How Will CER Influence Innovation and Industry Business Practices?

Robert Dubois, MD, PhD, NPC
Freda C. Lewis-Hall, MD, FAPA, Pfizer
Harlan Weisman, MD, Johnson & Johnson
FDA Has Concerns About Innovation

“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

CER Decreases 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 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

Garber AM, Tunis SR. NEJM 2009; 360;19; Peterson NEJM 2009; Murray Arch Intern Medicine 2010; The Pink Sheet, August 8, 2011
Hypothetical Life-Cycle Cash Flow

- Clinical Trials
- FDA Approval
- Launch, Promotion, Peak Sales, Competition

Net Revenues:
- $0
- $50

Cash Flows:
- - Cash Flows
- + Cash Flows
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

![Graph showing cash flows over years for different scenarios.](image-url)
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

<table>
<thead>
<tr>
<th>Revenue Factors</th>
<th>TNF Joint Progression</th>
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<tbody>
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<td>Market Size</td>
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<tr>
<td>Price</td>
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<tr>
<td>Effective Patent Life</td>
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<tr>
<td>Competition and Barriers to Entry</td>
<td>↔</td>
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<tr>
<td>Regulatory Stringency</td>
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<table>
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<tr>
<th>Cost of Development Factors</th>
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<tr>
<td>Clinical-Drug Development Times</td>
<td>↑↑↑↑</td>
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<tr>
<td>Clinical Trial Size and Length</td>
<td>↑↑</td>
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<tr>
<td>Number and Complexity of Trials</td>
<td>↔</td>
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<tr>
<td>Probabilities of Technical Success by Stage</td>
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<tr>
<td>Probability of FDA Approval/Priority Review</td>
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<td>Supply Cost of R&amp;D Capital</td>
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<tr>
<td>Net Impact on R&amp;D Investment</td>
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CER and Innovation: Two Elements Frequently Forgotten

Subsequent Indications
- Colon cancer
- Breast cancer
- Prostate Cancer
- Sarcoma

Incentives for Developing Future Products
- Product A
- Product A'
- Product B
- Product C

Incentives for Developing Future Products

Colon cancer
Breast cancer
Prostate Cancer
Sarcoma
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?