Diagnostics Update-- Snapshot of Key Policy Issues for Innovators

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AdvaMedDx

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AdvaMedDx-Who We Are

- Division of the Advanced Medical Technology Association (or AdvaMed)
  - World's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems
- AdvaMedDx committed to specifically address issues facing manufacturers of diagnostic products in the US and globally

Outline-Key Issues to Be Covered

- Update on HHS Common Rule/Biospecimens
- 21st Cures
- MDUFA
- Dx Reform
- Looking Ahead

HHS Common Rule/Biospecimens

- HHS Notice of Proposed Significant Changes via Rulemaking to "Common Rule" (9/8/15)
  - Proposal to require informed consent for the collection, storage, and secondary research use of leftover deidentified specimens
  - Would override longstanding FDA policy
  - Wide concerns among industry, research, and patient community re. significant implications for dx research and development from test validation to rare disease testing to personalized medicine

Final Common Rule Drops Biospecimens Proposal (1/19/17)

- Does not expand the definition of human subject to include deidentified specimens and thus not subject to the Common Rule
- Does not require consent to be obtained in order to conduct research involving deidentified specimens
- HHS reiterated significant public comments raising concerns about need for consent and negative impact on ability to conduct research
- Critical policy retained to ensure dx innovation and access to new technologies for patients

21st Century Cures

Advances Robust Slate Of Pro-Industry Reforms

- Key "Innovation Agenda" regulatory proposals, including:

☑ – Breakthrough Pathway at FDA
☑ – Revitalized "Least Burdensome" std.
☑ – Int'l standards recognition
☑ – Improved CLIA-waiver process
☑ – Use of Central IRBs
☑ – Class I/II exemptions update
☑ – Improved FDA panel process
☑ – Raises HDE cap

- Additional provisions in bill, including key healthcare delivery reforms (e.g, greater transparency in local coverage decisions)
- Now focused on implementation of Act

MDUFA Agreement--Highlights

- Improved total time to decision goals
- Goals for De Novo submissions
- Deficiency letter rationale documentation
- Pre-submission process improvements
- Independent assessments
- Patient engagement
- CLIA waiver improvements
- Additional provisions (e.g., Real World Evidence)

MDUFA Legislation and Timeline

- House and Senate Committee hearings on agreements (completed this month)
- House hearing next week re. “Additional Medical Device Priorities”
- Legislative mark-ups likely in May/June
- Complete action in summer (goal by August, final deadline of September 30).

Dx Reform

- Top priority for industry
- House E/C – Discussion draft introduced in ‘17
  - FDA oversight of all dx tests under proposal
  - Focus on role and value of dx
- AdvaMedDx support for comprehensive dx reform
  - Recognize unique role of dx/spur innovation
  - Support modernized risk based approach
  - Significant strides by FDA, but remains critical opportunities to further improve the regulatory process
  - Support increased predictability in evidence expectations

Looking Ahead

- New Administration
- New FDA Commissioner
- 21st Cures and MDUFA
  - Good for patients, industry, and FDA
- Growing recognition of role and value of dx as critical for public health