

Societal Implications of Comparative Effectiveness Research & Personalized Medicine:

How Can We Keep the Debate Rational?

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- “. . . [All] improvement is change, and **human systems resist change** . . . [I]mprovement requires a source of tension, discomfort with the *status quo*, sufficient to overcome this inertia.”



Public Perceptions: A Double-Edged Sword

- Can be an Asset



- Or a Liability

 bamaCare



A Shovel Ready Project



Primary Sources of Resistance

- Those with ideological agendas, &



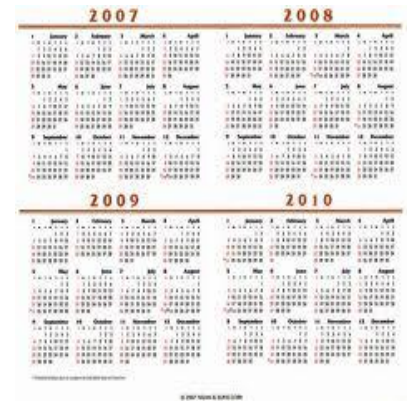
- Those fearing loss of a financial stake in the *status quo*



Keeping the Debate Rational

1. Re-frame the terminology

1. Emphasize “We’ve been doing it for years”



2. Control the agenda & the momentum



1. Re-frame the Terminology: What's in a Name?



- **Comparative Effectiveness Research**

Term itself a lightning rod for controversy?

– Too easy to confuse w cost effectiveness?

– Too easy to demonize with the R-word?

- **Patient Centered Outcomes Research**

Puts patient in the center – literally

– Undercuts allegation of one-size-fits-all, “cookbook medicine”



2. “We’ve Been Doing It for Years”

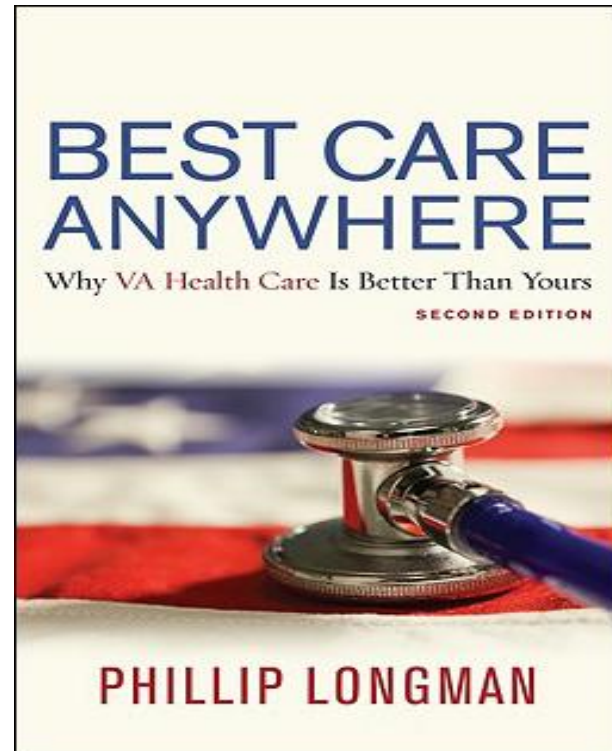
- **Clinical trials of new drugs & devices**

“Adequate and well-controlled”

- Amendment to FDCA in 1962 established “adequate and well-controlled studies” as the basis for determining efficacy of new drugs
- 21 CFR 314.126, on active control studies: “Similarity of test drug and active control can mean either that both drugs were effective **or that neither was effective.**”
- Further detailed in ICH E-9 and E-10

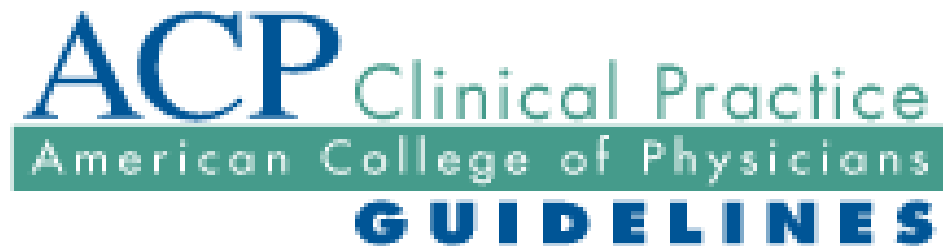
2. “We’ve Been Doing It for Years” (cont.)

- **Veterans Administration
health services**



2. “We’ve Been Doing It for Years” (cont.)

- **Practice Guidelines**



3. Control the Agenda & the Momentum

- **Take proactive stance re getting value for money**
 - Show “what works” (& what doesn’t)
 - Demonstrate cost saving potential
- **Emphasize: patient-centered medicine + effectiveness data = better care for individuals**

