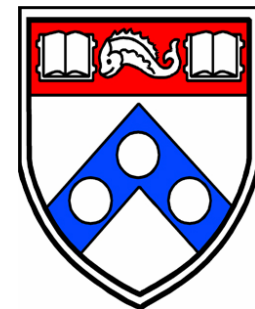


Alternative Means of Securing Research Support in a Difficult NIH Funding Environment

Glen N. Gaulton Ph.D.

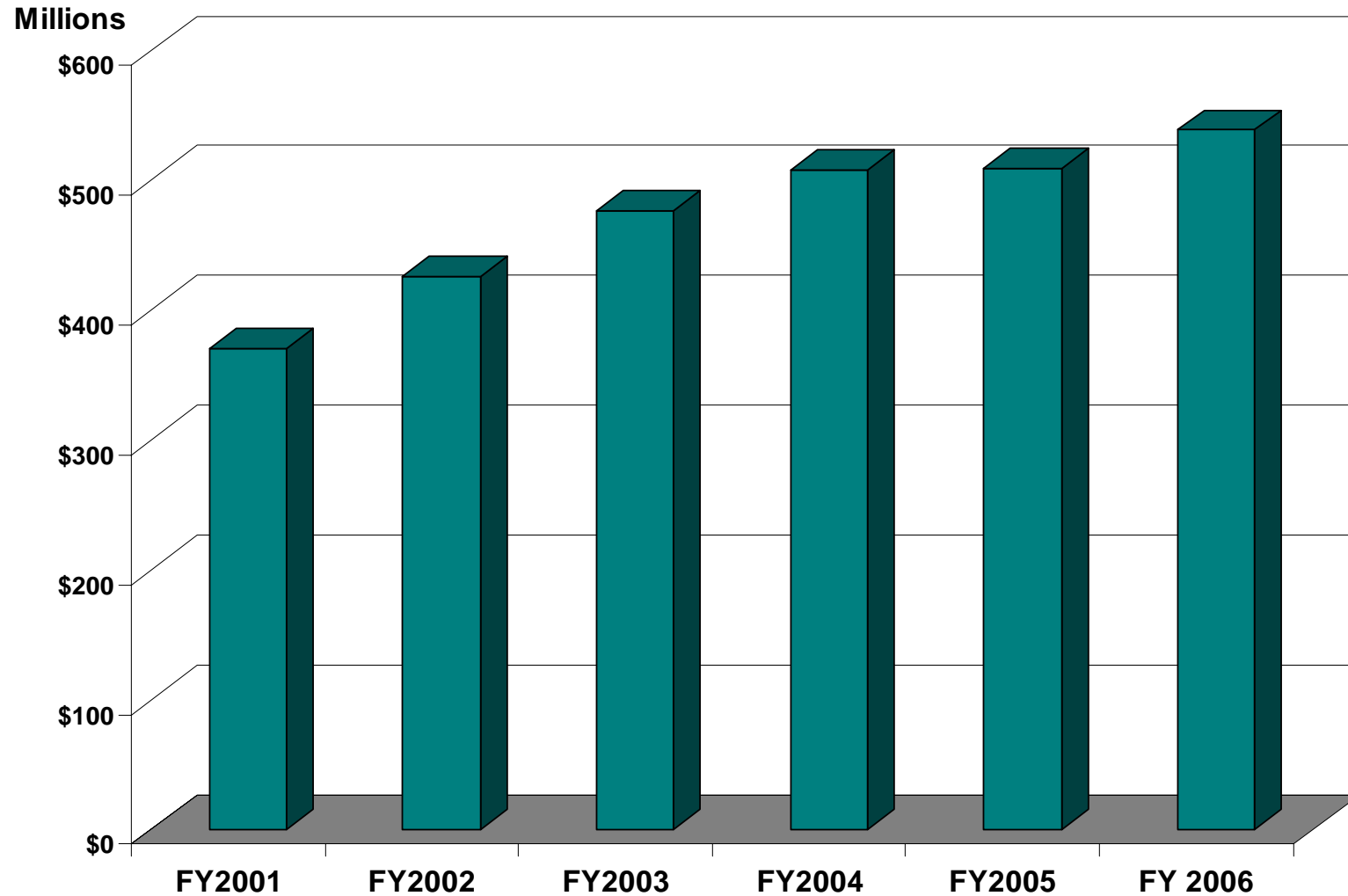
Vice Dean for Research & Research Training

Sept. 19, 2006



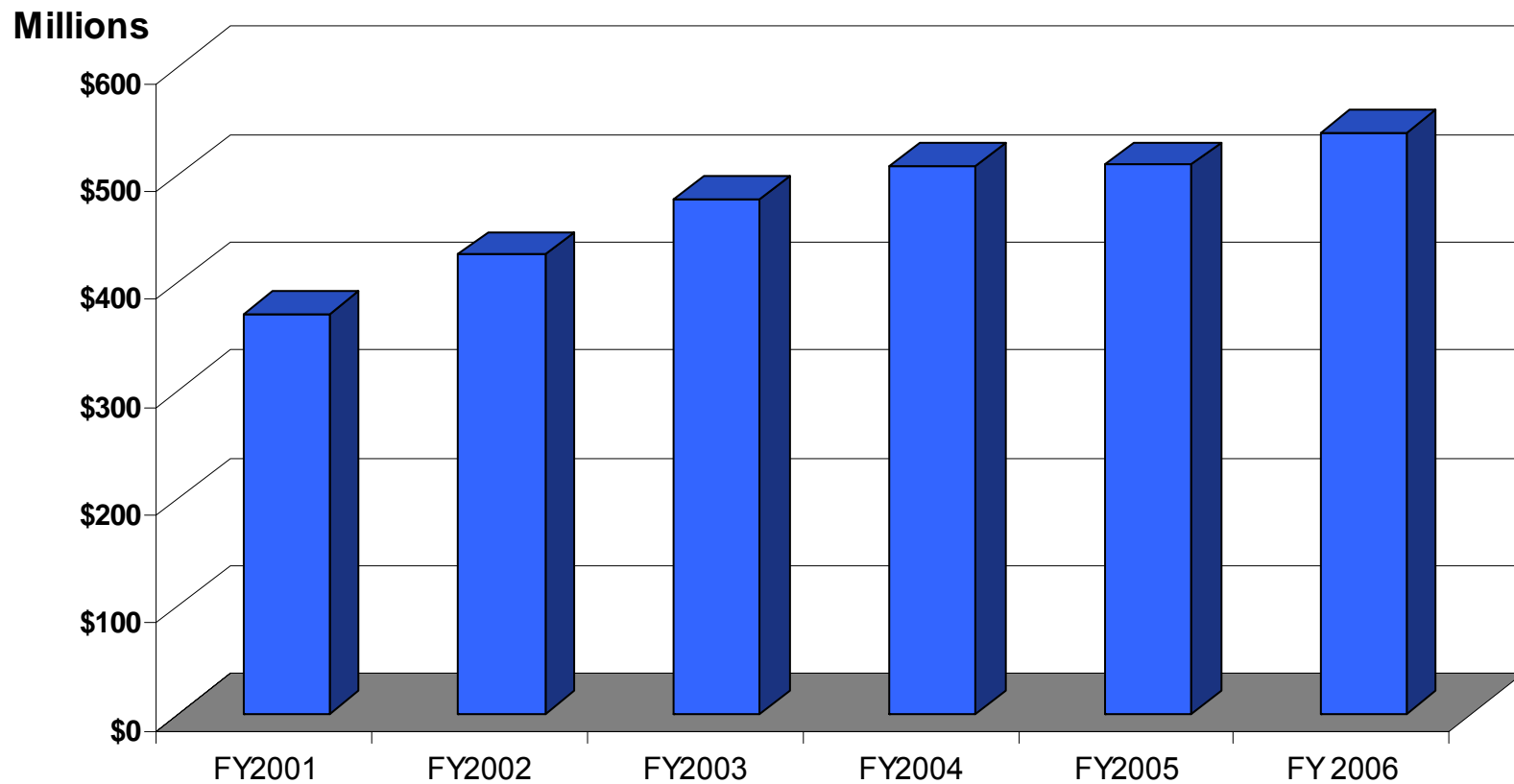
SOM- Proposals Submitted to the NIH

The School faculty submitted more than \$900 million in proposals in FY 2006, the highest amount ever.



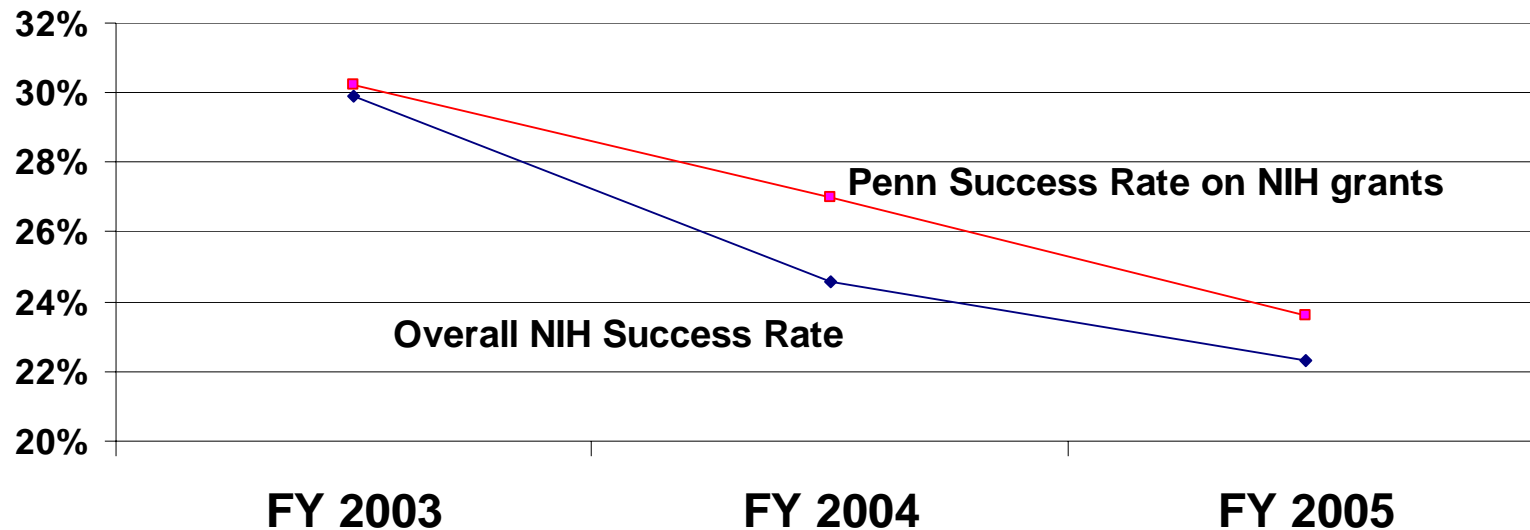
SOM- Awards Received from the NIH

The School had a 5.7% increase in awards received in FY 2006.



NIH Proposal Success Rates

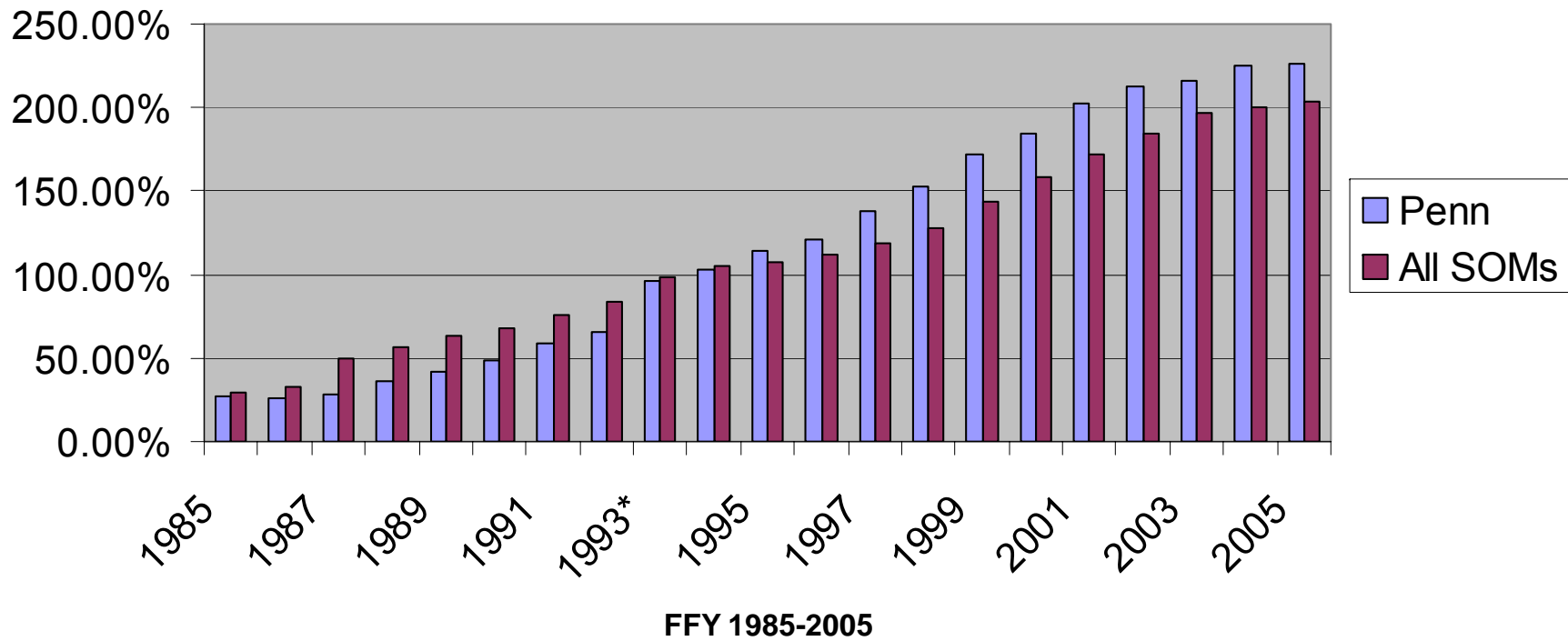
While the overall success rate of proposals to the NIH has been going down, Penn's success rate has been and remains above average.



Source: NIH, University database

Cumulative Growth in NIH Awards

Cumulative Growth in NIH Awards

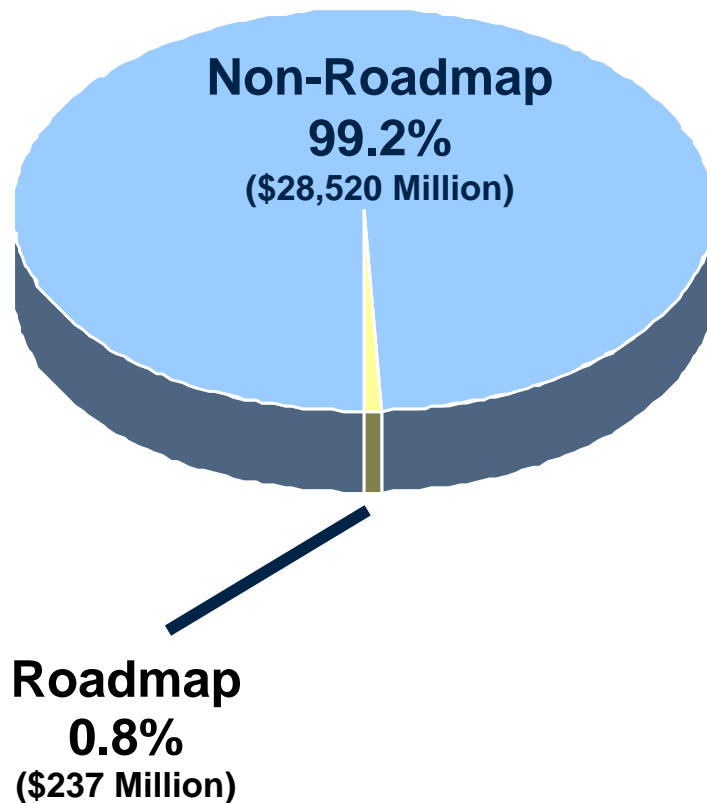




What caused this problem?

NIH Roadmap for Medical Research

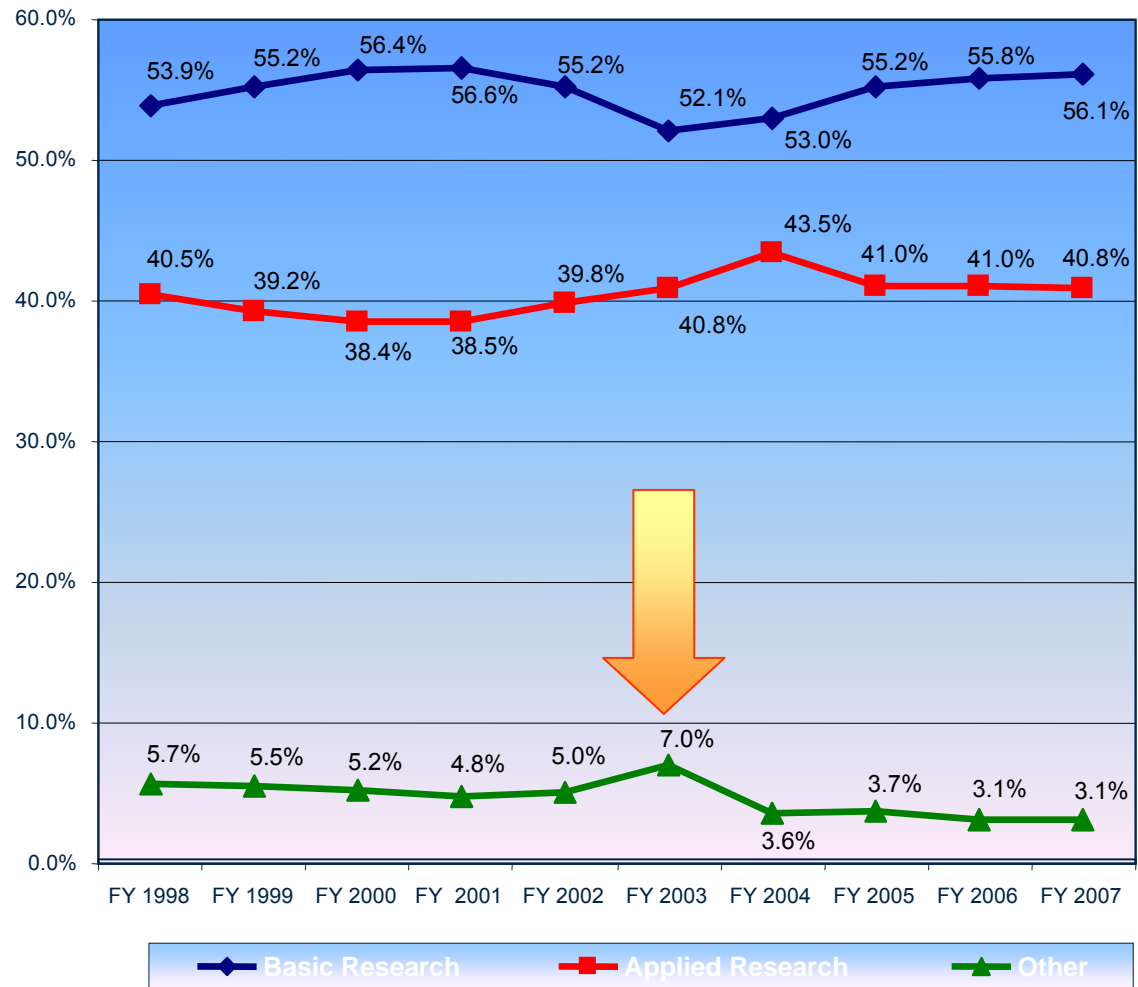
FY2005 Request = \$28,757M



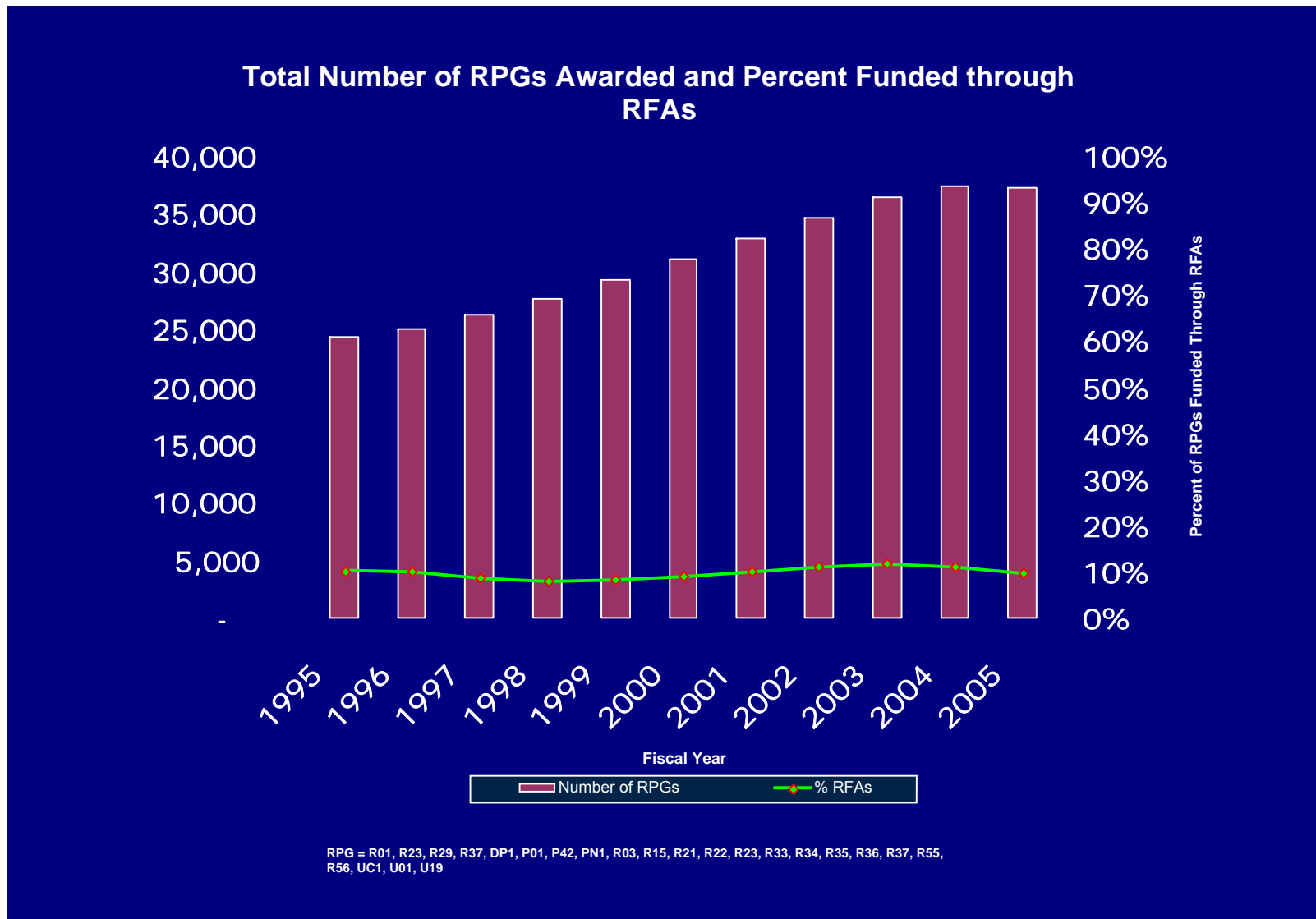
- Developed to increase synergy across NIH
- Not a single initiative but over 345 individual awards in FY 2005:
 - 40% basic
 - 40% translational
 - 20% high risk

Funds Being Diverted for Other Agendas?

Basic and Applied Research

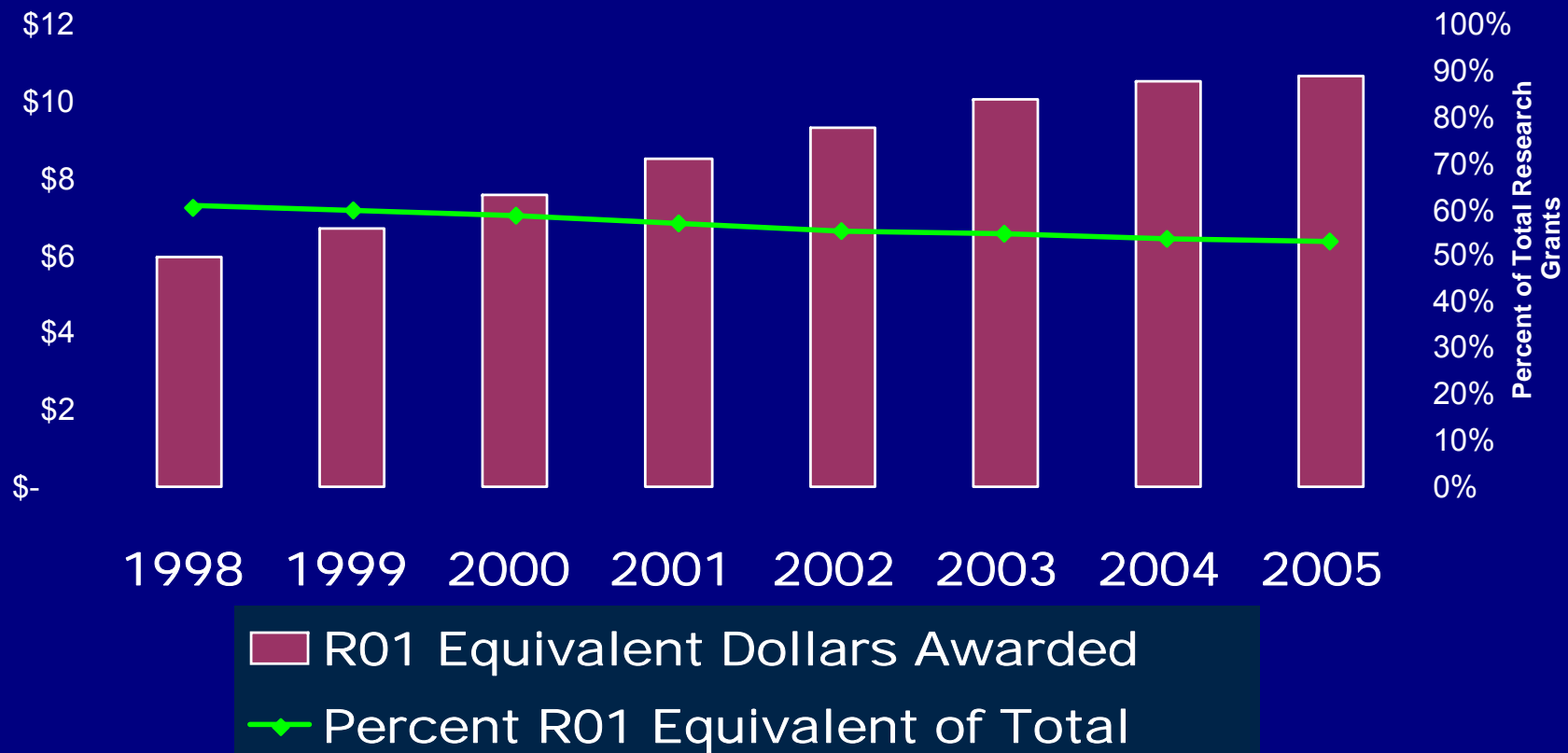


Total Number of RPGs Awarded

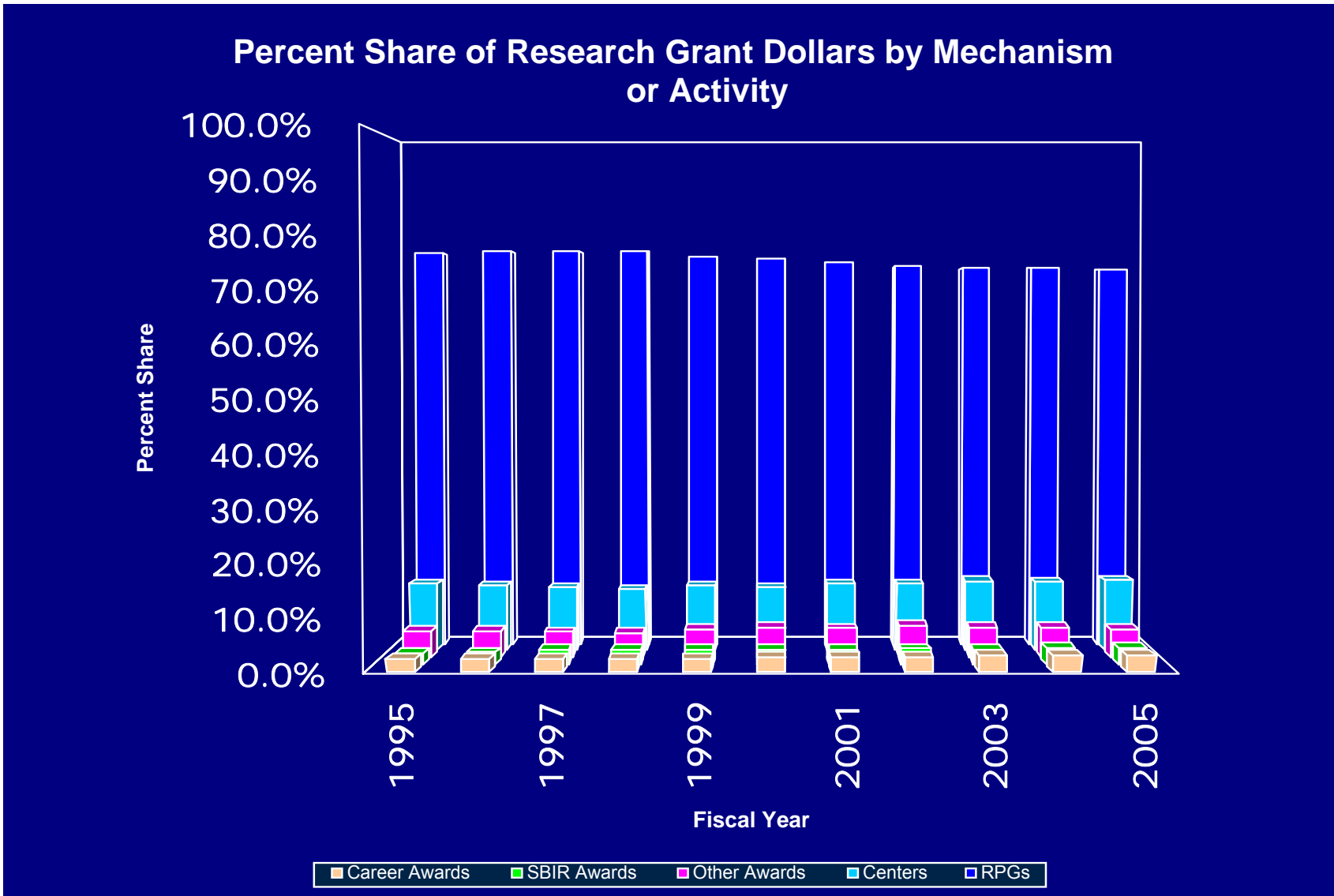


Funding of R01 Equivalent Grants

Funding of R01 Equivalent Grants and Percent of Total at Research Grants



The Funding Profile

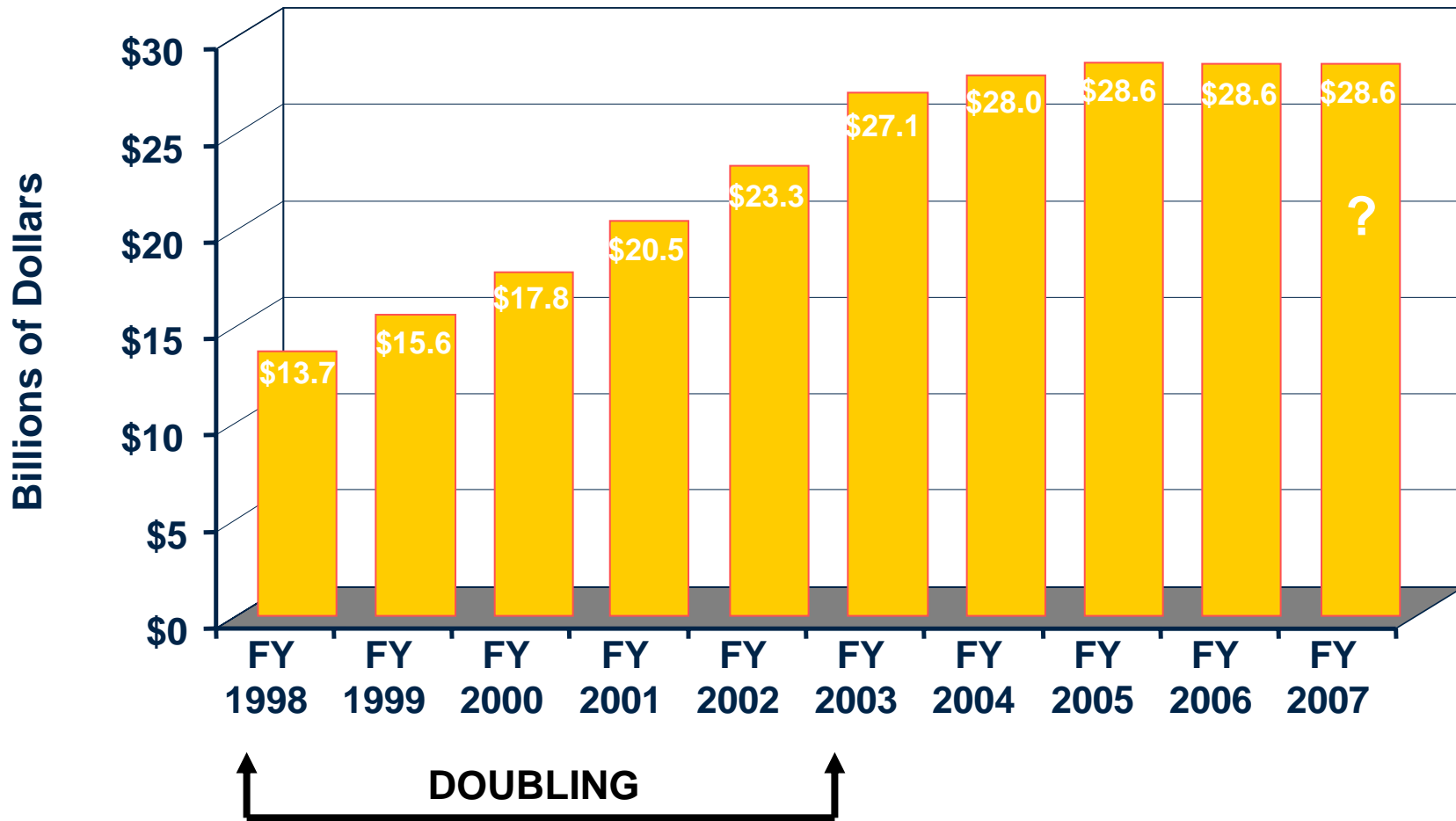


What Is Really Happening? 5 Fundamental Drivers

- **Large capacity building throughout U.S. research institutions and increase in number of tenure-track faculty**
- **Appropriations below inflation after 2003**
- **More grants submitted per faculty**
- **Increased grant budget size**
- **Budget cycling phenomenon**

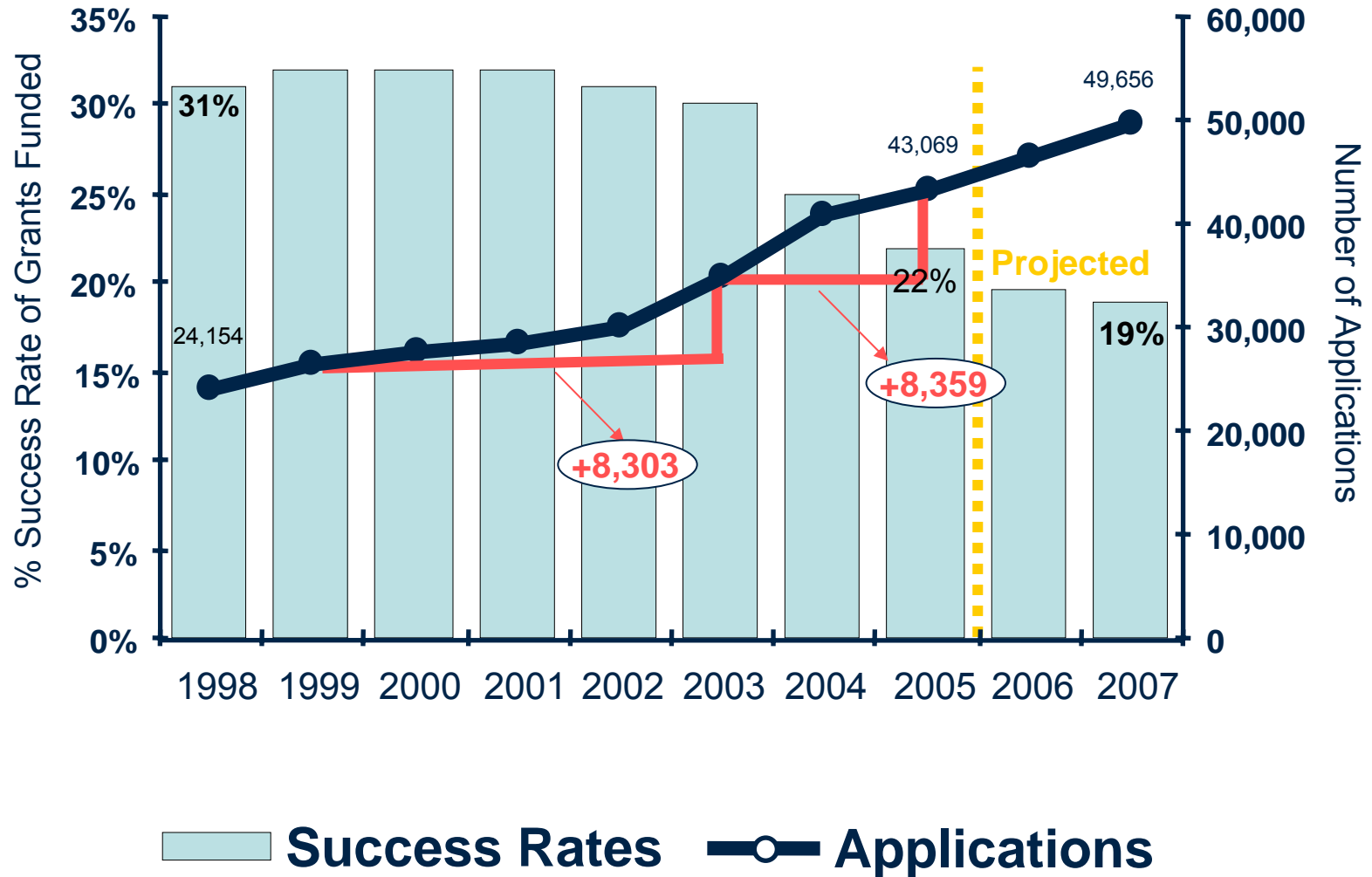


NIH Congressional Appropriations



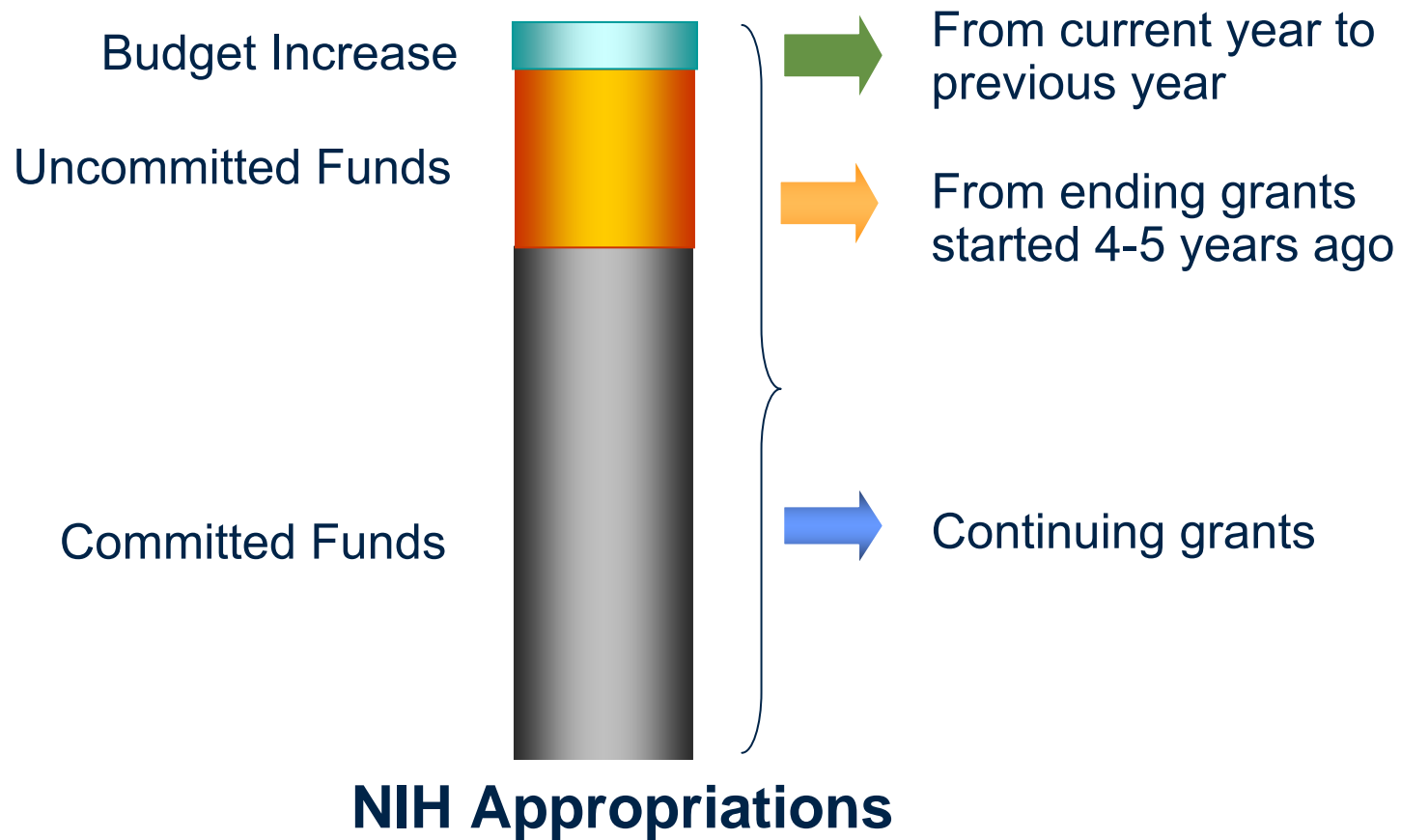
New Grant Applications and Success Rates

During and After Doubling Period

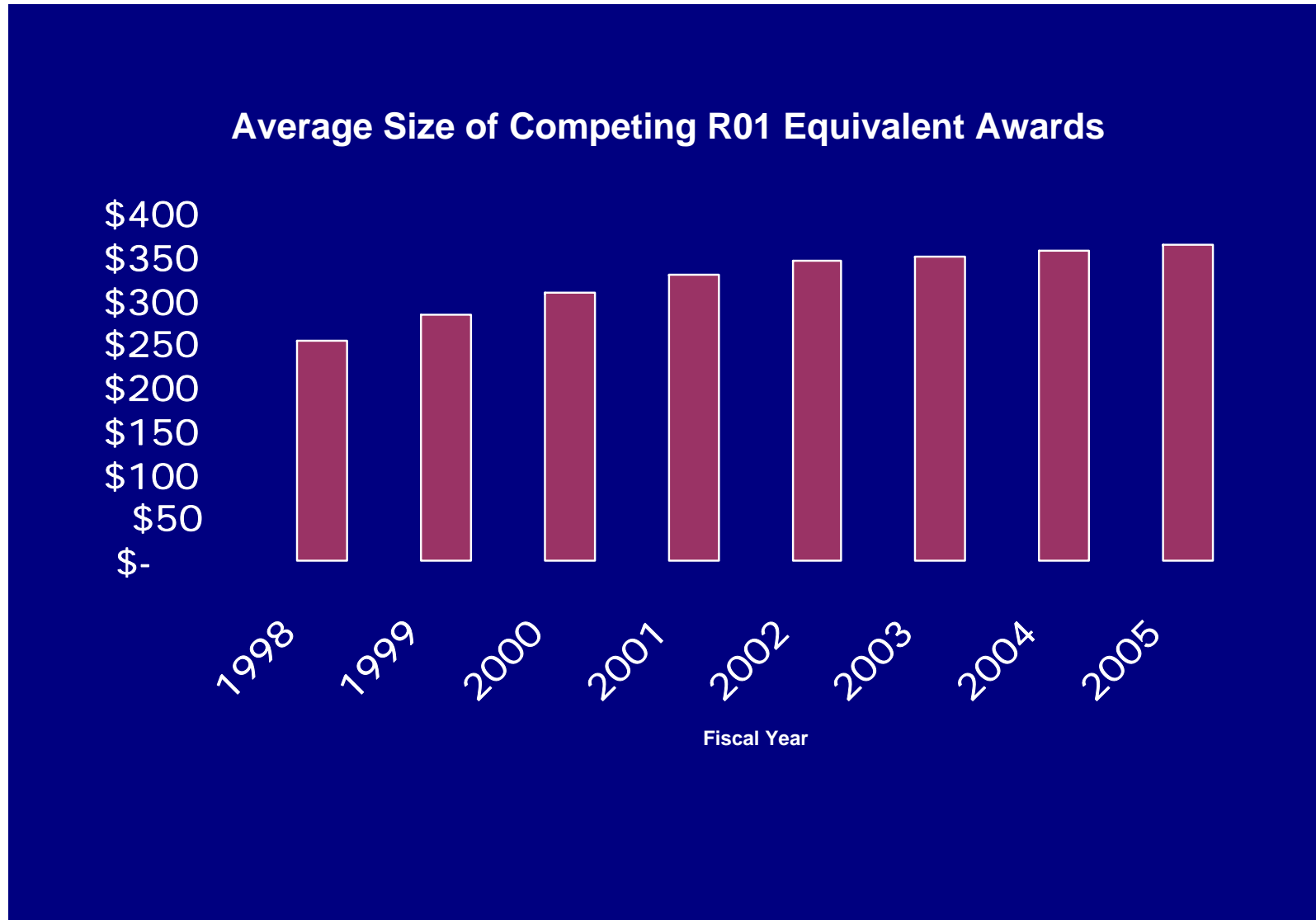


The Budget Cycling Phenomenon:

What Funds are Available in any One Year?



Competing R01 Equivalent Awards




R01 Equivalent* Includes R01, R23, R29 and R37

The Bottom Line:

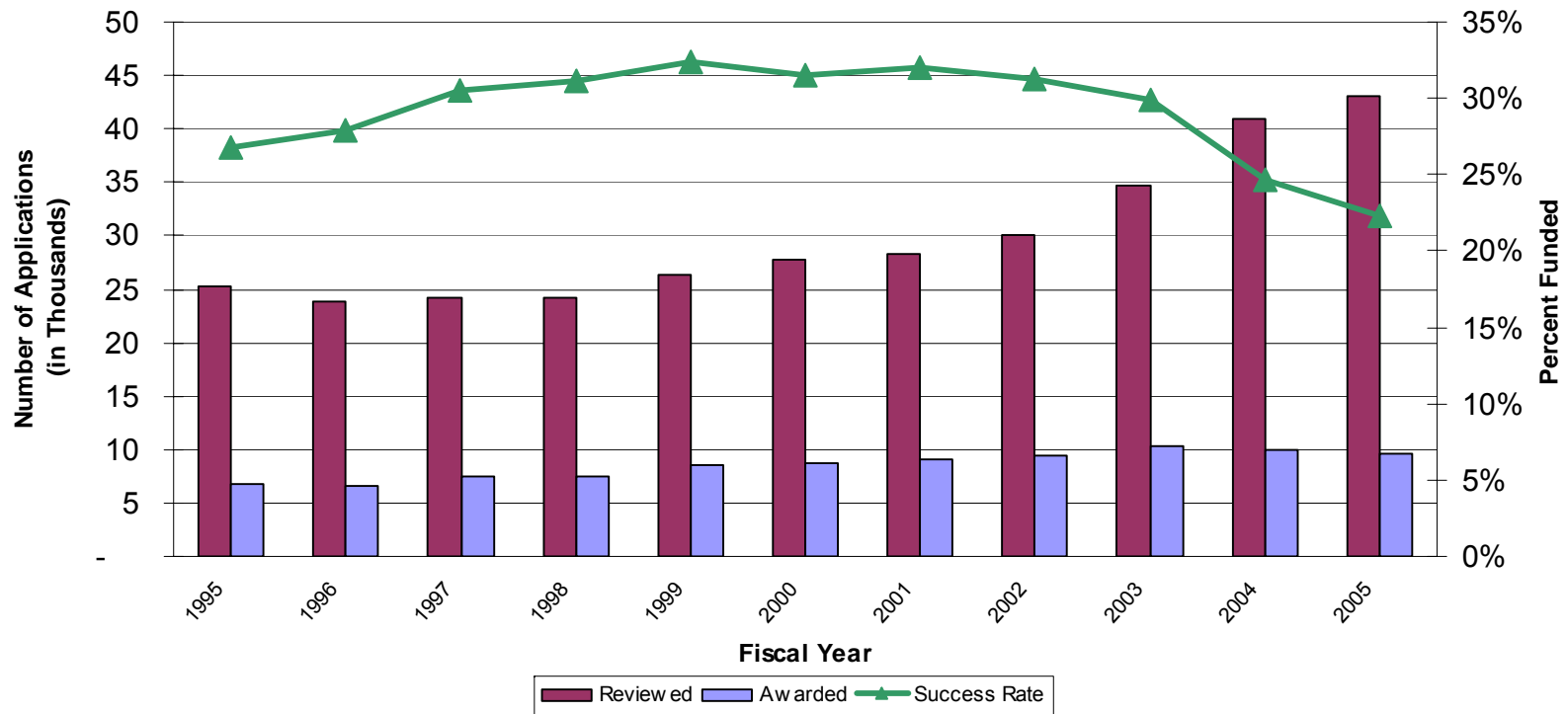
Demand for Grants “Took Off” Just as NIH Budget Was “Landing!”





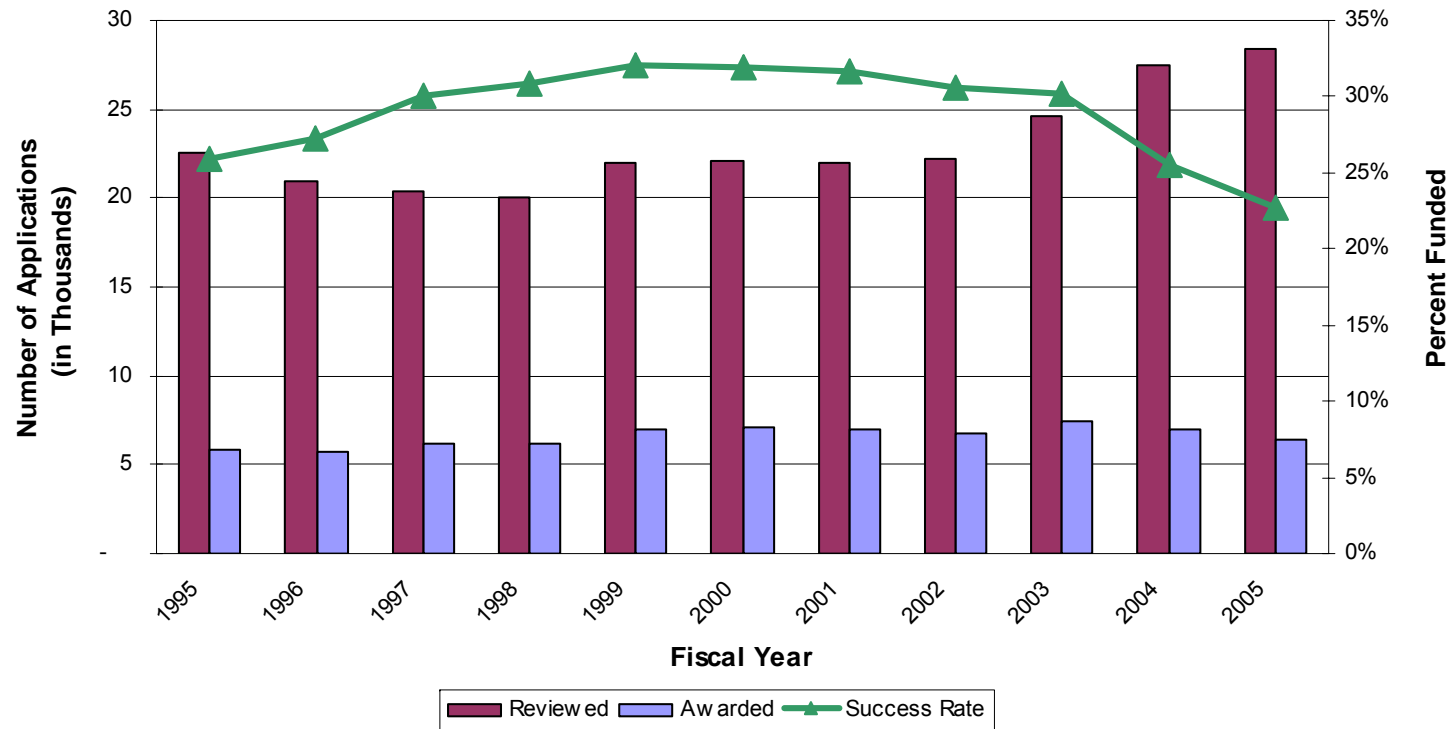
The Question on Everyone's Mind:
***What are MY chances
of being funded?***

Number of NIH Competing RPG Applications, Awards and Percent Funded (Success Rate)



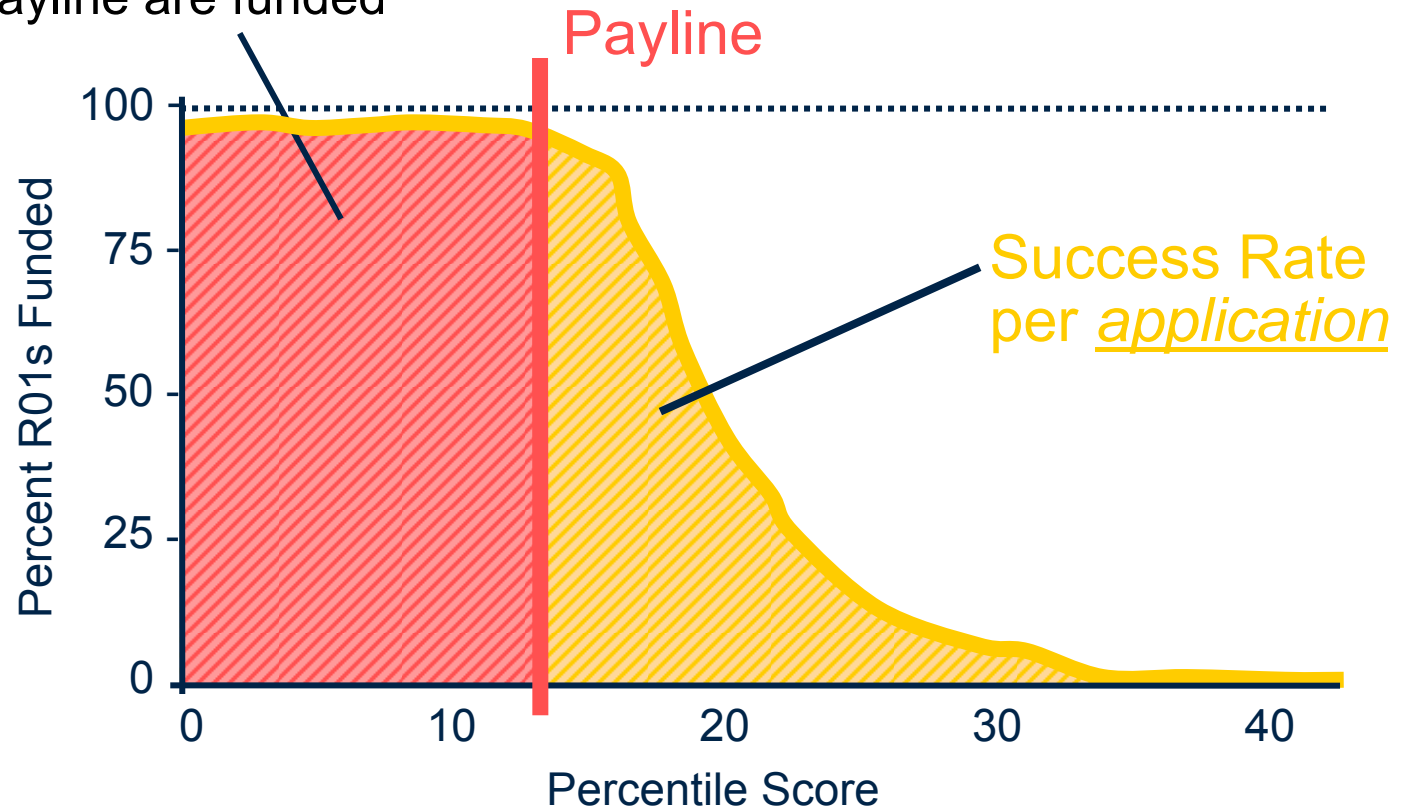
RPG = R01, R23, R29, R37, DP1, P01, P42, PN1, R03, R15, R21, R22, R23, R33, R34, R35, R36, R37, R55, R56, UC1, U01, U19

Number of NIH Competing R01 Equivalent* Applications, Awards and Percent Funded (Success Rate)



Payline Is Not Funding Cut-off Line

>99% of grants under the payline are funded



HOW CAN WE HELP?

- ◆ **New/unusual awards types at NIH - contracts**
- ◆ **Relief from IDC restrictions**
- ◆ **Pilot Grants**
- ◆ **Bridge Funding**
- ◆ **Increase ease of industry funding**
- ◆ **New funding agencies - Gates**

NIH Contracts

- ◆ **NIH buys services to support, conduct and acquire research. Service acquisitions range from building construction and management consulting, to complex clinical trials. NIH contracts exceeded \$2.77 billion in fiscal year 2001 and involved contract awards to universities, hospitals, state and local government agencies, non-profit and commercial organizations.**

NIH Contracts

◆ Special Considerations

- Expected deliverables and milestones
- More rigorous reporting requirements
- Bilateral --- NIH actively engaged in management
- Terms more restrictive (changes require prior approval)
- Terms and conditions often negotiated
- Fixed price vs. cost reimbursement
- Contact:
 - Stephanie Oram
 - Research Program Development Office Telephone: 215-898-0273
 - E-mail: oram@mail.med.upenn.edu

NIH Contracts

Awarded Contracts

| <u>No.</u> | <u>PI</u> | <u>Project</u> | <u>Dept</u> | <u>Total</u> |
|-------------|-----------|--|-------------|--------------|
| N01AI400037 | Roos | Bioinformatics Resource Centers For Biodefense: Apicomplexan Parasite Database | PGI | \$2,948,480 |
| N01HC425217 | Landis | NIH Roadmap: Scalable, prototypical, re-engineered research enterprise architecture for the conduct of clinical research within a broad-based frame work | CCEB | \$1,717,788 |
| N01HD403376 | Barnhart | CT: Randomized Controlled Study OfEfficacy/Safety/Acceptability of C31G | OB/GYN | \$371,880 |

Indirect Cost Relief Policy

General policy is to charge full indirect costs/F&A: 57%
basic/clinical research - 26.0% clinical trial

However - some agencies may not allow this

New Policy - effective September 2006:

- Assistant Prof (sf) - SOM will subvent all requests with appropriate % effort on salary
- Assoc/Full Prof (sf) - SOM will subvent 1 award with appropriate % effort on salary - others on review
- Non-Standing Faculty all ranks - Subvention of all career dev awards, fellowships and training, others on review

Pilot Grants and Seed Funds

SOM Pilot grants listed on the SOM research homepage:

<http://www.med.upenn.edu/research/faculty/pilotseedgrants.shtml>

McCabe Fund:

<http://www.upenn.edu/almanac/volumes/v52/n26/mccabe.html>

Penn University Research Foundation:

<http://www.upenn.edu/research/FundingFaculty.htm>

Bridge Funding (Under Review)

Goal: to ensure continued research support during funding lapses

Key Points:

- Continuation of existing project and essential lab personnel/ supplies
- One year support duration maximal
- Potentially exclusive of other on-going lab funding
- Projects must have been submitted and reviewed for renewal
- 3-5 page on line process
- Committee process considerations:
- Productivity, review comments/score, track record in area, appropriateness of expenses, associated IDC rate

Corporate Sponsored Research

School of Medicine established the Office for Corporate Alliances in 2002.

- Primary conduit to corporate sponsors
- Best practice for University and school offices
- Cross-entity alliances vs. individual SRA's

Corporate Alliance Partners

| | <u>FY04</u> | <u>FY05</u> | <u>FY06</u> | <u>FY07</u> <u>Forecast</u> |
|--------------------|---------------|---------------|---------------|--------------------------------|
| <u>GSK</u> | \$15M | \$17M | \$15M | \$15M |
| <u>AstraZeneca</u> | \$320K | \$225K | \$3M | \$4M |
| <u>Abbott</u> | \$70K | \$300K | \$290K | \$1.5M |

Clinical Research Potential Committee

Establish thought leaders (CRAC) to promote meaningful clinical research, to define resource needs, and to outline best practices.

CRAC Membership

| Last Name | Dept./Center/Inst. | Last Name | Dept./Center/Inst. |
|------------------|---------------------------|------------------|--------------------------------------|
| Baldassano, MD | Pediatrics | Margolis, MD | CCEB |
| Barnhart, MD | OB/GYN | Newman, MD | Otorhinolaryngology |
| Clark, MD | Institute on Aging | Nicholson, MD | Family Practice & Community Med. |
| Evans, VMD | Radiation Oncology | Ochroch, MD | Anesthesiology and Critical Care |
| Fadem | OCA | Propert, ScD | CCEB |
| Fairman, MD | Surgery | Rickels, MD | Psychiatry |
| French, MD | Neurology | Sallee | Cancer Center |
| Fromell, MD | OHR | Schnall, MD | Radiology |
| Furth, MD | Pathology & Lab Med | Schuchter, MD | Cancer Center |
| Gelfand, MD | Dermatology | Sieber | Orthopaedic Surgery |
| Hollander, MD | Emergency Medicine | Stineman, MD | Physical Medicine and Rehabilitation |
| Iqbal, MD | IDOM | Townsend, MD | Medicine |
| Karlawish, MD | Institute on Aging | Whitehead, PhD | Pharmacology |
| Kuna, MD | Ctr for Sleep | Gaulton, PhD | Ex-Officio Member |
| LeRoux, MD | Neurosurgery | Ellenberg, PhD | Ex-Officio Member |
| Maguire, PhD | Ophthalmology | Ellenberg, PhD | Ex-Officio Member |
| Maloney, RN | Neurosurgery | | |

CRAC Subcommittees

◆ Executive Steering Committee

- Jacqueline French (Neurology)
- Judd Hollander (ER)
- Kurt Barnhart (Ob-Gyn)
- Lynn Schuchter (Medicine/Oncology)
- Gregg Fromell (OHR)
- Susan Ellenberg (CCEB, OHR)
- Terry Fadem (OCA)

SUBCOMMITTEES

◆ Contracts, Study Costing/Budgeting, Study Financial Tracking

- David Margolis (Chair)

◆ Subject Recruitment and Clinical Research Coordinator Resources

- Sidney Evans (Chair)

◆ Multiple Review Process & Regulatory Burden

- Jason Newman (Chair)

◆ Space

- Judd Hollander (Chair and Exec. Committee representative)

New Alternative Funding Sources

The Gates Foundation

Grants awarded in 3 primary areas:

◆ Global Development Program

- reduce poverty and hunger and to expand access to information in the developing world

◆ Global Health Program

- access to existing vaccines, drugs, and other tools to fight diseases common in developing countries
- research to develop health solutions that are effective, affordable, and practical

◆ United States Program

- increasing the number of students who graduate from high school with the skills needed to succeed in college and work, improving lives of at-risk children, youth, and families in Washington state, expanding access to information through technology in public libraries

The Gates Foundation

- ◆ Accepts funding requests in two ways: through letters of inquiry (LOIs) and requests for proposals (RFPs)
- ◆ Competitive research funding in 2005 = \$1.36 b
- ◆ Current endowment = \$31.7 b

Priority Diseases and Conditions

- Acute diarrheal illness
- Acute lower respiratory infections
- Child health
- HIV/AIDS
- Malaria
- Malnutrition and under-nutrition
- Reproductive and maternal health
- Tuberculosis
- Vaccine-preventable diseases

Other Health Conditions

diseases that have a lower overall burden, but still have a disproportionate impact in the developing world:

- Helminthic infections
- Sexually transmitted infections
- Kinetoplastid diseases
- Cervical cancer caused by human papillomavirus.
- Other diseases: Meningitis, dengue, Japanese encephalitis, and trachoma.

Critical Enabling Strategies

To ensure that life-saving health interventions reach those who need them most

- Mobilize new resources for global health, including innovative financing and product procurement mechanisms.
- Build awareness of global health issues among decision-makers, the media, and the public.
- Strengthen public health leadership.
- Improve the collection and use of data and evidence for global health decision-making.
- Improve the delivery of, and demand for, key products and interventions.

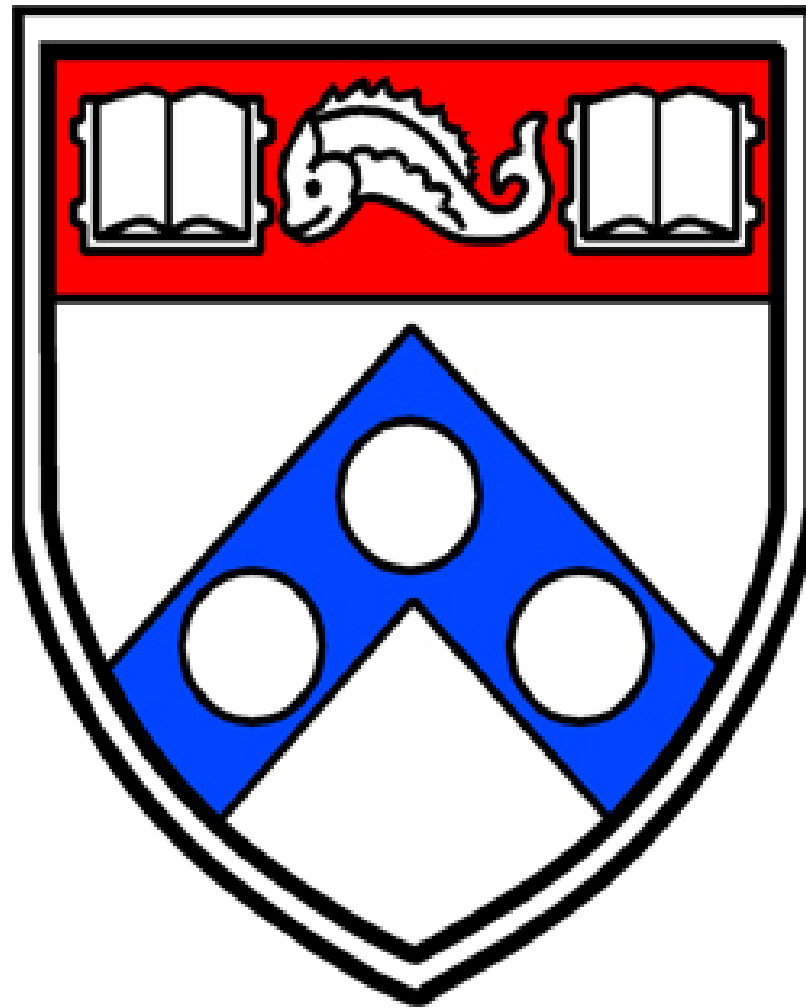
Gates- Global Health Areas

Examples of funded projects

- ◆ \$82.9 million to the Aeras Global TB Vaccine Foundation for vaccine development
- ◆ \$48 million to improve TB control strategies in communities with high rates of HIV/AIDS
- ◆ \$23.3 million for the Foundation for Innovative New Diagnostics to develop low-cost methods for diagnosing TB
- ◆ \$448 million for the Grand Challenges in Global Health initiative, which supports 44 innovative projects, such as research to stop insects from transmitting disease, and the development of vaccines that do not require refrigeration or needles

Summary

- ◆ Difficult times but quality wins out
- ◆ Be smart – diversify funding sources
- ◆ Be flexible – new applications for your research
- ◆ Take advantage of our new policies and support services
- ◆ Don't lose hope – NIH funding will rebound!



Critical Enabling Strategies

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