

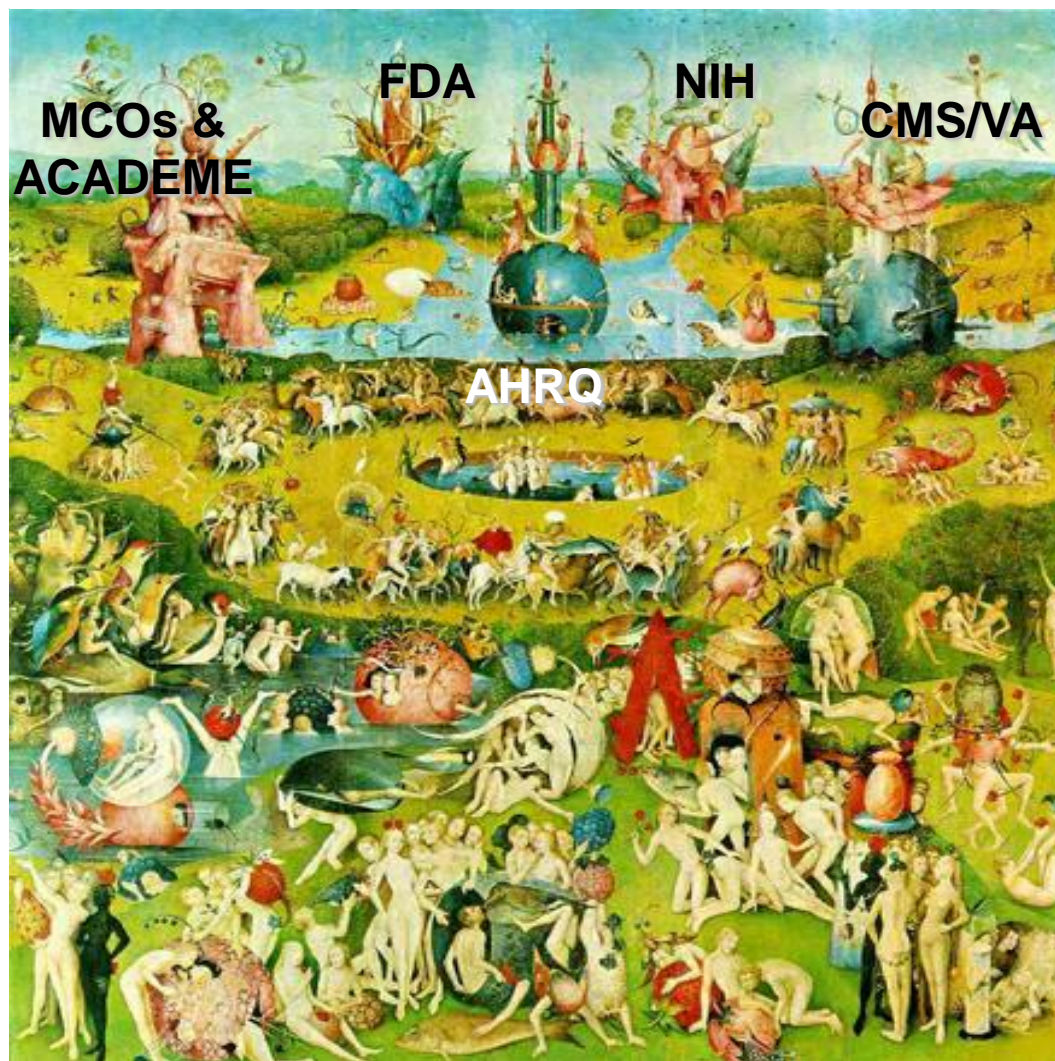
# Comparative Effectiveness Research and Personalized Medicine: **Policy, Science, and Business**

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*Policy Considerations: CER & Industry Structure*

*October 28, 2009*

# Garden of Earthly Delights



## Complicated Landscape

- Who conducts CER research is arguably as important in the long-run as what government does with the results .
- Structural significance equal to the establishment of the RCT as the basis for the drug industry in the 1962 Kefauver Amendments.

Anticipating PM language in the Patient-Centered Outcomes Research Act: “**groups of individuals with different...quality of life preferences.**”

# Lucrative Landscape

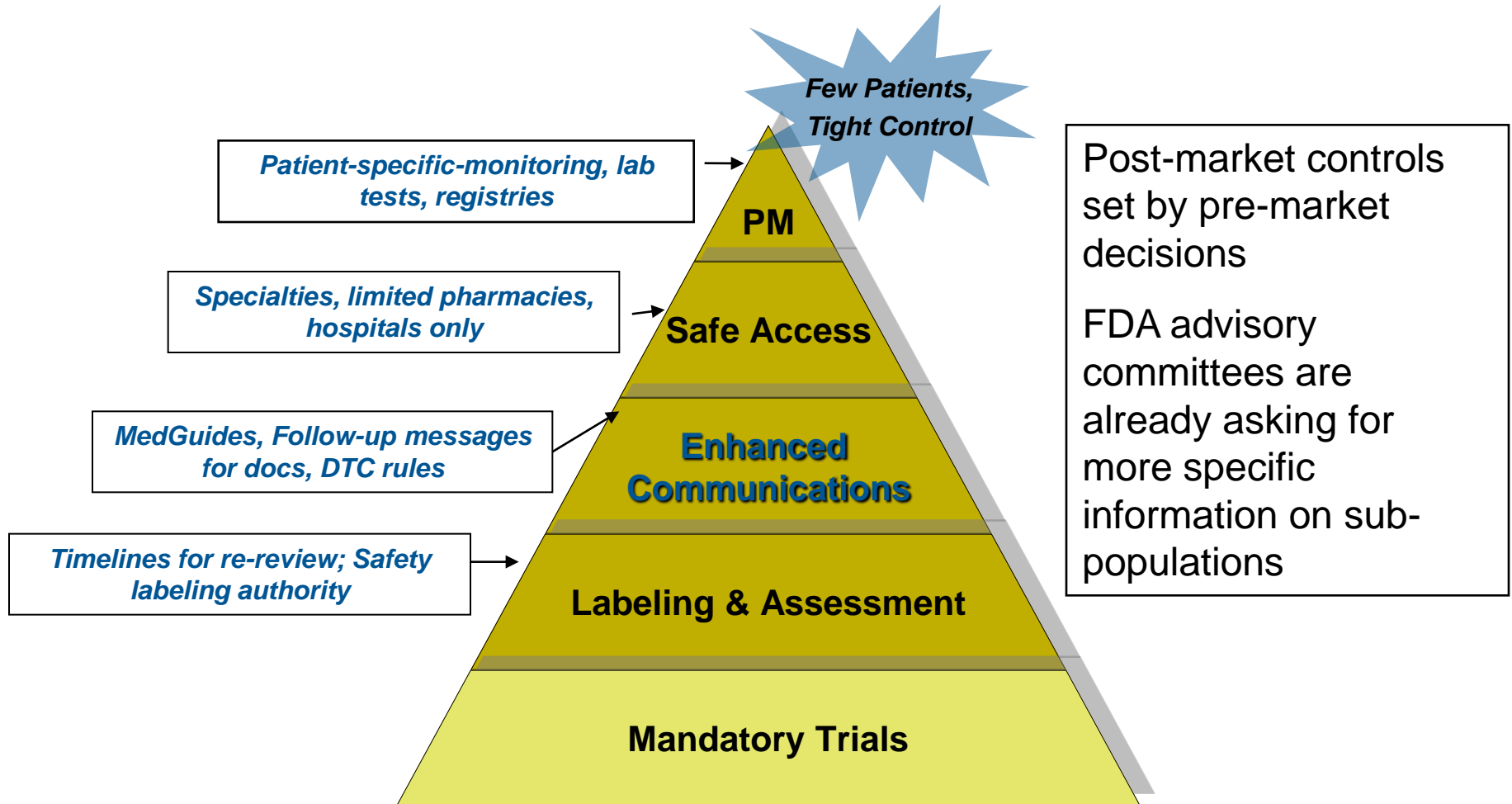
## Big Government

- ARRA Stimulus Funding
  - ARHQ \$300
    - Four times the funding for the agency in the FY 05-07
  - NIH \$400 million
    - Compared to \$120 million for ALLHAT
  - HHS Secretary \$400 million
- Land-rush to get in:
  - VA makes pitch:
    - “Largest research program embedded in an integrated health care system in the U.S., and possibly the world....”
    - “VA Research benefits from an unmatched electronic record....”
    - Running ALLHAT follow

## Big Business

- Ingenix (UnitedHealth)
  - \$1.8 billion dollar business
    - Up 26% in most recent quarter
    - UnitedHealth’s highest margin business, 13.3% operating profit
    - More than 50 companies purchased in past 10 years – including Lewin Group
  - UHC “provides Ingenix and i3 access to *one of the world’s largest patient databases*....”
- United Biosource
  - \$125 million investment Oct. 8 for: 20% of six-year-old company
  - “Continuous stream of evidence of product safety, economic value and medical effectiveness in the peri- and post-approval environment.”

# CER/PM Growing in Shadow of FDA/REMS



# Tried and True Marketing Tools

## Goals of Dissemination

- IOM recommends more effective use of communication and marketing principles
- Baucus-Conrad: “disseminate the findings of research to clinicians, patients, and the public in a comprehensible manner and form”

## FDA Precedents

- A speaker’s bureau for *Xenazine* to include local and national thought leaders.
- A slide deck for MSLS for *Cimzia*
- Registry of prescribing doctors and signed certificates for *Sabril*
- Mandatory detailing to five specialty groups for *Effient*.

# Takeaways

- CER rules will change the way drugs and other treatments are studied and accepted by the medical community and public
- Inflow of money is already building a new database/observational infrastructure
- FDA and industry may be taking care of a significant part of the dissemination challenge through REMS programs
  
- Great opportunity – Don't Bosch It.