

Technology Assessment in the US:

Sitting in his Nowhere Land,
Making all his nowhere plans for
nobody

History of Federal HTA in the US

- 1938: FDA (safety only)
- 1962: safety and effectiveness
- 1976: limited new FDA role for medical devices
- 1978-2006:
 - OTA review of CT scans
 - NCHCT
 - OHTA
 - CHCT
 - AHCPR...AHRQ

The HTA Landscape

- Pluralism vs. Fragmentation
 - FDA
 - CMS
 - CDC*
 - VHA*
 - AHRQ* (EPCs, DeCIDE)
 - States: DERP, MED, Washington HB 2575*
 - Health plans: BCBS TEC*
 - Academic*
 - Manufacturers*
 - Private HTA companies*

The US view of HTA

- Advisory
- “Pure” science
- Single, case by case evaluation for rapid input into forecasting/planning
- Not for assessing a package of services for a population
- Focus on clinical effectiveness: “net health benefit” and costs
- Methodological foundation = systematic review rather than CEA
- CEA is “dirty”

US attitudes toward HTA

- Improvement of effectiveness and efficiency.-- To improve the quality, effectiveness, and efficiency of health care delivered pursuant to the programs established under titles XVIII, XIX, and XXI of the Social Security Act.... (i) the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services (including prescription drugs)....
- (d) Limitation on CMS.--The Administrator of the Centers for Medicare & Medicaid Services may not use data obtained in accordance with this section to withhold coverage of a prescription drug.

Would NICE/USA kill innovation?

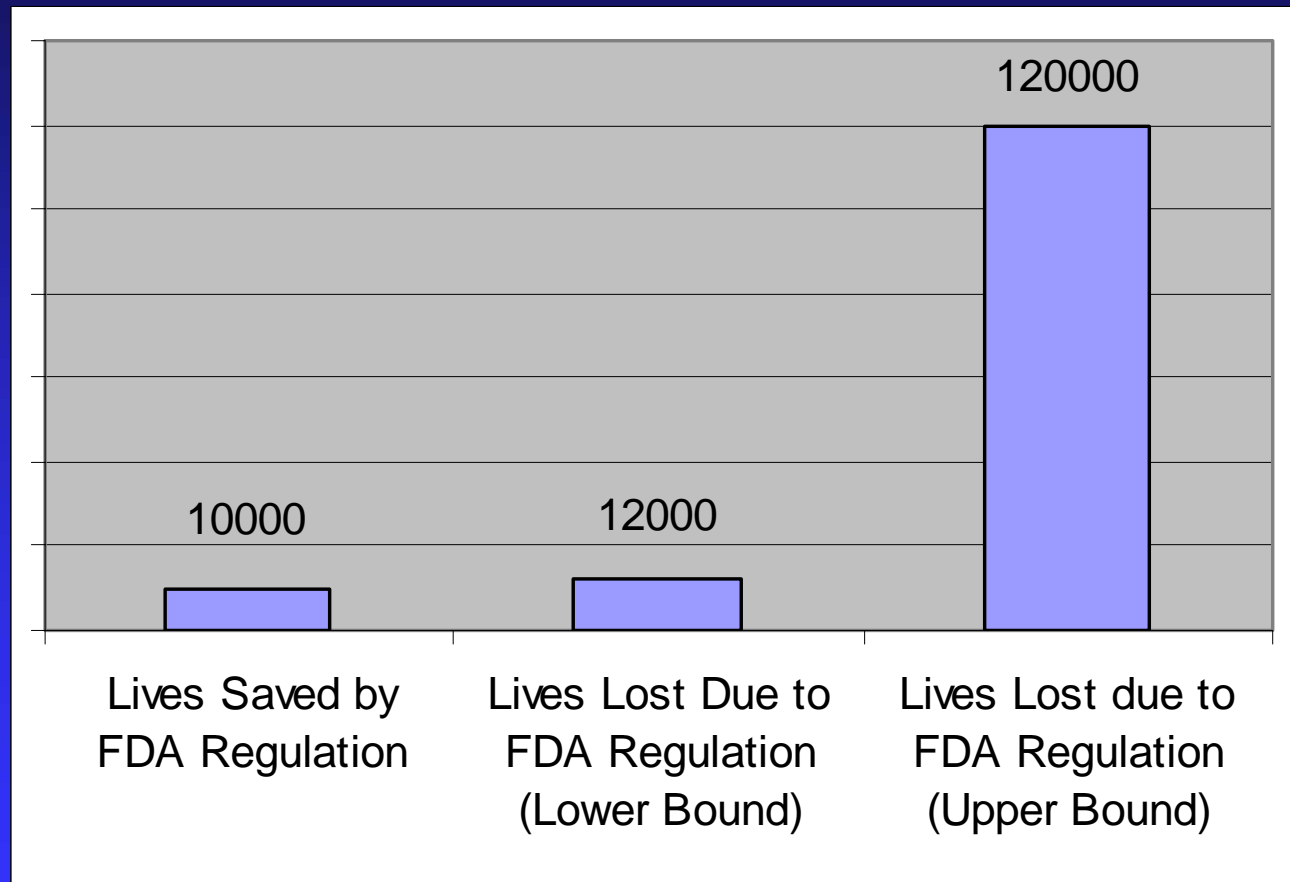
Genentech, Nov. 7, 2005

“Preliminary Data from Phase III Trials Show Lucentis is the First Investigational Therapy to Demonstrate Clinical Benefit over Visudyne in a Head-to-Head Study of Patients With Wet AMD”



VisionCare, Inc., Nov. 22, 2005
The Implantable Miniature Telescope. A study in AJO showed the device effective in more than 90% of participants with wet AMD....

Would NICE/USA harm patients?



Source: Gieringer, DH. *Cato Journal* 5, No. 1
(Spring/Summer 1985): 177-201

Would NICE/USA supplant your doctor?

“Assessing risks and costs, as well as benefits, has been central to the exercise of good medical judgment by individual physicians for decades. The advantage the individual physician has over any national center or advisory council is that he or she is dealing with individuals in need of medical care, not hypothetical cases.”

-----AMA representative's Congressional testimony

Are we edging toward a NICE/USA?

- Growing state attempts at HTA including cost-effectiveness analyses within drug classes
- Private health plans hungry for better evidence and tools to link benefits and coverage to “value”
- Academy of Managed Care Pharmacy (AMCP) dossier for economic data in formulary applications
- MMA, deficits, purchasers, ?public eager to find a principled way to set priorities and get good value for money
- Crescendo in emails, meetings, papers about EBM, cost-effectiveness and HTA in the US context shifting from the “should we?” to the “how do we?”