Impact of the Cures Act on the Medical Device Industry

Thomas Crane, Bethany Hills, & Rodney Whitlock

The presentation will begin shortly.
Speaker Information

Thomas Crane  
*Member, Health Law Practice*

Bethany Hills  
*Member, Health Law Practice*  
*Chair, FDA Practice*

Rodney Whitlock  
*Vice President, Health Policy,*  
*ML Strategies*
Housekeeping Notes for Audience

• The webinar will be recorded.
  – The recording and slides will be sent to all participants after the webinar.

• If you are calling in through your computer, please be sure to turn up the computer's volume.

• Questions will be answered at the end of the presentation.
  – Use the Q&A application to submit a question.
What We're Going to Cover

- **Topic 1**: Importance and Scope of Cures Act
- **Topic 2**: Political and Legislative Background
- **Topic 3**: Medical Device Provisions
- **Topic 4**: Additional Provisions Impacting Medical Devices
- **Topic 5**: Questions and Discussion
Importance and Scope of Cures
21st Century Cures: Scope and Importance

• Act is focused on Clinical Research and Innovation Access

• Themes
  – Increased government funding
  – Clarification and removal of regulatory burdens
  – Coordination and streamlined processes

• MINTZ LEVIN DEEP DIVE WEBINARS
  – Clinical Research – **February 2, 2017**
  – FDA Process/Structure- **February 15, 2017**

Research, Digital Health and Drug Highlights

• Much anticipated harmonization of the Common Rule and human subject protection regulations under FD&C Act
• Centralized IRB requirements for multi-site studies
• New payment amount and calculation for Part B drugs (ASP + 6%)
• Broadening of health care economic information definition allowing increased off-label communications, including to payors
• Requires FDA to implement a Real World Evidence framework for drugs
Political and Legislative Background
The Legislative Drama of 21st Century Cures: A Play in Three Acts

• How did this bill get done?
  – *Process determines policy*

• In a time of brutal partisanship, the House and Senate / Democrats and Republicans resolved their differences
  – *Why on this bill?*

• How did this bill become a major vehicle for numerous health care initiatives?
  – Process known as "clearing the decks"
Act One: Energy & Commerce Initiates 21\textsuperscript{st} Century Cures

- In early 2015, former E&C Chairman Fred Upton began process to introduce 21\textsuperscript{st} Century Cures.
  - Ambitious policy agenda laid out
    - Ultimately was dialed back significantly to increase Democratic buy-in
  - Where does buy-in emerge?
    - Feel-good bill that House GOP would move with or without Democrats
    - VP Biden

- After House committees reviewed and advanced legislation, July 2015, House passed bill overwhelmingly 344-77

- The Senate would spend the next sixth months devising its own strategy for advancing the bill
Act Two: Senate HELP Committee – early 2016

• Chairman Lamar Alexander (TN) and Ranking Member Patty Murray (WA) ushering bill through committee
  – Roadblocks: Sen. Elizabeth Warren (MA) demand for $50M in basic medical research funding

• Alexander separated Cures package into three distinct legislative packages.
  – Process used to move less controversial provisions through Committee
  – Three committee hearings were held (2/9, 3/9, 3/16)

• After passage, the bill stalled. Why?
  – Timing and election year politics

• Meanwhile, other unrelated, but relevant, initiatives stay on radar
Act Three: The Turning Point

• Democrats appeared content to run out the clock and rework legislation under a potential Clinton Administration
  – Following defeat, all motivations changed and set the stage for a "clear the decks"
• Upton, Alexander and Republicans set for victory by securing passage
• Democrats and Obama also can claim victory in addition to attaching other initiatives to legislation
  – Substance abuse funding
  – Mental health legislation
The Curtain Call

• Passed as a 300-page bill with three distinct titles in 2015 became a 1,000+ page bill, 18 title bill
  – Dialed back provisions
  – Unrelated, but health care relevant provisions included in this major vehicle
  – Process determines policy and in this case a bipartisan victory.
Medical Device Provisions
Medical Device Provisions

- S. 3051 Breakthrough Devices
- S. 3052 Humanitarian Device Exemption (HDE)
- S. 3059 Reusable Devices Cleaning Data & Validation
  - S. 3059 Finalize Modification Guidance
- S. 3057 CLIA Guidance
- S. 3060 Clarifying Health Software Regulation
- S. 3058 Least Burdensome Device Review
- S. 3052 Recognition of Standards
- S. 3054 and S. 3055 Class I and Class II Devices; Classification Panels
S. 3051 Breakthrough Device Pathway

• Requires FDA to establish an expedited process for devices targeting diseases with no FDA cleared or approved alternatives

• A "breakthrough device" is intended to treat or diagnose a "life threatening or irreversibly debilitating" disease and:
  – Represents a breakthrough technology
  – No approved/cleared alternatives
  – Significant advantages over alternatives OR
  – Availability of device in the "best interests of patients"

• Broader than drug breakthrough pathway criteria

• Broader application types that Expedited Access Pathway – includes 510k, de novo and PMA
S. 3051 Breakthrough Device Pathway

• Request for Designation – 60 FDA decision that cannot be retracted if future device cleared/approved (criteria (b))

• Benefits
  – Early and frequent FDA interactions,
  – timely dispute resolution,
  – streamlined review (appropriate FDA expertise, including available FDA staff to address IRB questions),
  – data development agreement and clinical protocol agreements
  – Expedited manufacturing and quality systems review
  – Advance notice before FDA seeks outside experts or advisory committee

• Guidance required within 1 year to clarify process and conditions

• 2019 Report to Congress regarding success of program
S. 3052 Humanitarian Device Exemption (HDE)

- S. 3052 Humanitarian Device Exemption (HDE)
  - Increases the current limitations in Section 520(m) of the FDCA from devices intended to treat or diagnose a disease or condition that affects no more than 8,000 individuals in the U.S. per year (up from 4,000)
  - Guidance document required within 18 months on "probable benefit"
  - FDCA 360j(m)(2)(C): the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.
S. 3059 Reusable Devices Cleaning Data & Validation

• Reusable device 510(k) submissions must include IFU and validation data on cleaning, disinfection and sterilization

• FDA to publish list of reusable device types within 180 days – required publication in Federal Register

• **HIDDEN PROVISION!**

• Device Modification – Final guidance must be issued not later than 1 year from close of comment period on draft guidance (Nov. 7, 2016)
  – 2011 Draft Guidance and Congress intervenes to retract
**S. 3057 CLIA Guidance**

- **Within 1 year issue a Draft Guidance**
  - revises “Section V. Demonstrating Insignificant Risk of an Erroneous Result – Accuracy” of the guidance entitled “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” and dated January 30, 2008
  - includes the appropriate use of comparable performance between a waived user and a moderately complex laboratory user to demonstrate accuracy

- **Within 1 and 90 days (close of comment period) issue Final Guidance**
S. 3060 Clarifying Health Software Regulation

• Regulation of Medical and Certain *Decision Support* Software
• Creates a statutory carve out from "device" definition of 5 types of software, *unless* the software obtains or analyzes "a medical image or a signal from an IVD device or a pattern...from a signal acquisition system" *or* is a Class III software
• If multiple software functions and one or more still meet "device" definition, FDA will regulate functions within jurisdiction (Hybrid approach)
• Fail safe if FDA believes a function is "reasonably likely to have serious adverse consequences" - publish in Federal Register
• Required Bi-annual report to Congress
S. 3060 Clarifying Health Software Regulation

• 5 Types of Software Excluded from "device" definition
  – Administrative support of health care facility (inc. lab workflow)
  – Maintain or encourage a healthy lifestyle, unrelated to diagnosis, cure, mitigation, prevention, or treatment of disease or condition
    o *FDA Wellness Guidance* - unregulated
  – Electronic patient records for transfer, store, convert formats, or display patient information (do not "interpret or analyze")
    o *FDA Mobile Medical Applications Guidance* - enforcement discretion
  – Transfer, store, convert formats or display lab test or device data; OR
    o *FDA MDDS non-enforcement policy*
  – Decision Support Purposes
    o Display information about a patient,
    o Support or *provide* recommendations to a health professionals AND
    o Enable HCP to independently review software recommendations
S. 3058 Least Burdensome Device Review

• Existing statutory requirement that FDA consider the least burdensome means of showing substantial equivalence or reasonable assurance of safety and effectiveness
• Training of all staff involved in reviews
• Effectiveness audit of training and implementation of least burdensome requirement (18 months post enactment)
• Consider role of available postmarket information when requesting additional information in a PMA review
• Provide a "least burdensome" statement of considerations for each 510(k), PMA or IDE
S. 3052 Recognition of Standards

• FDA required to make a determination on a request to recognize a standard within 60 days
  – Rationale provided and made public
• FDA staff training on recognized standards
• FDA must update existing guidance documents to harmonize with recognized standards
S. 3054 and S. 3055 Class I and Class II Devices; Classification Panels

• FDA must identify additional Class I (within 120 days) and Class II (within 90 days) Devices that no longer require a 510(k)

• FDA must update this list, conducting subsequent reviews, every 5 years

• Classification Panels –
  – "adequate expertise" defined with specificity
    o Clinically relevant specialty and knowledgeable of technology

• Sponsor may correct misstatements, provide clarification, call in experts

• Enhanced role or Sponsors throughout the process
Additional Provisions Impacting Devices
• S. 4009 and 4010 Local Coverage Determinations and New Ombudsman
• S. 3056 Local IRB
• S. 3034 Devices Used in Regenerative Therapy
• S. 3038 Combination Product Innovation
• S. 3073 Intercenter Institutes Established
Local Coverage Determination Changes and Pharma and Med Tech Ombudsman

• § 4009 requires greater transparency by Medicare Administrative Contractors in their Local Coverage Determination Process, including requirements to provide summary of evidence and rationale for the LCD.

• § 4010 creates an Ombudsman within CMS to "respond to complaints, grievances, and requests" from Pharma and MedTech manufacturers that regarding "coverage, coding, or payment."
S. 3056 Local IRB

- Removes existing requirement that local IRB at each site in a multi-site study review and approve a device study
S. 3034 Devices used in Regenerative Therapy

• FDA must issue, within 1 year, a guidance document to clarify how devices used in the recovery, isolation, or delivery of regenerative advanced therapies will be evaluated

• Coordinates with S.3033 Accelerated Approval for Regenerative Advanced Therapies
Primary Mode of Action Clarifications

- In determining the primary mode of action of a combination product, the Secretary shall not determine that the primary mode of action is that of a drug or biological product solely because the combination product has any chemical action within or on the human body
- Sponsor may request FDA's rationale for POMA and mechanisms for registering disagreement and appeal

- Sponsor may request a meeting and be granted in 75 days
- Binding written agreements
- Leverage earlier FDA determinations
  - "approved constituent part"
  - If no right of reference, appropriate patent certifications
S. 3073 Intercenter Institutes Established

• Within 1 year establish at least one Intercenter Institute for a major disease area
  – Coordination of staff
  – Streamline review
  – Scientific programs around disease
  – Enhanced interactions with stakeholders and other research centers

FDA's Oncology Center of Excellence (2016) – Cancer Moonshot
  – FDA may use this as its "one" required Institute
  – FDA's Jenkins (drug review) cautions against expanding beyond cancer due to inefficiencies
    o "it is not a model that should be replicated for every therapeutic category across the agency"
Questions?

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• Part II: The Impact of Cures on Clinical Research
  – Thursday, February 2, 2017
    o 1:00 – 2:00 PM ET

• Part III: The Impact of Cures on the FDA
  – Wednesday, February 15, 2017
    o 1:00 – 2:00 PM ET