XAVIER HEALTH

Interview with John M. Taylor, Esq.

Principal, Compliance and Regulatory Affairs

Greenleaf Health

Former Deputy Commissioner & Counselor to the FDA Commissioner

Differences in FDA Legal Authority Across Commodities

Why and what is the impact?

Focus of Interview

- Much of this interview is based on exploring the "why" behind the FDA Safety and Innovation Act that was passed by Congress in 2012 (FDASIA).
  - Title VII of FDASIA – "Globalization provisions"
  - Focus is largely on drugs

- There are stark differences in FDA authority across commodities – pre and post FDASIA.
  - Why, and what is the impact?

Stark Differences in Authority

- **Title VII addresses the challenges of globalization**
  - Dramatic increase in drug imports
  - Complex and fragmented global supply chains
  - Increased unknowns with respect to product safety, quality and integrity
  - Increased threat of fraudulent and substandard drugs

- **Title VII assists FDA's efforts to transform itself into a global agency**
  - No longer a domestic agency operating in a globalized world
  - Goal – global agency prepared for a regulatory environment where product safety and quality know no boarders

Stark Differences in Authority

- **Title VII Increases FDA's ability to:**
  - Collect and analyze data to enable risk informed decision making. Sections 701-704, 713-715
  - Advance risk based approaches to facility oversight/shift towards a more strategic, risk-based approach to regulation and enforcement. Sections 705 and 706
  - Partner with foreign regulatory authorities/leverage resources through information sharing and recognition of foreign inspections. Sections 710 and 712
  - Drive safety and quality throughout the supply chain through strengthened tools. Sections 707-709, 711, and 716-718

FDA Mandatory Recall Authority

Mandatory Recall Authority

1. **How has FDA Mandatory Recall Authority evolved?**
   - Statutory Authority:
     - Devices 21 U.S.C. 360h(e)(1)
     - Foods infant formula 21U.S.C. 350a(e), general food 21 U.S.C. 350l(a)
     - Biologics 42 U.S.C. 262(d)(1)
     - Tobacco 21 U.S.C. 387h(c)(1)

2. **What are the differences in authority across pharma and device?**
   - Devices – reasonable probability that device would cause serious adverse health consequences or deaths.
   - Drugs – No authority under the FD&C Act
   - Biologics PHS Act

3. **Why are there differences?**
   - History of product recalls

FDA Allocation of Resources

FDA Allocation of Resources

1. **What are the differences across pharma and device in legal authority FDA has to implement risk based decisions related to its resource allocation?**

   - Title VII Section 705
     - Eliminates minimum inspection requirement for domestic drug establishments
     - Requires FDA to target both domestic and foreign inspections based on risk

   - Title VII Section 706
     - Allows FDA to obtain records from a drug manufacturer in lieu of, or in advance of an inspection

FDA Allocation of Resources

2. **How does this impact FDA's interest in using metrics to assess quality from one company to another?**
   - Collect/analyze data to enable risk informed decision making
   - Advance risk based approval to facility oversight
   - Shift towards more strategic risk based approach to regulation

3. **Where does the funding come from for FDA resources?**
   - Appropriations from Congress
   - User Fees from Industry

Mutual Reliance

Mutual Reliance

1. **What are the differences between what used to be "Mutual Recognition" and what is now "Mutual Reliance"?**
   - Mutual recognition – past and present usage
   - Mutual reliance – present usage

2. **What is the legal basis for FDA engaging in cooperative agreements with other regulatory authorities for inspectional coverage?**
   - Title VII Section 712 Allows FDA to enter into written agreements with foreign governments to recognize the inspections of foreign drug establishments, purpose is to facilitate FDA's risk based inspections

Mutual Reliance

3. **In what ways is FDA getting more involved with global regulatory authorities?**

   - Mutual Reliance Initiative
   - PIC/S
   - International Medical Device Regulators Forum – Medical Device Single Audit Program

Import Authority

Import Authority

1. **Explain the differences in import authority FDA has for drugs, devices and food – pre and post FDASIA**
   - Appearance Standard/Standards for Admission
   - Inspections at facilities and ports of entry
   - Legal tools

2. **Why are there differences?**
   - Impact of FDASIA and The Food Safety and Modernization Act (FSMA)

FDA Inspectional Authority

FDA Inspectional Authority

1. **What is the significance of FDA considering a drug adulterated if a company "delays, denies, limits or refuses" an inspection as outlined in FDASIA?**
   - Title VII Section 707 provides this authority
   - Helps address jurisdictional challenges of globalization
   - Guidance issued in October 2014 explains the scope of the provision

2. **Is there similar legal authority for devices and food?**
   - Similar legal authority for both devices and food
   - FSMA provides FDA with explicit authority for food – 21U.S.C. 384c(b)

FDA Inspectional Authority

3. **Are there examples of FDA using this authority, and any trends associated with that use?**

   - FDA identifies and tracks firms that have offered articles for import but have refused inspection aka Red List
   - Drug, Device, and Food firms have been cited

Dr. Robert Califf, FDA Commissioner

What are some significant steps you see FDA taking under the direction of the new commissioner, Dr. Robert Califf?

Dr. Califf's priorities include:

- Strengthening the FDA workforce
- Ensuring the availability of patient information
- Real world evidence
- Clinical Trial reform
- Patient engagement in medical product development
- Improving communication between FDA and the scientific community
- Opioid abuse

Thank you! John M. Taylor, Esq.

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1. 3rd Thursday Lunch & Learn Series. August 18, 2016.
2. Mission Critical Leadership Summit. September 14-15, 2016.
3. Xavier Combination Products Summit. November 2-3, 2016.
4. FDA/Xavier PharmaLink Conference. March 14-17, 2017.
5. FDA/Xavier MedCon Conference. May 2-5, 2017.

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