

FASEB NEWSLETTER

Quality Life Through Research

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New Team Handed Leadership Reins of FASEB

On July 1, a new team took over the leadership helm of the Federation, and they immediately embarked on a series of meetings with the heads of major organizations in the scientific community. Beginning his term as FASEB's President is David G. Kaufman, MD, PhD, a Professor of Pathology and Laboratory Medicine in the School of Medicine at the University of North Carolina at Chapel Hill. Kaufman recently served as President-Elect of FASEB under outgoing President, William R. Brinkley.

New to the leadership is President-Elect Mary Hendrix, PhD. Hendrix is Professor and Head of the Department of Anatomy and Cell Biology at The University of Iowa College of Medicine in Iowa City and the Associate Director of Basic Science Research at The University of Iowa Cancer Center. Rounding out the new leadership team is David Brautigam, PhD, Vice-President of Science Policy for the Federation, and Immediate Past President Brinkley. The addition of the Vice-President of Science Policy to the leadership ranks of FASEB bespeaks a greater emphasis on science policy issues.

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FASEB's Incoming President Identifies His Key Priorities for Federation

Incoming President David G. Kaufman, MD, PhD, met recently with several members of the scientific press and identified his key priorities for his term as FASEB's President. He stressed that the role of the Federation is to provide the perspective of working scientists to the government and the public.

In regards to FASEB's Public Affairs agenda, Kaufman emphasized the doubling of the budget for the National Institutes of Health – 15% each year for five years – as the top priority of the Federation. “We are at a critical juncture on the road to finding treatments and cures for dread diseases. It is imperative

that we capitalize on the opportunities that lie before us today. In order to do so, we must have the necessary financial resources. Doubling the budget for the NIH sets us on that path.”

But Kaufman noted that

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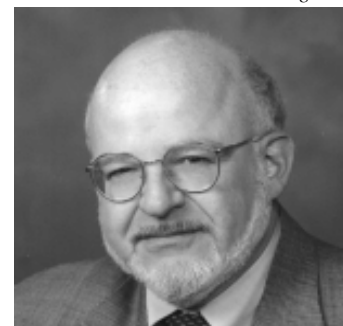
FASEB President David G. Kaufman, MD, PhD

investments in the other agencies that fund biomedical research are equally as important. Therefore, his second public

affairs priority is increases for the National Science Foundation and other agencies funding science. “We wish to make the case,” Kaufman told the reporters, “for the importance of progress in chemistry,

physics, mathematics, and computer science to the ability to pursue biomedical research.”

In the arena of Science Policy,



Kaufman highlighted three areas of concern to FASEB at this time – the plight of the physician-scientist, the deleterious effect of the burden of excessive regulations on research, and the need to communicate scientific progress to the public. The recent evolution of FASEB's Science Policy Committee, according to Kaufman, will allow for the sustained evaluation of these problems into greater depth, and for the development of campaigns to address these problems.

Kaufman believes strongly that FASEB can enhance the voice of the individual scientist. His ultimate goal as President? He seeks to improve the day-to-day conditions of the scientists who are members of FASEB societies. ■

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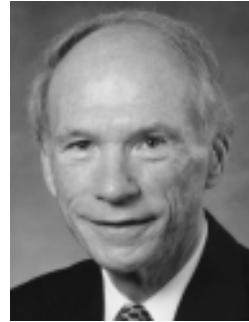
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Guest Opinion ... by Daniel Foster, MD
Why the Disappearing Physician-Scientists?



I work in a science-focused medical school and I am a science-focused chair of internal medicine. I believe students and residents at Southwestern appreciate the bedrock necessity of science for modern medicine. Despite this, too few seriously consider a career building that foundational bedrock, the career of physician-scientist. It is a national problem. Why? Serious questions rarely have single answers - there usually are polyanswers. I mention three that I consider critical.

1. There is the problem of plausibility structure. The vast majority of medical students start their careers undifferentiated. They know

they want to be physicians and not much else. In their course of study, a repertoire of identities becomes possible – one of which is physician-scientist, basic or clinical. It is a minority career with a different worldview from the majority career, the practice of medicine. In sociologic terms, it constitutes a cognitive minority. Its worldview is that research is an absolute good. If one is to join and remain in a cognitive minority, plausibility structures are required: visible truth symbols that identify the life as good, fulfilling, and possible. In the physician-scientist world, the plausibility structures have to be the scientists themselves. At the risk of sounding judgmental, there are problems. Successful scientists and physician-scientists are often invisible to students and residents. Even if we attend on wards, we are frequently not attractive as teachers and clinicians. We have let these skills drift away. We often spend little effort supporting medical students who do research. Finally, we rarely convey a sense of joy in what we do. In brief, there is a role model deficit.

2. There is the problem of the magnetism of modern medicine. I believe we have completely missed the fact that the attractive power of modern medicine is immense. To take care of a sick human being with the powerful tools available today is regularly fulfilling, sometimes exhilarating, and immediately rewarding. There is a mantra in academic medicine these days that says you can only do one thing well. It is not possible to be a triple threat, it is said. Practically, what the students and residents hear is that physician-scientist is an untrue term. You can be a scientist or a physician, but not both in any meaningful sense. And if the students/residents think they have to give up medicine, they will generally walk away. I believe that the fear of having to leave medicine is a powerful and under-recognized negative force in the decrease in physician-scientists. Space precludes the argument, but I think we should be saying exactly the opposite: you can be a scientist and still be a physician. You may, in the long term, be a better physician because of your research.

3. There are sociological problems. We have to do something about medical school debt, but that is not all. We have to humanize the training experience so the trainees do not feel isolated or mere pawns in the mentor's research. We have to spread the word that funding will likely be available. We have to remove the big-business mentality that has infected even our best academic centers under the press of managed care. That mentality sees every faculty member as a cost center, not an asset. It sees research as a threat and thereby devastates morale. Residents and students notice. Fiscal responsibility does not require that apostasy.

Whether these issues can be solved is problematic. I hope. ■

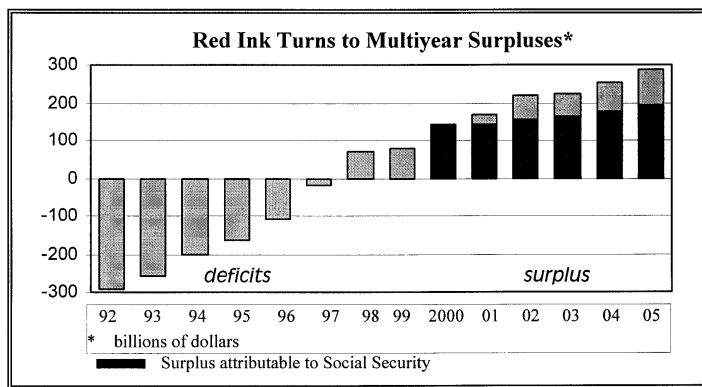
Daniel W. Foster, MD, holds the Donald W. Seldin Distinguished Chair in Internal Medicine and is Chairman of the Department of Internal Medicine at the University of Texas Southwestern Medical School at Dallas, his alma mater. He is a member of the American Society for Biochemistry and Molecular Biology, the American Society for Clinical Investigation, the Association of American Physicians, and the Institute of Medicine of the National Academy of Sciences. Recently, he served as President of the Association of Professors of Medicine. He was also the host of a nationally televised program on PBS, "Daniel Foster, M.D.," which aired for four seasons.

Exploding Government Surplus Fails to Trigger Science Budget Deal – Despite Historic NIH Support Levels

FASEB Anticipates Political “End-Game” – Escalates Efforts

By FASEB Consultant Michael A. Stephens, Van Scoyoc Associates

Despite a dramatic one trillion dollar increase in the estimate of the federal government surplus over the next 15 years, the Republican leadership in Congress made little progress during June and July in reaching agreements with their Democratic counterparts on the basic budget parameters for Fiscal Year 2000, which begins on October 1. This is particularly disappointing since the July re-estimates of government finances by both the Congressional Budget Office and the President’s Office of Management and Budget predicted, for the first time, true “on-budget” surpluses for FY 2000 – i.e., after excluding the surplus attributable to Social Security.

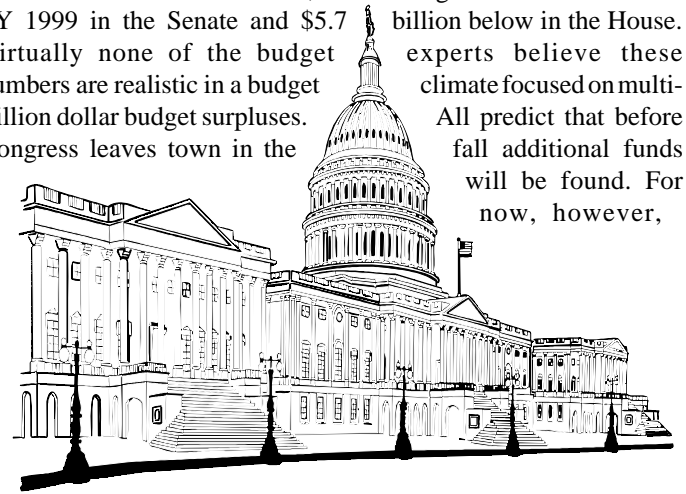


Tax Cuts vs. New Spending

Rather than using these funds to provide the basis for reallocating resources to key domestic programs – an act widely believed as necessary – the new surplus figures rekindled a long standing battle over tax cuts and new spending, including a new Medicare drug benefit. This battle is expected to tie up Washington’s political process for several more months before common sense and budget pressures bring Republicans and Democrats to the bargaining table. Decision-makers will either meet in a budget “summit” to determine a compromise on the tax and spending issues, or in an ugly, end-of-year budget deal, which focuses strictly on the remaining appropriations bills, including those funding the National Institutes of Health and the National Science Foundation. Without a budget deal allocating additional funds for domestic programs, the key subcommittees responsible for science funding have been given budget ceilings within which they must operate that are dramatically below last year’s spending.

Subcommittee Allocations

The House and Senate Subcommittees for Labor, Health and Human Services, and Education, which fund the National Institutes of Health, have ceilings under the 1997 Balanced Budget Agreement that are \$10 billion and \$8 billion, respectively, below FY 1999 spending levels. For the VA-HUD Subcommittees, which fund the National Science Foundation, the ceilings are \$9.5 billion below FY 1999 in the Senate and \$5.7 billion below in the House. Virtually none of the budget numbers are realistic in a trillion dollar budget surplus. Congress leaves town in the



both President Clinton and Republican conservatives are insisting on maintaining the tight discretionary spending caps. This means that biomedical researchers could experience substantial disappointment with the initial spending bills if the Appropriations Committees consider them during the summer months. While this likely would be a temporary situation reversible in final negotiations, it could represent a loss of momentum difficult to recover from fully.

It is possible that more moderate Republican leaders may add some funding to the existing caps in late July, just enough to move bills forward, but not enough to complete action on the spending bills. Such a bold strategy, essentially initiating the process of “busting the caps”, would not likely provide sufficient funds for NIH and NSF but it could begin moving them in the right direction. As this letter was being finalized, the situation was very fluid. A follow-up report will be included in the next letter.

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Subcommittee Ceilings

FY 2000 spending ceiling as of July 1999

dollars in billions

	<u>FY 99 enacted</u>	<u>House allocation</u>	<u>Senate allocation</u>
LHHS Subcommittee—NIH	88.8	78.1	80.4
VA-HUD Subcommittee—NSF	72.0	66.2	62.4

Varmus Presents His E-biomed Proposal to FASEB's Publications Committee

On June 2, NIH Director Harold Varmus spoke to the FASEB Publications and Communications Committee about his "E-biomed" proposal, a plan to develop a central, comprehensive, publicly accessible on-line database of scientific articles. Accompanied by David Lipman, head of the National Center for Biotechnology Information and contributing author of the E-biomed proposal, Varmus reviewed the details of the proposal and answered a variety of questions posed by the members of FASEB's Publications Committee. He began his discussion by placing it in the context of the ongoing revolution in publishing, suggesting that this was time for action by those who wanted to shape it.

According to Varmus' plan, *E-BIOMED: A Proposal for Electronic Publications in the Biomedical Sciences*, "E-biomed is intended to be a new and more effective means to organize, disseminate, use, and store the information and ideas generated by the international biomedical research community. We envision a system for electronic publication in which existing journals, newly created journals, and an essentially unrestricted collection of scientific reports can be accessed and searched with great ease and without cost by anyone connected to the Internet. In a sense, what we are proposing is an electronic public library of medicine and other life sciences. Journals that participate in the E-biomed system would be expected to exercise expert review and editing functions. The NIH, in conjunction with other organizations, would contribute technical expertise, participate in the development of the governance of the system, and help with financial support." (For full text of the E-biomed proposal, see www.nih.gov/welcome/director/ebiomed/ebiomed.htm.)

Varmus suggested that there were shortcomings in the current system of publication that resulted in inefficient allocation of costs and labor, as well as unmet publication needs in the research community. The benefits of the single repository for authors are: rapid publication, one-stop submission, and the addition of possible commentaries to the articles. Benefits to readers would be: barrier-free access, one-stop searching/reading, inclusion of "journal approved" articles.

FASEB's Publications and Communication Committee members addressed a number of questions to Varmus and Lipman. In particular, they wanted to know more specifically how the proposed system will be funded and who will pay for it. Questions about management were raised, and several people pointed to concerns about general oversight as well as quality control. Participants inquired as to the statutory authority and public oversight for a decision of this magnitude as well as government competition with the private sector. The problems of editing and processing a large volume of manuscripts were discussed.

Many of these concerns were echoed by FASEB Member Societies in letters to Varmus written in response to his request for comments on the E-biomed proposal. While the societies supported the concept of increased and enhanced dissemination of scientific information via electronic avenues, they all cited several problems with E-biomed, including its redundancy to current on-line journals published by scientific societies; its lack of details on financial and logistical aspects; and its potential threat to the peer-review process. Several of the letters reviewed the proposal line-by-line, outlining its criticisms of some of the specifics of the plan.

For example, the letter from the American Physiological Society (APS) questioned the need to create the E-biomed publishing structure. "According to the draft proposal, the reason for eliminating the existing system of scholarly journals is that it is relatively slow and cumbersome and has not adequately embraced the opportunities provided by the Internet." APS argued that many of the leading societal and non-profit publishers are already on the Internet. APS itself publishes over 35,000 pages annually in 14 scientific journals, all of which are available on the web.

"Is this the best use of NIH funds? Should funding of E-biomed be a priority over research grant funding? In bad years, will the NIH reduce resources to this program to preserve research funding? Who then will sustain the effort? . . . Should more consideration be given to organizing the existing electronic efforts of publishers to achieve the goals of the proposal (for example, NIH-sponsored grants to societies to underwrite the cost of electronic submission, publication, and translation of prior years into a digital form, potentially making these resources available free to researchers?)"

ASIP letter to NIH Director Harold Varmus

"First and foremost," stated the American Association of Immunologists' (AAI) letter, "we find that this proposal compromises the cornerstone of the scientific method: peer review. The process described in [the E-biomed] proposal is vague, but if taken at face value it does not ensure a rigorous peer-review process," thereby dismantling a system that has served the scientific community well for over 300 years. AAI also mentioned concerns over the creation of a monopoly by having a sole, centralized publisher – and the conflict of interest that arises by having that monopoly in the hands of the "funding agency charged with carrying out the assessment of the scientific accomplishment of an investigator now also [carrying] out one of the most important signifiers of that merit – publishing."

The American Society of Biochemistry and Molecular Biology (ASBMB) – who publishes the *Journal of Biological Chemistry*, the first journal to make its entire text, including figures, available on-line – notes in its letter that "the implementation of a monolithic organization responsible for all of scientific communication could become unwieldy. The establishment of a Governing Board [as in the E-biomed proposal] may have a consequence of impeding the healthy diversity of existing journals. . . . The advantage of scientific societies controlling the publication of some of the most prestigious journals should not be dismissed without careful thought." ASBMB recommended that further study be given to other ways to reach the objectives of E-biomed – i.e., the maximum use of the Internet to further scientific communications.

The American Society of Investigative Pathology (ASIP) concluded its letter by asking several important questions. "Is this

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What We've Been Doing . . .

FASEB Supports Plan to Delay Implementation of Proposed FOIA Changes

Concerns over the proposed changes to Circular A-110 prompted Representatives James Walsh (R-NY) and David Price (D-NC) to sponsor an amendment which would have delayed for one year a new requirement that research data from federally funded projects be made available under the Freedom of In-

formation Act (FOIA). Last October's Omnibus Appropriations Bill (P.L. 105-277) directed the Office of Management and Budget to open up FOIA procedures to all data produced under federal awards. FASEB has been concerned that these proposed changes would significantly interfere with scientific progress. The Walsh-Price amendment to delay its implementation, however, failed by a vote of 25-33 when it was offered to the FY 2000 Treasury-Postal Service funding bill during House Ap-

propriations Committee consideration on July 13.

Earlier that day, FASEB President William R. Brinkley sent a letter to all members of the House Appropriations Committee urging them to support the Walsh-Price amendment. In his letter, Brinkley stressed the point that "[the proposed expansion of FOIA procedures into the scientific arena] would have unintended and undesirable consequences and could cause great damage to biomedical research."

As this issue of the newsletter goes to press, FASEB is anticipating a possible revision by

OMB to the earlier notice of proposed rule making which would soften the impact of the law by excluding confidential patient information from its purview. The FASEB Newsletter will be monitoring these developments and will report on any new actions in its next issue.

FASEB Opposes Animal Welfare Act Coverage of Rats, Mice, and Birds

FASEB and five of its member societies submitted comments in opposition to a pro-

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A Legal Look at the Proposed Modifications to Circular A-110

At the behest of FASEB, Robert P. Charrow, Esp. was asked to review the proposed changes to OMB Circular A-110 that would allow third parties to sue for data produced under federal research grants. He analyzed the issue and its potential impact on the pursuit of biomedical research from a legal perspective.

According to Charrow, the provisions of the Freedom of Information Act are quite broad. FOIA requirements apply only to records in the possession of the Federal government and certain circumstances have been exempted from its purview – including those that jeopardize issues of privacy, proprietary information (i.e., trade secrets), and classified information. The proposed modifications – originally included in last year's Omnibus Appropriations Act as the result of an amendment sponsored by Senator Richard Shelby (R-AL) – seeks to open up the FOIA's reach into some of these areas which it had previously excluded.

In his analysis, Charrow notes that while the Shelby amendment applies only to *rules* put out by the Federal government, there is some question as to whether Federal *notices* will be subject to FOIA provisions. Notices often cite hundreds of studies and, if there is an FOIA request from an individual, the Federal agencies must produce the data.

What is the impact likely to be on research? Charrow believes that if it is limited to regulations, the impact is likely to be minimal to the community (but perhaps huge to an individual researcher). However, if its scope includes policies and general notices – the impact could be far greater. And even if a research study is not cited, an outsider can make a formal comment citing a study, and thereby make that study subject to FOIA provisions.

The following analysis prepared by Charrow makes it clear that there are still several ambiguities with the language of the proposed modification to Circular A-110 that could put research under the scope of the Freedom of Information Act, and could put scientific pursuits at great risk.

What is the Proposed Modification to Circular A-110?

The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. 105-277, § 117(d), 112 Stat. 1681-

495 (Oct. 21, 1998), contained the following proviso, known as the Shelby Amendment:

Provided further that the Director of OMB amends Section -.36 of OMB Circular A-110 to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act: Provided, further, that if the agency obtaining the data does so solely at the request of a private party, the agency may authorize a reasonable user fee equaling the incremental costs of obtaining the data.

The apparent purpose of the legislation was to ensure that if agencies (e.g., EPA, OSHA) relied on publicly funded studies to formulate government policy then the data underlying those studies should be available to the public. However, on its face, the legislation is not that narrowly drawn and could reach all data, whether the study is used to formulate policy or not.

How does the OMB proposal limit the scope of the legislation?

A private awardee would only be required to forward raw data to a government agency for ultimate production to a requester, if the

Data relat[es] to **published** research findings produced under an award that were **used** by the Federal Government in developing a **rule**....

Each term in bold face type has a special meaning that could limit the scope of the Circular's requirements.

1) **The Term "Rules" Has A Narrow Meaning:** The OMB proposal only applies to "rules." A rule is a formal legal mechanism by which an agency either makes law or interprets existing law. Most agencies use vehicles other than rules to announce a new policy. Thus, some very controversial scientific policies have been issued as Notices, as opposed to rules, and the research cited in those Notices would not be subject to the OMB Circular. For

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Brinkley Organizes Delegation to Meet with Speaker of the House of Representatives

On June 24, a delegation of scientists – brought together by FASEB President William R. Brinkley, PhD, at the behest of House Labor, Heath and Human Services, Education Appropriation Subcommittee Chairman John Porter (R-IL) – met with the Speaker of the U.S. House of Representatives, Dennis Hastert (R-IL). This discussion was the second such gathering organized by FASEB in recent years. In 1995, John Porter and then-FASEB President Sam Silverstein led a group of scientists and corporate directors to a meeting with Representative Newt Gingrich (R-GA), who was Speaker at that time (see the June 1995 issue of the *FASEB Newsletter*).

Chairman Porter opened the meeting by introducing the principal participants to Speaker Hastert: Michael Brown (winner of the 1984 Nobel Prize in Physiology/Medicine and Faculty Member at the University of Texas Southwestern Medical Center), Joseph Davie (Vice Present for Research at Biogen), David Frohnmayer (President of University of Oregon and member of the NIH Council of Public Representatives), Jack Fellows (Vice President, University Corporation for Atmospheric Research), and Robert Serafin (Director, National Center for Atmospheric Research). Each of these individuals gave testimony as to the multitude of benefits derived



The Hastert Group: Robert Serafin, Joseph Davie, FASEB's Bill Brinkley, Representative John Porter, David Frohnmayer, Michael Brown, and Jack Fellows.

from recent investments in biomedical research.

FASEB's Brinkley spoke first, thanking the Speaker for the support that recent Congresses have provided for NIH and NSF. He emphasized that this was an era of exciting new opportunities in biomedical research. Brinkley told the Speaker that recent funding increases were important in the recruitment of bright young American students to careers in the sciences, warning that a reversal of the funding pattern

could actively discourage those same students from becoming the future generation of American scientists.

Michael Brown described how America is beginning to see the pay off from recent investments in biomedical research into new areas, such as cancer, that have previously been resistant to therapeutic intervention. He noted that investment in science is on the threshold of returning dividends

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FASEB Holds Conference on the Future of Physician-Scientists

Close to 100 individuals concerned about the declining numbers of physician-scientists met on June 15-16 at the FASEB campus to explore this issue. The conference featured presentations by 16 experts who spoke on three main themes: *Physician-Scientists: Why Do They Matter?*; *The Fate of the Physician-Scientist*; and *Opportunities for Synergy Between MDs and PhDs*. The collective comments of these speakers made it very clear that the plight of physician-scientists in the research arena is a very real problem – one that will worsen without effective measures to correct it. Clearly, physician-scientists can effectively compete in biomedical research, but they are choosing not to do so.

Why are they not choosing to enter into this critical pursuit? The central focus of the conference, entitled *Physician-Scientists and Career Opportunities*, sought to answer that question. In their presentations, the speakers identified two intervals during which a promising physician-scientist might be deterred from research pursuits – during the pipeline (i.e., training) and during the pathway (i.e., early-mid career) of a physician’s professional life. Among the obstacles inhibiting medical students from pursuing research are the decline of role models; perceptions about career opportunities; and increasing debt burden. Once an individual obtains a medical degree, several barriers still preclude scientific pursuits, including lower incomes than those in practice; increased clinical burdens which leaves less time for research; and departmental “cultures” that are hostile to expansive research. Conference participants explored potential avenues to combat this issue – some of which would require additional financial resources and other additional effort on the part of the scientific community.

The meeting concluded with a closed-door FASEB session where society delegates identified several areas for further review and a committee was formally engaged to pursue these issues and develop recommendations for the consideration of the Federation. This committee has already begun to work on a document for the approval of society delegates to the conference. A complete report with data and recommendations on the training and career track of the physician-scientist will be released this fall. ■



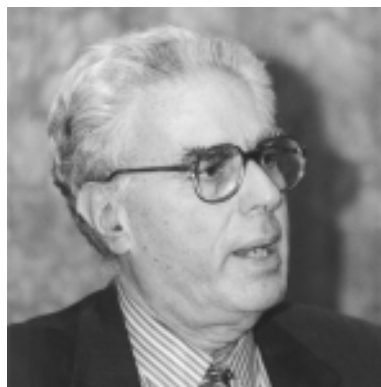
Former NIH Director James Wyngaarden Talks With Meeting Co-Chairs David Kaufman and Nicola Partidge at the Physician-Scientist Consensus Conference



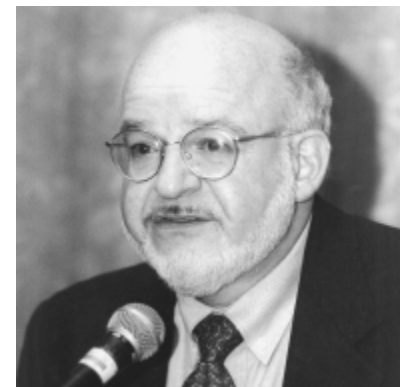
Drs. David Kaufman, FASEB’s President-Elect, and David Korn, ASIP Representative and Senior Vice President for Biomedical and Health Sciences Research at the American Association of Medical Colleges, at Conference Reception.



Dr. Nicola Partidge Welcomes Participants to the Physician-Scientist Consensus Conference



IOM’s Kenneth Shine Speaks to Society Representatives at Physician-Scientist Conference



Dr. David Kaufman Introduces Keynote Speakers at the Conference Kick-Off Dinner

What We've Been Doing . . .

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posal to extend Animal Welfare Act (AWA) coverage to rats, mice, and birds. All of the organizations filed statements emphasizing that current regulations are adequate to insure humane treatment of laboratory research animals.

In his May 13 letter to USDA, FASEB President William R. Brinkley, PhD, noted that “[o]ur opposition to the proposed amendment is consistent both with our interest in animal welfare and with our concerns about redundant and counter-productive regulations. The proposed change will increase regulatory burden and redundancy, lead to inappropriate use of resources, and retard progress in research.”

Specifically, Brinkley pointed out that USDA itself reports that 90% of the rats, mice, and birds used for research in the U.S. are already covered by voluntary accreditation and/or the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals. Furthermore, these standards often exceed those in AWA regulations. Brinkley concluded that inclusion of rats, mice, and birds under AWA regulations will “increase the cost and complexity of regulatory activities without producing any measurable benefits to animals or research.”

To view the complete text of Brinkley’s letter, see www.faseb.org/opar.animal/aphiscomm.html. For copies of the societies’ letters, see the websites of APS (www.faseb.org/aps/rats_commentletter.htm) and ASPET (www.faseb.org/asp/PAPOSAWA.htm#top). ASNS, AAA, and AAI also submitted comments on this issue.

FASEB Board Members Deliver Funding Message to Capitol Hill

In conjunction with their May meeting, members of the Federation’s Board of Directors went up to Capitol Hill to speak to their representatives about the importance of investing in biomedical research. Among these Board members participating in the meetings include Palmer Taylor (ASPET), Sue P. Duckles (ASPET), Mary Barkley (Biophysical), Roger Pederson (SDB), Robert Nissenson (ASBMR), Barry Shane (ASNS), James Schafer (APS), and David Kaufman (ASIP). They were accompanied by the following society public affairs officers: Alice Ra’anan (APS), Jim Bernstein (ASPET), Tracy Lawless (ASNS), Tim Leshan (ASCB), and FASEB Budget Consultant Shirley Ruhe. These sessions provided an excellent forum for the exchange of information between FASEB’s working scientists and the key lawmakers and congressional staff who mold, shape, and develop the appropriations bills that fund life sciences research.

Board members spoke on the exciting opportunities that lie ahead in the arena of biomedical research, and the need to capitalize on these possibilities to bring about new ways to treat and cure diseases. In response, they were cautioned by decision-makers on the effect of tight spending caps on discretionary programs, and they were told that the funding situation would “come to a head” this fall. The scientific community was strongly encouraged to keep delivering their message to Capitol Hill in order to create a momentum for increased resources for biomedical research.

FASEB Supports Increased Funding for Shared Instrumentation

Calling it “critical for the success of the biomedical research enterprise to upgrade obsolete, shared instrumentation and to fund new types of shared instrumentation,” FASEB announced its support for legislation to provide an authorization of \$100 million for the NIH Shared Instrument Grant (SIG) Program and to lift the current cap on SIG awards from \$500,000 to \$1.5 million. These provisions were part of the “Twenty-First Century Research Laboratories Act.”

In a May 5 letter to the bill’s author, Senator Tom Harkin (D-IA), FASEB President William R. Brinkley, PhD, stated, “FASEB recognizes the need for building the capacity necessary to support the future growth of NIH-funded research. We believe that research infrastructure is an essential component of this goal, and are in favor of mechanisms that promote it, so long as these funds do not come at the expense of programs for investigator-initiated research. We believe that it is most vital to protect the funding base for RO1 grants – which fuel the engine that drives progress in biomedical sciences.”

The Instrumentation and Infrastructure Needs Subcommittee of FASEB’s Science Policy Committee conducted the review of this bill at the behest of Senator Harkin. Subcommittee Chair David Speicher is currently working on a design for a survey on instrumentation needs, with a targeted dissemination date for this fall. (See the June 1999 issue of the *FASEB Newsletter* for more information on the survey.)

FASEB Reviews NIH’s Report on the Effect of Regulations on Research

FASEB President William R. Brinkley, PhD, sent a letter to NIH Director Harold Varmus in support of efforts by that agency to reduce regulatory burden and expressed the Federation’s gratitude to Varmus for undertaking the critical study on this issue. FASEB’s Regulatory Burden Subcommittee of the Science Policy Committee, led by Subcommittee Chair J.R. Haywood, conducted the review of NIH’s regulatory burden report.

In his May 5 letter, Brinkley stated that “[t]he report captures the essence of many of the problems facing the research community and contains several excellent suggestions that could enhance its productivity. We encourage timely implementation of the suggestions made by the workgroups, particularly those that require minimal change in existing policy. We also strongly endorse the report’s recommendation that some issues should be raised to the level of the Office of Science and Technology Policy, so that policy changes can be coordinated across multiple Federal agencies. This approach would offer the opportunity to not only amend existing regulations, but also initiate changes in laws where appropriate.”

Furthermore, Brinkley called on the NIH to implement the report’s recommendations as soon as possible. He concluded, “The scientific community stands prepared to work with NIH and other Federal agencies to continue its farsighted efforts to promote research productivity by establishing an appropriate level of regulation and oversight.”

Brinkley Speaks at Commonwealth Fund Conference

FASEB President William R. Brinkley spoke at a conference of the Commonwealth Fund on June 14. During his presentation, Brinkley noted the Federation’s keen interest in the plight of the Academic Health Centers (AHCs) as much of the nation’s biomedical research – and most of its

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What We've Been Doing . . .

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training – takes place in those institutions. Moreover, Brinkley pointed out that funding for research and training is derived largely from clinical revenues in these centers. Unfortunately, he added, managed care and third party providers have siphoned off all of the money that had once been directed to basic science departments. Given that research is not a priority of the managed care

industry, Brinkley concluded, the entire research and training enterprise at AHCs has suffered and is in severe jeopardy.

Brinkley briefed the audience on FASEB's policy recommendations in areas that affect AHCs. These recommendations, derived from the Federation's FY 2000 Federal Funding Consensus Conference deliberations, were on the following top-

ics: Research Planning; Patient-Oriented Research; Graduate Training; Facilities; and Infrastructure. (For details on the specifics of these recommendations, see the FASEB homepage at www.faseb.org/opar/fund2000.)

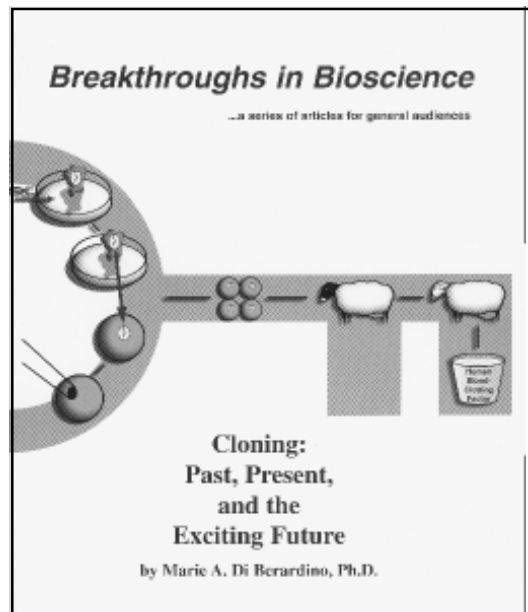
The Commonwealth Fund is a philanthropic foundation established in 1918 with broad charge to enhance the common good. It car-

ries out this mandate through efforts to help Americans live healthy and productive lives and to assist specific groups with serious and neglected problems. In July 1995, the Fund established the Task Force on Academic Health Centers in response to concerns about the impact of health care financing changes on the mission of the country's 125 academic health centers. ■

**SPC Update...
Breakthroughs in Bioscience
Article Explores Past, Present, and
Future of Cloning**

Cloning: Past, Present, and the Exciting Future, by Marie A. DiBerardino, PhD, is the latest article in FASEB's *Breakthroughs in Bioscience* series. It includes an historical overview of cloning and describes the potential benefits of cloning research, stating "[w]e are only beginning to understand the molecular changes involved in nuclear reprogramming, yet this line of basic research may result in some of the most beneficial applications to humans. It might permit us to de-differentiate mature cells and re-differentiate them into specific cell types required for tissue repair." DiBerardino discusses how this vital biomedical research may lead to the repair of diseased and damaged human tissues and organs, and to possible treatments and cures for diabetes, cancer, Parkinson's disease, and other neurodegenerative diseases.

The *Breakthroughs in Bioscience* series was created to help educate the general public about the benefits of fundamental biomedical research. Each article delineates the sequence of accomplishments in an area of research to illustrate how investment in basic research brings about dividends in saved lives, decreased medical costs, improved quality of life, and increased public confidence in science and medicine. It also informs readers that this process is largely done through research funded by the National Institutes of Health and the National Science Foundation. ■



Plans for SPC Face-to-Face Meeting Are Underway

The members of FASEB's Science Policy Committee will hold a Face-To-Face meeting in Arlington, Virginia on September 14. During this gathering, the SPC will be examining research policy issues of concern to the scientists represented by the Federation. In addition, they will develop long-term goals for the Committee and an action agenda for the coming year for each of the SPC subcommittees – Regulatory Burden, Intellectual Prop-

erty, *Breakthroughs in Bioscience*, Instrumentation and Infrastructure Needs, and Career Opportunities. Participants will also discuss whether additional subcommittees are needed to explore current or new policy issues. The SPC serves as the organization's "think tank," developing long-term, proactive policy statements in support of biomedical science, and advises the Public Affairs Executive Committee on these concerns. ■

Other Breakthroughs in Bioscience Articles:

- Unraveling the Mystery of Protein Folding
- Cardiovascular Disease and the Endothelium
- The Polymerase Chain Reaction
- Blood Safety in the Age of AIDS
- Serendipity, Science, and a New Hantavirus
- Controlling Hypertension: A Research Success Story
- Helicobacter pylori* and Ulcers: a Paradigm Revised

All Breakthroughs articles are available on the FASEB Public Affairs homepage at www.faseb.org/opar/opar.html. Reprints may be obtained by calling (301) 571-0657.

Former FASEB President Featured Speaker at Australian Medical Research Week Events

Under the auspices of the Australian Society for Medical Research (ASMR), Australia annually celebrates the importance of medical research and the latest national and international scientific achievements in a week of events held in each of its capital cities during late May/early June. These special events include forums, exhibits, and luncheons/dinners with concomitant interviews and stories in the print and electronic media that are designed to give the general public a better understanding of medical research and its impact on society. This year, Ralph Bradshaw, PhD, past-president of FASEB, was invited by the ASMR (with the generous support of AMRAD, an Australian biotech company) to be the keynote speaker for the program. He gave addresses in Hobart, Perth, Adelaide, Sydney, Melbourne, and Brisbane on the theme "The Renaissance in Medical Research," and participated in other related forums, discussions, and interviews.

Photo by Snappy Pics



Drs. Ralph Bradshaw and Peter O'Loughlin, Treasurer - ASMR during the ASMR Medical Research Week activities in Adelaide.



The featured speakers at the ASMR Medical Research Week banquet in Melbourne on June 3: (from l. to r.) Dr. Matt Gillespie, President - ASMR, The Honorable Dr. Michael Woolridge, Australian Minister for Health and Aged Care, Dr. Bradshaw, and Mr. Peter Wills, Chair of the HMRSR committee.

The topic was particularly timely because of the release of Australia's federal budget only two weeks earlier containing the announcement that the country would dramatically increase its commitment to medical research by doubling the allocation to the National Health and Medical Research Council – the agency primarily responsible for such funding (and thus similar to the NIH) – over the next five years. This substantial increase parallels a similar plan in the U.S. to double the budget for the NIH and reflects a growing world-wide enthusiasm that the potential benefits of these research efforts will be translated into material improvements in public health and the quality of life for all people. A major factor behind the budget increase was an eighteen-month study by a special committee appointed by The Honorable Michael Woolridge, Federal Minister for Health and Aged Care, to broadly review medical and health issues and to provide an analysis with recommendations that would serve the Australian government as a 'blue print' for future planning. The Health & Medical Research Strategic Review (HMRSR) Committee was composed of ten Australians and three overseas members and was masterfully chaired by Peter Wills, a Sydney businessman and Chairman of the Board of the Garvan Institute, an internationally recognized center for medical research. (Bradshaw served as one of the foreign

participants). The report – entitled "The Virtuous Cycle" (but better known in Australia as the Wills Report) – emphasized the importance of the relationship of academia, industry, and government in maintaining the research enterprise and was based on extensive studies and correlative data that was gathered from germane sources around the world. FASEB was one of these sources and members of the Wills Committee met with then-Executive Director Michael Jackson, Director of the Office of Public Affairs Howard Garrison, and consultant Mike Stephens in Bethesda in July 1998 as part of the information accrual process. The final report provided detailed suggestions for the implementation of changes in policy and practice that stand to revolutionize medical research through revitalization of the academic research community and the considerable expansion of the biotechnology industry in that country. Both Woolridge and Wills were also featured speakers at the dinners in Sydney and Melbourne.

Dr. Nicola Partridge, a native Australian who is member of FASEB's Science Policy Committee, stated of these events, "It is most refreshing that the Australian government has paid heed to the tremendously successful U.S. commitment of resources to medical research. This is a striking change from previous policies, and the Wills Report, the ASMR, and Dr. Bradshaw are to be congratulated for the result."

Another important factor behind the budget increases was the active advocacy programs of the ASMR. In this regard, the ASMR plays a very similar role in Australia as FASEB does in the U.S. in arguing for increased support for medical research at the federal level. ASMR President Matt Gillespie of St. Vincent's Medical Research Institute in Melbourne, Treasurer Peter O'Loughlin of the Institute of Medical & Veterinary Science in Adelaide, and a Board of Directors comprised of representatives of the different states presently oversee the organization's many scientific, political, and public outreach activities. In their remarks in Sydney and Melbourne, both Mr. Wills and Dr. Woolridge acknowledged the importance of these activities in the events leading up to the announcement of the increases. Thus the similarities between the successful lobbying efforts of ASMR and FASEB is striking and further demonstrates the importance of involving scientists directly in educating both the public and the political leaders about medical research and the necessity of supporting it. ■

Member Society News . . .

Jerry R. Mitchel Appointed ASPET'S New President

Jerry R. Mitchel, MD, PhD is the new President of the American Society for Pharmacology and Experimental Therapeutics. Mitchell is Chairman and CEO of ClinTrials Research, Inc. in the Research Triangle, North Carolina. He received his MD and PhD in Pharmacology from Vanderbilt University. His research has focused on drug discovery and mechanisms of drug toxicity by chemically reactive intermediates, including oxygen and the important protective role of glutathione against these toxicities. In 1990, he was designated a "Citation Superstar" in *The Scientist* newspaper with a ranking of 151 overall among all scientists worldwide and 17th among pharmaceutical scientists.

APS Launches New Online Journal to Focus on Link Between Genes and Function

On July 13, The American Physiological Society launched Physiological Genomics, a new online journal created to provide the scientific community with a vehicle for the rapid dissemination of information about genetic physiology – the influence of genes on physiological function. The journal will be posted to the World Wide Web on July 15, 1999 at <http://www.physiolgenomics.org>.

Articles for Physiological Genomics will be submitted, reviewed, and published online, with a paper version of the journal published as needed for archival purposes. The on-line submission and review process will be handled through the APS web site at <http://www.apscentral.org>. This utilization of World Wide Web information technology will not only speed up the publication process, it will also make it possible for researchers to provide readers with large data sets and to display results in dynamic formats that would be impossible to produce on a printed page.

Delegation

Continued from page 6

to the American people, and only by continuing this investment through sustained support for biomedical research can we ensure continued progress on these fronts.

Highlighting the deep roots of the Biotech industry in academic research, Joseph Davie noted the importance of actually applying the knowledge gained from new discoveries. Davie informed the Speaker that about half of the products in the Biogen pipeline come from discoveries made at universities. For example, Davie pointed out the 1992 discovery of a gene by a university scientist that came to the attention of Biogen in 1993. Today, Biogen is on the verge of a major new drug that will dramatically improve

organ transplantation and which also has important implications for the treatment of diabetes.

In a particularly moving discussion, University of Oregon President David Frohnmayer told

“Our future as a nation depends on two investments: education and technology. Research is fundamental to both....Now is not the time to back away from research. It is the best investment that we can make.”

the speaker about his three daughters, all of whom suffered from Fanconi anemia, a rare genetic disorder. One daughter died several years ago of a stroke, a complication of Fanconi anemia that is now far less common thanks

AAA Sets New Award Deadlines

New deadlines have been set for all awards of the American Association of Anatomists (AAA), with some coming earlier to facilitate the selection process and others coming later to coincide with EB abstract submissions. Nominations for the R.R. Bensley Award for contributions in cell biology and the Charles Judson Herrick Award for young investigators in comparative neuroanatomy must be received at AAA by September 15. Each award recipient will present a special lecture at the AAA Annual Meeting during EB 2000 in San Diego.

AAA also offers several student awards, including: Student Travel Awards for members who are first authors of a paper (poster or platform) presented at EB; the AAA Langman Award for the best platform presentation by a first-author graduate student; the AAA Outstanding Dissertation Award for a student completing training in 1999; and awards related to work in electron microscopy and imaging. Applications for these prizes must be received by November 8, along with the EB abstract submission form.

For more information, contact AAA at 301-571-8314 or see the AAA Web site at www.anatomy.org/anatomy/.

Student Minority Luncheon Heads West

The AAA-FASEB Student Minority Luncheon moves to the West Coast this spring, where the minority focus in the San Diego area will be on Hispanics, who comprise 40% of the total population.

AAA is working with LLAMA (Latinas/Latinos Achieving More Academically), a program of the San Diego City School District that coordinates educational outreach activities. LLAMA will assist in recruiting minority students – including Afro-Americans, Asians, and Native Indians – to attend the April luncheon at EB 2000.

In order to suggest a keynote speaker for this event, contact AAA at 301-571-8314 or apendleton@anatomy.org.

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to research. Frohnmayer also told the Speaker that when his second daughter died of leukemia, another complication of Fanconi anemia, a new therapy was just emerging from laboratory

of science contribute significantly to the quality of life. Using examples from their own field of research – atmospheric science – they catalogued research-based improvements in transportation, especially air travel, and emphasized how research of all kinds led to increases in economic productivity.

Summarizing the discussion, Chairman Porter told the Speaker that research lengthens and improves lives. “It is one of the most important investments that we can make,” Porter said, “Our future as a nation depends on two investments: education and technology. Research is fundamental to both....Now is not the time to back away from research. It is the best investment that we can make.” ■

Congressman John Porter (R-IL)

research. Hope for his third daughter now lies with research and the prospect of new therapies involving gene therapy and transplantation.

Jack Fellows and Robert Serafin described how other fields

Circular A-110

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example, chemicals newly classified as carcinogens or suspected carcinogens are published by the National Toxicology Program as Notices in the Federal Register and not as rules.

2) The Term “Used” Has A Narrow Meaning: To trigger release, the data at issue would have to have been used in developing a rule. Thus, according to the OMB preamble, an agency would have to affirmatively reference the study in the reference section to the proposed rule before the requirements of the Circular would be triggered. However, once triggered, an agency would have to move quickly enough so as to respond to the FOIA request before the comment period to the proposed rule (usually 60 or 90 days) closes.

How will the Circular impact the research community?

Whether the Circular will have a profound effect or no effect is difficult to gauge. One can argue that its impact will be modest given that it applies only to research actually used in developing rules. Each year, relatively few rules are issued which affirmatively rely on scientific studies. However, certain rules issued by certain agencies – *e.g.*, EPA and OSHA – frequently cite to thousands of studies. A researcher could find his research the subject of a FOIA request merely because it is cited by a federal agency in its rulemaking. OSHA’s permissible exposure limit rule of 1989, for instance, occupied over 500 pages in the Federal Register and cited to hundreds, perhaps thousands of studies. *See* 54 Fed. Reg. 2332 (Jan. 1, 1989). The rule could have a significant impact on any researcher whose work happens to be cited in such a rule.

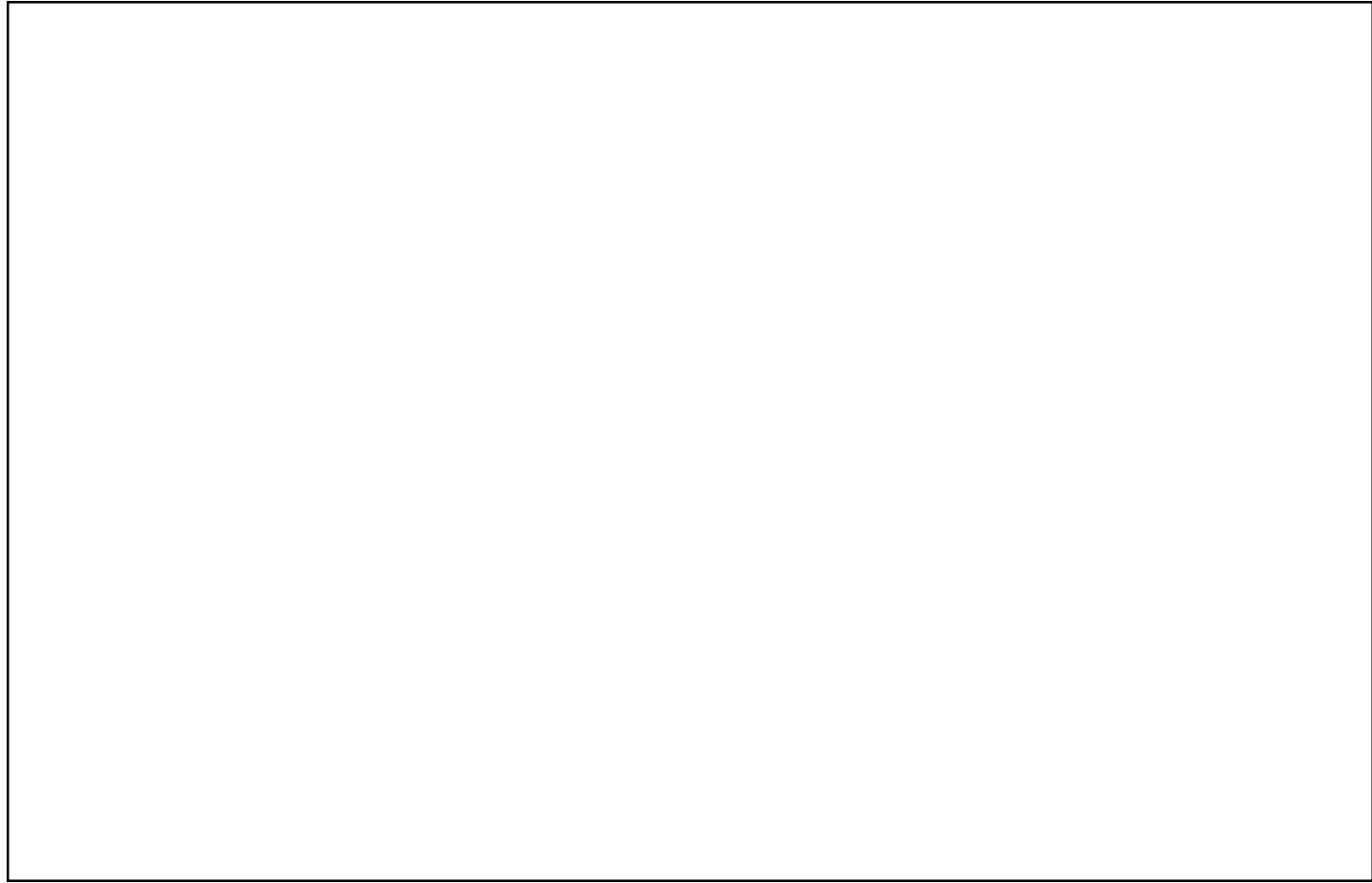
What are the ambiguities in the current proposal?

1) What Does the Term “Data” Really Mean? The definition of “data” does not answer certain critical questions. For example, “data” includes “any raw underlying information necessary to validate researching findings.” This definition is potentially so broad that it could easily encompass specimens and make them subject to FOIA to extent that they contain “information.”

2) When is an Article Really “Published?” There is some question as to what the term “publication” means. Specifically, if a study has not been published in a peer-reviewed journal, but has been referenced in a proposed rule, does that mean that the data are subject to a FOIA request? The OMB proposal’s language is not clear, but would appear to imply that in such a case, the data would be subject to FOIA

Are There Outstanding Legal Issues Worth Noting?

The Appropriations Act raises a host of legal issues – some constitutional and others statutory. One of the more intriguing such issues is whether the Shelby Amendment actually survives beyond this fiscal year. Specifically, provisions in an appropriations act normally are deemed to last for a single fiscal year unless the language of the act expressly notes the contrary. The language associated with the proviso under scrutiny contains no such language and therefore, one could argue that it dies on September 30, 1999. If a rulemaking is based solely on a statute that dies on September 30, one can argue that any rule would also die on that day. ■



Member Society News . . .

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ASIP To Offer Course on Concepts in Molecular Biology

For the twelfth time, the American Society for Investigative Pathology is offering a course on concepts in molecular biology from October 7-10, 1999 in Bethesda, MD. Organized by Mark E. Sobel, MD, PhD, this course is designed for basic scientists, clinical investigators, residents, and graduate students, as well as diagnostic and experimental pathologists, who wish to become conversant with basic principles and concepts of recent advances in biotechnology. While for many it is a refresher course, for others it is an expansion on their current curriculum and for some it is new material. Emphasis is placed on understanding nucleic acid molecular biology and its application to diagnosis and pathogenesis of human disease. For more information contact the ASIP by phone at (301) 530-7130; e-mail: asip@pathol.faseb.org; or visit their website at http://asip.uthscsa.edu/cmb_info.html.

Government Surplus

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NIH Support

This current, negative environment for appropriations is particularly unfortunate for the National Institutes of Health, which is enjoying its strongest support in Congress in a quarter century. Not since President Nixon declared war on cancer in 1971 has Congress been in such bi-partisan agreement on the need to increase funding for the NIH. Key appropriations champions John Porter (R-IL), Arlen Specter (R-PA), and Tom Harkin (D-IA) remain committed to the long-term goal of doubling NIH funding over five years. Other congressional leaders, while shying away from overtly endorsing the doubling notion in a public way, are calling for substantial increases. There are virtually no naysayers in Congress. Presidential candidates seem also to be picking up the NIH mantle, and both Republican Elizabeth Dole and Democrat Al Gore have endorsed

the doubling concept.

Not since President Nixon declared war on cancer in 1971 has Congress been in such bi-partisan agreement on the need to increase funding for the NIH.

In the end, FASEB believes that congressional support can be translated into sizable increases for NIH and other science agencies. To encourage this, FASEB leaders have focused advocacy during the summer on congressional leaders (see story

on the June 24 meeting with new House Speaker Dennis Hastert (R-IL) on page 6.) This is being done both individually and in cooperation with partners from patient advocacy organizations and associations representing academic health centers. We will continue our efforts to support our legislative champions in this critical endeavor throughout the fall. ■

ASCI Hosts Joint Meeting with Association of American Physicians

The American Society for Clinical Investigation and the Association of American Physicians are hosting a Joint Meeting May 5-7, 2000 at the Hyatt Regency Baltimore, Baltimore, MD. For further information, contact Rhonda Simmons, ASCI/AAP Joint Meeting Office at 609-848-1000, x443.

Biophysical Society Announces 44th Annual Meeting

The Biophysical Society's 44th Annual Meeting will be held February 12-16, 2000 in New Orleans, LA. The National Lecture, "Structure and Dynamic cAMP-dependent Protein Kinase," will be presented by Susan Taylor of the University of California, San Diego. The program includes 15 symposia, three workshops, and subgroup meetings.

The meeting will also feature more than 2,700 posters and over 150 exhibits. The Abstract Deadline is October 3, 1999, and the advance registration deadline is December 9, 1999. For up-to-date information, please contact the Biophysical Society at 301-530-7114, society@biophysics.faseb.org, or visit our website www.biophysics.org/biophys/society/annmtg. ■

E-biomed

Continued from Page 4

the best use of NIH funds? Should funding of E-biomed be a priority over research grant funding? In bad years, will the NIH reduce resources to this program to preserve research funding? Who then will sustain the effort? . . . Should more consideration be given to organizing the existing electronic efforts of publishers to achieve the goals of the proposal (for example, NIH-sponsored grants to societies to underwrite the cost of electronic submission, publication, and translation of prior years into a digital form, potentially making these resources available free to researchers?)”

ASIP, as well as the other FASEB Member Societies, pledged their help to the NIH in developing ways to achieve the common goal of better communication via the Internet. Indeed, the letter from the American Society for Pharmacology and Experimental Therapeutics (ASPET) suggests a different role for the NIH in this arena. “One constructive role NIH could play is to establish an electronic repository that contained the full text, fully searchable versions of past scientific literature. By guaranteeing the maintenance of this archive and providing tools through which it could be searched, NIH could play a constructive complementary role to that of the academic publishers and one that would represent collaboration rather than needless competition.”

For the full text of some of letters written by FASEB Member Societies, see the following websites – APS: <http://www.faseb.org/aps/NEWS/APSletter.html> and the accompanying commentary at <http://www.faseb.org/aps/NEWS/APSCOMMENTARY.html>; ASIP: <http://asip.uthscsa.edu/varmus.htm/>; and ASPET: www.faseb.org/asp/ebiomedposition.pdf. ■

New Team

Continued from Page 1

On July 8, Kaufman, Hendrix, Brinkley, and Brautigan spent the day meeting with the heads of several key organizations in the scientific community in Washington to introduce themselves and to discuss matters of mutual interest. They met with C. Peter Magrath, President of the National Association of State Universities and Land-Grant Colleges, and Jerold Roschwalb, its Director of Government Relations; Nils Hasselmo, President of the Association of American Universities; and Arthur Bienenstock, Associate Director for Science, and Rachel Levinson, Assistant Director of Life Science, at the Office of Science and Technology Policy. In addition to funding for research, one of the main topics of conversation at all three meetings was the FOIA/A-110 issue, a critical concern to each of these organizations as well as to FASEB (see page 5 for more details). These groups have a history of collaboration with Federation on issues relating to science, and FASEB’s leaders conveyed the hope that we will continue to work effectively in the future to ensure the sustained growth of the nation’s research capacity.

The FASEB President functions as the Federation’s chief executive officer and chair of the FASEB Board of Directors. This individual is selected by the Board from its members who are in their second year of a four-year term. In addition, he/she is the chair of the Public Affairs Executive Committee (PAEC) and provides leadership in developing and implementing public policy on behalf of the Federation. The President also serves as the principal spokesperson for FASEB and meets frequently with members of Congress, federal administration officials in research agencies, and leaders of other scientific organizations on issues of concern to scientists. ■

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