



How Will CER Influence Innovation and Industry Business Practices?

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FDA Has Concerns About Innovation

THE WALL STREET JOURNAL.

“The number of new products in the development pipeline is not where we’d like it to be. Timelines are long, costs are high and rates of failure are distressingly high.” ...Federal regulators need to be “a gateway not a barrier” [Hamburg, FDA]”

FDA’s Proposed Solutions:

- Fellowships to young entrepreneurs in business school
- Cultivate liaisons with successful entrepreneurs to advise improvements
- New emphasis on personalized medicine needing updated approval strategy
- New deputy FDA commissioner to oversee regulatory process
- Expedited drug development pathway for threatening conditions without adequate current treatment

“FDA Tries To Mend Fences With Med-Tech Start-Ups, Investors” T. Hay, WSJ, October 5, 2011



CER Creates Incentives



Does Comparative-Effectiveness Research Threaten Personalized Medicine?

Alan M. Garber, M.D., Ph.D., and Sean R. Tunis, M.D

As CER guides individual patient care, it will also guide and promote innovation. In some cases, federal support of the research will reduce the development costs of new medical technologies. Emerging CER methods promise to be more rapid, relevant, and efficient

CER Decreases Incentives

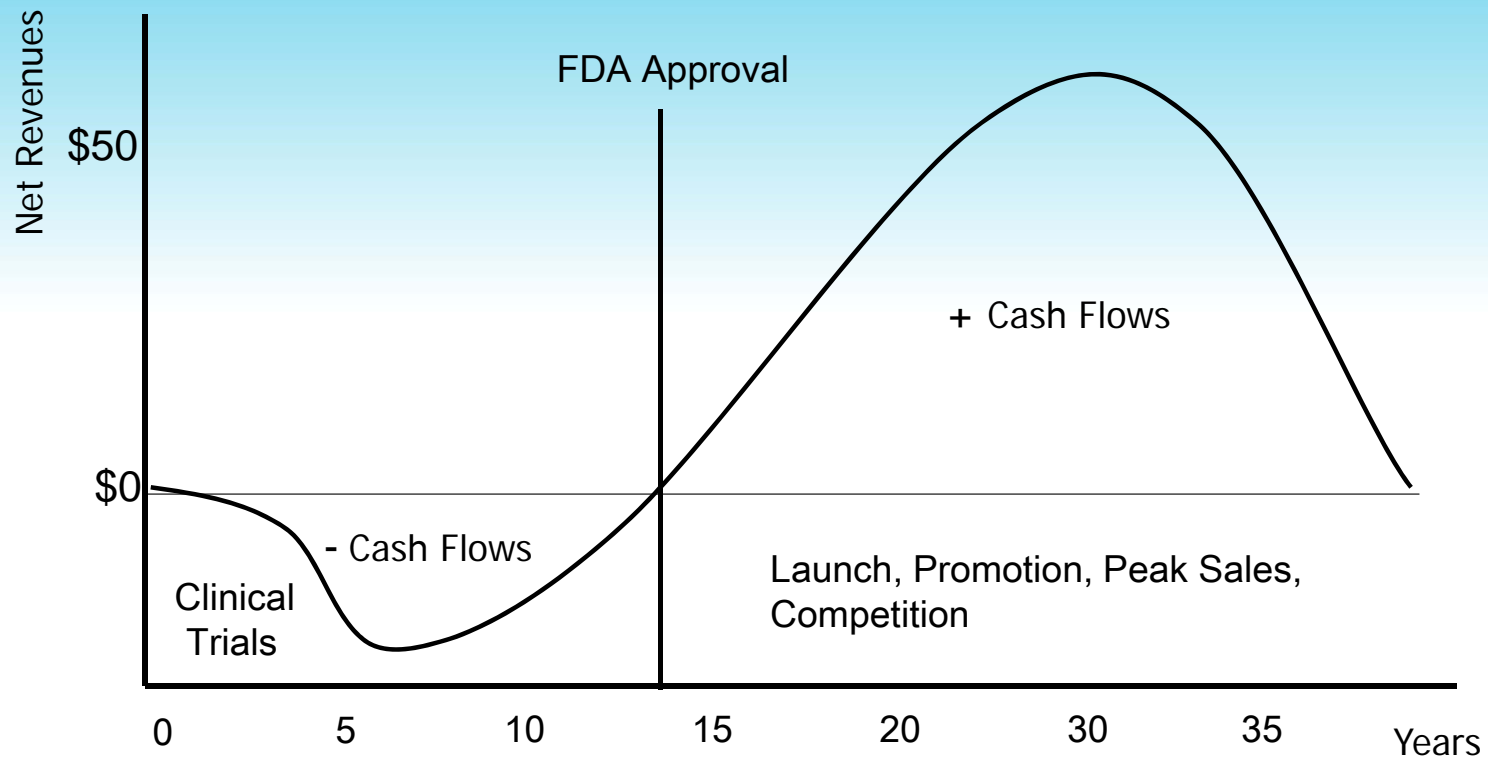
“The Pink Sheet”

CER Could Lead to \$10 Billion Per Year Drop in R&G – Think Tank Analysis

August 08, 2011

Investments in drug and medical device research and development will decrease as comparative effectiveness research conducted under the Patient-Centered Outcomes

Hypothetical Life-Cycle Cash Flow



CER Will Impact the Cost of Innovation

COSTS



- Long-term endpoints
- Active comparators
- Multiple subgroups

REVENUES



- Broader outcomes
- Personalized medicine supports higher pricing
- Increased adoption of new evidence

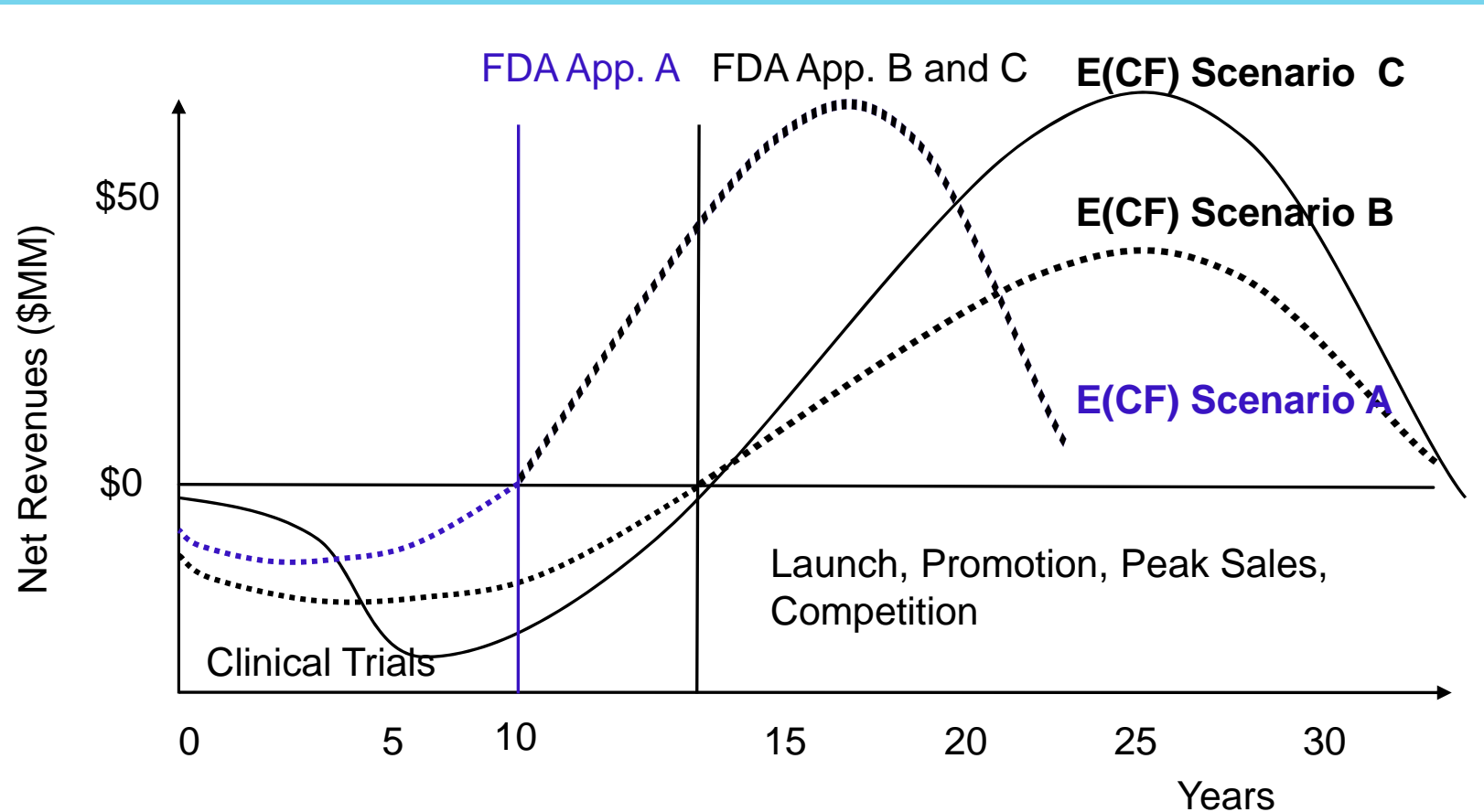


- New trial designs accepted
- Personalized medicine results in smaller studies



- Personalized medicine market size
- Payers require CER
- CED

Cash Flows Greatly Differ Based Upon the CER Scenario



A CER and Innovation Case Study

TNF- Inhibitor

Original approval based upon
ACR20 scores at 24 weeks

Request for joint progression
based upon long-term data



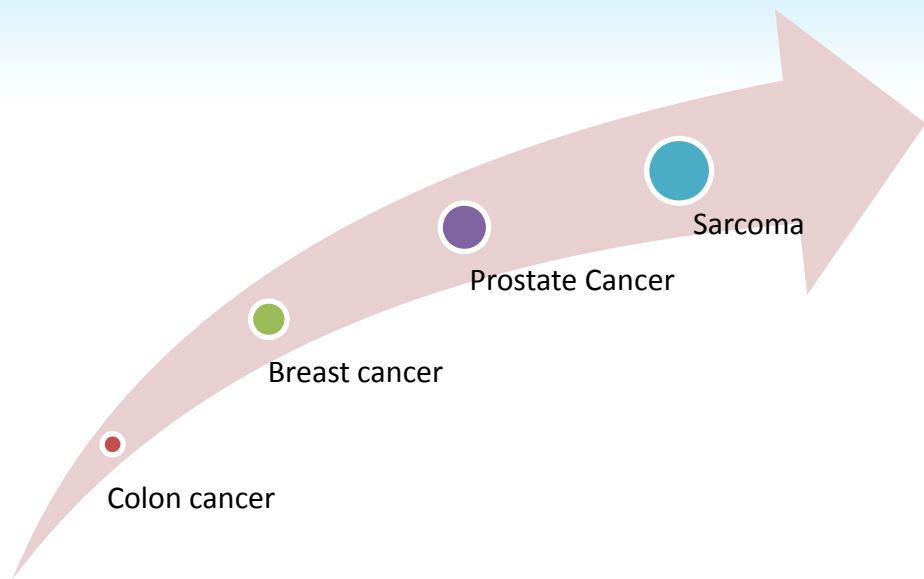
Possible CER Effects on Key Innovation Factors

	TNF Joint Progression
Revenue Factors	
Market Size	↓
Price	↑
Effective Patent Life	↓
Competition and Barriers to Entry	↔
Regulatory Stringency	↔
Cost of Development Factors	
Clinical-Drug Development Times	↑↑↑
Clinical Trial Size and Length	↑↑
Number and Complexity of Trials	↔
Probabilities of Technical Success by Stage	↓
Probability of FDA Approval/Priority Review	?
Supply Cost of R&D Capital	?
Net Impact on R&D Investment	?

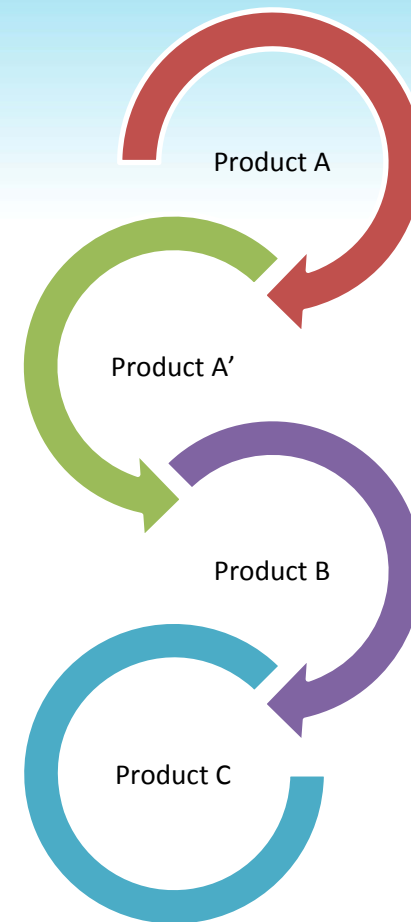


CER and Innovation: Two Elements Frequently Forgotten

Subsequent Indications



Incentives for Developing Future Products



Questions to Ponder

- Wearing your Pfizer or J&J hat, how has (or how will) CER effect the development and commercialization of new products?
- Removing your commercial hat, what should PCORI do to strengthen the incentives for innovation and minimize adverse consequences of CER?
- What should regulators, public payers, and private managed care plans do (if anything) in response to the above?

