Association of Medical Device Manufacturers October 8, 2015

Jeffrey N. Gibbs
Hyman, Phelps & McNamara, P.C.
Washington, DC
jgibbs@hpm.com
www.hpm.com
www.fdalawblog.net

Hyman, Phelps & McNamara PC

The First Amendment and FDA: A Timeline

- 1791 – The First Amendment is ratified
- 1938 – Congress enacts the Federal Food, Drug and Cosmetic Act
- 1960's, 1970's and 1980's – FDA occasionally seizes books, without considering First Amendment implications

2

Timeline

- Early 1990s – FDA challenges company distribution of peer-reviewed reprints discussing off-label uses
- FDA seeks to restrict industry support of Continuing Medical Education (CME) programs
- The Washington Legal Foundation (WLF) sues (1994)

3

FDA and The First Amendment Today

- There is no question that FDA is subject to the First Amendment
- There is no question that FDA will need to rethink its approach to restricting communications about truthful, non-misleading communications
- Some of the long-accepted legal principles about off-label communications are now in question
- But, there are substantial questions about what the practical day-to-day impact is for IVD companies

4

What It Does Not Mean

- That Companies can make false or misleading statements. See Harkonen (false press releases)
- Put patients at risk. See Caputo (failed First Amendment defense in prosecution for modifying device that caused blindness)
- That can make unsubstantiated claims
- That FDA is changing its written policies
- That the False Claims Act (FCA) is not applicable to off-label information
  - FCA is the basis for the biggest settlements
- That companies should scrap their policies on promotion and rely on “Free Speech”
- That companies should run off-label ads for IVDs

5

What It Does Mean

- IVD companies should be aware that the law is changing
- Some FDA policies may be difficult to enforce, e.g., the details of the Good Reprint Practices' policy, such as a ban on highlighting any part of an article or limits on oral discussions
- More flexibility for sales representatives
- The general/specific policy should be rethought by FDA

6

The First Amendment and Social Media

- Starting point: Companies have constitutional protection for truthful, non-misleading information
- The public also has First Amendment rights to communicate with companies and each other
- FDA has not – and could not – prohibit device companies from using social media

7

The First Amendment and Social Media (cont'd)

- FDA has proposed restrictions regarding the use of social media, e.g., sufficient details on risks in a tweet
  - WLF Backgrounder: Some of FDA's restrictions are unconstitutional (September 25)
- My perspective: FDA's ability to take enforcement action based on non-adherence to details of policies is up for debate if a company engages in truthful, non-misleading communications

NB: Does not mean IVD companies should ignore FDA's policies or proposals

8

Conclusion

- First Amendment has historically played little to no role in analyzing Device/IVD promotional issues
- That is changing
- Prediction: Will not readily be reflected in FDA policy
- Battle may shift away from “off-label” and more to false/misleading
- Advice: Do not make significant changes in company policy, but there will be areas where companies should consider greater flexibility

9

LDTs – A Recap

- FDA issued its proposal approximately one year ago
- On January 8-9, 2015, FDA held a public meeting to discuss the proposal
  - Wide variety of perspectives
  - Many comments did not address the very specific questions that FDA had posed
  - Many concerns expressed over specific elements of the proposal, e.g., the definition of rare disease
  - Many objections to FDA regulation of LDTs at all
  - Other comments strongly supported the concept

10

LDTs – A Recap (cont'd)

- Comment period closed on February 2, 2015
- FDA received 236 comments
- 170 comments have been made publicly available
- Comments represent diversity of perspectives
- American Clinical Laboratory Association strongly suggested it would sue if LDT proposal adopted
  - Several potential grounds, including lack of authority and violation of the Administrative Procedure Act

11

Diagnostic Test Working Group (DTWG)

- Group of labs and device firms came together to develop alternative proposal
- All diagnostics would be subject to some degree of regulation
  - LDTs would be regulated with level of regulation varying by risk
  - Low-risk LDTs would face very low regulation
  - IVDs would be regulated by FDA, but generally at a less stringent level than today
    - Called "*in vitro* clinical tests" (IVCTs)
- Reportedly working with House Energy & Commerce Committee on revised proposal

12

Association of Molecular Pathologists (AMP)

- AMP submitted its own proposal for legislation
  - Modernize the Clinical Laboratory Improvement Amendments (CLIA), including premarket review by the Centers for Medicare & Medicaid Services (CMS) or its designated third parties
  - FDA would only review the submission if the laboratory voluntarily chooses to go through FDA PMA/510(k) process or if a protocol is high-risk and the laboratory does not want to give the proprietary information to the CMS or third-party reviewer.
    - LDTs called Laboratory-Developed Protocols

13

College of American Pathologists

- Similar in many respects to AMP
- Would amend Federal Food, Drug, and Cosmetic Act to subject High-Risk LDTs to existing FDA pre-market and post-market requirements
- Would modify CLIA to subject low and moderate-risk tests to CMS regulation
  - CMS or third party would review moderate-risk tests

14

What's Next?

- FDA could issue a final guidance that is essentially unchanged from proposal
  - FDA likely would be sued
- FDA could issue a substantially revised guidance
  - In final, and FDA could be sued
  - In draft, with the opportunity for further comment
- FDA could completely revamp and start all over

15

What's Next? (cont'd)

- Congress could pass legislation
  - Multiple ideas being floated
  - NB: Congress can barely/can't pass a budget
- A policy is adopted late next year and then rescinded by a new Administration
- Nothing happens publicly and a new Administration decides to modify/revisit/ push ahead/drop the idea

16