

Secretary's Advisory Committee on Genetics,
Health, and Society Meeting- October 19, 2005

Policy Perspectives on a Large U.S. Population Study from Members of the Scientific Community

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Which policy issues are most critical to you?

- The prioritization of the study relative to other large-scale studies
- Study goals and how well the study is designed so that useful data are produced
- Cost and possible effects on research project grants

Prioritization relative to other large-scale studies

- What is the mechanism by which this study is prioritized relative to other large-scale studies, such as the Children's Health Study?
- Are we sure that other long-term studies have been mined as much as they could be?

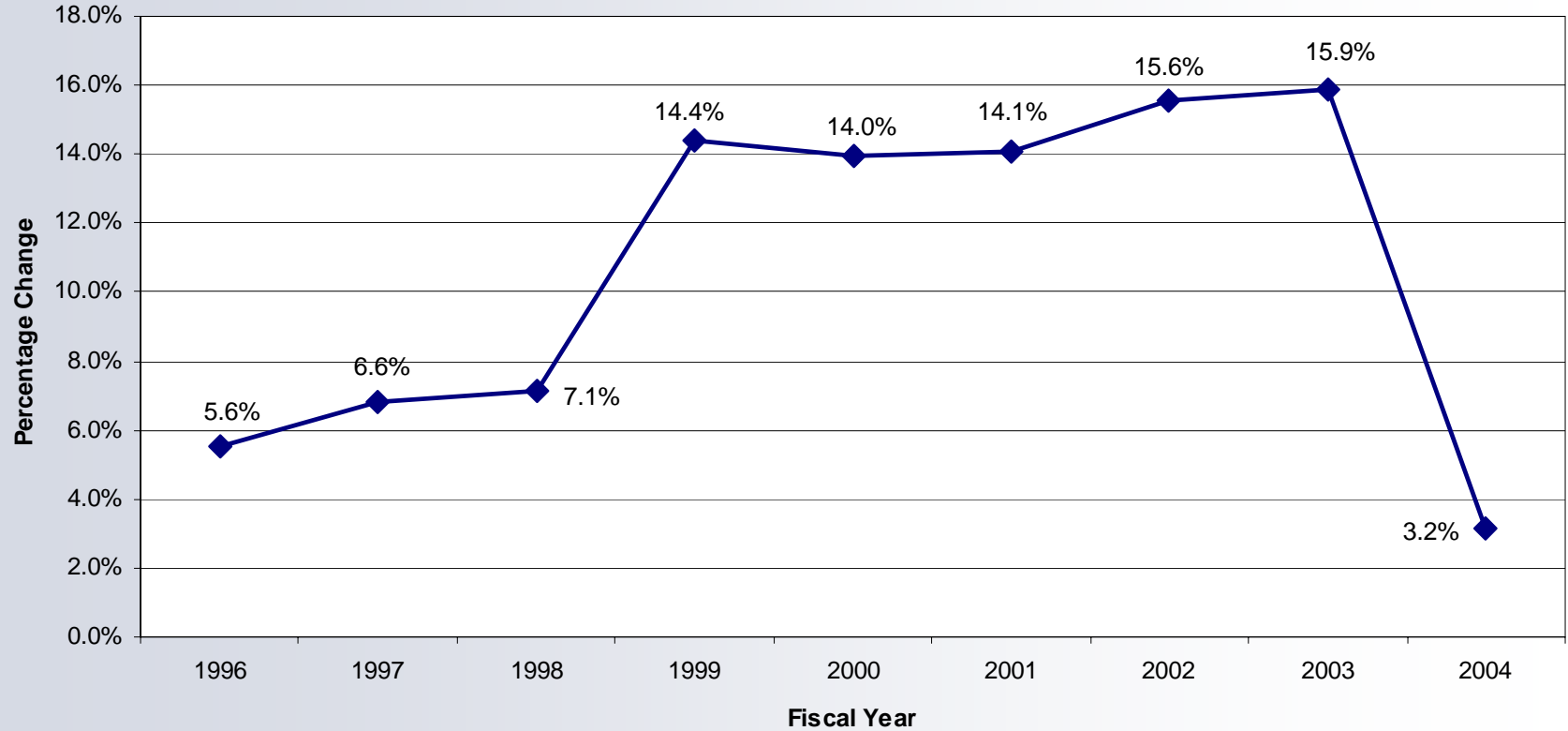
Study goals and outcomes

- How will protocols and data analyses be decided? How will they be modified, if at all, as the science progresses?
- How will data be collected, stored, and made available? Under what conditions will investigators have access to data and materials for use in their research?
- How will genetic and other personal information be protected?
- Does our current healthcare system have sufficient technology and infrastructure to support data collection and sharing?
- Is there a way to restrict or focus the study more?

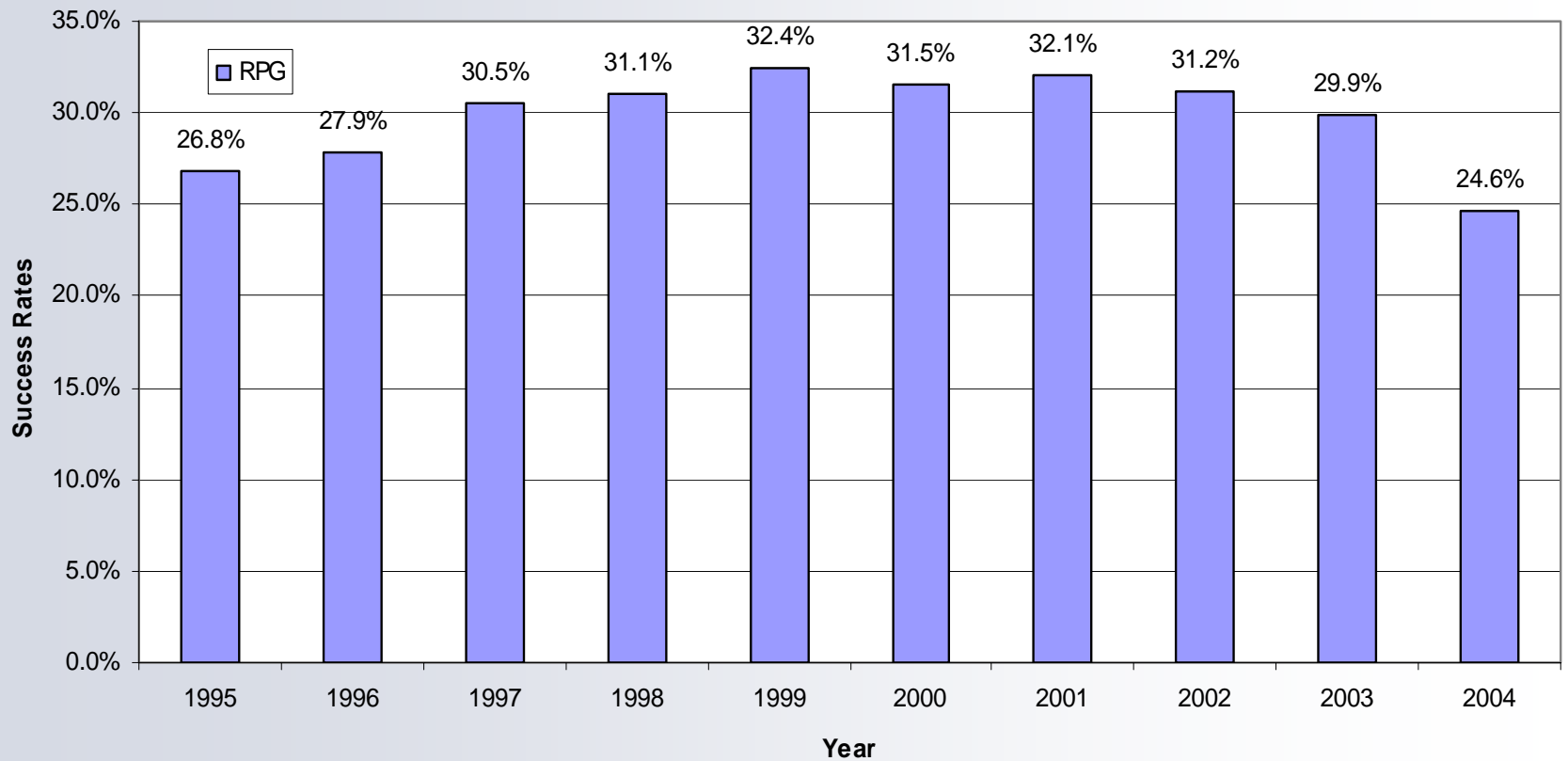
Cost and effects on research project grants

- This is a very expensive endeavor at a time when NIH funding is not increasing, and success rates and paylines for R01s are decreasing.
- In order to fund this study in the current fiscal environment, what would be the trade-offs for investigators?

Percent change in NIH budget



Success rates for NIH grants have been decreasing in recent years



To fund this study, what would be the trade-off for investigators?

- What would happen to success rates if R01 money was used to fund this study?
- Hypothetical scenario: If the estimated cost of a study is \$3 billion and \$350 million were cut out of the R01 budget in one year, approximately 1,000 fewer R01 grants could be awarded. Based on 2004 data, the success rate for R01s would drop from 24.9% to 21.3%.

Are there conditions under which you think such a study should not be allowed to go forward?

- FASEB's long-standing position is that investigator-initiated, competitive, peer reviewed grants should remain the core mechanism for distributing research funding.
- This study should only be undertaken if funded through sources that do not compromise investigator-initiated projects.