

IVDMIA Draft Guidance

Public Meeting Comments

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Perspectives of a patient advocate balancing optimism with cynicism

Marti Nelson Cancer Foundation

Disclosures

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What are the Important Issues?

“Wisdom consists of the anticipation of consequences.”

Norman Cousins

- Without effective government oversight, a significant minority of business people, with the assistance of their lawyers, will mislead, cheat or defraud consumers
- Government regulation, unwisely formulated and administered, can stifle innovation and deprive consumers of the benefits of life-saving and life-enhancing technology and products

At the risk of oversimplification. . .

- Current CLIA regulations came about because consumers were harmed by poor quality controls, sloppy procedures, and unreliable results leading to inappropriate medical care
- Current FDA regulations arose from death and injury caused by faulty or dangerous products and misleading or false marketing claims

Unfettered capitalism has led to:

- Automakers marketing minivans to families as “station wagons of the '90s,” but concealing the lack of safety features required in passenger cars
- Nutritional supplement products with unreliable content labels and fraudulent performance claims
- Artwork on breakfast cereal boxes misrepresenting the contents as containing fruit
- Misleading direct-to-consumer advertising of drugs by pharmaceutical companies. . .

Regulation of Claims Is Important

- With only CLIA regulation, “snake oil salesmen” can exploit consumers with unsupported test claims
- Validation of claims must be more rigorous for tests offered directly to consumers than current CLIA regulations provide
- FDA should regulate the clinical claims made for IVDMIA tests with a phase-in period to avoid harm to existing products that have not previously been FDA regulated

Why FDA in addition to CLIA?

- FTC does not have the resources nor depth of expertise to control health-care fraud
- CLIA does not adequately regulate the validity of claims made for increasingly complex tests
- Trends in personalized medicine and D-T-C advertising raise the risk that unreliable diagnostics can cause harm
- Despite the protestations of venture capitalists and marketing executives, most medical and technological advances do not occur so fast that FDA approval procedures are responsible for delays in medical use

However. . .

Dangers of the Draft Guidance

- The FDA currently does not have the resources to keep review timelines short
- Good products could be withdrawn from market
- Ambiguities and minor conflicts between CLIA regulations and FDA regulations give lawyers plenty of opportunity to obscure the view of the forest by excessive focus on individual trees

More Dangers. . .

- Delays in marketing approval will inhibit investment in innovative technologies and deprive consumers of their benefits
- Innovations will be slower to reach routine medical practice
- Prices will increase as the cost of the regulatory burden increases as measured by both time and money

FDA Needs More Resources

- Internal technical expertise needs to be expanded
- Researcher-Reviewer staff expansion will better enable achieving Critical Path goals
- More resources will reduce the risk of costly delays in review
- More resources will reduce the need for and risks of selective enforcement

Suggested Clarifications and Modifications to the Draft Guidance

- Products already in clinical/commercial use, validated by third party or peer-reviewed processes, should be “grandfathered,” or exempted from immediate compliance with new regulations
 - Example: Oncotype™ DX breast cancer assay
 - Example: AlloMap® molecular expression testing
- Existing tests should not be newly labeled “experimental” by the FDA - insurance coverage issues
- Clarify the standards specific to different technologies, since not all IVDMIAs are created equal

Additional Suggestions. . .

- Create a mechanism for provisional approval for IVDMIAs used for rapidly emerging or mutating infectious diseases
- Clarify how IVDMIAs will be categorized by the FDA as either class II or class III devices
- Reconcile any conflicts between CLIA and FDA requirements in plain English (the SEC does a pretty good job of using plain English these days)

And, Finally. . .

- The FDA Draft Guidance is a good start at achieving the proper balance between certainty and risk
- Clear, plain English regulations can prevent fraud without hindering innovation
- Implementation of a modified version of the Draft Guidance can protect consumers going forward without jeopardizing access to current legitimate products and services
- Effective regulation can be a positive factor for investors by ensuring that profits flow to people who have earned them

Thank you

“Nothing will ever be attempted, if all possible objections must be first overcome.”

Dr. Samuel Johnson

- Questions via e-mail?
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