

FDA Update

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Waiver Guidance

- Final guidance is now completed
- Useful input from multiple sources albeit some a bit late
- Clearance process
- Plan for draft regulation

Waiver Guidance

- Document is detailed
- Document includes concepts to address the tension between value of access and performance
- Stronger risk management sections
- Rubber hits the road is relevant benchmarks for tension

Not the Only Visible Guidance

- ASR Questions and Answers
- In Vitro Diagnostic Multivariate Index Assay (IVDMIA)

ASR Questions and Answers

- Not new but explanatory
- Clarify boundaries
- Address inadvertent or deliberate non-conformity to regulation

IVDMIA

- Does represent new interpretation of existing regulations and laws
- Identification of a subset of laboratory developed tests that are novel, non-transparent, and not user friendly – constitute high risk
- Document espouses elimination of enforcement discretion in regulation of these

Both In Media Res

- Comment periods extended to March 5
- IVDMIA was subject of public workshop for input
- Beg broader issues
- Two legislative fixes on the table: Obama and Kennedy

Novel New Devices

- Agendia MammaPrint
- First expression array
- First IVDMIA
- Intended for use in breast cancer prognosis
- Review time of 130 days

Critical Path Initiatives

- Voluntary Genomic Data Submissions
- Co-development guidance
- Artificial pancreas working group

Emergency Preparedness

- Diagnostics sentinel in declaration of emergency
- Proactive work across HHS and other entities
- Challenging to demonstrate performance

Flexible Regulatory Toolbox

- Pre-IDEs
- Expedited reviews
- Real time reviews
- De novo classifications

If you build it, we will approve

- Cystic fibrosis (109 days)
- Avian flu (14 days)
- MammaPrint (12 days)
- UGT1A1 (9 days)