FDA Priorities under Commissioner Gottlieb

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Overview

- Scott Gottlieb’s background
- The relative importance of Commissioner’s office priorities
- Drug pricing
- Opioids
- Medical device innovation
- Drug innovation
- Enforcement priorities
- Organizational changes and FDARA
- Globalization
The Commissioner’s Office (versus or with the Centers)

- An insider’s take on CDER and the Commissioner’s office
- Coordination
- Budget
- Approval decisions
- Enforcement decisions
- Policy making
  - Formal versus informal
FDA and Drug Prices: Pre-Gottlieb and continuing

- Initially “not our area”
- Effect of Generic Drug User Fees
- FDA’s new Office of Pharmaceutical Quality and “patient first”
- FDA’s new “Concept of Operations” for pharmaceutical quality
- Drug reimportation (the “Canada issue”)

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On June 27, FDA published a list of off-patent, off-exclusivity branded drugs without approved generics and implemented a policy expediting review of generic applications where competition is limited.

FDA is working to prohibit restrictions by innovator companies on the drug samples that a generic company needs for drug development.

FDA will limit perceived efforts of innovator companies to block a generic approval by leveraging the requirement that brands and generics share a single shared REMS.

FDA is considering modifying its Unapproved Drug Initiative, which calls for unapproved drugs to be removed from the market when a New Drug Application is approved.

FDA is working with the FTC to determine whether there should be limits on “pay for delay” agreements and is referring anticompetitive behavior to the FTC.
Opioids

- Pre-2014 role
- Stigma
- Packaging
- New pathways
- Opana ER
- Education
- Mail facilities
Medical device innovation

- Digital Health Innovation Plan
  - 21st Century Cures Act – software and apps that are intended only for maintaining a healthy lifestyle are generally outside the scope of FDA regulation
  - Pre-Cert for Software Pilot Program – pre-certified companies have reduced burdens

- Medical Device Development Tools (MDDT)
  - FDA qualifies tools – determines if they measure what they should
  - Examples include Clinical Outcome Assessment, Biomarker Test, Nonclinical Assessment Models
  - FDA qualified Kansas City Cardiomyopathy Questionnaire

- Direct-to-consumer (DTC) access to genetic health risk (GHR) testing
  - Notice of intent to allow GHR tests to be exempted from pre-market review
  - One-time review to ensure they meet FDA’s requirements, then a firm may enter market with new GHR tests without review
  - Special controls for these tests
Drug Innovation and Generics

- 21st Century Cures and Commissioner Califf
- Sarepta Exondys 51 saga – patient involvement
- Office of New Drugs and Dr. Woodcock
- Orphan Drug Modernization Plan
  - Reduce backlog
  - Encourage pediatric studies
- Complex generic drug development
  - Draft guidance on pre-ANDA meeting requests
  - More meetings
- Patient focused drug development under 21st Century Cures
Enforcement Priorities Overview

- Scott Gottlieb in 2011: “Instead of calling for targeted fixes of troubled plants, the agency has often required manufacturers to undertake costly, general upgrades to facilities. As a result, in 2010, product quality issues – and the subsequent regulatory actions taken by FDA to address these problems - were involved in 42% of the drug shortages.”

- CDER approach
  - More standards, data, uniformity
  - Greater efficiency
  - Manufacturing technologies

- CDRH approach
  - Case for Quality
Enforcement Initiatives

- Quality metrics pilot
- New inspection protocol project
- Emerging Technology Team
- Supply chain management
- Data integrity
Organizational changes

- ORA Program alignment
- CDER reorganization
- CDER “Concept of Operations”
  - Change in how to interact with FDA
  - Earlier exposure to subject matter experts
  - Change in decisionmaking authority
  - Time limits
    - 45 days for ORA to complete Establishment Inspection Report
    - 90 days for ORA to classify NAI and VAI inspections
    - 6 months for warning letters
- CDRH reorganization
FDARA Drug Improvements

- Application of relevant GDUFA and PDUFA provisions to all drugs
- Goal of completing GCP, GLP, and GMP inspections within 6 months of receiving priority applications and 10 months of receiving standard applications (PDUFA)
- Guidance on risk-based site selection model (GDUFA)
- Inform firm of NAI and VAI inspection results within 90 days of inspection (GDUFA)

FDA annual public metrics (GDUFA)
- Approval times
- Median time from beginning of inspection to 483 issuance
- Median time from 483 issuance to warning letter, import alert, and regulatory meeting
- Median time from date of warning letter, import alert, and regulatory meeting to resolution of OAI status
FDARA’s Medical Device Improvements

- Why MDUFA provisions may become relevant
- FDA must review and update processes and standards for routine inspections of domestic and foreign device establishments to ensure greater transparency, which will include better communication before, during and after the inspection.
- In certain circumstances, FDA must provide feedback to companies regarding proposed corrective actions to inspectional observations within 45 days. FDA must issue draft guidance on process improvements within 18 months.
- FDA must adopt policies providing that inspections occur on consecutive days.
- FDA must adopt standardized communication templates.
- FDA must announce most inspections in advance.
Globalization

- US-EU Mutual Recognition Agreement
  - Problem of duplicate inspections
  - EU and US to “recognize” each other’s GMP surveillance inspections
  - Does not apply to pre-approval inspections, GCP inspections, or enforcement decisions
  - On November 1, FDA confirmed the capability of the inspectorates of Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the UK
  - FDA to complete assessment by July 15, 2019
  - Expansion?

- Congressional pressure and recent GAO report calling for increased oversight over foreign drug manufacturing

- Leaked White House document lists as its one FDA priority “increase overseas inspections to safeguard imported drugs”

- Trump Administration’s trade policy