Industry Update

Allyson B. Mullen, Hyman, Phelps, & McNamara PC

AMDM 2019 IVD Focus Meeting

Agenda

- Key Developments in the last year
- Industry-wide trends
- Looking ahead to 2020 and beyond

Key Developments

- Several important IVD-specific draft and final guidance documents
  - IVD Specific: CLIA Waiver, Labeling for IVD Companion Diagnostic Devices for Specific Group or Class of Oncology Therapeutic Products
- Also several Center-wide guidances
  - Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program (May 2019)
  - Considerations for Uncertainty in Making Benefit-Risk Determinations in Medical Device Premarket Approvals, De Novo Classifications, and Humanitarian Device Exemptions (Aug. 2019)
  - The Special and Abbreviated 510(k) Program Guidances (Sept. 2019)

Key Developments

- Proposed De Novo Rule
  - Increased requirements for submissions (e.g., advertisements, bibliography of all published and unpublished reports, and samples, if requested)
  - FDA proposes QSR inspections as a condition of marketing authorization
  - Expanded grounds for denial

- Paper copy submission requirement

- FDA “enforcement actions” regarding pharmacogenomic testing companies
  - October 31, 2018 – Safety Warning
  - April 2019 – Innova Warning Letter
  - Spring/Summer 2019 – Nonpublic calls to individual companies

Trends

- Challenges with clinical data and establishing clinical validity
  - Frequent issues with clinical data (e.g., interpreting success)
  - Unless benefit has been clearly established, companies are struggling to gain traction with benefit/risk arguments
  - Consider early discussions with FDA as to performance requirements/expectations

- Continued LDT enthusiasm (and disdain)
  - Many novel tests are still entering the market as LDTs
  - Potential future regulation is not deterring LDT innovation or adoption
  - FDA seems to now be creating new carve outs to its LDT regulation (e.g., PGx testing). More could follow if legislation is not enacted.

Trends

- State Regulation
  - Lab test reporting and authorization requirements changing frequently
  - Need to keep up with what the states are doing
    - For example, New York State now has different applications for various types of LDTs (e.g., lifestyle tests, tests used in clinical studies)
- Escalations and Appeals
  - Final appeal regulations issued in July 2019
  - The process is working – don't be afraid to push back when needed
  - Updated Additional Information request letter template now includes a least burdensome flag – appears may be designed to try to resolve issues before they get to an appeal

Looking Ahead

- VALID Act
  - Discussion draft issued in December 2018
  - Framework **very** similar to FDA's Technical Assistance
  - High-level overview
    - Two-tier classification (high/low risk)
    - High risk would be required to undergo premarket review (essentially PMA approval)
    - Others could be pre-certified (very limited in scope of what could be grouped together)
    - Limited (time and scope) grandfathering
    - Labs would be required to comply with certain QSR elements and CLIA for lab operations
    - General purpose products (e.g., test platforms) would face an uphill battle

Looking Ahead

- Promotion and FDA enforcement action
  - Lack of enforcement action with regard to promotion hasn't gone unnoticed by industry
  - Seeing more aggressive promotional claims (e.g., RUOs and pushing the bounds of cleared indications)
  - Keep an eye on competitors
  - FDA is taking some action, but it appears to be non-public (e.g., untitled letters)
  - Also consider other Agencies (e.g., Customs, FTC)

Questions & Discussion

Contact Information

Allyson B. Mullen
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, NW
Suite 1200
Washington, DC 20005
(202) 737-9639
amullen@hpm.com
www.hpm.com
www.fdalawblog.net