



Tomorrow's Doctors, Tomorrow's Cures

Legislative and Regulatory Report

AAMC Advisory Panel on Research

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Learn

Serve

Lead



Association of
American Medical Colleges

Status of FY 2009 Funding

- President signed “Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009” P.L. 110-329 on September 30
- Bill funds most federal programs at FY 2008 levels through March 6, 2009
- CR includes full-year FY 2009 spending bills for Defense, Security, Military Construction/VA

Status of FY 2009 Funding

- VA Medical Care - law provides \$40.4 billion, a \$3.46 billion (9.4 percent) increase over FY 2008
- VA Research – law provides \$510 million, a \$30 million (6.3 percent) increase over FY 2008
- Law does not include designated funding for VA research facilities improvement

NIH Budget Chronology

[in billions]

FY 2008 Actual	\$29.230	+\$0.331 (1.1%)
<i>FY 2008 Supplemental [Enacted June 30]</i>	<i>+\$0.150</i>	
FY 2008 Adjusted	\$29.380	+\$0.481 (1.7%)
House Subcmte. Bill	\$30.379	+ \$1.000 (3.4%)
Senate Committee Bill	\$30.255	+ \$0.875 (3.0%)

Senate NIH Proposals

- **July 16 – Senators Specter and Harkin announce \$5.2 billion “NIH Emergency Supplemental Appropriations Act of 2008” (S. 3272), including \$1.2 billion for NCI “consistent with the Institute's professional judgment budget and the recent recommendations of the cancer research community”**

Senate NIH Proposals

- **July 22 – Senate Appropriations Chair Byrd announces he would postpone until September consideration of a second FY 2008 supplemental spending package that reportedly includes \$500 million for the National Institutes of Health (NIH).**
- **July 30 – Senate Appropriations Chair Byrd releases “Chairman’s Mark” of a second stimulus package that includes \$500 million for NIH**

Senate NIH Proposals

- **September 25 – Senate Majority Leader Reid and Byrd release “economic recovery package” that includes \$1.2 billion for NIH**
- **September 26 – Senate vote on motion to limit debate fails to gain 60 votes**

Future Prospects – Obama

Double research budget of key science agencies over a decade, such as the NIH, NSF, DOE – Office of Science, and NIST.

“These **sustained and predictable increases** in research funding will allow the United States to accomplish much: expanding the frontiers of human knowledge, providing greater support for high-risk, high-return research and for young scientists, and harnessing science and technology to address the “grand challenges” of the 21st century: energy, health, climate change, national security, information technology, and manufacturing capacity.”

Future Prospects – Obama

- Encourage **rapid translation of medical research** into public health benefits, hopefully shortening the time it takes for biomedical research to reach the American public.
- Advance stem cell research by **reversing President Bush's ban on stem cell lines**.
- Advance genomics to improve medicine, making “it a priority to transform basic genomics research into the new field known as “personalized medicine,” to help predict susceptibility to many diseases. They will strive for modernized genetic tests, improving the safety and effectiveness of drugs, and ensure genetic privacy.
- Focus on prevention and health promotion, increasing the research done on prevention and healthy living.

Future Prospects – McCain

- **John McCain has voted to double the funding for National Institutes of Health (NIH), and as President will make sure that our researchers have necessary funding to defeat cancer once and for all.**
- **He will work to better coordinate the efforts between the government sector, including the National Cancer Institute (NCI), National Institutes of Health (NIH), and the private sector, especially with a focus on translational research so new discoveries in laboratories can be translated quickly and more efficiently to patients' bedsides. He will also engage the next generation of researchers early in this fight through academic curriculums and internships.**
- **The McCain-Palin campaign will encourage clinical trials.**

Future Prospects – McCain

A one-year spending pause. **Freeze non-defense, non-veterans discretionary spending for a year** and use those savings for deficit reduction. A one-year pause in the growth of discretionary spending will be imposed to allow for a comprehensive review of all spending programs. After the completion of a comprehensive review of all programs, projects and activities of the federal government, we will propose a plan to modernize, streamline, consolidate, reprioritize and, where needed, terminate individual programs.

2008 Fulfilling the Promise Hill Briefings

May 19 – Autism

Thomas Insel, M.D.

Director

National Institute of Mental Health

Joseph Piven, M.D.

Professor, Dept of Psychiatry

University of North Carolina – Chapel Hill
School of Medicine

September 29 -- Stroke

Story Landis, Ph. D.

Director

National Institute of Neurological Disorders
and Stroke

Karen Furie, M.D., M.P.H.

Director, Stroke Service, Massachusetts General Hospital

The screenshot displays the 'Fulfilling the Promise' website interface. At the top left is the logo 'Fulfilling the Promise' and at the top right is the 'AAMC' logo. Below the logo is the text 'Research News from the Nation's Medical Schools and Teaching Hospitals' and the date 'February 2008'. The main content area is divided into several sections: 'Capitol Hill Briefing to Focus on Autism', 'See How the NIH Supports Medical Research', 'Medical Firsts', 'Learn More', and 'Possible trigger for Parkinson's discovered'. Each section contains a brief summary of the research or news item, along with links to full reports or fact sheets. The layout is clean and professional, with a white background and blue accents.

www.aamc.org/ftp



NIH Advocacy Pilot Overview

Concept: To generate *public support and pressure for sustainable and predictable increases* in the budget for the National Institutes of Health through *targeted advertising* in selected congressional districts and states

NIH Advocacy Pilot Overview

- **Focus Groups**
 - Two sets in up to 4 cities
- **Ad concept development**
- **Additional opinion research/testing**
- **Ad placement in “second tier” media markets (2009)**
- **Evaluation**



Phase One

**Six focus groups of Business/
Community/Political Leaders and
Opinion Elites conducted in three cities:**

- **Jackson, MS - March 20**
- **Seattle, WA - March 31**
- **Youngstown, OH - April 3**

Focus Groups Objectives

- **Assess understanding about medical research;**
- **Gauge awareness about NIH;**
- **Test compelling messages;**
- **Evaluate effective messengers; and,**
- **Assess potential to engage the public.**

Three Core Messages

- **Hope**
- **Return on Investment (ROI) – Improved Health Outcomes**
- **Local/Community Benefits – What does it mean to me and my family?**

Phase Two [June – October]

- Retained advertising/public affairs agency [Porter/Novelli]
- Developed ad concepts
- Testing in second round of focus groups

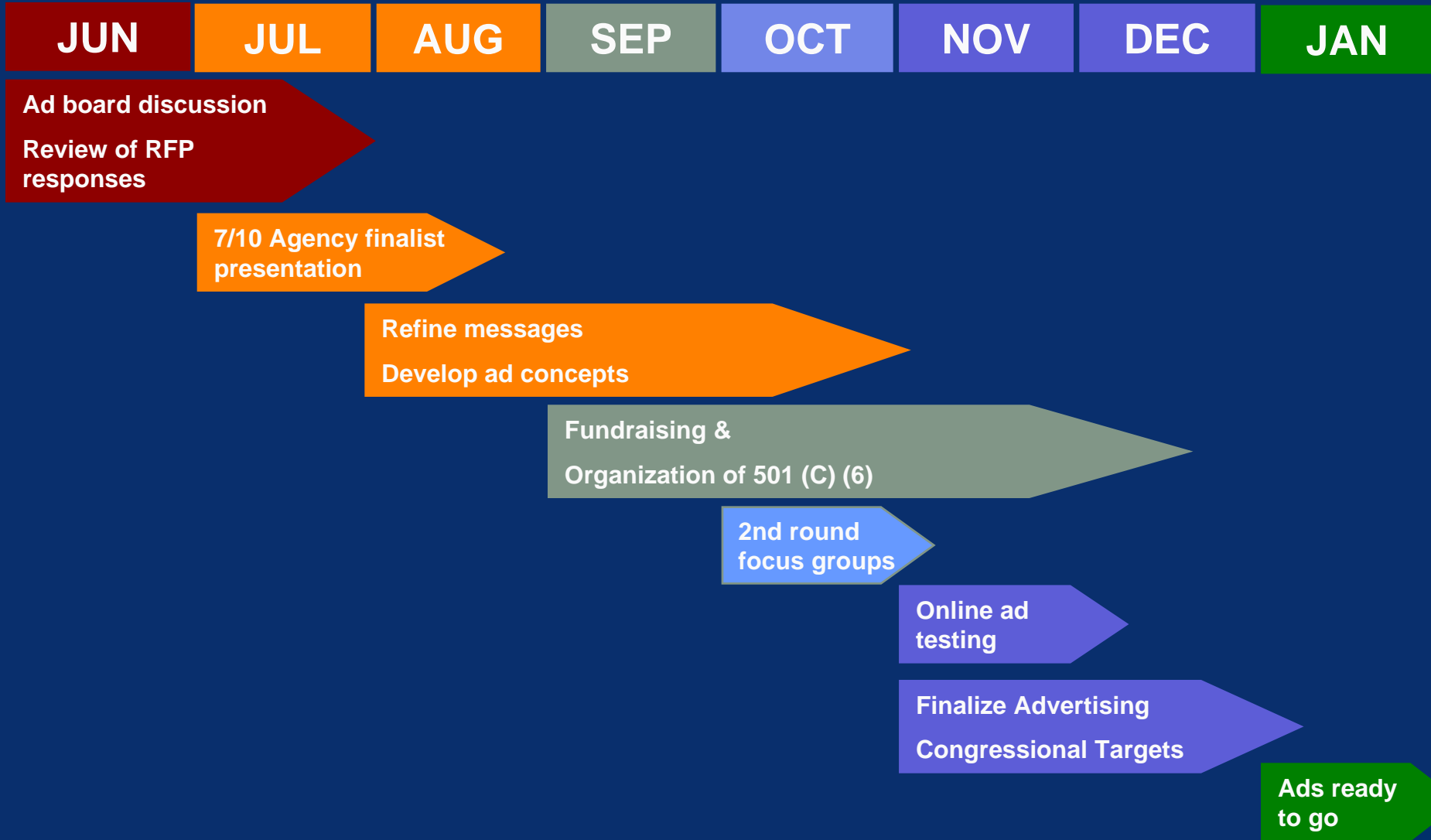
Second Focus Groups

- Tampa, FL – October 1
- Milwaukee, WI – October 6
- Waco, TX – October 14
 - Opinion Elites
 - Business, Community, Political Leaders
- Test effective messages to motivate the public – 3 effective message themes from first focus groups
- Test via 5-7 ad concepts
- Assess potential to motivate public

Next Steps

- **Establish not-for-profit coalition 501 (C)(6)**
- **Fundraising strategy**
 - **Leadership contributions**
 - Patient groups
 - Scientific societies
 - Academic institutions
 - Health care industry
 - Other advocacy organizations
 - **Broader Outreach**

Timeline



Future Issues

- **Human Embryonic Stem Cell Research**
- **Conflicts of Interest**
- **Comparative Effectiveness Research**
- **Protection of Human Research Subjects**
- **Privacy Issues in Health IT Bills**

“Physician Payments Sunshine Act” (S. 2029/H.R. 5605)

- S. 2029 introduced 9/6/07 by Sens. Grassley (R-IA) and Kohl (D-WI)
- H.R. 5605 introduced 3/13 by Rep. DeFazio (D-OR)
- Manufacturers must disclose quarterly to HHS anything of value given to doctors (e.g., payments, gifts, honoraria, travel)
- Requires Secretary to post information on public web site
- AAMC endorsed revised bill in May 2008
- Grassley spoke to AAMC Executive Governance in September 2008

Comparative Effectiveness

- S. 3408: Introduced July 31 by Senate Finance Committee Chair Max Baucus (D-Mont.) and Budget Committee Chair Kent Conrad (D-N.D.)
- Establishes a public-private Health Care Comparative Effectiveness Research Institute
- Establishes a Comparative Effectiveness Research Trust Fund (CERTF) to finance the Institute
- Effective FYs 2012 -2018 CERTF would receive funding from the Medicare Part A and Part B Trust Funds, as well as assessments on private health plans

Human Subjects Protection

Reps. DeGette (D-Colo.) and Doggett (R-Texas) introduced “Protection for Participants in Research Act of 2008” (H.R. 7140) on Sept. 26

- **Expands common rule to all human subjects research**
- **Harmonizes common rule and FDA protections**
- **Secretary to consider modifications of common rule on issues such as exemptions from or expedited IRB review and IRB composition**

Human Subjects Protection

- **Specifies IRB activities**
- **Specifies institutional responsibilities regarding conflicts of interest**
- **Improves monitoring of high-risk research**
- **Authorizes Office of Human Research Protections and specifies actions on Compliance and enforcement**

Human Subjects Protection

- **Requires Secretary to promulgate regulations to enhance the protection of people with diminished decision-making capacity in research**
- **Requires Secretary to report to Congress on increasing the number of IRB members whose primary expertise is in nonscientific areas and the number of IRB members who are not affiliated with the institution served by the Board**

Health Information Technology and Privacy

- **S. 1693: “Wired for Health Care Quality Act”**
 - Approved by Senate HELP Committee on June 27, 2007
- **H.R. 6357: “PRO(TECH)T Act”**
 - Approved by House Energy and Commerce Committee on July 23, 2008
- **H.R. 6898: “Health-e Information Technology Act of 2008”**
 - Introduced by House Ways and Means Chair Pete Stark (D-Calif.) on September 15, 2008