Funding at the FDA

Financial Independence Inside and Out

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Independence

- Not subject to control by others: self-governing
- Not affiliated with a larger controlling unit
- Not requiring or relying on something else: not contingent
- Not looking to others for one's opinions or for guidence in conduct
- Not bound by or committed to a political party

Merriam-Webster Dictionary

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Independence for FDA

- Financial Independence
  - Adequate funding through appropriations
  - Limits on user fees
  - Conflicts of interest
- Independence from outside pressure
  - Inappropriate political intervention
  - Inappropriate industry intervention

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Resources

- “An agency whose crucial mission is to protect and advance the public health should not have to go begging for resources”, Institute of Medicine 2006
- 80% of FDA budget is for salaries
- 70% of scientific staff surveyed by Union of Concerned Scientists (997 respondents) did not believe that FDA had sufficient resources to effectively perform its mission.

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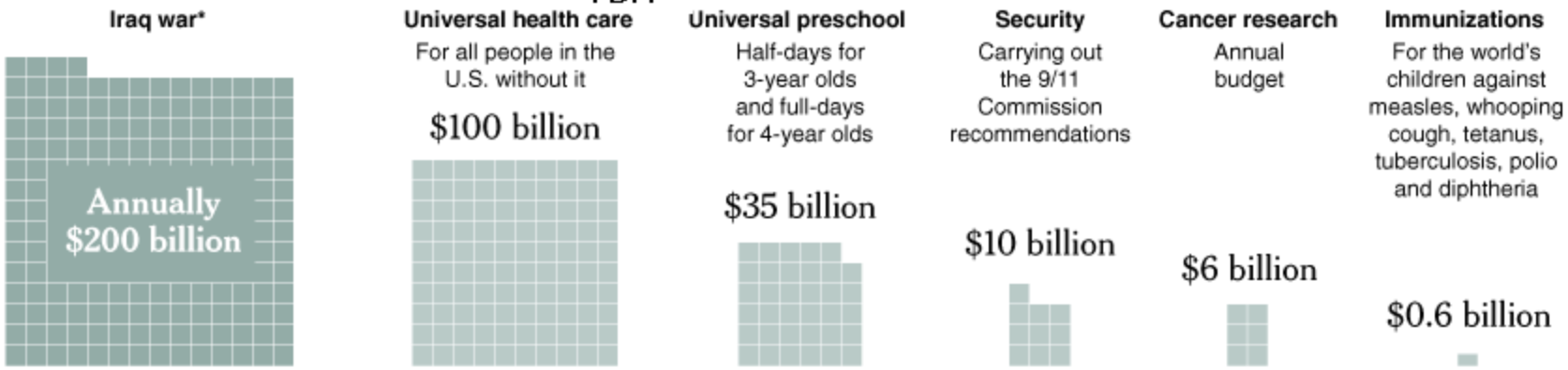
Putting the Annual Cost of ~~War~~ FDA in Perspective



*Includes $120 billion in annual military expenses plus the future cost of veteran medical care and disability payments, the cost of rebuilding the military after the war, and the increased cost of oil as a result of the war.

All costs are annual.

Sources: Scott Wallsten and Katrina Kosec (war costs); Linda Bilmes and Joseph Stiglitz (war costs); Kaiser Family Foundation (health insurance); Jane Waldfogel, Columbia University School of Social Work (preschool); National Cancer Institute (cancer research); Unicef (immunizations)

The New York Times

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Impact of PDUFA

- "Given a choice of having PDUFA or an appropriation of equal amount, which would you take?"

  Question posed by former FDA Commissioner Frank Young to colleagues Donald Kennedy, David Kessler, and Jane Henney

Answer agreed by all 4 – "Appropriations"

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Effect of PDUFA Resources

- Association of increased review staff at CDER leads to reduced review time
  - This association began before PDUFA
- Staff increases began in 1987, average reduction of 3.3 months/100 additional CDER staff
- Decline in approval times not attributable to PDUFA except through provisions of resources
  - Carpenter et al., 2003, Health Affairs

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Effect of PDUFA clock

- Effects on reviewer behavior: high proportion of approvals concentrated in months and weeks prior to PDUFA deadline
- Deadlines appear to affect decisions “the rate at which drugs experience post-marketing regulatory events is appreciably higher for drugs approved in the months before the PDUFA deadlines, compared with others
  - Carpenter, et al., 2007, SKAPP workshop

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Overview of FDA Advisory Committees

- Used when FDA seeks outside expert advice
- Members selected and paid by FDA but are external scientists, clinicians, consumer, patient and industry representatives
- 4 year terms
- AC meetings are open to public and the press
- Data comes from product sponsor and from FDA reviewers
- Members discuss and vote on whether product is safe and effective
- Meetings can be product specific or on more general topic

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COI in FDA Advisory Committees

- 2006 Lurie et al., JAMA, studied AC meetings between 2001-2004
  - 73% had at least one member with COI
  - 22% more than half of members had COI
  - 41% of COI were with sponsoring companies
  - Large range:
  - 10% in Reproductive and Urologic Drugs AC to 51% in Anesthetic and Life Support Drugs AC
  - 7 out of 16 ACs rates below 20%
  - Growing concern that increasing number of public comments from individuals and orgsanizations with financial COI

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Can Conflicts alter voting behavior?

- Not always clear
- Lurie et al. 2006 concluded that excluding members with conflicts would not have changed overall vote outcome at any meeting
- 2005 AC meeting on COX-2 inhibitors
  - 93% of conflicted members voted in favor
  - 56% of non-conflicted members voted in favor

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Pool of potential AC members

- Currently less than 500 AC members
- 125 MD-granting medical schools in US
- Over 123,000 medical school faculty in 2006
- Over 4000 pharmacy faculty in 2005
- Over 7,000 faculty at schools of Public Health in 2005
- NIH awarded over 54,000 grants to over 3000 institutions in 2005

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Current FDA DRAFT Guidance

- More stringent policy proposed March 07
- If COI exceeds $50,000, cannot participate
- If COI less than $50,000, could only participate if need outweighed potential conflict
- If need is great, for member with COI less than $50,000, then participation as non-voting member only

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COI provision in FDAAA

- Increased recruitment activities for advisory committee members'
  - Outreach to academia, professional organizations, patient and consumer groups
  - Making contacting FDA easier
  - Connecting to Federal grantees (NIH, CDC, AHRQ, VHA)
- Limitations on number of waivers
  - Reduced by 5% each year for 5 years.
- Disclosure of waivers at least 15 days in advance
- Annual Reporting requirements

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Looking to the Future

- FDA Amendments Act of 2007 (FDAAA)
- Strengthen the Science
- Increase Transparency
- Expand Resources
- Limit Conflicts of Interest

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