March 2013

All of FDA’s stakeholders working together for a strong, well-funded FDA
FDA: Underfunded, Vitally Important

• FDA relatively small, underfunded for decades
• Agency appropriated $2.5B to oversee:
  • 100% of drugs, vaccines, medical devices, cosmetics and 80% of our nation’s food supply
  • Products that are nearly 25% of all consumer spending
• Strong FDA essential to U.S. economy, jobs, balance of trade; critical to homeland security
• Unlike other U.S. regulatory agencies, all stakeholders (including industry) support increased funding for the agency
FDA Regulates . . . 25% of Consumer Spending

- Pet food and animal feed
- Food additives
- Cosmetics
- Infant formulas
- Vaccines, blood products, biologics
- 80% of nation’s food supply
- Dietary supplements
- Microwaves and x-ray equipment
- Medical devices
- Drugs
FDA Responsibilities Grow Each Year

Increases in funding have prevented crisis... but not fully supported growing responsibilities

FROM CONGRESS

• Tobacco control (2009)
• Biosimilars (2010)
• Food Safety (2011)
• Drug and device innovation and safety (2012)

Possible 2013: compounding, counterfeiting/track & trace, and drug shortages

OTHER ADDITIONAL RESPONSIBILITIES

• Globalization
• Scientific complexity
• Promoting innovation
• Public health emergencies
• National security
• Growth of industry
New Laws Add Costs; Impact Existing Responsibilities

- FDA Amendments Act of 2007 added a slew of new responsibilities and created a funding shortfall.
- FDA’s reviews slowed substantially for two years.

CDER Pending Applications with Overdue PDUFA Goals

- New laws: enormous resources to implement; permanently increase agency responsibilities.
Barely Staying Ahead of County Schools

- In FY 07, FDA received less than the Montgomery County School system, where the agency is located.

- FDA’s big gains since 2007 are being eroded

<table>
<thead>
<tr>
<th></th>
<th>FY 07</th>
<th>FY 08</th>
<th>FY 09</th>
<th>FY 10*</th>
<th>FY 11</th>
<th>FY 12</th>
<th>FY 13</th>
</tr>
</thead>
<tbody>
<tr>
<td>MC Public Schools</td>
<td>$1.85 billion</td>
<td>$1.98 billion</td>
<td>$2.07 billion</td>
<td>$2.20 billion</td>
<td>$2.10 billion</td>
<td>$2.09 billion</td>
<td>$2.170 billion</td>
</tr>
<tr>
<td>FDA appropriated funds</td>
<td>$1.57 billion</td>
<td>$1.72 billion</td>
<td>$2.04 billion</td>
<td>$2.35 billion</td>
<td>$2.45 billion</td>
<td>$2.51 billion</td>
<td>Post-sequester: $2.395 billion</td>
</tr>
</tbody>
</table>

http://montgomeryschoolsmd.org/

* Reflects approximately $80 million added to pay debt service on a one-time basis.
• FDA is a staff-intense organization:
  • more than 80% staff costs,
  • rent and utilities are fixed costs—paid first
  • little grant and contracting to cut
• If cuts occur (sequester, FY 13, or FY14):
  • food will be less safe and consumers may be hurt,
  • drug and device approvals will be slower, conflicting with promises made to consumers and companies,
  • problems with imports and globalization will become more numerous (2100 fewer food inspections, per WH)
The loss of $209 million will be met by fewer inspections, short-staffing of FDA offices/functions, cuts to training and travel (critical for inspections and international standard-setting) and cancelling contracts and grants.

<table>
<thead>
<tr>
<th>Sequestration</th>
<th>FY 13 Continuing Resolution (thru 3/27/13)</th>
<th>Less Sequester Amounts</th>
<th>Net Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Budget Authority Appropriations</td>
<td>$ 2.521 billion</td>
<td>$ 126 million</td>
<td>$ 2.395 billion</td>
</tr>
<tr>
<td>User Fees (including tobacco and generics user fees)</td>
<td>$ 1.647 billion</td>
<td>$ 82 million</td>
<td>$ 1.565 billion</td>
</tr>
<tr>
<td>Totals</td>
<td>$ 4.168 billion</td>
<td>$ 209 million (rounded)</td>
<td>$ 3.960 billion (rounded)</td>
</tr>
</tbody>
</table>
Food Safety Modernization Act

FSMA Signed into Law—January 2011

Fundamental Overhaul of Food Laws

Risk-Based Inspections

Change from Re-active to Pro-active System

New Import Program

Safer Food Supply

Reduced Foodborne Illness
New Drug and Device Laws

• **Biologics Price Competition and Innovation Act**
  - BPCIA signed into law March 2010
  - First fully new drug approval pathway in 30 years
  - Creates competition in $60B+ biotech drug market

• **FDA Safety and Innovation Act**
  - FDASIA signed into law July 2012
  - Overhauls drug and device approval processes
  - Dozens of new rules and programs to implement

• **4 major laws in 3 years; more expected in 2013**
Massive increase in need for safety inspections:

- **Food Imports**: 10% annual increase from 2005-2011
  - 10-15% of all food consumed in U.S. is imported
  - Nearly 2/3 of fruits and vegetables are imported
  - 80% of seafood is imported

- **Device Imports**: 10% annual increase from 2005-2011
  - 50% of all medical devices used in the US are imported

- **Drug Imports**: 13% annual increase from 2005-2011
  - 80% of API used in the U.S. are manufactured abroad
  - 40% of finished drugs are manufactured abroad
FDA Foreign Offices (more coming)

- Headquarters
  - Silver Spring, MD

- Mexico City
- San Jose
- Santiago
- Pretoria
- London
- Parma
- Brussels
- Amman
- New Delhi
- Mumbai
- Beijing
- Shanghai
- Guangzhou
Drugs, Devices, Vaccines, Diagnostics, Cosmetics: All Involve More Complex Science

Sponsors Need More Meeting Time; Other Feedback from FDA
Applications Require More Patients, Study Sites, Analysis
Enhanced Timeliness and Consistency of Product Review
Expansion of Pre- and Post-Market Safety
Enhance Innovation, Speed Approvals

Safe and Effective Medical Products to Meet Patient Needs
### Drug Protocol Complexity & Execution Burden Increasing!

<table>
<thead>
<tr>
<th>All Therapeutic Areas, All Phases</th>
<th>00 – 03</th>
<th>08-11</th>
<th>% Change 00-11</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unique medical and compliance procedures per protocol (median)</td>
<td>20.5</td>
<td>30.4</td>
<td>48%</td>
</tr>
<tr>
<td>Total procedures per protocol (median)</td>
<td>105.9</td>
<td>166.6</td>
<td>57%</td>
</tr>
<tr>
<td>Total investigative site work burden (median units)</td>
<td>28.9</td>
<td>47.5</td>
<td>64%</td>
</tr>
<tr>
<td>Total eligibility criteria</td>
<td>31</td>
<td>46</td>
<td>58%</td>
</tr>
<tr>
<td>Median study duration in days</td>
<td>140</td>
<td>175</td>
<td>25%</td>
</tr>
<tr>
<td>Median number of CRF pages per protocol (CRF = case report forms)</td>
<td>55</td>
<td>171</td>
<td>227%</td>
</tr>
</tbody>
</table>

Source: Getz, Campo, Kaitin. Variability in Protocol Design Complexity by Phase and Therapeutic Area, DIJ 2011 45(4); 413-420; Tufts Center for the Study of Drug Development
Conclusion

The U.S. Food and Drug Administration:

- broad mandate for a relatively small agency
- core function of government
- mission and responsibilities are increasing
- needs funding to transform into a 21st century regulatory agency

FDA should be a priority…and deserves exceptional status when appropriations decisions are made
A strong FDA benefits all Americans

Patients, consumers, health professionals, industry....and the whole world benefits, too.

For more information, contact:

Ladd Wiley, Executive Director
lwiley@StrengthenFDA.org
202-887-4083

Steven Grossman, Deputy Exec. Director
sgrossman@StrengthenFDA.org
301-539-9660