federal Networks and Critical Infrastructure (support for cybersecurity efforts of critical infrastructure entities)
- National Institute of Standards and Technology (NIST) Voluntary Framework (v1.0 - Feb 2014, v1.1 – April 2018)

FDA Cybersecurity History



FDA Cybersecurity Work Products

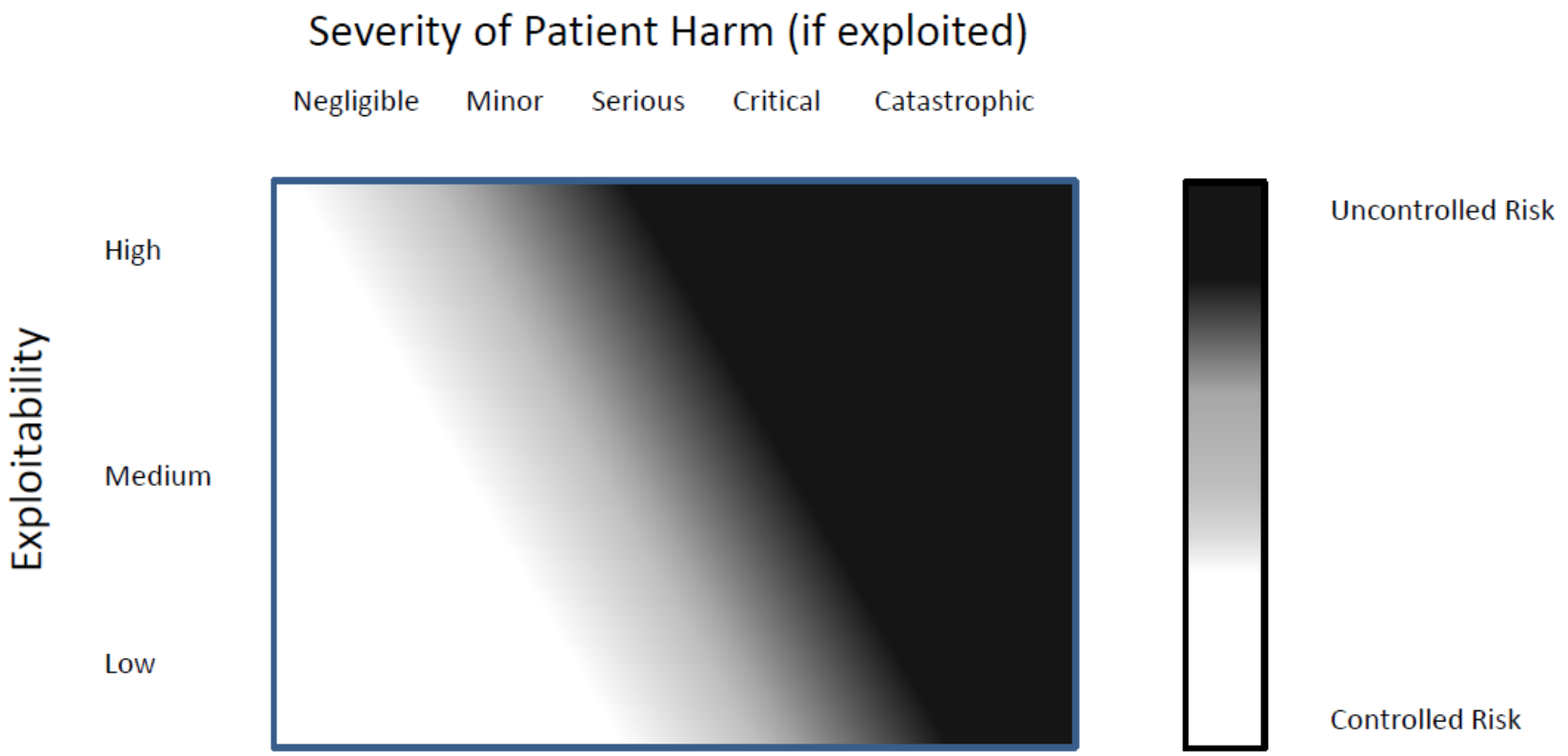
Key Principles of FDA Premarket Cybersecurity Guidance

- Shared responsibility between stakeholders, including healthcare facilities, patients, providers, and manufacturers of medical devices
- Address cybersecurity during the design and development of the medical device
- Establish design inputs for devices related to cybersecurity, and establish a cybersecurity vulnerability and management approach as part of the software validation and risk analysis that is required by 21 CFR 820.30(g)

Key Principles of FDA Postmarket Management of Cybersecurity in Medical Devices

- Use a risk-based framework to assure risks to public health are addressed in a continual and timely fashion
- Articulate manufacturer responsibilities by leveraging existing Quality System Regulation and postmarket authorities
- Foster a collaborative and coordinated approach to information sharing and risk assessment
- Align with Presidential EOs and NIST Framework
- Incentivize the “right” behavior

Postmarket Cybersecurity Risk Assessment



Lessons Learned—Evolving Our Thinking

- Coordinated vs. non-coordinated disclosure of device vulnerabilities
  - Ability to get to ground truth as fast as possible so that mitigations can be proactively communicated and executed in a timely manner
    - JnJ Animas Insulin Pump
  - Non-coordinated disclosure results in delayed assessments, communications, and mitigations
    - St Jude/Abbott pacemakers and ICDs
- Impact on HPH critical infrastructure and potential disruption of clinical care
  - Patching operating system is not routine with safety-critical systems
    - WannaCry Global Cyber Attack (May 2017)
    - Petya/notPetya (July 2017)
  - Delays in diagnosis/treatment intervention can result in patient harm too
- Potential for remote, multi-patient (i.e., scaled) attack of highest concern for harm

Medical Device Safety Action Plan:
Advancing Medical Device Cybersecurity

- Update premarket cybersecurity guidance
- Consider seeking additional premarket and postmarket authorities to:
  - Require that firms build capabilities to update and patch device security into a product's design and to include appropriate data supporting this capability in premarket submissions to FDA
  - Require firms to develop a "Software Bill of Materials" (SBOM) and to share with customers
  - Require that firms adopt policies and procedures for coordinated disclosure of vulnerabilities as they are identified
- President's FY 2019 Budget proposes appropriations to help establish a CyberMed Safety (Expert) Analysis Board (CYMSAB) functioning as a public-private model, and serving the ecosystem as a neutral entity; also proposes appropriations to support FDA device cybersecurity capabilities

Current FDA Efforts

- Update medical device cybersecurity premarket guidance
  - Address subset of devices for which potential of harm resulting from remote, multi-patient attack exists
  - Address subset of connected devices for which lack of availability (functionality disabled or manipulated) may result in disruption to clinical care, causing potential for harm
- Cybersecurity preparedness and incident response (MITRE collaboration)
  - Test plans containing a set of realistic testing scenarios for medical devices in the clinical environment to help foster regional and national preparedness
  - Develop preparedness and response "playbooks" for FDA and third parties
    - FDA Medical Device Cybersecurity Preparedness and Response Playbook
    - Regional Preparedness and Response Playbook for Medical Device Cyber Resilience
  - Support development of sandbox for clinical simulation and testing in safe space
  - Develop MOUs with emerging ISAOs to enhance information-sharing, with an emphasis on information relevant to patient safety and treatment

(Cont'd)

Current FDA Efforts

- Create clinical rubric for Common Vulnerability Scoring System (CVSS) as medical device development tool (MDDT)
- Co-lead public-private sector stakeholder engagement in SBOM workstream
- Initiate CYMSAB pilot by engaging our stakeholders on potential models and operating structures
- Participate in Medical Device Innovation Consortium's development of a playbook for coordinated vulnerability disclosures
- Review and evaluate legislative proposals that catalyze and accelerate progress

Cross-Agency Collaborative Efforts

- Cybersecurity Working Groups
  - CDRH Cybersecurity Working Group coordinates and collaborates with Department colleagues, including the HHS Cybersecurity Working Group, in response to medical device cybersecurity incidents and other activities
- Healthcare Sector Coordinating Council
  - FDA contributed subject matter expertise to the Healthcare Industry Cybersecurity Task Force in development of the report issued in June 2017
  - FDA taking the lead on implementation of Imperative No. 2, “Increase the security and resilience of medical devices and health IT”
- Coordination with DHS
  - Routine coordination in which FDA provides clinical subject matter expertise to evaluate and respond to potential cybersecurity vulnerabilities and/or incidents involving medical devices
  - Currently discussing execution of Memorandum of Agreement to formalize information-sharing processes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