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

Policy Considerations: CER & Industry Structure

October 28, 2009
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

Post-market controls set by pre-market decisions

FDA advisory committees are already asking for more specific information on sub-populations

Few Patients, Tight Control

Mandatory Trials

Labeling & Assessment

Enhanced Communications

Safe Access

Specialties, limited pharmacies, hospitals only

Patient-specific-monitoring, lab tests, registries

MedGuides, Follow-up messages for docs, DTC rules

Timelines for re-review; Safety labeling authority

More Patients, Less Control

October 28. 2009
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.