NCI Director’s Update

Dr. John E. Niederhuber
Director, National Cancer Institute

National Cancer Advisory Board
June 14, 2007
NCI Director’s Update

• Status report on FY07 actuals
• FY2008 Labor/HHS bill
• NCI Community Cancer Centers Program pilot
• Some personal thoughts
NCI’s Congressional Appropriations

<table>
<thead>
<tr>
<th>Year</th>
<th>Dollars in billions</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY98</td>
<td>$2.5</td>
</tr>
<tr>
<td>FY99</td>
<td>$2.9</td>
</tr>
<tr>
<td>FY00</td>
<td>$3.3</td>
</tr>
<tr>
<td>FY01</td>
<td>$3.8</td>
</tr>
<tr>
<td>FY02</td>
<td>$4.2</td>
</tr>
<tr>
<td>FY03</td>
<td>$4.6</td>
</tr>
<tr>
<td>FY04</td>
<td>$4.8</td>
</tr>
<tr>
<td>FY05</td>
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<tr>
<td>FY06</td>
<td>$4.8</td>
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<tr>
<td>FY07</td>
<td>$4.8</td>
</tr>
<tr>
<td>FY08</td>
<td>$4.8</td>
</tr>
</tbody>
</table>

Note: PB indicates a projected budget of $4.8 billion.
FY 2007 Operating Budget Development

• Inflation is ~3% to 4% (BRDPI)
• Develop reallocation pool = ~$60M
• JR effective Feb. 15
Revised Continuing Appropriations Resolution, 2007

• Type 5s (noncompeting) reduced by 2.9%

• NIH–wide target of 1,500 awards to new investigators
  
  — (FY05 = 1,458; FY06 = 1,363)

• ICs required to use half of the money they retain from Roadmap to fund additional competing RPGs

  — NIH to fund 500 more RPGs (average cost $324K)
New Cancer Centers

Dan L. Duncan Cancer Center, Baylor College of Medicine, Houston

Irving Weissman, M.D. Director

Stanford Comprehensive Cancer Center, Stanford, Calif.

C. Kent Osborne, M.D. Director
2007 – Final Quarter

- JR not finalized until Feb. 15th
- End-of-year R01 payline: ~13th percentile (est.)
- End-of year *RO1 payline: ~19th percentile (est.)

<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007 (est.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total RPG</td>
<td>5,070</td>
<td>5,147</td>
<td>5,172</td>
<td>5,175</td>
</tr>
<tr>
<td>Competing</td>
<td>1,492</td>
<td>1,292</td>
<td>1,280</td>
<td>1,314</td>
</tr>
<tr>
<td>New Invest.</td>
<td>208</td>
<td>235</td>
<td>184</td>
<td>205</td>
</tr>
</tbody>
</table>
2007 – Final Quarter

• ~20% competing pool reserved for exceptions
• Type 5s targeted at 2.9% below commitment of record, per NIH policy
• SPOREs were about 3% below FY2006
• Centers were increased 2% from FY2006
• Coop. Groups flat with FY2006
• Training 2.6% below the FY2006 level
FY 2008 President’s Budget

• NIH PB request is $28.849 billion: $232 million (0.8%) over the FY 2007 Annualized CR

• NCI PB is $4.782 billion: 0.2% lower (-$9 million) than the FY 2007 Annualized CR
FY2008 Labor/HHS Appropriations Bill

• House subcommittee mark up June 7

• Would appropriate $29.650 billion to NIH
  – $750M (2.6%) over JR07
  – $1.029 billion (3.6%) over the FY08 PB

• Provides $4.870 billion to NCI
  – $73M (1.5%) over JR07 (+$63.2M Roadmap)
  – $88M (1.8%) over FY08 PB (+$63.2M RM)
Increase to NIH is an investment to:

• “Increase the number of new and competing research grants by approximately 545 over last year” (~10,645)

• “Lift a two-year freeze on the average cost of new research grants”

• “Help train the next generation of researchers”

• “Provide $110.9 million for the National Children's Study and $300 million for the global AIDS fund”

FY2008 Labor/HHS Appropriations Bill (cont’d)

• House would continue to fund the Common Fund from the NIH OD, rather than from the ICs
• Bill provides $495 million for the Common Fund
  – ↑$12 million (2.5%) over FY 07
NCI FY 2008 Operating Budget Development

<table>
<thead>
<tr>
<th>FY 2007 Appropriation</th>
<th>$4,797,639</th>
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</thead>
<tbody>
<tr>
<td>FY 2008 House Subcommittee Mark</td>
<td>$4,870,382</td>
</tr>
<tr>
<td>Difference ’07 to ’08</td>
<td>$72,743</td>
</tr>
<tr>
<td>Percent Change ’06 to ’07</td>
<td>1.5%</td>
</tr>
</tbody>
</table>

(dollars in thousands)
## FY 2008 Operating Budget Development

<table>
<thead>
<tr>
<th></th>
<th>Amount (in thousands)</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtotal Available</td>
<td>$72,743</td>
<td>1.5%</td>
</tr>
<tr>
<td>Less:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Potential NIH Director’s 1% Transfer</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>• Potential DHHS Secretary’s Transfer</td>
<td>?</td>
<td></td>
</tr>
<tr>
<td>Subtotal Available</td>
<td>72,743</td>
<td>1.5%</td>
</tr>
<tr>
<td>NIH Taps/Assessments Increase</td>
<td>-20,000</td>
<td></td>
</tr>
<tr>
<td>Subtotal Available</td>
<td>$52,743</td>
<td>1.1%</td>
</tr>
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</table>
## FY 2008 Operating Budget Development

<table>
<thead>
<tr>
<th>Amount (in thousands)</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subtotal Available</strong></td>
<td>$52,743</td>
</tr>
<tr>
<td>NCI-wide Requirements:</td>
<td></td>
</tr>
<tr>
<td>• Competing RPG Increase (est.)</td>
<td>- 38,000</td>
</tr>
<tr>
<td>• Rent/Lease/Utilities Increase</td>
<td>- 10,900</td>
</tr>
<tr>
<td>• Small Business Program Increase</td>
<td>- 2,000</td>
</tr>
<tr>
<td>• Mandated Salary Increases</td>
<td>- 15,500</td>
</tr>
<tr>
<td><strong>Subtotal Available</strong></td>
<td>-13,657</td>
</tr>
<tr>
<td>NCI Director’s Reserve</td>
<td>- 25,000</td>
</tr>
<tr>
<td><strong>Subtotal Available</strong></td>
<td>- $38,657</td>
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## FY 2008 Operating Budget Development

<table>
<thead>
<tr>
<th>Subtotal Available</th>
<th>Amount (in thousands)</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- $38,657</td>
<td>- 0.8%</td>
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</tbody>
</table>

### Potential Recoveries/Redeployments:
- Phaseouts/Reductions to ongoing programs
- Noncompeting RPGs

### Available for New Initiatives/Expansions/Restorations

Goal is to generate ~$60 million for reallocation to highest-priority items.
Summary

• NCI budget will continue to be less than inflation
• Attempting to find and fund best science and best scientists
• Need to manage expectations
• Need to continue scientific growth and maintain balance
• Need to leverage additional resources
NCI Community Cancer Centers Program Pilot Sites
NCI Community Cancer Centers Program

Pilot Goal: Sponsor multiple pilot sites for three years to identify critical factors that define a state-of-the-art community cancer center that will be incorporated into a future program.
Cancer care continuum

Potential for improvement at transitions ( )
or during types of care delivery ( )
NCCCP quality of care is affected by multiple levels of influence.
Research Focus Areas and Development of Best Practices

• Clinical Research
  – Increase trial accrual/minority accrual; can we do early phase trials?
  – Participation in Research Networks

• Disparities
  – Decrease healthcare disparities
  – Increase community outreach
  – Increase Patient Navigation
Research Focus Areas and Development of Best Practices

• **Quality of Care**
  – Use of evidence-based guidelines
  – Multidisciplinary care

• **Survivorship**
  – Survivorship plans
  – Palliative care
  – Hospice
Research Focus Areas and Development of Best Practices

- **Biospecimen initiatives**
  - NCI Best Practices for Biospecimens
  - IT related to biospecimens
  - Privacy/data sharing issues
  - Biospecimen Network exploration

- **Information Technology**
  - caBIG™ implementation assessment
  - Privacy/data sharing issues
Research Focus Areas and Development of Best Practices

• **Overall Program**
  - Appropriate program components
  - Cancer Medical Staff credentialing
  - Academic linkages
  - Institutional Commitment
  - Knowledge exchange among sites
  - Federal and state program linkages
Evaluation Plan

- **Independent evaluation contractor throughout the pilot program duration**
- **Quantitative and qualitative metrics across components through the 3 years**
- **Evaluate the implementation, operations and performance of NCCCP pilot sites**
  - Process assessment
  - Impact assessment
NCI Community Cancer Centers Program Pilot Sites

- Billings Clinic, Billings, Montana
- Hartford Hospital, Hartford, Connecticut
- St. Joseph’s/Candler, Savannah, Georgia
- Our Lady of the Lake Regional Medical Center, Baton Rouge, Louisiana
- Sanford University of South Dakota Medical Center, Sioux Falls, South Dakota
- Spartanburg Regional Hospital, Spartanburg, South Carolina
- St. Joseph Hospital, Orange, California
NCI Community Cancer Centers
Program Pilot Sites (cont’d)

• Christiana Hospital, Newark, Delaware

• Ascension Health of St. Louis will operate:
  – St. Vincent Indianapolis Hospital, Indianapolis, Indiana
  – Columbia St. Mary’s, Milwaukee, Wisconsin
  – Brackenridge Hospital, Austin, Texas

• Catholic Health Initiatives of Denver will operate:
  – Penrose-St. Francis Health Services, Colorado Springs, Colorado
  – St. Joseph Medical Center, Towson, Maryland
  – A coordinated site of three hospitals in Kearney, Lincoln, and Grand Island, Nebraska
NCI Community Cancer Centers Program Pilot Sites
Three Years from Now…

Through research, we will have determined the best methods to enable the provision of state-of-the-art, multispecialty care and early-phase clinical trials in community-based locations to meet the needs of the people.
Growth and survival factors

Cytokines and chemotactic factors

Proteases

ECM

Growth and survival factors

BLOOD VESSEL

Cancer is a disease of staggering complexity...

Integrated Cancer Biology Program
Centers for Systems Biology (NIGMS)
Centers for Nanobiology
Cancer genome project; whole genome scanning
Centers for proteomics
Network centric biomedicine

- Sub-cellular imaging
- protein
- capture
- physics
- energy
- gradients
- dimension of time
- technology development
- reciprocal signaling
– The discovery process is too long and too costly
– No longer test one drug at a time
– Regimens rather than single agents
A Continuum of Science

NCI is an honest broker between government, academia, and the private sector
Evaluation Oversight Committee

• Mary Fennell, PhD (Chair), Brown Univ.: applications of organizational theory to healthcare organizations; extensive community-based cancer program evaluation experience

• Steven Clauser, PhD, NCI: healthcare outcomes research and applied research

• Thomas Gribbin, MD, Medical Director Lacks Cancer Center of St. Mary’s Healthcare-Grand Rapids, Mich.: models of cancer care; survivorship issues

• Mark Hornbrook, PhD, Kaiser Permanente Center for Health Research: healthcare cost and utilization analysis; economic evaluation methods, patient classification methods, health status measurement, predictive modeling, and health-based payment systems
Evaluation Oversight Committee

- **Timothy Johnson, PhD**, U. Ill, Chicago: survey methodology and health behaviors in disadvantaged populations
- **Maureen Johnson, PhD**, NCI NCCCP Project Officer
- **Bryan Weiner, PhD**, UNC Chapel Hill; the adoption, implementation and sustainability of innovations in healthcare organizations; conducted CCOPs evaluation
- **Jane Zapka, ScD**, U. South Carolina; qualitative and quantitative research, program evaluation, quality improvement, managed care, and other health services research, including the continuum of cancer care
- **Joy Beveridge, MS**, Ad Hoc Member, SAIC Project Manager
Evaluation Oversight Committee

Consultants to Committee

• **Arnie Kaluzny, PhD, UNC Chapel Hill; organizational factors affecting program implementation and change in a variety of health care organizations, with specific emphasis given to cancer treatment, prevention and control; continuous quality improvement initiatives in both organizational and primary care settings; and the study of alliances within health care**

• **Donna O’Brien, MHA, Healthcare Consultant: Expertise in the design, formation, and management of health systems, networks, and partnerships. NCI-designated Cancer Center management experience**
2006 – Final Quarter

- Mid-year increase in taps for utility costs of almost $4 million
- End-of-year R01 payline: 12th percentile; *RO1 payline: 18th percentile
- 15% of competing pool reserved for exceptions
- Type 5s generally 2.35% below commitment of record
- SPOREs were about 6.1% below FY2005
- Centers were increased 3.9% from FY05
- Training 1% above the FY05 level
Summary: NCI Myths and Facts

- **1,280 competing RPGs** in 2006 (↓ from 1,492 in 2004)
- **5,172 total RPGs** in 2006 (↑ from 5,070 in 2004)
- **$324,000 average $ per competing grant** in 2006 (↓ from $346,000 in 2003)
- **7% of the competing pool** went to RFAs in 2006 (↓ from 9% in 2004)
- **5,679 individual investigators supported** in 2006 (↑ from 5,636 in 2004)
- **$42.8M to Roadmap** in 2006 (↑ from $16.2M in 2004)
- **$60M in flexible dollars** (↓ from $108M in 2005)
Baseline pilot program components

• Community cancer center
• Clinical trials experience
• Disparities & community outreach
• Hospice and palliative care
• Information technology
• Biospecimen initiatives
Quality of Care Relates to Several Other NCCCP Components
Evaluation Plan

• Independent evaluation contractor throughout the pilot program duration
• Quantitative and qualitative metrics across components through the 3 years
• Evaluate the implementation, operations and performance of NCCCP pilot sites
• Process Assessment
  – Implementation experience of the pilot sites
  – Assess feasibility, best practices, relationships to NCI-designated Cancer Centers and other Federal, state and community resources
  – Replicability potential of the NCCCP model components
    – Role of hospital executive level support/institutional commitment
    – Role of the medical staff to determine which factors support an effective NCCCP Program
    – Implementation of effective models to address healthcare disparities
    – Assessment of operational costs necessary to support an effective NCCCP program
• Impact Assessment
  – Enhancing delivery of evidence-based cancer screening and therapies through multidisciplinary care
  – Improve physician participation and accrual rates in clinical trials, especially among minority individuals
FY 2007 Operating Budget Development
Cancer Centers Program

T-2s on a sliding scale FY 2007

• Outstanding to low Excellent Peer Review Scores will receive some increase over current level

• Mid Excellent Peer Review Scores will be funded at current funding level

• High Excellent Peer Review Scores will receive a percentage below their current funding level

• Peer Review Scores 200 and above receive more significant decreases and a shorter award period
Measuring whether we can deliver care in the community setting—or what needs to be changed.
<table>
<thead>
<tr>
<th>Description</th>
<th>Amount (in thousands)</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2006 Obligations P30 (excludes Minority)</td>
<td>$254,518</td>
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<tr>
<td>Program Reduction Exercise (↓10%)</td>
<td>-22,000</td>
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<tr>
<td>EC Approved Restoration</td>
<td>26,081</td>
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<tr>
<td><strong>Subtotal Available</strong></td>
<td><strong>258,599</strong></td>
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<tr>
<td>Noncompeting @ 2.9% reduction from Commitment of Record</td>
<td>-178,020</td>
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<tr>
<td><strong>Subtotal Available</strong></td>
<td><strong>80,579</strong></td>
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<tr>
<td>Recycled Extensions with 2.9% Reduction</td>
<td>-28,233</td>
</tr>
<tr>
<td>Planning Grants – most in final year in FY 2007</td>
<td>-3,503</td>
</tr>
<tr>
<td><strong>Subtotal Available</strong></td>
<td><strong>48,843</strong></td>
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## FY 2007 Operating Budget Development

### Cancer Centers Program

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<tr>
<th>Amount (in thousands)</th>
</tr>
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<tbody>
<tr>
<td><strong>Subtotal Available</strong></td>
</tr>
<tr>
<td>AVON</td>
</tr>
<tr>
<td>Other Supplements</td>
</tr>
<tr>
<td><strong>Subtotal Available</strong></td>
</tr>
<tr>
<td>Two New Centers @ $1.5 each</td>
</tr>
<tr>
<td><strong>Subtotal Available</strong></td>
</tr>
<tr>
<td>Keep FY 2006 One-Shots in Place (requires supplements)</td>
</tr>
<tr>
<td>T2s on Sliding Scale</td>
</tr>
<tr>
<td><strong>Subtotal Available</strong></td>
</tr>
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## FY 2007 SPORE Budget

<table>
<thead>
<tr>
<th>Description</th>
<th>No.</th>
<th>Amount in thousands</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-competing grants w/ 2.9% reduction</td>
<td>40</td>
<td>$83,848</td>
</tr>
<tr>
<td>Competing grants</td>
<td>11</td>
<td>24,304</td>
</tr>
<tr>
<td>Extensions partially funded (A1, A2)</td>
<td>10</td>
<td>8,937</td>
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<tr>
<td>AVON Supplements</td>
<td></td>
<td>403</td>
</tr>
<tr>
<td>Admin. Supplements (Clinical Trials)</td>
<td></td>
<td>2,217</td>
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<tr>
<td>Minority Branch Supplements</td>
<td></td>
<td>1,000</td>
</tr>
<tr>
<td><strong>Total FY 2007 SPORE Budget</strong></td>
<td>61</td>
<td><strong>$120,709</strong></td>
</tr>
</tbody>
</table>

FY 2006 obligations (including Minority Branch) = $125,019 (↓ 0.4%)