Why What We Are Doing is So Important

Human and Economic Burden of Cancer

1,444,920 Americans were diagnosed with cancer in 2007
559,650 died of cancer in 2007
$206.3 billion spent on healthcare costs for cancer in 2006
47 million Americans lack health insurance

Estimated # of New U.S. Cancer Cases

1998: 1,228,600
2002: 1,284,900
2007: 1,444,920
Reversing the Curve: Cancer Deaths Decline
U.S. Death Trends: Cancer of All Sites, 1975-2004

- 1993-2003: overall decline -1.1%
  - 2002-2004: -2.1% per year
- 1993-2002, decline for men -1.6% per year
  - 2002-2004: -2.6% per year
- 1992-2002, decline for women -0.8% per year
  - 2002-2004: -1.8% per year
- Incidence rate for female breast cancer dropped 3.4% per year from 2001 through 2004

Rates are age-adjusted to the 2000 U.S. standard million population.
Sources: Incidence data – NCI SEER Program; Mortality data – CDC NCHS NVSS
Estimated Number of Cancer Survivors in the United States

11,941,043 survivors in 2007
NCI’s Challenge

Adjusted by BRDPI*

-12% loss in purchasing power since 2004

* BRDPI: Biomedical Research and Development Price Index

(http://officeofbudget.od.nih.gov)
Director’s Update

• NCI FY08 budget
• President’s budget FY09
• Some thoughts about the future
### NCI FY 2008 Operating Budget Development

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2007 operating budget</td>
<td>$4,797,639</td>
</tr>
<tr>
<td>FY 2008 appropriation</td>
<td>$4,805,088</td>
</tr>
<tr>
<td>Difference ’07 to ’08</td>
<td>$7,449</td>
</tr>
<tr>
<td>Percent Change ’07 to ’08</td>
<td>+0.16%</td>
</tr>
</tbody>
</table>

(dollars in thousands)
NCI FY 2008 Operating Budget Development

<table>
<thead>
<tr>
<th>Description</th>
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<tbody>
<tr>
<td>Subtotal Available</td>
<td>$7,449</td>
<td>0.16%</td>
</tr>
<tr>
<td>Less Est. NIH Taps/Assessments</td>
<td>-20,000</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>
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</tr>
<tr>
<td>Subtotal Available</td>
<td>-12,551</td>
<td>-0.26%</td>
</tr>
</tbody>
</table>
## NCI FY 2008 Operating Budget Development

<table>
<thead>
<tr>
<th>NCI-wide Requirements</th>
<th>Amount (in thousands)</th>
<th>Percent change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subtotal Available</td>
<td>-12,551</td>
<td>-0.26%</td>
</tr>
<tr>
<td>NCI-wide Requirements:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Mandated Salary Increases</td>
<td>-21,500</td>
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<tr>
<td>• Rent/Lease/Utilities/Renovations Incr</td>
<td>-10,000</td>
<td></td>
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<tr>
<td>• Small Business Program Increase</td>
<td>0</td>
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<tr>
<td>NCI Director’s Reserve</td>
<td>-25,000</td>
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</tr>
<tr>
<td>Subtotal Available</td>
<td>-69,051</td>
<td>-1.44%</td>
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</tbody>
</table>
## NCI FY 2008 Operating Budget Development

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<tr>
<th></th>
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<tbody>
<tr>
<td><strong>Subtotal Available</strong></td>
<td>- $69,051</td>
<td>- 1.44%</td>
</tr>
<tr>
<td><strong>Partial Restoration of Cuts</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Centers</td>
<td>- 7,855</td>
<td></td>
</tr>
<tr>
<td>• SPORES</td>
<td>-3,588</td>
<td></td>
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<tr>
<td>• Coop Groups/CCOPs</td>
<td>-8,504</td>
<td></td>
</tr>
<tr>
<td>• Infrastructure Restorations/Increases</td>
<td>-6,000</td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal Available</strong></td>
<td>-94,998</td>
<td>- 1.98%</td>
</tr>
</tbody>
</table>
NCI FY 2008 Operating Budget Development Process

• NCI leaders evaluated programs with an eye toward reduced or flat budgets ahead
  - FY08 operating budget target for each Division, Office and Center (DOC) is based on a 3% reduction

• Created a pool of funds for NCI-wide mandatory increases and reallocation for specific initiatives
# NCI FY 2008 Operating Budget Development

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<tr>
<td>Subtotal Available</td>
<td>- $94,998</td>
<td>- 1.98%</td>
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<tr>
<td><strong>Potential Recoveries/Redeployments:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Phaseouts/Reductions Res DOCs</td>
<td>49,382</td>
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<tr>
<td>• Phaseouts/Reductions Infrastructure</td>
<td>6,778</td>
<td></td>
</tr>
<tr>
<td>• Noncompeting RPGs</td>
<td>46,228</td>
<td></td>
</tr>
<tr>
<td>• Competing RPGs</td>
<td>8,136</td>
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<tr>
<td>• NCI-Frederick Redeployment</td>
<td>40,000</td>
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<tr>
<td><strong>Available for New Initiatives/Expansions/Restorations</strong></td>
<td><strong>$55,526</strong></td>
<td></td>
</tr>
</tbody>
</table>
NCI FY 2008 Operating Budget: NCI Operating Policies

NCI operating policies

• 1% inflationary adjustments on non-competing grants
  - ~2% decrease from commitment for non-modular grants

• No cut to modular non-competing grants

• NCI to award fewer competing RPGs than FY 2007 (1,312 to 1,283)

• Average cost of competing RPGs 3% above FY 2007
NCI FY 2008 Operating Budget: NCI RPG Policies

NCI RPG policies

- **Type-2** (competing continuing grants) will receive 3% above current levels

- **Type-2 modular grants** recommended for 7 modules or fewer will receive 5% above current levels

- **Type-1** (new competing grants) will be cut ~17%
NCI FY 2008 Operating Budget: NCI RPG Paylines

NCI RPG Paylines

- R01: 12th percentile
- *R01s: 19th percentile (will hit NIH target)
- Large R01s (over $700K):
  - 14th percentile for 1st and 2nd rounds
  - TBD for 3rd round
- P01: Selected on a case-by-case basis
Examples of Downsized and Stopped Programs

Office of Centers, Training, and Resources

• Integrating Aging and Cancer Research (co-funded with NIA)
  – NCI funding of $4M-$5M will not be renewed

• Supplements for Imaging Response Assessment Teams in Cancer Centers
  – NCI funding of $2M will not be renewed
Examples of Downsized and Stopped Programs

Div. of Cancer Control & Population Sciences

• Transdisciplinary Tobacco Use Research Centers
  – FY2008 is final year of RFA, funded at $7.2M. No proposed RFA renewal
  – NCI is joining a NIDA PA; For TTURC program, anticipate spending $2M-4M, rather than $7.2M/yr

• Long Term Cancer Survivors research RFA
  – FY2008 funding reduced by $1.7M
Examples of Downsized and Stopped Programs

Division of Cancer Prevention

• CCOP cancer treatment trial accrual
  - FY05: 7,948 patients
  - FY06: 6,402 patients
  - FY07: 6,100 patients (estimate)

• CCOP cancer prevention & control trials:
  - FY05: 5,211 patients
  - FY06: 4,994 patients
  - FY07: 4,500 patients (estimate)
Examples of Downsized and Stopped Programs

Division of Cancer Treatment and Diagnosis

• CTEP Interdisciplinary Research Teams for Molecular Target Assessment
  – Eliminated in FY07; $1.4M

• Cancer Imaging Program’s Development of Contract Imaging Drugs and Enhancers
  – Eliminated in FY07; $1.6M

• Cancer Diagnosis Program: breast and prostate cancer tissue resources unfunded or eliminated
## FY 2009 President’s Budget

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<tr>
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<tr>
<td>FY 2009 PB for NCI</td>
<td>$4,809,088</td>
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<tr>
<td>Difference ’08 to ’09</td>
<td>$4,000</td>
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<td>+0.1%</td>
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</tbody>
</table>

(dollars in thousands)
Disease with Genetic Component

Identify Genetic Defect(s)

Diagnostics

Preventive Medicine

Pharmacogenomics

Therapeutic Developments
- Gene Therapy
- Drug Therapy

Accelerated by Human Genome Project and HapMap

Time

Courtesy Francis Collins, NHGRI
Functional Genomics

Alterations in cellular function

Cell biology and protein carbohydrate chemistry

Regulation of gene expression

Whole genome sequencing

Genome-wide association studies

Normal vs. abnormal phenotype

Genes and environment

Somatic mutations

Germline markers of risk

Behavioral science

Therapy

Prevention

Populations w/ disease (environmental risk exposure)

Large populations

Longitudinal history

Therapy

Prevention

Behavioral science

Populations w/ disease (environmental risk exposure)

Large populations

Longitudinal history

Alterations in cellular function

Cell biology and protein carbohydrate chemistry

Regulation of gene expression

Whole genome sequencing

Genome-wide association studies

Normal vs. abnormal phenotype

Genes and environment

Somatic mutations

Germline markers of risk
Theoretical Physics

- Feb. 25-27, 2008
- “Integrating and Leveraging the Physical Sciences to Open New Frontiers in Oncology”
- Workshop to explore opportunities to incentivize collaborations
- Leaders in physics, chemistry, mathematics and cancer research
AACR/NCI Cancer Prevention Think Tank

• Bring together scientists and clinicians from basic, translational, and behavioral research areas, to think broadly about molecular prevention

• Develop a comprehensive cancer prevention strategy
  – Bring technology into prevention program
  – Emphasize translational science in prevention
  – Enhance behavioral science program

• Co-chairs: Raymond DuBois, John Niederhuber
Annual Translational Research Meeting

- Replace the summer SPORE meeting with an annual meeting
- Co-Chaired by Drs. Sheila Prindiville and Lynn Matrisian
- Planned for the Fall 2008 in Washington, D.C.
The SBIR Bridge Award in Drug Development

Target Identification & Validation
Preclinical Development (Lead Development, Animal Studies, File IND)
Safety Review
Clinical Trials
NDA Review
Commercialization

Phase I & Phase II SBIR
Private Investment

The “Valley of Death” is the problem
TRWG Implementation

- Dr. Lynn Matrisian (co-chair of the TRWG) now at NCI on an IPA
- Integrating with the CCCT
- Translational Research Operation Committee planned
  - Established under the Clinical Trials Advisory Committee (a Federal Advisory Board)
Translational Research Working Group Goals

- Improve coordination and collaboration and instill a culture of active, goal-oriented management
- Improve identification of the most promising early translation research opportunities
- Tailor new and existing programs to facilitate early translational research progress
- Enhance operational efficiency and effectiveness
Role of Clinical Research Center

NCI Initiatives

- Continue to strengthen Medical Oncology
- Recruiting new chief of Laboratory of Pathology
- Pathology space renovations in Bldg 10
- Developing an Oncology Imaging Center
- Exploration of a Satellite Center at Suburban Hospital
- Strengthening fellowship training
- Participation in rare diseases clinic
The Clinical Research Center as a National Resource
### 2009 Professional Judgment Budget

**Fiscal Year 2008 estimate** | $4,925,740
---|---
Current services increase | $334,638
Subtotal | $5,260,378

<table>
<thead>
<tr>
<th>Fiscal Year 2009 professional judgment</th>
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<tbody>
<tr>
<td>• Increase success rate for RPGs</td>
</tr>
<tr>
<td>• Basic and translational science for personalized medicine</td>
</tr>
<tr>
<td>• Linking science and technology</td>
</tr>
<tr>
<td>• Reaching all communities</td>
</tr>
<tr>
<td>• Prevention and early detection</td>
</tr>
<tr>
<td>Subtotal</td>
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**Total, NCI** | $6,028,386

Dollars in thousands