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Legislative Update

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Agenda

- New Laws Affecting IVDs
- Bills Under Consideration by Congress
- Proposed EMEA IVD Directive Revision
- Issues on the Horizon

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New Laws Affecting IVDs

- Budget Resolution (113 Pub. L. 46)
- Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, or "PAHPRA" (113 Pub. L. 5)

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Budget Resolution (113 Pub. L. 46)

- Continuing Appropriations Act, 2014
  - Government Open through January 15, 2014
  - Extended Debt Ceiling Until February 7, 2014
- Immediate Consequence – Backlogs
- Future consequences
  - Are we headed for another shutdown on January 15th?

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PAHPRA (113 Pub. L. 5)

- Emergency Use Authorization (EUA) : Allows marketing of unapproved products, or unapproved uses of approved products for medical countermeasures ("MCM")
- Old law: An actual emergency was required for an EUA
- New law: An EUA may be issued –
  - based on "a public health emergency, or a significant potential for a public health emergency";
  - that affects or has "significant potential to affect national security or the health and security of U.S. citizens living abroad"; and
  - is related to chem/bio/nuclear agenct "or a disease or condition that might be attributable to the agent."

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PAHPRA (113 Pub. L. 5)

- The new law gives FDA more flexibility to use EUAs
- Since the laws passage earlier this year, there have been EUAs for IVDs that detect:
  - H7N9
  - Middle East Respiratory Syndrome Coronavirus
- Under the old law (passed in 2004) FDA used the EUA provision to authorize tests for H1N1

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PAHPRA (113 Pub. L. 5)

- Some other important changes –
  - Expands the time period for collection and analysis of information about an MCM's safety and effectiveness for a reasonable period beyond the effective period of the EUA
  - Permits IVD complexity assessments as part of EUA
  - Allows pre-positioning of MCM's in anticipation of approval or clearance, or issuance of an EUA
  - Permits FDA to waive quality system/GMP req's
  - Allows FDA to extend the shelf-life of stockpiles

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Bills in Congress

- Diagnostic Innovation Testing and Knowledge Advancement Act, or the "DITKA Act" (H.R. 2085)
- Medical Testing Availability Act (H.R. 3005)
- MODDERN Cures Act (H.R. 3116/3091)
- Cutting Costly Codes Act (S.972)

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DITKA Act (H.R. 2085)

- Tries to create incentives for innovative diagnostics by changing the process for determining fee schedule amounts
- Lead Sponsor: Peter Roskam (IL-6)
- Last Action (5/24/13): Referred to (1) Energy & Commerce; Health Subcommittee and (2) Ways and Means

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DITKA Act (H.R.2085)

- Establishes a transparent fee-setting process based on consideration of several factors, including:
  - Impact of patient care
  - Test characteristics and resources needed to develop it
  - Claims data
  - Lab charges
  - Private Insurance rates
  - Advisory Panel Recommendations
    - Law Establishes an Advisory Panel
- Requires HHS to develop a process for assigning temporary HCPCS codes until a final HCPCS is added

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Medical Testing Availability Act (H.R. 3005)

- Overturns controversial part of FDA's draft RUO guidance
  - An RUO would not be misbranded based on
    - Non-RUO use by the user, or
    - Communications between customer and company about the product (e.g., technical support, customer service)
- Lead Sponsor: Michael Burgess (TX-26)
- Last Action (8/2/13): Referred to Energy and Commerce; Health Subcommittee

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MODDERN Cures Act (H.R. 3116/3091)

- Objectives
  - Advance diagnostics
  - Encourage research on "dormant therapies"
- Geared toward companion diagnostics
  - Finding: "Advanced and innovative diagnostic tests have the potential to dramatically increase the efficacy and safety of drugs by better predicting how patients will respond to a given therapy."
- Lead Sponsor: Lance Leonard (NJ-7)
- Last Action (9/20/13): Referred to Energy and Commerce; Health Subcommittee

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MODDERN Cures Act (H.R. 3116/3091)

- Section 101 – Establish "Advanced Diagnostics Education Council"
  - Create a standard terminology guide for IVDs
  - Comprised of Agency officials (FDA, NIH, CDC, etc.), CMOs/CSOs of patient advocacy organizations, and other experts
- Section 102 – Incorporates reimbursement changes similar to H.R. 2085

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MODDERN Cures Act (H.R. 3116/3091)

- Section 103 – Promoting development of innovative diagnostic tests
  - Developed by or with participation of a therapeutic developer; and
  - Demonstrated through valid scientific information (e.g., peer-review lit.) to –
    - Improve identification of patients who should/not get the therapeutic (Companion Dx); or
    - Detect a FDASIA "qualifying pathogen"

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MODDERN Cures Act (H.R. 3116/3091)

- Developing a Dx can add time to therapeutic market exclusivities (e.g., Hatch-Waxman exclusivity)
  - 12 months for co-developed diagnostic
  - 6 months for otherwise-developed diagnostic
- Could be used twice for the same drug
  - Once per indication
- Dormant Therapy – Encourages development of therapies that otherwise go undeveloped due to weak or no patent protection by offering 15 years of market exclusivity.

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Cutting Costly Codes Act (S.972)

- Would prohibit replacement of ICD-9 with ICD-10 in implementing HIPPA code setting standards
- Calls for a GAO study
- Lead Sponsor: Tom Coburn (OK)
- Last Action (5/16/13): Referred to Senate HELP Committee

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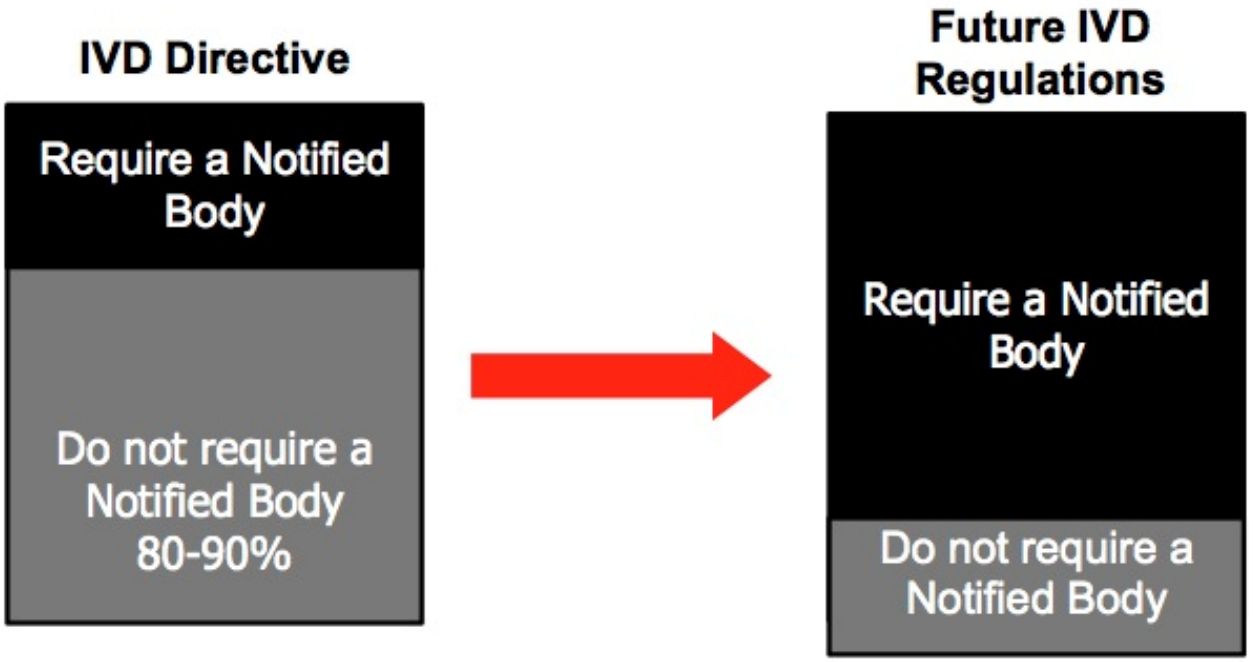
EMEA: IVD Directive Revision

- Significant Increase in the Use of Notified Bodies

Quantum Leap



Credit to Erik Vollebregt, Axon Lawyers, for educating me on EU issues and lending mat'ls

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EMEA: IVD Directive Revision Conformity Assessments

- Biggest changes because of implementation of GHTF classes A-D
- The existing modules established under the 'New Approach' do not change – see annexes VIII to X, however
  - EC verification module was deleted
  - The concept of batch testing has been clarified

CLASS	RISK LEVEL	GHTF EXAMPLES
A *Similar to general IVDs*	Low Individual Risk and Low Public Health Risk	Instruments, reagents e.g. prepared selective culture media specimen receptacles
B *No IVDD equivalent*	Moderate Individual Risk and/or Low Public Health Risk	Self tests *All IVDs not in A, C or D e.g. Vitamin B12, Point of Care, Urine test strips.*
C *Similar to Annex II list B*	High Individual Risk and/or Moderate Public Health Risk	Blood glucose self testing, HLA typing, PSA, screening, Rubella *STD, Cancer markers, cardiac markers, genetic tests*
D *Similar to Annex II list A*	High Individual Risk and High public Health Risk	HIV Blood donor screening, HIV Blood diagnostic

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EMEA: IVD Directive Revision Conformity Assessments

Class	Comments
Class A	Sole responsibility of the manufacturer, except if intended for near-patient testing, have a measuring function or are sold sterile
Class B	Notified body checks the quality management system
Class C	Notified body checks the quality management system and checks the technical documentation of representative samples.
Class D	Explicit prior approval of the design or of the type of the device and of the quality management system before they may be placed on the market

* Notified bodies regularly conduct surveillance assessments in the post-market phase.

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EMEA: IVD Directive Revision Companion Diagnostic

- "A device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy"
- Class C risk classification, although this is up for debate in amendments
- Design or type examination
  - whereby the notified body shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the European Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.
- Also consultation in case of changes affecting the suitability of the device in relation to the medicinal product concerned are made

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EU: IVD Directive Genetics Debate

- Many tests of genetic material or markers may trigger:
  - data protection laws
  - IVD laws (even if there no medical purpose or diagnosis for an individual)
- Many analyses conducted in the course of a clinical trials (include post-market follow-up studies) and health technology assessments may inadvertently trigger IVD laws
- The ENVI Committee of the EU Parliament proposed additional regulatory burden of mandatory counselling prior to genetic testing

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Other Issues on the Horizon?

- LDT regulation
  - FDASIA Section 1143: Notify House and Senate Committees of intent to regulate LDTs 60 days before issuing guidance
    - No word on notification yet
  - Bill from 112th Congress: H.R.3207, Modernizing Laboratory Test Standards for Patients Act of 2011
    - CLIA "on steroids"
    - Bill has not been revived in 113th Congress to date
- CMS Payment Cuts
  - Letters signed by many House and Senate Members opposing proposed Medicare cuts for pathology services
- Transitional IVDs
- 510(k)s
- CLIA Waivers

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Questions?

Feel Free to Ask Now or e-mail me: jboiani@ebglaw.com