Opportunities for a 21st Century Approach to Regulation of Advanced Diagnostics

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Paul Radensky
Genetic Alliance

McDermott
Will & Emery

Genetic Testing in a Changing Regulatory Landscape

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Paul Radensky, MD, JD
McDermott, Will & Emery LLP

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Regulatory: framework within existing law

- FDA
  - IVDMIA draft guidance
  - ASR FAQ final guidance
  - Gene expression in breast cancer special controls guidance
  - Other pharmacogenomic and genetic test guidances
- CDC molecular testing guidelines

Legislative proposals

- Kennedy/Smith—regulating all LDTs as medical devices
- Obama/Burr—broader genomics legislation with decision matrix to set regulatory requirements
- P. Kennedy—House complement to Obama/Burr; revised version expect to be introduced in this Congress shortly; registry of tests
- Other possible bills

Industry proposals

- American Clinical Laboratory Association
  - FDA consultative role under CLIA
- AdvaMed
  - Risk-based, least burdensome framework under FDA
- Coalition for 21st Century Medicine
  - Risk-based, advanced diagnostics-specific framework (registry and risk-based pre/post market requirements)
- Other proposals

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Regulatory principles

GA+105 other groups sent a letter to Secretary Sebelius 4/2009 outlining 3 core principles for regulation of advanced diagnostics

Rulemaking

"Oversight of all advanced diagnostics (including *in vitro* diagnostic test kits and laboratory developed tests [LDTs]) should be risk-based and built upon an expanding base of advanced scientific capacities within the Department of Health and Human Services (HHS) and its agencies and in collaboration with extramural experts to augment HHS's capabilities as needed. Food and Drug Administration (FDA) regulation of advanced diagnostic LDTs can be implemented and can strike the essential regulatory balance described above only through formal notice-and comment rulemaking."

Registry

"A registry should be developed and maintained that includes the name of the laboratory performing a specific test, the name of the laboratory or manufacturer that developed the test, and information to support claims about the analytical validity and clinical validity of that specific test or test method. Submission of information to this registry should be mandatory for all advanced diagnostic assays."

CLIA

"Oversight of clinical laboratory quality systems by the CLIA program should be strengthened to assure that the information provided by advanced diagnostic testing is accurate, reliable and timely. FDA and the Centers for Medicare & Medicaid Services (CMS) should avoid unnecessary duplication in oversight and reconcile any conflicts in regulation between the medical device rules and regulations under CLIA."