Director’s Update

Dr. John E. Niederhuber
Director, National Cancer Institute

National Cancer Advisory Board
6, 2007
Director’s Update

• Budget Update: 2007 and 2008
• President Bush’s Visit to NIH
• NIH Reform Act of 2006
• Reorganization of the NCI Office of the Director
• Clinical Trials Advisory Committee
<table>
<thead>
<tr>
<th>FY 2006 obligations</th>
<th>$4,790,059</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2007 President’s Budget</td>
<td>$4,753,609</td>
</tr>
<tr>
<td>Difference ’06 to ’07</td>
<td>- $36,450</td>
</tr>
<tr>
<td>Percent Change ’06 to’07</td>
<td>- 0.8%</td>
</tr>
</tbody>
</table>

After we pay for mandated increases such as taps, utilities, Roadmap, etc., our deficit is ~$122 million (-2.6%).
FY 2007 Operating Budget Development

- NCI Executive Committee Portfolio Review
  - Identified ~$175 million of reductions and phase-outs
  - Created a pool of ~$60 million

- EC created a list of new initiatives and previously reduced existing projects to be considered for funding from pool
  - EC members independently gave each item a priority score and recommended funding level
  - Scores were collected and items ranked
  - Prioritized list discussed by EC; adjustments made
  - Additional items on list will be considered if funds become available
FY 2007 Operating Budget Development

**NIH Guidelines under a full year CR:**

- No inflationary adjustments on non-competing grants
  - approximately 3% decrease from commitments of record for all grants
- NIH to award the **same number of competing RPGs as awarded in FY 2005** (about 9,600) with particular emphasis on new investigators
- Average cost of competing RPGs same as FY 06
FY 2007 Budget

• January 31: House passed Revised Continuing Appropriations Resolution for the 2007 year
  – Bill provides $28.9 billion for NIH: an increase of $620 million over FY 2006

• February 15: Current Continuing Resolution expires
Revised Continuing Appropriations Resolution, 2007

• Sets the Common Fund (which includes the NIH Roadmap) in the NIH OD at $483 million
  — increase of about $150 million

• No specific increase to most ICs
  — ICs retain funds previously earmarked for the NIH Roadmap and funds that were transferred to CMS in FY 2006 ($267 million total)

• NIH will also receive funds to partially pay for the 2007 COLA increases for Federal salaries
Revised Continuing Appropriations Resolution, 2007

<table>
<thead>
<tr>
<th>Common Fund</th>
<th>New $</th>
<th>Transfers within NIH</th>
<th>Total adjustments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roadmap (PB 2007)</td>
<td>$361</td>
<td>$ 82</td>
<td>$443</td>
</tr>
<tr>
<td>Junior Pioneer Awards</td>
<td>40</td>
<td></td>
<td>40</td>
</tr>
<tr>
<td><strong>Total Common Fund</strong></td>
<td><strong>$401</strong></td>
<td><strong>$ 82</strong></td>
<td><strong>$483</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NIH OD Programs</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>New Investigators</td>
<td>91</td>
<td></td>
<td>91</td>
</tr>
<tr>
<td>National Children’s Study</td>
<td>58</td>
<td>11</td>
<td>69</td>
</tr>
<tr>
<td>New activities related to reauthorization bill</td>
<td>7</td>
<td></td>
<td>7</td>
</tr>
<tr>
<td><strong>Total OD</strong></td>
<td><strong>$156</strong></td>
<td><strong>$ 11</strong></td>
<td><strong>$167</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>NLM for NCBI</td>
<td>5</td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>NCMHD</td>
<td>4</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>NCRR</td>
<td>34</td>
<td></td>
<td>34</td>
</tr>
<tr>
<td>HHS Transfers</td>
<td>20</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td><strong>Total Other</strong></td>
<td><strong>$ 63</strong></td>
<td><strong>$ 93</strong></td>
<td><strong>$ 63</strong></td>
</tr>
</tbody>
</table>

| **Total**                        | **$620** | **$ 93**            | **$713**          |

*(Dollars in millions)*
Revised Continuing Appropriations Resolution, 2007

• NIH to fund 500 more RPGs

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

• ICs to use half of the money they retain from Roadmap to fund additional RPGs
Revised Continuing Appropriations Resolution, 2007

NCI Level

<table>
<thead>
<tr>
<th></th>
<th>FY 2006</th>
<th>FY 2007 Annualized CR</th>
<th>FY 2007 House</th>
</tr>
</thead>
<tbody>
<tr>
<td>NCI (w/o Roadmap)</td>
<td>$4,747,229</td>
<td>$4,750,522</td>
<td>$4,793,356 (+$46,127)</td>
</tr>
<tr>
<td>CMS transfer</td>
<td>3,293</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Roadmap</td>
<td>42,834</td>
<td>42,834</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>$4,793,356</td>
<td>$4,793,356</td>
<td>$4,793,356</td>
</tr>
</tbody>
</table>

(Dollars in thousands)
## NCI Research Project Grants

<table>
<thead>
<tr>
<th></th>
<th>FY 2006</th>
<th>FY 2007 Annualized CR</th>
<th>FY 2007 House (est.)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No.</td>
<td>Amount</td>
<td>No.</td>
</tr>
<tr>
<td>Noncompeting</td>
<td>3,892</td>
<td>$1,596,655</td>
<td>3,878</td>
</tr>
<tr>
<td>Admin. supplements</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>49,089</td>
<td></td>
<td>49,870</td>
</tr>
<tr>
<td>Competing</td>
<td>1,280</td>
<td>415,067</td>
<td>1,244</td>
</tr>
<tr>
<td>Total</td>
<td>5,172</td>
<td>$2,060,811</td>
<td>5,122</td>
</tr>
</tbody>
</table>

Assumes that NIH will continue its current grant policies of reducing noncompeting awards 3% from the commitment of record and no increase in the average cost of competing RPGs.

(Dollars in thousands)
## NCI Research Project Grants

### Competing

<table>
<thead>
<tr>
<th></th>
<th>FY 2006</th>
<th>FY 2007 Annualized CR</th>
<th>FY 2007 House (est.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average cost</td>
<td>$324</td>
<td>$324</td>
<td>$324</td>
</tr>
<tr>
<td>R01 payline (percentile)</td>
<td>12th</td>
<td>11th</td>
<td>12th</td>
</tr>
<tr>
<td>Success rate</td>
<td>19.4%</td>
<td>18.0%</td>
<td>18.9%</td>
</tr>
</tbody>
</table>

Assumes that NIH will continue its current grant policies of reducing noncompeting awards 3% from the commitment of record and no increase in the average cost of competing RPGs.

(Dollars in thousands)
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

• NIH Roadmap increases by $72 million to $486 million
Director’s Update

• Budget Update: 2007 and 2008

• President Bush’s Visit to NIH

• NIH Reform Act of 2006

• Reorganization of the NCI Office of the Director

• Clinical Trials Advisory Committee
“I love coming to the NIH; it is an amazing place. It is an amazing place because it is full of decent, caring, smart people, all aiming to save lives.”
Reversing the Curve: Cancer Deaths Decline
Reversing the Curve: Cancer Deaths Decline
Reversing the Curve: Cancer Deaths Decline
Reversing the Curve: Cancer Deaths Decline
Director’s Update

• Budget Update: 2007 and 2008
• President Bush’s Visit to NIH
• NIH Reform Act of 2006
• Reorganization of the NCI Office of the Director
• Clinical Trials Advisory Committee
NIH Reform Act of 2006

• Third omnibus reauthorization in NIH history (first in 14 years)
  – Signed by the President
    January 15, 2007

• Key provisions
  – Divisions of Program Coordination
  – Common Fund
  – Council of Councils
  – Scientific Management Review Board
  – Authorization of appropriations
  – Reorganization
  – Reporting
Office of Portfolio Analysis and Strategic Initiatives (OPASI)

• Alan M. Krensky, M.D., NIH Deputy Director for the Office of Portfolio Analysis and Strategic Initiatives (OPASI)
  – M.D., University of Pennsylvania, 1977
  – Served at the Stanford University School of Medicine as:
    • Professor of pediatrics
    • Chief of the Division of Immunology and Transplantation Biology
    • Assoc. Chair for Research in the Department of Pediatrics
    • Assoc. Dean for Children’s Health
NIH Reform Act of 2006: Implementation

• Ad Hoc Working Group of the NIH Steering Committee
  – Chaired by NIH Deputy Director Dr. Raynard Kington
  – Conduct detailed analysis and propose plans for its implementation
  – Comprised of IC Directors and NIH OD leadership in legislation, policy, management, communications, extramural and intramural activities, budget, and the Office of the General Counsel
NIH Reform Act of 2006: Implementation Groups

- **Jeremy Berg**: Organization of Division of Program Coordination, Planning and Strategic Initiatives (DPCPSI); trans-NIH coordination/planning
- **Richard Hodes**: Coding
- **Betsy Nabel**: Establishment of Scientific Management Review Board (SMRB); reorganizations; registration fees
- **John Niederhuber**: Reporting
- **Francis Collins**: Foundation of the NIH
- **Tony Fauci**: Peer review; demonstration programs; research training authority
- **Steve Katz**: Director’s Discretionary Fund; 1% transfer; Clinical and Translational Science Awards (CTSA)
Director’s Update

• Budget Update: 2007 and 2008
• President Bush’s Visit to NIH
• NIH Reform Act of 2006
• Reorganization of the NCI
  Office of the Director
• Clinical Trials Advisory Committee
Director’s Update

• Budget Update: 2007 and 2008
• President Bush’s Visit to NIH
• NIH Reform Act of 2006
• Reorganization of the NCI Office of the Director

• Clinical Trials Advisory Committee
NCI Federal Advisory Groups
Clinical Trials Advisory Committee

- Established in response to the Clinical Trials Working Group (CTWG) recommendations that an extramural oversight committee be formed to advise the NCI Director on clinical trials

- Chaired by NCI Director

- Members appointed by NCI Director
  - 10 members hold concurrent membership on NCAB, BSA, BSC, or DCLG
  - 14 members represent the broad clinical trials community
U.S. Clinical Trials Treatment Sites
(# of Sites by State that Currently have Patients Enrolled on an Open Trials)

Total Sites = 1,878
2004 Data
Clinical Trials Infrastructure

- NCI’s Clinical Trials Cooperative Group Program (the “Groups”) is distinctive among NIH-supported clinical trials programs:
  - A clinical trials infrastructure that is continuously available to test new therapeutic strategies
  - Consists of researchers at institutions affiliated with the Groups who jointly develop and conduct trials in multi-institutional settings across state boundaries
  - Flexible research agenda allows change of strategy in response to changing scientific opportunities and new discoveries
A Continuum of Science

Work in submolecular space
Trans-NCI Programs

Clinical Imaging Program

- Research and service components
- Molecular/functional imaging, profiling & therapy
- Integrates 3-D high-resolution electron microscopy
- Industry partnership for technology development
- Imaging incorporated into the majority of clinical trials at NCI
Simian immunodeficiency virus in 3D

Sougrat, Bartesaghi, Bennett, Subramaniam (2007)
New technologies for imaging cancer cells

Interior of MNT-1 melanoma cell at 30 nm resolution

Sriram Subramaniam, CCR NCI/NIH
Stereo view of interior of MNT-1 melanoma cell