The Changing Regulatory and Policy Environment for Diagnostics - What to expect in 2015 and Beyond

2015 AMDM Annual Meeting

April 23, 2015

What Can We Expect Beyond 2015?

- What's Past is Prologue..
- If there's one thing that history teaches us it's that history repeats itself.
- To View the Future, Let's review how we got to where we are today then look ahead

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Pre - 2000

- DCLD Review Time Performance Mostly Slow and Inconsistent
- Understanding of Process Poor
  - Industry
  - DCLD/CDRH

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2002

- MDUFMA (et sequelae)
  - User Fees to FDA
  - Review Time Performance Goals, etc.
  - Reduction in Such Times Gradual and Positive
  - Development of Guidance and Standards

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2007

- NCI/FDA/Industry Workshop on Development of Markers for Clinical Decision Making. Bethesda, MD
  - Goal: To Formulate a Set of Recommendations that will Assist Investigators in Optimizing the Process for Predictive Biomarker Development and/or Co-Development of Drugs and Devices. These Recommendations will be Published in a Definitive "issues-to-consider" Document
    - Mainly Academia, Professions and FDA
    - An early beginning leading to many important current initiatives

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2008

- Secretary's Advisory Committee on Genetics, Health and Society (SACGHS)
  - Recommendations included:
    - Establishment of a Genetic Test Registry by NIH
    - Oversight required for the myriad Genetic tests offer by laboratories as LDT's
    - LDT's heretofore under "enforcement discretion" by FDA since 1976

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2008

- CLIA Waiver – “You can have it, I don’t want it!”
  - CLIA Waiver Guidance Published after “back and forth” between CDC and CDRH over the years
  - Issue still hotter that ever with some progress being made with dual pathway and review time limits
  - 2014 Ebola “scare” underscored the value of waived POC testing
  - Future Plagues will require waived POC testing

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2010

- Public Meeting on Oversight of LDT's, Hyattsville, MD
- First Public Meeting to involve all stakeholders and led to much discussion, little action
- 2nd quinquennial LDT meeting at NIH, January 2015
  - See you in 2020..

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2011

- Ultra High Throughput Sequencing?
- First Public Meeting on Ultra High Throughput Sequencing for Clinical Diagnostic Applications - “Harnessing Innovation in Next Generation Sequencing” (June 2011)
- “NGS is changing the way we look at genomics,” - Alberto Gutierrez, Ph.D
- Subsequent Meeting February 2015. …FDA wants industry to teach us about NGS…

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2012

- Emerging Diagnostics Proposal/Transitional IVD Proposal formulated by Industry (Can you spell IVAT?)
- Pilot underway currently with several companies participating
- 21st Century Cures???

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Today - 2015

- What has History Taught Us?

- Public Meetings involving all stakeholders very Important and Fruitful (Flu, Corona, Ebola, etc.)
- Industry and Agency Cooperation at Highest Level Ever
- Public Health is Beneficiary of this Cooperation
- Hard Work, Open Minds and “The Prize” have Worked for All

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Tomorrow – 2015 and Beyond

- 21st Century Cures
- FDA Reform
- Uptick in M&A Activity after many Stagnant Years
- CMS Payment Reforms and Models

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Tomorrow – 2015 and Beyond

- What is the next NGS-like or Highly Multiplexed test-like Technology?
- What is the next Plague?
- Who will occupy the White House, The House, The Senate?
- Who is the next Margaret Hamburg?

- What Difference Does it Make?
- Process in Place, Keep it Thriving and Moving Forward

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