From the President

Remember when you joined AFMR? Chances are your initiation came through a mentor or a positive role model who felt that membership in AFMR would benefit your career. Since its establishment in 1940 by Dr Henry Christian, one of the key goals of AFMR (then AFCR) has been the promotion of medical research through programs that foster the career development of junior investigators. To this day, AFMR continues to introduce new scholarship, leadership, advocacy, and career development programs to meet this goal. That objective is particularly critical today, as we are approaching a workforce crisis in medical research. While the number of NIH scientists and academic faculty has remained at steady state for the past two decades, numbers will decline precipitously in the next one to two decades if new investigators are not recruited and retained at an increased rate. In 1980, average age of NIH PIs was 39, with 37 being the average age of new PIs. Today, new PIs are 42, and the average age of PIs is 51, with approximately one in eight being between 65 and 80 years old. We simply are not attracting, training, and retaining enough junior researchers to replace the retiring research workforce. Thus, the success of the AFMR mission is more critical now than ever before.

Grim Outlook for NIH Budget

A long struggle between the Congress and the White House resulted in an extremely disappointing NIH budget for the current fiscal year. In FY 2008, NIH will operate with a budget of $29.2 billion, a $329 million increase over last year. However, the actual growth for NIH programs is much less because $200 million of the increase will be transferred from NIH to the Department of State for the Global HIV/AIDS fund. Following is a brief chronology leading up to the final outcome:

- The original NIH budget proposed by the President would have reduced the NIH budget by $278 million and increased the NIH contribution to the Global AIDS fund by $200 million, making the actual cut in NIH programs more severe.
- In November, Congress approved a $1.1 billion (3.8%) increase for NIH, but unfortunately, this was vetoed by the President. When Congressional negotiators proposed a compromise in which they would “split the difference” between the President’s original request and the Congressionally approved funding levels, the White House promised a second veto.
- In late December, the White House agreed to sign a bill that would reduce overall spending in the HHS Appropriations by an across-the-board cut of 1.8% in most programs of the Department of Health and Human Services, the Department of Education, and the Department of Labor. As a result, the final spending bill passed by Congress and signed by the President included essentially all of the cuts he had proposed.

More Washington Highlights Inside:

Future of CTSA Program
AFMR TRANSLATIONAL SYMPOSIA

to be presented at Experimental Biology 2008
April 5-9, 2008 /San Diego Convention Center

Please Join Us at EB 2008 for the Second Annual
AFMR-Translational Medical Research Development Workshop*
Saturday, April 5, 2008 / 4:00 - 7:00 PM

Strategies for Innovation and Interdisciplinary Translational Research: Research and Career Benefits and Barriers

- What promotes creativity and innovation in medical research?
- How can you bridge your research across disciplines and from bench to bedside?
- In practice, how does this impact career and research development?

AFMR is pleased to present this workshop to discuss strategies for innovating and developing interdisciplinary, translational research and researchers. Panelists experienced in translational research and various academic and non-academic research settings - such as the NIH-funded Clinical and Translational Research Centers, Stanford’s Bio-X Center, The Institute for Systems Biology, and Industry-sponsored “Incubators,” - will explore what works and what challenges are faced by institutions and researchers as we strive to develop novel solutions, bridge knowledge between disciplines and successfully bring research from bench to bedside to practice. The workshop is designed to promote discussion and brainstorming about current programs and new possibilities.

WORKSHOP FACULTY

Lars Berglund, MD, PhD, Center for Clinical and Translational Research, PI & Director
Associate Dean for Clinical and Translational Research
Professor of Medicine, University of California at Davis

William Mobley, MD, PhD, Director, Neuroscience Institute
Stanford University School of Medicine

Marc Facciotti, PhD, Assistant Professor
Genome Center & Dept. of Biomedical Engineering, University of California at Davis
Formerly: Institute for Systems Biology, Post-Doctoral Fellow in Systems Biology

Mark J. Benedyk, Ph.D., Head, La Jolla Incubator
The Pfizer Incubator, LLC

Workshop Chair: Deborah Zucker, MD, PhD, Past-President, AFMR
Institute for Clinical Research & Health Policy Studies, Tufts-NE Medical Center

4:00-4:20: Welcome and Introduction Dr. Deborah Zucker

Dr. Lars Berglund
Dr. William Mobley

Dr. Marc Facciotti

5:50-6:20: Industry Approaches: Biotech/Pharma Incubators
Dr. Mark Benedyk

6:20-6:45: Panel and Audience Discussion

6:45-7:00: Networking and Refreshments

*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.
President provides only $29.2 billion for the NIH, an increase of $329 million (1.1%) over FY 2007. However, factoring in the additional $200 million transfer to the Global HIV/AIDS Fund, the increase in NIH programs is reduced to just $133 million (0.5%) over last year.

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.” The AFMR will continue to monitor the budget closely and alert members when letter-writing or calls to Congressional offices would be appropriate.

### NATIONAL INSTITUTES OF HEALTH

<table>
<thead>
<tr>
<th>Institute Name</th>
<th>FY 2007 Comparable (Amount in Thousands)</th>
<th>FY 2008 Final (Amount in Thousands)</th>
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* Does Not Include $99,000 for the Global HIV/AIDS Transfer Fund in 2007
** Does Not Include $294,759 for the Global HIV/AIDS Transfer Fund in 2008
# Includes $483,000 for the Common Fund in 2007
## Includes $495,608 for the Common Fund 2008
To address this opportunity, active participation from our membership is essential. In turn, AFMR has developed **several new initiatives that will substantially increase the benefit of membership to our junior investigators**. These initiatives are outlined below. We ask that you consider them and ask young investigators who might gain from these initiatives to join AFMR.

**Scholarship**

AFMR provides a venue for scholarship through the national and regional meetings and the AFMR journal, the *Journal of Investigative Medicine*. This year, the National Meeting, (Chicago April 24th - 25th 2008) will be held in conjunction with the Mid-Western Regional Meeting and features the Henry Christian, Outstanding Investigator, and Junior Investigator awards. We are very happy to announce that AFMR has **rekindled collaboration with AAP (Association of American Physicians) and ASCI (American Society for Clinical Investigation)**. The Henry Christian and Junior Investigator Award winners will present their work at the AAP/ASCI Joint Meeting immediately following the National Meeting. This renewed relationship once again gives entry and mid level investigators exposure to the nation’s premier physician scientists in an intimate environment. The Eastern Regional Meeting (Washington, DC, April 8, 2008) features a **collaboration with the Clinical Research Forum** in which a joint session will be held immediately following the Eastern Meeting at the Fairmont Hotel. This session will outline changes in the approach to and challenges presented by translational research in the new Millennium. The Southern (New Orleans, LA Feb 21-23, 2008) and the Western (Carmel, CA Jan 30 – Feb 2, 2008) Regional Meetings continue to offer **strong trainee travel award programs** ($22,500 in the West and $40,000 in the South). At both meetings, a majority of abstracts are podium presentations. This gives junior investigators the opportunity for feedback from more senior investigators in a fashion not possible at large subspecialty meetings. These meetings feature practical and well attended career development workshops with titles such as “Manuscript Preparation and Peer-Reviewed Publication”, “Career Development Workshop”, “Be a Better Teacher! Help Your Learners and Yourself”, and “Introduction to Biostatistics Workshop”.

The *Journal of Investigative Medicine* will be published by Lippincott, Williams, and Wilkins beginning in January 2008. We are very excited by the positive relationship that we have developed with this publisher. As part of this arrangement, **page charges will be waived for members of AFMR**. This is a high value benefit of membership. Essentially, **membership fees are recouped after the first two pages of a published manuscript**. Please consider JIM when submitting manuscripts, as the quality and quantity of manuscripts submitted has been increasing significantly in the last few years.

**Advocacy**

AFMR is deeply concerned that the vision of the Clinical Translational Science Award program enacted by Dr. Elias Zerhouni is not being interpreted at all institutions in a fashion that adequately supports the training and research of junior investigators. This is further hampered by recent the cuts in funding to the CTSA. For 2006 awardees, budgets will be cut by 5% per year until renewal. For 2007 awardees, the budget will be capped at 35-45% of previous funding for the GCRC and training programs. With indirect costs included in the total rather than added to the total, most programs are left with inadequate funding to meet the core objective of the CTSA, to act as a home for the training of the next generation of translational researchers. Many are finding that the resources for clinical research are actually eroding under this program. The following is a summary of a recent survey sent to AFMR members by Lynn Morrison of Washington Health Advocates, “One CTSA institution projects that the number of patient studies supported will drop from 80 under the prior GCRC to 50-60 under the CTSA. Several institutions report that the support for patient research units (formerly GCRCs) is being cut by as much as 50% (even after correcting for the reassignment of responsibility for informatics and other previous functions of the GCRC). Numerous institutions are reporting that nursing personnel are being replaced with less skilled ancillary personnel. Within some CTSA-funded institutions, patient-oriented researchers are being charged “fees” for resources that had been provided previously by the GCRCs at no charge. Because the researchers predicated their grant budgets on the availability of these resources, they have no funds to cover the additional costs. Investigators must scramble to find funds for these additional, unexpected costs or simply cancel the human studies in their grants.”

To address our concerns on the Hill, AFMR’s advocate, Lynn Morrison of Washington Health Advocates, has been working tirelessly to inform Congress of the effects of reduced resources for junior investigators and is lobbying for increased funding for the CTSA program to completely fund the budgets approved by the NCRR Council in 2006-2007 and to maintain an adequate budget to do the same for the 2008-2009 CTSA. The ultimate goal is to ensure that the vision of the CTSA, to train the next generation of translational investigators, be preserved. **AFMR members may be called upon to participate in a grass roots lobbying effort**. Our tax status as a nonprofit corporation limits the amount of membership income that we can spend on advocacy. Because

(continued on next page)
From the President (continued from previous page)

The AFMR leadership is very aware of the challenges that face young investigators today. As a result, we are always seeking to introduce and refine programs that act to develop the careers of its junior members.

Career Development

The AFMR leadership is very aware of the challenges that face young investigators today. As a result, we are always seeking to introduce and refine programs that act to develop the careers of its junior members. For instance, a new initiative is being piloted at the Southern Regional Meeting this year. In collaboration with the Southern Society for Clinical Investigation (SSCI, the senior sister society to SAFMR) young faculty AFMR members will meet with SSCI members to discuss career objectives and milestones. Oftentimes, junior investigators feel that they would like to gain the perspective of external faculty when making career decisions. This extramural career counseling program fills a need for this segment of our membership. To enroll for this program, go to www.afmr.org and choose an advisor from the list.

The Southern and Western Regional Meetings feature practical and well attended career development workshops with titles such as “Manuscript Preparation and Peer-Reviewed Publication”, “Career Development Workshop”, “Be a Better Teacher! Help Your Learners and Yourself”, and “Introduction to Biostatistics Workshop”. The Western Regional Meeting offers “Breakfast with the Investigator” sessions for students, while the Southern Regional Meeting features the “Chairs’ Breakfast” in which select house staff meet Medicine Chairs from across the region.

AFMR is pleased to announce the launch of the Career Connection Resources website (www.afmr.org/****). This site is designed to give junior investigators the references and tools they need to navigate a medical research career. Topics covered are grant writing and administration, time management, issues for the developing medical scientist, sources of research funding, lab management, research training opportunities, responsible research conduct, and intellectual property.

Leadership

An often overlooked benefit of AFMR membership is the opportunity to assume leadership roles early in one’s career. The opportunities for leadership are varied. While progression from one position to another is not prescribed, members can serve as institutional representatives, regional councilors, regional officers, national councilors, and national officers. These positions can provide valuable leadership experience for those inclined to administrative service. To make the process of attaining these positions more transparent, members may self-nominate and obtain instruction on the institutional representative web site (http://www.afmr.org/membersOnly.cgi click on “institutional representatives”). Those seeking elected office may be nominated on either the regional or the national web sites after a call for nominations is sent by email. We encourage our members to explore the possibilities of AFMR leadership in this exciting time of transition in clinical research.

Many may ask, “What am I getting from AFMR membership?” After reading about our new and continuing efforts to provide a home for young investigators, it is our hope that you have found the answer. However, the time is now to consider what we can do for our national clinical research enterprise by supporting the future generation of medical investigators. Current members, we ask that you renew in a timely fashion so that our advocacy, scholarship, and career development efforts can continue to grow and maintain quality. We urge you to consider becoming an active participant in AFMR by serving as an institutional representative, councilor, or officer. Publicize AFMR at your local research day and department/division meetings. Encourage junior investigators to explore the opportunities of career development, advocacy, scholarship, and leadership through AFMR membership just as your mentor did for you.
SENIOR APPROPRIATIONS COMMITTEE MEMBERS QUESTION FUTURE OF CTSA PROGRAM

In September, the NIH announced a major change in the funding policy for the new Clinical and Translational Science Awards. Because of inadequate budgeting for the program: 1) CTSAs funded in the first round were cut by 5% across-the-board; and 2) the additional funding provided in CTSA awards made in FY 2007 was capped at 35-45% of pre-existing NIH clinical research support—significantly below the increases of up to $6 million originally pledged by NIH when the program was initiated. This has raised considerable concern on Capitol Hill, particularly given the fact that the Congress provided the NIH with nearly 100% of the funds requested for the CTSA program in fiscal years 2006 and 2007.

In December, Representatives Nita Lowey (D-NY) and Rosa DeLauro (D-CT), both senior members of the House Appropriations Committee, sent a letter to NIH Director Elias Zerhouni expressing concerns about the planning and implementation of the CTSA program. Of particular importance, the Lowey/DeLauro letter requested information as to the realistic funding needs of the CTSAs in future years. The letter notes that “…the Congress requires reliable funding projections for FY 2008-2010 if the CTSA program is to succeed…”

In addition, the letter expressed concern about whether the NIH was assuring compliance with previous Congressional instructions to assure that the infrastructure and clinical research resources previously provided by the GCRCs is maintained or enhanced within the CTSA institutional awards. The Lowey/DeLauro letter states:

Reduction of investigator access to clinical research resources is unacceptable given the significant amount of additional funding provided by Congress for the CTSA, the need to assure the translation of basic scientific discoveries to humans, and the clearly stated Congressional intent that the services provided by the GCRC be maintained or enhanced.

The letter inquires as to what NIH is doing to implement a policy for the CTSAs that ensures that “NIH complies with previous Congressional directives that the necessary resources and infrastructure remain available for clinical investigators.”

The letter concludes with an expression of support for an outside evaluation of the CTSA program conducted by an independent organization that would include recommendations for the budget necessary to fully fund the CTSAs as originally envisioned. Of particularly interest, Representatives Lowey and DeLauro suggest an analysis of the amount of funding in the CTSAs devoted to institutional indirect costs as compared to the previous administrative/overhead costs of the GCRCs and K training awards. Many in the clinical research community are concerned that with a 45% cap on growth and a substantial increase in the portion of the grant going to pay the full indirect cost rate, the CTSA award could actually reduce direct cost support for clinical research and training in some institutions as compared to the previous GCRC and clinical K awards.

AFMR President James Oates applauded Representatives Lowey and DeLauro for taking the initiative to analyze the future of the CTSA program in greater detail.

“Representatives Lowey and DeLauro have been great friends of clinical research, and AFMR officers have met with both of them many times. They have taken our concerns to heart and are doing everything they can to assure that the next steps in the transition to the CTSA program are taken with more reliable information about the budget required,” Oates said.

The AFMR will continue to monitor the CTSA transition closely and keep members informed regarding NIH and Congressional Actions.

CTSAs: Concern is Widespread

It is not just leading Members of Congress who have major concerns about the planning, budgeting and implementation of the CTSAs. Institutional leaders of the CTSA programs have questioned the viability of the program within the significantly revised funding parameters. In late October, a group of almost 100 clinical research nurses sent a letter to Congressional appropriations leaders expressing the view that inadequate funding for the CTSA was limiting support for clinical research nurses and detailing ways in which this would “…compromise patient care, patient safety and the quality of research data.” Most investigators in CTSA-funded institutions responding to preliminary surveys by both the AFMR and the Association of Patient-Oriented Research indicated that the CTSA initiative has not been beneficial:

• In the APOR survey, only 12% of respondents said they were “better off” under the CTSA award, with 67% experiencing no change and 21% indicating that they are “less well off.”

• In the AFMR survey, 44% of respondents believed that the support for patient studies in their institutions had actually been diminished by the transition to the CTSA, with less than one-third believing the impact had been positive.

Attention AFMR Members: Are you interested in a position on the National Council? Visit the AFMR website at www.afmr.org to view a list of open positions and to indicate your interest.
Changes in the Journal of Investigative Medicine

Michael J. McPaul, M.D., Editor in Chief

With the publication of volume 56, issue number 1, the Journal of Investigative Medicine enters its 15th year of publication as a peer-reviewed journal. This issue also marks the transition to a new era, as we begin our association with our new publisher, Lippincott, Williams, and Wilkins. This change marks an important milestone in the evolution of the JIM, as the resources and reach of our new publisher will greatly improve the visibility and impact of work that is published in the Journal of Investigative Medicine.

In keeping with the mission of the AFMR, the Journal of Investigative Medicine seeks to publish original manuscripts detailing the results of high quality clinical and translational research. In addition, the Journal provides an avenue by which investigators can publish scholarly reviews relevant to the research-focused mission of the AFMR. Such contributions include summaries of methodological, ethical, or regulatory information that is related to the conduct of clinical and translational research. Finally, JIM provides a platform for its readers to contribute observations and commentary regarding issues or ideas that are important to the biomedical research community.

The present is a challenging and exciting time in the areas of clinical and translational research. New initiatives at the NIH are effecting important and fundamental changes in the way that research is being conducted. The AFMR is uniquely situated to publish the results of research that is conducted as a part of these changes and to serve as a voice to help to influence the course of these changes.

Types of Manuscripts considered in the Journal of Investigative Medicine

Original Contributions are reports of original work that embody scientific excellence in clinical or translational research. In general, the text of the manuscript will average approximately 6,000 words.

Brief Reports are designed to permit the presentation of material that is meritorious, but which is not sufficient to warrant publication as an Original Contribution. Examples of material that would be appropriate for such a format include: (1) a study that makes limited but provocative observation(s), and (2) excellent but negative studies focused on important topics.

Review Articles are scholarly syntheses focused on topics of general interest to the readership of the Journal. Review Articles are may be solicited by the Editors, but unsolicited manuscripts will also be considered.

Each year the AFMR sponsors symposia at the annual Experimental Biology meeting. These presentations are summarized in high quality review manuscripts that are published in the Journal of Investigative Medicine.

Manuscripts derived from the proceedings of symposia or detailing the outcomes of important scientific meetings will be considered if addressing areas of broad interest to the membership of the AFMR.

Research Tools and Issues permits the publication of scholarly works and reviews focused in areas of broad interest to the research community. Manuscripts addressing topics relevant to the conduct of clinical research, mentoring, and career development are of particular interest. It is anticipated that in most instances manuscripts will not exceed 6,000 words and will include no more than six display items.

“At the Forefront” is a venue to permit the presentation of novel ideas and controversies. Material for “At the Forefront” may be solicited by the Editors. Unsolicited contributions will also be considered.

“Perspectives” provides a forum for the expression of views relating to material published in JIM and may address material published as an original contribution or brief report or as a contribution to “At the Forefront”. Although “Perspectives” may be solicited by the Editors, unsolicited contributions will also be considered.

“Seminal observations” - In general, case reports are not considered for publication in the Journal of Investigative Medicine. In selected instances, however, case reports illustrating provocative concepts or pathophysiologic mechanisms will be considered.

In addition, each issue contains a number of recurring features:

“JIM interviews” are conducted with prominent figures within the biomedical research community. JIM interviews are designed to provide information of interest to AFMR members about specific developments or programs and to provide insights of use in career planning and development.

“Comings and Goings” highlights the recruitments and departures of important figures in medical research and central to the making of research policy in the United States.

“News” highlights important developments in the US biomedical research community.

“In Memoriam” notes the passing of important figures in the biomedical research community.

“Grants and Contracts” summarizes research opportunities available from the NIH and other funding sources that are of potential interest to AFMR members.

ATTENTION AFMR MEMBERS – Important Information for Online Access

When viewing the Journal online at www.lwwonline.com, AFMR members need to add the “AFMR” to their member numbers (for example AMFR1234) to register for online access.