wiley

Introduction to Device Law & Regulation Workshop: Enforcement & Compliance

Brandon J. Moss

bmoss@wiley.law
202.719.7554

April 14, 2022

Sources of "Enforcement"

- U.S. Food and Drug Administration's (FDA) Jurisdiction
- Two Categories of Action:
  - Administrative:
    - Actions taken directly by the Agency, but can be appealed through the federal judicial system
  - Judicial:
    - Decided upon and taken by federal courts at the request of the U.S. Department of Justice and the FDA

Process for Identifying Violations

- Investigations have many potential sources:
  - Inspections: Routine and for cause
  - Complaints
    - From members of the public
    - From internal whistleblowers
  - Voluntary disclosures
  - Criminal investigations
  - IG investigations

Prohibited Acts

- Prohibited under FDCA § 301, 21 U.S.C. § 331:
  - The introduction or delivery for introduction into interstate commerce of an adulterated or misbranded device.
  - The adulteration or misbranding of any device in interstate commerce.
  - The receipt in interstate commerce of any device that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.
  - Failure to register and/or list.
  - Failure to comply with MDR obligations.
  - Failure to file a 510(k) before marketing a device when needed.
  - Submission of a false or misleading report to FDA.

Enforcement Actions & Letters

- Untitled Letters/Warning Letters
- NIDPOE
- Seizures
- Injunctions/Consent Decrees
- Administrative Sanctions
- Recalls
- Criminal Prosecution/Penalties
- Civil Money Penalties

Untitled/Warning Letters

- Untitled Letter: An Untitled Letter is an initial correspondence with regulated industry that cites violations that do not meet the threshold of regulatory significance for a Warning Letter.
- Warning Letter: A Warning Letter is an informal, advisory correspondence, issued to achieve voluntary compliance and to establish prior notice.
  - Typically, a Warning Letter notifies a responsible individual or firm that the Agency considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act (FDCA), its implementing regulations and other federal statutes.
  - A Warning Letter is one of the Agency's principal means of achieving prompt voluntary compliance with the FDCA. Warning Letters are issued only for violations of regulatory significance.

Untitled/Warning Letters (cont.)

- Primary Reasons for Receiving a Warning Letter
  - Failing to heed FDA's prior admonition
  - Making promotional claims outside the 510(k) clearance
  - Changing a product's classification
  - Promoting products without required clinical data

NIDPOE

- Notice of Initiation of Disqualification Proceedings and Opportunity to Explain: A NIDPOE letter informs the recipient clinical investigator that the FDA is initiating an administrative proceeding to determine whether the clinical investigator should be disqualified from receiving investigational products pursuant to the FDA's regulations.
  - Generally, the FDA issues a NIDPOE letter when it believes it has evidence that the clinical investigator repeatedly or deliberately violated FDA's regulations governing the proper conduct of clinical studies involving investigational products or submitted false information to the sponsor.

Seizure

- Seizure: Attachment of goods through court order by a U.S. Marshal pursuant to Section 304 of the FDCA.
  - Lot-specific seizure: Seizure of all units in a specific lot or batch of a product
  - Open-ended seizure: Seizure of all units of a specific product, regardless of lot or batch
  - Mass seizure: Seizure of all products and equipment at an establishment/facility
  - Multiple seizures: Seizure of the same product in more than one district court

Suits for Injunction

- Authorized by FDCA § 302, 21 U.S.C. § 332
- Judicial Action
- Complaint filed alleging specific violations against company and/or individuals
  - History of noncompliance and problems
  - Outline continuing violations
  - Relief sought: Restrain and enjoin defendant from continuing to manufacture and introduce into interstate commerce the violative product until certain remedial actions are taken by the defendant.

Suits for Injunction (cont.)

- Complaint will be served upon defendant, who will have opportunity to file an answer and respond to the government's Motion for Injunction and/or temporary restraining order (TRO).
- Types of Injunctions
  - TRO: Granting of a TRO occurs in troublesome circumstances; potential harm to the public
    - According to FDA's Regulatory Procedures Manual § 6-2-6, "Injunctions with TRO's have the highest priority ranking of all legal actions".
  - Preliminary Injunction
  - Permanent Injunction

Suits for Injunction – Consent Decree Provisions

- Consent Decree of Injunction
  - Enjoins company from taking certain actions
    - Requires company to fix problems
    - Inspections to ensure company is in compliance with good manufacturing practices
    - Outside consultants
    - FDA inspections
    - Pay fees for continuing supervision and reinspection by FDA

Administrative Sanctions: Administrative Detention & Banned Devices

- If the FDA determines that there is a reason to believe that a device is adulterated or misbranded, the FDA can order the device to be detained for up to 30 days.
  - May lead to product seizure
  - 21 U.S.C. § 334(g)
    - If the FDA finds that a device presents substantial deception or an unreasonable risk of illness, it may initiate proceedings to ban the device by promulgating a regulation.
      - 21 U.S.C. § 360(f)

Recalls

- Recall: A "recall" is a firm's removal or correction of marketed products, including its labeling and/or promotional materials, that the FDA considers to be in violation of the laws it administers. The agency would initiate legal action for example, seizure or other administrative or civil actions available to the agency if the product was not recalled. Recall does not include market withdrawal or a stock recovery.
- Recall Classification: "Recall classification" is a numerical designation, I, II, or III, that is assigned by the FDA to a particular product recall that indicates the relative degree of health hazard.

Recalls (cont.)

- **Class I recall**: A situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall**: A situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
- **Class III recall**: A situation in which use of or exposure to a violative product is not likely to cause adverse health consequences.
- **Market withdrawal**: Occurs when a product has a minor violation that would not be subject to FDA legal action. The firm removes the product from the market or corrects the violation. For example, a product removed from the market due to tampering, without evidence of manufacturing or distribution problems, would be a market withdrawal.

Additional Enforcement Tools

- Debarment
  - FDCA § 306, 21 U.S.C. § 335a, provides for both mandatory and permissive debarment for corporations and individuals under certain circumstances.
- Publicity
  - FDCA Section 705, 21 U.S.C. § 375, provides that the FDA shall cause "to be published from time-to-time reports summarizing all judgments, decrees, and court orders," and that the agency shall disseminate "information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer"
    - The FDA regularly issues press releases and FDA Enforcement Reports, holds press conferences, testifies at congressional hearings, and sends representatives to comment before the national media on current issues.

Administrative Actions – FY 2021 Trends

- Lingering pandemic effects
  - Facility inspections down
    - Use of remote record reviews
  - Enforcement down . . . and different
  - Focus on COVID claims
- Effect of new leadership?

Civil Money Penalties

- FDCA § 303(f)(1)(A), 21 U.S.C. § 333(f)(1)(A) provides for civil money penalties for violations of the FDCA related to devices
  - Under this provision, unless covered by certain listed exceptions, “any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding”

The False Claims Act

- False Claims Act (FCA)
  - Government's primary civil tool for prosecuting fraud on the government.
  - Can be civil or criminal.
  - FCA prohibits:
    - Knowingly presenting or causing another to present a false or fraudulent claim for payment or approval; or
    - Knowingly making a false record or statement material to a false claim; or
    - Knowingly making a false record or statement material to an obligation to pay money to the government, or knowingly concealing an obligation to pay money to the government.

The False Claims Act

- **Four Elements**
  - Claim or statement for payment or approval of payment
  - False or fraudulent
  - "Knowledge" of the falsehood – actual knowledge, reckless disregard, or deliberate ignorance (§ 3729(b)(1))
  - Materiality

The False Claims Act

- **Both the Government and citizens have standing to bring an FCA case:**
  - Brought by the Government
    - The FCA is the federal Government's primary civil litigation tool against fraud.
  - *Qui Tam*
    - Private individuals, known as "whistleblowers" or "relators," can bring *qui tam* suits on behalf of the Government and get a percentage of the recovery plus attorneys' fees.
- **The Government can dismiss *qui tam* actions.**
  - 31 U.S.C. § 3730(c)(2)(A)

The False Claims Act

Heavy Hammer: Treble Damages Plus Statutory Penalties

- The FCA allows for treble damages, and theories of damages vary widely
  - Benefit of the Bargain
  - Value of the Contract
- Penalties
  - Penalties for each false statement/submission can add up, even when damages are small
  - Penalties are indexed:

	DOJ Penalty Assessed After				
	8/1/2016	2/3/2017	1/29/2018	6/19/2020	**12/13/2021**
Minimum	10,781	10,957	11,181	11,665	**11,803**
Maximum	21,563	21,916	22,363	23,331	**23,607**

86 Fed. Reg. 70740 (Dec. 13, 2021)

False Claims Act

- FY 21 = Second-largest annual total recoveries ever
  - U.S. Department of Justice (DOJ) recovered $5.6 billion in settlements and judgments.
  - Once again, most recoveries were in the health care industry:
    - Over $5 billion recoveries
  - Highest original action recoveries tracked: approx. $3.9 billion
- Record new matters:
  - Lowest number of relator suits in over 10 years.
  - Second highest number of original actions in over 25 years.

The False Claims Act

- FCA recoveries against device manufactures and sellers
  - AKS
  - Off-Label Promotion
  - U.S. Physician Payments Sunshine Act
  - Product Quality
  - Other Health Program Theories

The False Claims Act

- AKS Theory: Arthrex
  - Allegation: DOJ alleged the company paid kickbacks to an orthopedic surgeon to induce his use and recommendation of their products that were disguised as royalty payments.
  - Settlement: $16M, required CIA

The False Claims Act

- Off-Label Promotion Theory: Biocompatables
  - Allegation: Company promoted its embolization device, which was designed to be inserted into blood vessels to block the flow of blood to tumors, for use as a “drug delivery” device, outside of its FDA-approved use without substantial evidence to support the use, thereby casing the submission of false claims to government health care programs.
  - Settlement: $25 million for FCA
    - PLUS $11 million in criminal fines and forfeitures

The False Claims Act

- Product Theory: St. Jude
  - Allegation: Between November 2014 and October 2016, it knowingly sold defective heart devices to health care facilities that, in turn, implanted the devices into patients insured by federal health care programs.
  - Settlement: $27M

Future of FCA Enforcement Actions

- Healthcare will continue to be a priority
- Emerging Theory: “Fraud on the FDA”
- Focus on Cybersecurity
- Role of Agency “Guidance”

Criminal Prosecution

- Misdemeanor Liability (21 U.S.C. § 333(a)(1))
  - Any “person” who violates a provision of Section 301 is subject to imprisonment for not more than one year and/or a fine of up to $1,000.
- Felony Liability (21 U.S.C. § 333(a)(2))
  - Government must establish “intent to defraud or mislead” OR repeat violation after prior conviction.
  - Subject to imprisonment for not more than three years and/or a fine of up to $10,000.
- The term “person” includes individuals, partnerships, associations, and corporations (21 U.S.C. § 321(e)).

Criminal Prosecution (cont.)

- Strict Liability
  - There is strict liability for responsible corporate officials under the FDCA.
  - Individual may be convicted of a criminal offense under the FDCA even if the defendant is unaware of any wrongdoing.
    - *United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277, 284-285 (1943)
  - There is a question whether strict liability in the felony context presents a due process of law issue.
    - E.g., *Andersen v. United States*, 544 U.S. 696 (2005)

wiley

Questions?

Brandon J. Moss
Wiley Rein LLP
2050 M Street NW
Washington, DC 20036
(202) 719-7554 (office)
bmoss@wiley.law