FDA's Oversight of Labeling, Advertisitng and Marketing of Genetic Tests

Steven I. Gutman, M.D.
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in Vitro Diagnostic Devices

Labeling

What is a label?

- Manufacturer's Product Monograph
  - Also known as: package insert
- The basis for approved promotion of the product *by the manufacturer*
  - "*off label*" promotion is not allowed
  - "off label" practice of medicine is

FDA

- Sets labeling requirements
- Monitors advertisements and promotional labeling
- Watches to ensure use appropriate for approvals

IVD Labeling

809.10(b)

- 15 components
- Most important are:
  - intended use
  - indications for use

IVD Labeling– 809.10

- Proprietary name and Establishment name
- Intended use(s)
- Summary and explanation
- Principles involved in device function
- Information on reagents
- Information on instruments
- Information on specimen collection and preparation

IVD Labeling– 809.10

- Outline of procedures
- Procedure for calculating results
- Limitations of device
- Expected values
- Specific performance characteristics
- Bibliography
- Name and place of business
- Date of label

Advertising: FDA Act

- The Act does not define advertisement
- FDA interprets term to include supplementary or explanatory information
- Products misbranded if labeling or advertising is false or misleading

FDA and Advertising

- Watches to ensure off-label use not promoted in device ads or labels
- Does not exert authority over laboratory ads or labels with exception of ASR disclaimer in test reports when appropriate

In House Tests and Advertising

- FDA does not have authority over ads
- FDA does not have authority over marketing patterns – direct to consumer
- ASR rules does indicate if In House Test made using ASR it should not be sold OTC
- FTC has primary jurisdiction for OTC devices (per 1954 agreement)

Direct to Consumer Advertising

FDA has guidelines for pharmaceuticals

- Based on truthful and balanced presentation of facts
- If violative could lead to misbranding

Diagnostic Devices

- Pharmaceutical General principles not outlined or directed toward devices but applicable

New Trends in Product Review

Increased Flexibility Since FDAMA

- 510(k) alternatives include special and abbreviated 510(k)s
- PMA alternatives include modular PMAs
- De novo 510(k) process – modernization act allows easier classifications
- Least burdensome focuses review on relevant endpoints

CDRH Strategic Plan

- Total Product Life Cycle
- Knowledge Management
- IVD Program Change
- One Stop Shopping

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SACGT Recommendations

Challenging

- Broad menu for HHS with suggestions for enhancements in oversight by CMS, FDA, and CDC
- FDA charged with regulating new genetic tests
- Risk based
- Non-chilling
- Informed by professional societies

SACGT Recommendations

- Risk based
- Non-chilling
- Informed by professional societies

Data Collection Group

- Data template
- Burke model
- Leonard model
- FDA model

Review Templates

- FDA has adopted these
- Key features of FDA review
- Replace final review memos

Review Templates

Administrative Information

- 510(k) number
- Analyte
- Type of test
- Applicant
- Proprietary and established names

Review Templates

Regulatory Information

- Regulatory information
- Intended Use
- Device description
- Substantial equivalence information
- Standard/guidance document used

Review Templates

Scientific Information

- Test principle
- Performance characteristics
- Conclusion
- Other supportive information
- Contact information

Review Templates

- Tool for future use
  - Standardized
  - Streamlined
  - Transparent (www.fda.gov/cdrh/oivd/)
    - Goal: Electronic format
    - Meanwhile :Paper templates

May or may not be useful for future genetic regulation

FDA Future Directions:

Microarrays and Other Technology

- Under statute all new device is class III
- ASR is one type of new device
- Microarray may not be class I exempt if it falls outside description of class I
- All devices exemptions have limitations
- Even microarrays that might satisfy description of ASR classifications may trip limitations

FDA Revisit of ASRs

- Collaborative with other parts of HHS
- Not focused on genetic testing alone
- Part of overall risk management initiatives without genetic exceptionalism
  - Likely emphasize Commissioner's goals of risk based and cost effective regulation
  - Likely to emphasize Commissioner's goal of informed consumers
  - Likely to take time

FDA Plan

Central issue is Risk / Benefit

- Challenging issue for SACGT
- Challenging issue for FDA
- Input expected from professional groups
- Input welcome