FDA Advisory Committees: Independent Scientific Advice?

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Criteria for FDA Approval

- **Safe** (over the short-term)
- **Effective** (compared to placebo)
- **FDA reviews studies** -- studies are conducted and analyzed by the company
FDA Advisory Committees

Goal: Advice from independent scientists regarding approval, withdrawal and labeling

For new or controversial products

How many would you expect to be recommended? Half?
Drugs and Devices: 1998-2005

- Random: 89 Advisory Panels
- 79% recommended for approval
  - 97% of these were approved by FDA
- 44% of those not recommended were approved anyway
They like to vote “yes”

- 75% of Drug Committee members recommended approval
  (50% - 98%)

- 80% of Device Panel members recommended approval
  (57% - 91%)


Scientific Standards?

- “It’s kind of like old-fashioned medicine. It’s not much good, but it probably won’t do much harm either.”

- “I voted yes. But don’t take that to mean that I don’t have grave concerns about the safety of this drug.”
Scientific Standards?

- “There seems to be confusion about what safe and effective mean. There have been 3 comments that this meets the standards for approval but we are not sure that the product is actually good.”

- “Since I’m ignorant of most statistical issues, in my ignorance I can be very impressed with the data.”
Unanimous Votes

- 54% of Drug Committee votes were unanimous
- 67% of Device Panel votes were unanimous
- ALL Arthritis Drugs and Ophthalmic Devices were recommended
Who are these agreeable scientists?

- 2/3 are MDs
- At least one conflict of interest per panel
- **Definition:** Depending on the product for work is **NOT** a conflict of interest
Conclusions

- NOT really one man one vote
- “Choices” and Consensus > Science
- Individuals can sway the group

Independent?

- The FDA likes when the advisors recommend approval, and often disagree with the rare recommendations to reject