From the President

Where We Are in the AFMR and Where We Hope to Go in the Coming Year

This has been a year of change at the AFMR. First, we witnessed the development of a political change throughout the land with the election of Barack Obama to the highest office in the free world. A shift in funding from Iraq to the NIH was in the air. Near universal, although not quite universal, health care coverage for the masses is on the table. Increased funding for medical research, with the potential for an elimination of previous restrictions on stem cell research, and real increases in NIH funding have been envisioned as real possibilities. But, down came the economy and those visions have been placed on a temporary hold. We’re weathering the storm at the AFMR. Like many other organizations, we’ve seen a downturn in our investment portfolio, but with our push to recognize and treat the crisis in clinical research, we’ve been invigorated. We also realize, along with some members of Congress, that the clinical research enterprise is an economic stimulus in its own right.

We are trying to spread the word that not only is the $28 billion budget of the NIH insufficient, but what the NIH receives is not always spent in the right ways. NIH created the roadmap - but for some, this has been an array of one-way streets from the bench to the bedside: that has defined translational research. Often forgotten is the return route: taking the clinical observation back to the lab. Clinical research is suffering. There are fewer and fewer clinical investigators, and they are becoming older, or are leaving the field. I was appalled that a recent AAMC survey found 17% of those completing MD-PhD programs opted for private practice. I suspect few of those who remained in research chose a clinical investigator path. Clinical responsibilities have increased, as has the disparity in pay between clinical investigators and their counterparts participating in

The American Federation for Medical Research says Daschle Must Cure Clinical Research Crisis if Change is to Take Hold in U.S. Health Care System

AFMR Pledges Full Organizational Support to Daschle and Obama Administration to Mitigate U.S. Clinical Research Crisis

The American Federation for Medical Research (AFMR) announces its full support of Former Senate Majority Leader Tom Daschle’s appointment to the post of Health and Human Services secretary. Mr. Daschle will serve as President-elect Obama’s top administration official to overhaul the nation’s health care system.

As a result of its work since 1940, the AFMR believes firmly that improving clinical research in the U.S., which weakened significantly during the Bush administration, is a lynchpin to achieving

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sustainable change in the U.S. health care system. The AFMR pledges the full support of its human resources, medical expertise and scientific knowledge to Mr. Daschle and the Obama administration for the advancement of clinical research, including its leading U.S. physician members and Nobel laureates who have made significant contributions to modern medicine and patient care through clinical research.

“Medical science and the U.S. health care system cannot progress without clinical research,” said Dr. Alan Buchman, president of the AFMR and a prominent physician in gastroenterology. “Yet our nation has neglected the advancement of clinical research – that which involves patients directly – which can prevent disease, lead to more effective disease treatments, medical breakthroughs for chronic diseases, and cut the astronomical costs and inefficiencies that plague our health care system. Mr. Daschle has the opportunity to fix this fundamental issue early on, which will have an enormous positive ripple effect on the rest of the health care system,” said Buchman.

The U.S. clinical research crisis stems from two primary issues:

1) Federal budget cuts for the NIH, particularly in funds spent on clinical research and the education and training of future clinical investigators and physician-scientists, and 2) Lack of support for future physician-scientists, whose job it will be to bring modern medicine and quality patient care to future generations.

According to the Centers for Disease Control and Prevention, chronic diseases account for seven out of 10 deaths in the U.S. and for 75% of every health care dollar spent each year. Yet federal funding for clinical research has decreased in recent years, and funding that has been apportioned, has gone mainly to basic research rather than clinical research – the only kind of research that generates disease-specific breakthroughs and patient treatment alternatives.

The NIH budget for the current fiscal year, $29.2 billion, represents a $329 million increase over last year, but the actual growth for NIH programs is much less because $200 million of the increase was earmarked for the Department of State Global HIV/AIDS fund. When the $200 million is subtracted from the budget, the actual increase in NIH programs is reduced to just $133 million (0.5%) over last year. It is not yet known how the FY 2009 budget will be impacted, although the statement accompanying the signed bill from President Bush indicated his intention to submit an FY 2009 budget proposal that will “once again restrain spending.”

One program impacted by the tightening of the NIH budget is the Clinical Translational Science Award program (CTSA) – the NIH-supported clinical research program intended to speed the translation of scientific discovery to the treatment of patients. As a result of the cuts, the NIH is unable to fully fund the evolution and expansion of the CTSA program, which has become a critical training and research structure for junior investigators.

Another alarming issue is the growing scarcity of human resources in the clinical research field. The current generation of physician investigators is aging rapidly and there aren’t enough investigators to replace them because support for new investigators entering the field has decreased significantly in recent years.

According to the NIH, the average age of physician scientists in 1980 was 39. By 2015, the average age is expected to be 52. If action is not taken now, the U.S. will face a critical shortage of qualified physician investigators within the next decade, creating a massive knowledge gap between aging physicians and the next generation of physicians.

“The cost of not advancing research and training future physician scientists is one that will be paid by the entire world. The United States is a global feeder pool of physician scientists,” said Buchman. “A further breakdown in clinical research and failure to revitalize the physician-scientist workforce of the future will impact medical breakthroughs, treatments and critical training throughout the world. The pharmaceutical industry cannot be counted on to undertake clinical research alone, and from an economic standpoint, clinical research dollars are being focused away from the U.S. and concentrated on China and India.”

The AFMR is an international, multi-disciplinary association of physician scientists engaged in all areas of patient-oriented clinical, translational and laboratory research. The organization promotes understanding of advances in the prevention, diagnosis and treatment of disease, facilitates the exchange of ideas and information among physicians and investigators concerned with the treatment of disease and works to improve public health by fostering research across medical disciplines through public policy initiatives and educational programs. The AFMR also works to develop future generations of clinical researchers through its own programs, while encouraging public, private, and governmental investment in such initiatives.
Medical science cannot progress without clinical research¹. Yet the last thing that appears to be on the minds of government leaders is the advancement of clinical research so that our nation’s physicians may continue to pursue medical breakthroughs and treat future generations of patients with chronic diseases.

Clinical research is not being funded adequately because current funds allotted by the government are apportioned predominantly to basic research rather than to clinical research, which is the only kind of research that generates disease-specific breakthroughs and patient treatment alternatives. Lobbying efforts on Capitol Hill for more clinical research funds have also proven to be a futile exercise over the past two years.

While pre-election discussion of Obama health-care policy was peppered with talk of socialized insurance, a Medicare-like government plan for people under age 65, expanded Medicaid, and employers required to provide insurance for employees or pay higher taxes, one element of change never rolled off the tongues of candidates, pundits, or analysts – the advancement of clinical research in this country. Ironically, this conspicuously absent element is a lynchpin to achieving sustainable change in the malfunctioning U.S. health care system.

President-elect Obama has his work cut out for him on countless fronts, but when it comes to fixing the U.S. health care system, the new administration must address the bigger picture first by taking steps to mitigate the nation’s crisis in clinical research before trying to tackle other systemic issues.

Chronic diseases account for seven out of 10 deaths in the U.S., according to the Centers for Disease Control and Prevention (CDC). Such diseases also account for 75% of every health care dollar spent in this country each year. Yet our nation is increasingly neglecting the advancement of clinical research, which can prevent disease, lead to more effective treatments and cures, and cut the astronomical costs that have leaders on Capitol Hill grousing.

Another issue that must be addressed is the growing scarcity of human resources in the clinical research field. The current generation of physician investigators is aging rapidly and there aren’t enough investigators to replace them because support for new investigators entering the field has decreased significantly in recent years.

According to the National Institutes for Health (NIH), the average age of physician scientists in 1980 was 39. By 2015, the average age is expected to be 52. If action is not taken now, the U.S. will face a critical shortage of qualified physician investigators within the next decade, creating a massive knowledge gap between aging physicians and the next generation of physicians whose responsibility it will be to sustain global health for generations to come.

Grim Outlook for NIH Budget

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At this point, there is little reason for optimism that the NIH will fare better in FY 2009. The statement accompanying the announcement that the President had signed the bill indicated the President’s intention to submit an FY 2009 budget proposal that will “once again restrain spending.”

One program impacted by the tightening of NIH budget is the Clinical Translational Science Award program — the NIH-supported clinical research program intended to speed the translation of scientific discovery to the treatment of patients. Such budget cuts means that NIH is unable to fully fund the evolution and expansion of the CTSA program, which has become a critical training and research structure for the junior investigators who will usher modern medicine into the future.

The cost of not advancing research and training future physician scientists is one that will be paid by the entire world. The United States is presently a global feeder pool of physician scientists. A breakdown in clinical research and a failure to revitalize the physician-scientist workforce of the future will impact medical breakthroughs, treatments and critical training throughout the world.

With Obama taking office in January and a new NIH director slated to be seated at an undetermined time in 2009, the near-term fate of clinical research is unknown. But one thing is certain – the election season has ushered in new possibilities for change.

¹: The Institute of Medicine defines clinical research as “research conducted with human subjects in a patient or an outpatient setting.”
AFMR SESSIONS at Experimental Biology 2009
April 18-22, 2009 / New Orleans, Louisiana
All rooms are in the Ernest N. Morial Convention Center

MONDAY, APRIL 20, 2009

10:30-12:30, Room 255-257
Leptin: From Bench to Clinical Applications*‡
Christos Mantzoros

15:15-17:15, Room 242
Fragile X-Associated Tremor/Ataxia Syndrome: Genotype, Animal Models, Phenotype and Intervention*
Paul Hagerman

TUESDAY, APRIL 21, 2009

15:15-17:15, Room 238
Deborah Zucker

WEDNESDAY, APRIL 22, 2009

8:00-10:00, Room 243
Adhesion Complex Related to Proteins in Myocardial Rhythm and Function*
Robert S. Ross

10:30-12:30, Room 255-257
Systems Biology Investigations of Glucocorticoid Efficacy in Tissue Remodeling*
Robert J. Freishtat and Eric P. Hoffman

*This symposium is supported by a grant from the National Center for Research Resources (NCRR), a component of the National Institutes of Health (NIH) and its contents are solely the responsibility of the authors and do not necessarily represent the official view of NCRR or NIH.
‡This program is funded in part by an educational grant from Amylin Pharmaceuticals, Inc. which had no control over its content. No personally identifiable information regarding you is provided to any grant supporter.”
The leadership of CSCR and MWAFMR are pleased to present the 2009 Combined Annual Meeting. The Combined Annual Meeting has a rich history and always strives to provide a forum for young investigators at the fellow and associate/assistant professor level. This is also one of the few multi-specialty meetings with a broad focus where the attendees can learn about research techniques used in other specialties of medicine and apply those techniques to their own research.

Some highlights of the meeting include Department Chair Sessions, the Oral Abstract Session, the CSCR Hickam Lecture and the MWAFMR Keynote Speaker. New for 2009 - CSCR and MWAFMR will offer digital posters to those selected for the Moderated Poster Presentations during the Welcome Reception Poster Session on the evening of April 23rd and the Luncheon Poster Session on the afternoon of April 24th. During each of the poster sessions, Moderated Poster Presentations will be held for the top submissions in various subspecialties of medicine. Some of our expert reviewers for the Moderated Poster Presentations include James Cook, Greg Vercellotti, Neal Weintraub, David Kamp, and Terrence Barrett.

To assist young investigators who wish to attend the meeting and present their research to leaders in their fields, the following grants and awards are being offered: 30 grants in the amount of $1,000 each will be made available to K08, K23 and K30 Awardees. The Outstanding Young Investigator Award, Cardiovascular Award and Trainee Travel Awards will be offered. The MWAFMR/Centocor Scholar’s Program is available by merit-based invitation. The 2009 Combined Annual Meeting will take place immediately prior to the annual meeting of ASCI/AAP.
clinical trials in private practice. There are fewer mentors. There are fewer investigator-initiated trials. There are those that believe clinical research can be done by the drug companies alone. Well, the economy appears to have hit the pharmaceutical industry pretty hard too, and they themselves have had to outsource clinical research to overseas organizations due to the rising expense of clinical research in the USA, our regulatory burden, and the lack of appropriately qualified clinical investigators. They have also had to recruit from a shrinking pool of qualified medical researchers for their own ranks. We have lost an economy of clinical research to India and China. Regardless, Pharma cannot be counted on to make astute clinical observations and translate those into the understanding of disease pathogenesis and cures. That is the role of the clinical investigator — the dying breed. Academic investigators ask the questions and determine the direction for investigation. It is then up to the pharmaceutical industry to translate these discoveries into direct patient care.

There is a crisis in the interface of industrial and academic investigation. I think this stems in part from the old American adage, that a mistake can never be just corrected, it must be over-corrected. Abuses and conflicts of interest between academia and the pharmaceutical industry have been, and continue to be, issues whether it is suppressed clinical data, the use of ghost writers, or suppression of negative clinical data by describing trends only when they serve to benefit one party. On the other hand, the pharmaceutical industry has historically funded substantial and investigator-initiated clinical research, and perhaps equally if not more important, medical education. Someone is going to have to pay for medical education and for the education and training of the next generation of clinical investigators.

The pharmaceutical and academic medical industries should complement each other, not compete with each other. Honesty can no longer be counted on. Yet, over-burdensome regulation does not necessarily promote honesty, but more often abandonment and unfortunately, deceit. Someone is going to have to pay for novel clinical investigation designed to obtain clinical data so that more significant government funding can be secured.

The Clinical Translational Science Awards (CTSAs) are being rolled out, but in many cases funded at under 50%, in an attempt to support additional programs. The CTSA has been a valid attempt to move clinical research into the community and to help train new clinical investigators. However, even the eventual goal of the program falls far short of the number of GCRCs they are replacing. We worked with NASCRR on a House of Representatives sign-on letter to increase support for the CTSA program. However, we must also recognize that clinical research is performed outside of the auspices of the NIH. The DOD, USDA, VAMC, and even the FDA all fund clinical research. Funding is not as substantial as it should be in any of these agencies.

What are we to do? We have initiated a public relations campaign to increase public awareness of the AFMR, and to educate the public on the importance of and impending crisis in clinical research. The AFMR is working on ways to educate the public through the media. We issued a press release that was covered by some 900 websites, newspapers and other electronic media on the appointment of former Senator, Tom Daschle, whom we support as a significant step in the right direction. We held a conference call with Dr. Tachi Yamada of the Gates Foundation to increase their awareness of the crisis in clinical research and help drive them to help domestic research funding. We met with industry leadership to discuss the crisis and what that meant for them and to enlist their support for our initiatives. The AFMR will be convening a day-long workshop to address Clinical Research Issues on April 14, 2009 in Washington, D.C. It is expected this meeting will include members of Congress, White House staff, the NIH, Pharma, academic medicine, the mainstream press, and members of the major specialty and subspecialty societies in medicine who will be invited to attend.

Our new website (www.afmr.org) is designed to be more informative for our membership, our colleagues, and the public. We are creating features for the public, including education (what clinical research is, major discoveries by AFMR members, etc.) and press releases, as well as a feature that will allow for tax deductible donations to our mission.

We are working to increase the visibility of the AFMR and its mission through exhibit booths at Digestive Disease Week (DDW), the American College of Cardiology Annual Meeting, and the Endocrine Society Annual Meeting in 2009. In the future, we plan to exhibit at additional meetings. We will be promoting our multi-disciplinary approach that crosses divisional and departmental boundaries. We will be promoting our Regional Meetings; Western (Jan. 28-31, 2009 in Carmel), Southern (Feb. 12-14, 2009 in New Orleans), Eastern (April 15, 2009 in Washington, DC), and Midwestern (April 23-24, 2009 in Chicago) to the press when important research is being presented or landmark presentations are being delivered. We will also be promoting these meetings to their regional constituents as unique and ideal places for students, residents, fellows, and junior faculty to present their work.

The AFMR continues to provide translational research sessions at Experimental Biology, as in past years; EB09 is slated for New Orleans, Apr. 18-22, 2009. Thanks largely in part to an NIH grant initiated by Dr. Debbie Zucker of Tufts, the AFMR hopes to attract basic investigators to our sessions and link them to clinical and translational investigation.

We have developed a liaison with the American Association for the Advancement of Science (AAAS) on a career development website (funded in part by Burroughs Wellcome) and have begun an investigation into the possibility of either the re-establishment of the Tri-Societies (AFMR, ASCI, AAP) meeting, or to expand the current link between the AFMR and ASCI/AAP meetings. Our Henry Christian and Outstanding Research Award winners will be presenting their research at the MWAFMR/CSCR meeting as well as at the ASCI/AAP meeting. We are also exploring a strategic relationship with the AAP, ACRT, and the developing CTSA directors’ society in terms of joint scientific and educational programming, as well as in lobbying efforts. The AFMR is beginning what we hope to be an annual Career Development Workshop in association with the MWAFMR/CSCR meeting in Chicago (on April 23, 2009) and immediately preceding the ASCI/AAP meeting. This workshop will feature nationally-recognized leaders in medicine.

Some may say there are too many organizations involved in the promotion of clinical research. I say there are either not enough, or not enough doing anything to address the current crisis. Perhaps there are too many organizations with overlapping missions and egos that sometimes prevent the development of strategic alliances, so that when it comes to Congress or the public less is accomplished because we all speak different words. The AFMR plans to be a leader in the development of strategic alliances with other organizations designed to achieve our overall goals - to arrest the crisis in clinical research by securing appropriate funding for the training of the next generation of investigators, assuring increased and continued high priority clinical research, funding, and retaining the best and the brightest in clinical investigation. But ultimately, this can only be accomplished once all stakeholders who support these ideals come together and speak with one voice.
Benefits of AFMR Membership

**AFMR Member? Renew online! Not a member? Join today! [www.afmr.org](http://www.afmr.org)**

- Advocacy on behalf of medical investigators and researchers - the AFMR has direct Washington representation on Capitol Hill, and also works with other related societies to pool resources to get important messages directly to members of Congress
- Updates on Public Policy and Clinical Research Funding including regular AFMR email alerts and “call your Congress representative” notifications
- A complimentary print and online subscription to the *Journal of Investigative Medicine*, the AFMR’s official journal
- No page charges on publications in the *Journal of Investigative Medicine* for AFMR members
- A dedicated Members’ Only area on the AFMR website where members can update their records, access the journal, seek information on other AFMR members in their city or state, and obtain important grant and career information through an ever-expanding portal
- Opportunity to apply for a series of substantial Awards - including the AFMR Outstanding Investigator Award, Junior Physician Investigator Awards, the Henry Christian Awards, and AFMR Regional Scholar Awards
- Reduced registration fees at Regional Meetings as well as the AFMR National Meetings
- Notification of all upcoming abstract deadlines for important national and regional meetings
- Opportunity to present and showcase your work at Regional and National Meetings as well as to present symposia at Experimental Biology each year - a forum for translational research
The American Federation for Medical Research Foundation was established in 1989 to foster medical research and support programs aimed at developing the careers of physician scientists. The Foundation collaborates with other organizations to fund special research award programs, promote initiatives that enrich the education of research trainees, and honor outstanding achievements in the biomedical research community. In 2009, the Foundation will present the following awards:

**Outstanding Investigator Award**
Presented annually to an outstanding investigator age 45 or younger in recognition of excellence in biomedical research. To be considered, individuals must be nominated by two individuals. The winner receives an Outstanding Investigator Award and a prize of $5,000.

**Henry Christian Awards**
Given to presenters and first authors of outstanding abstracts submitted in each abstract category for the 2009 AFMR Regional Meetings or the ASCI/AAP Joint Meeting. Presenters at the Western Regional Meeting, the Southern Regional Meeting, the Combined Midwestern Meeting in Chicago, Illinois, and the Eastern Regional Meeting in Washington, DC who meet the requisite criteria are eligible.

**Junior Physician-Investigator Awards**
A candidate must be a physician who has held a full-time medical school faculty appointment for five years or less. Candidates must have submitted an abstract for the 2009 AFMR Regional Meetings or the ASCI/AAP Joint Meeting. Presenters at the Western Regional Meeting in Carmel, the Southern Regional Meeting in New Orleans, the Combined Midwestern Meeting in Chicago, Illinois, and the Eastern Regional Meeting in Washington, DC who meet the requisite criteria are eligible and will be judged on both the quality of the abstract submitted and their career accomplishments. Awards of $2,500 will be presented to two winners.

**FOR ADDITIONAL INFORMATION AND COMPLETE CRITERIA AND TO ACCESS AN APPLICATION**
VISIT [www.AFMR.org](http://www.AFMR.org).

**General Eligibility**
To qualify for consideration of an award, applicants must be AFMR members in good standing. If you are not currently an AFMR member, you must submit a membership application along with the award application. A membership application can be completed online at the AFMR website, [www.afmr.org](http://www.afmr.org).