FASEB News

"Quality Life Through Research"

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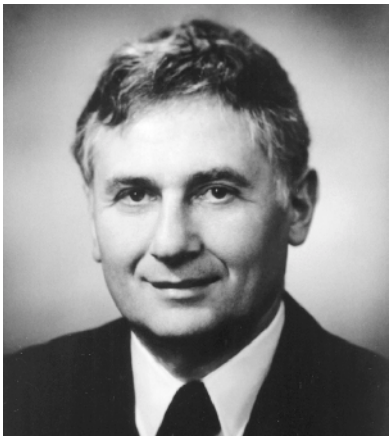

Steven L. Teitelbaum, top, and Alfred H. Merrill, bottom, have been selected as FASEB's President-Elect and Vice President-Elect for Science Policy, respectively. See page 6 for more details.

Highlights

FASEB Holds Conference on Government-Academic-Industrial Partnerships

In the span of six years, the scientific community has gone from an era of insufficient resources to an era of significant growth in resources, noted Samuel C. Silverstein, a professor and head of the Department of Physiology and Cellular Biophysics at the Columbia University College of Physicians and Surgeons. "Our science also has undergone a profound change. We have gone from the pre-genomic to the genomic era, and from an era in which information technology played a much smaller part in medical research than it does now. It is evident that genomics and informatics are revolutionizing medical research. There can be little doubt that they will ultimately revolutionize medical practice."

Dr. Silverstein was one of the keynote speakers during FASEB's May 6-7, 2001 conference on *Government-Academic-Industrial Partnerships: Bioethics and Genome Research.* The balance of his talk and the ensuing policy conference explored the potential impacts of genomics and informatics on medical practice as they relate to research. "The policy gathering illuminated the complex and changing relationships between academia, the government, and industry by focusing on the impact of partnerships in genome research," said FASEB President Mary J. C. Hendrix. "It also provided an important opportunity for the scientific community to discuss – in an open forum – the challenges, guidelines, and bioethical and legal implications for participating in research partnerships."

*See **Policy Conference** on Page 4*

FASEB Board Meets: Condemns Public Library of Sciences Action, Votes to Join National Health Council

At is May 7 and 8 meeting, the FASEB Board considered a number of issues ranging from the election of officers for 2002-2003 to the governance of the Federation. Another key issue on its agenda was a response to a petition that calls for scientists to boycott society journals that do not comply with demands made by the Public Library of Science (PloS).

The PLoS is asking that journals grant unrestricted, free distribution rights to any and all original research reports within six months of their initial publication date, and that this content be distributed through PubMed Central (National Library of Medicine, National Institutes of Health) or similar online public resources. These demands have not been made in coordination with publishers or with consideration of the business models required for successful journal publishing. FASEB societies have raised objections to the evolving details of this plan and noted potentially undesirable consequences.

The FASEB Board denounced this coercive action. In a statement issued May 11, board members said: "As publishers, scientific societies are responsible for the peer review of articles, production and distribution of content, and historic archiving of their journals. Expenses associated with these efforts are recovered from various sources including subscriptions. FASEB supports the right of its member societies to independently establish policies and practices for online access that will assure the viability of their publications."

Societies now allow open access to the titles and abstracts via Pub Med. In addition, most journals allow free and open access to the full-text of articles to non-subscribers between six to 12 months after publication.

*See **Board Meeting** on Page 5*

FASEB News

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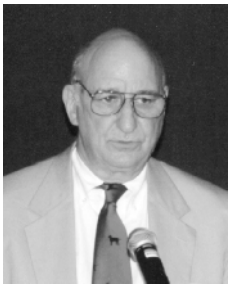
Guest Opinion

The Debate Over Medical Records Privacy: Why Should FASEB Care?

By Samuel C. Silverstein

While the spectacular advances in cell and molecular biology and biotechnology in the last two decades have markedly improved the quality of medical research and practice, they have not yet fundamentally changed either. In contrast, the revolutions in genetics and informatics have initiated a paradigm shift in biomedical research, and they presage a comparable paradigm shift in medical practice.



Samuel C. Silverstein

The sequencing of the human genome, coupled with extraordinarily powerful new methods in DNA diagnostics such as chip technologies, allow us to identify relationships between physiological states and gene expression patterns. They allow us to identify gene rearrangements, mutations and polymorphisms at a rate previously thought impossible. Additionally, information technology is advancing at a phenomenal pace. Given the enormous financial incentives for further advances, it is not a big stretch to predict that the technology required to store and process the data from tens of thousands of chip experiments – and to store and analyze clinical and genomic data on millions of people – will be available by 2005. Indeed it may already be available.

But there are impediments to bringing all this to fruition. One of those is the widespread public concern about the privacy of medical information, and especially genetic information. Congress recognized the need to protect the public against adverse uses of all types of medical information, including genetic information, by insurers and employers. But despite good faith bi-partisan efforts, Congress was unable to find the right balance between the interests of individual privacy and the compelling public benefits that are derived from the use of medical information to further biomedical, behavioral, epidemiological and health services research. So it fell to the Clinton Administration to write health information privacy regulations. These were announced with much fanfare in the closing days of the Clinton Administration and implemented by the Bush Administration a few weeks ago.

Not unexpectedly, these regulations have been criticized by the health insurance industry and by hospitals as costly and unworkable. The rules have also been quietly opposed by medical schools, which view them as potentially damaging to medical research and education.

These regulations – which are difficult to read and take up 1,600 pages of the *Federal Register* – define what can and cannot be done with medical records and specimens such as blood, biopsies, surgical and autopsy specimens. According to an analysis by the Association of American Medical Colleges (AAMC), these privacy regulations provide powerful disincentives for health providers to cooperate in medical research because they impose heavy new administrative, accounting, and legal burdens, including fines and criminal penalties, and because they are ambiguous in defining permissible and impermissible uses of protected health information. This is of great concern when viewed in the context of the opportunities for discoveries in medicine, and for improvements in health care that could arise from large-scale comparisons of genomic data with clinical records.

The capacity to link genomic data on polymorphisms and mutations of specific genes with family histories and disease phenotypes has enabled medical scientists to identify the genes responsible for monogenic diseases such as cystic fibrosis, Duchenne's muscular dystrophy, and familial hypercholesterolemia. Such analyses will be even more important in identifying genes that contribute to polygenic diseases such as adult-onset diabetes, atherosclerosis, manic depressive illness, various forms of cancer, and schizophrenia. Indeed, this is one of the reasons that Jeffrey Trent and his associates have organized the International Genomics Consortium, that deCODE purchased access to the genetic and clinical data base of Iceland, and that Arthur Holden founded First Genetic Trust.

The AAMC analyzed these privacy regulations from several perspectives: the

administrative costs of implementing them; their potential impact on medical education; and, their potential effects on research. Let me review with you just one of their concerns with respect to research so you will have a better sense of the urgency of the problem.

These regulations require that all individual identifiers be stripped from archived medical records and samples before they are made accessible to researchers. On the face of it, this does not seem unreasonable. But as one digs deeper it becomes apparent that de-identification of these records is not a simple matter. De-identification must be simple, sensible and geared to the motivations and capabilities of health researchers, not to those of advanced computer scientists who believe that the public will be best served by encrypting medical data so even the CIA would have difficulty tracing them back to the individual to whom they relate.

The definition of identifiable medical information should be limited to information that directly identifies an individual. The AAMC describes this approach to de-identification as proportionality. It recommends that the burden of preparing de-identified medical information be proportional to the interests, needs, capabilities and motivations of the health researchers who require access to it. AAMC says that the bar for de-identification has been set at too high a level in the new privacy regulations.

For example, presently, these regulations require that "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information individually identifiable" must certify that the risk is very small that information in a medical record could be used alone or in combination with other generally available information to link that record to an identifiable person. This certification must include documentation of the methods and the results of the analysis that justifies this determination.

Alternatively, the rules specify 18 elements that must be removed from each record. These include zip codes and most chronological data. Removal of these data would render the resulting information useless for much epidemiological, environmental, occupational, and other types of population-based research.

As the privacy rules now stand, device identifiers and serial numbers also must be removed from medical records before they can be shared with researchers. This would make it difficult for researchers to use these records for post-marketing studies of the effectiveness of medical devices.

The AAMC argues, and I agree, that sound public policy in this area should encourage to the maximum extent possible the use of de-identified medical information for all types of health research. The AAMC has urged the Secretary of HHS to rethink the approach to de-identification and to create standards that more appropriately reflect the realities of health research and the motivations and capabilities of health researchers, not the exaggerated fears of decryption experts.

This is a classic confrontation between individual and societal rights. Since Hippocrates there has been widespread agreement that an individual's medical history and problems should be held in confidence. At the same time, there is equally widespread agreement that societies have legitimate interests in ascertaining the health status of their citizens, the incidence of specific diseases, and the efficacy of treatments for these diseases.

So far, FASEB has not been involved in the privacy issue. But it's time for FASEB to join with AAMC and others to assure that the privacy regulations are changed so that all members of our society can benefit from our investment in medical and health research. Such information is needed now more than ever. (Subsequently, Steven L. Teitelbaum, who will serve as FASEB's president in 2002-2003, has said he plans to make this issue a top priority during his tenure.)

While improved privacy regulations are essential, they will not reassure everyone. Toward that end, we need to undertake at least three additional steps in which FASEB society members can provide badly needed leadership:

- First, in the genomic era many, perhaps most, individuals will have genetic tests. Therefore, we must educate our faculty, house staff, students, and the public about the benefits and complexities of the new genetics.
- Second, we must train faculty, house staff and health professions students to obtain informed consent from patients for use of historical and phenotypic data in conjunction with blood and tissue samples for research.
- And third, we must implement existing technologies, and develop better ones, to assure the accessibility and security of medical records.

Dr. Silverstein is professor of Physiology and Cellular Biophysics, and of Medicine at Columbia University's College of Physicians and Surgeons and a former FASEB president. This essay is an excerpt of his speech May 6, 2001 at the FASEB conference on "Government-Academic-Industrial Partnerships: Bioethics and Genome Research." The full text of his lecture can be found at www.faseb.org/opar/news/docs/springconf.pdf. For the AAMC analysis referenced in this essay, go to www.aamc.org/advocacy/issues/research/confid.htm.

***Policy Conference**, from page 1*

FASEB organized the conference to highlight some of the issues and opportunities presented by the increasing number of new partnerships that are developing between universities and private industry, many of which involve government support of research activities. "These partnerships, on the surface, offer a conduit for the translation of innovative ideas from the university sector to the industrial development of commercialized products that have tremendous promise for society and can impact the national and global economy," said Dr. Hendrix, who also serves as the Deputy Director and Associate Director, Basic Research of the Cancer Center at The University of Iowa. "Although the public has reaped significant returns on its investment in academic-government-industrial partnerships, the growing number and size of these relationships has also generated concern about the distribution of costs and benefits. As faithful stewards of the public investment in biomedical research, we have a responsibility to address the bioethical issues that have emerged as consequences of the explosion of genome research applications and our emerging partnerships."

On Sunday evening, Dr. Silverstein offered an overview of the multi-faceted issues associated with university-industry partnerships. An excerpt of his talk, *Medical Research in the 21st Century: New Challenges and New Opportunities at the Interfaces Between Academia, Industry and Government*, can be found in this issue on page 2. The following day was broken into three sessions. In the morning, panelists discussed the challenges related to bioethics and genome research and examined how the translation of genomic medicine into clinical practice is affecting health care; privacy and confidentiality issues for patients and research subjects; and, the intellectual property implications of partnerships. Paul Gilman, the director of public policy for Celera Genomics, presented a model for data sharing in the private and public sectors. FASEB Board Member John A. Smith, of the department of pathology at the University of Alabama at Birmingham, talked about the problems, realities and potential of public domain models in clinical data.

During lunch, Ruth Kirschtein, the acting director of the National Institutes of Health, talked about her views on academic-industry partnerships. During the afternoon session, distinguished scientists from industry, government, and academia talked about partnership guidelines and challenges.

Ruth Kirschtein, Acting Director, NIH, gives keynote luncheon address at FASEB policy conference.

"As we are closing in on clearer conflict of interest protocols for individual investigators and faculty members, the issue of *institutional* conflict of interest remains troublesome," said Mary Sue Coleman, president of the University of Iowa. Experts "suggest that when the university itself owns equity or receives royalties, the conflict is a problem of even greater magnitude. A couple of well-publicized cases illustrate the staggering amounts of money at stake. Just this past year, the University of Rochester in New York has won what may be 'the most lucrative patent ever awarded to an academic institution,' 'a sweeping patent on the science underlying a new class of anti-inflammatory drugs knows as COX-2 inhibitors.' With a potential market of $10 billion, the University of Rochester is suing Searle and Pfizer, and possibly Merck eventually, for royalties on drugs based on the patented discovery."

In 1999, she continued, Glaxo Wellcome agreed to pay the University of Minnesota and one of its professors royalties on the sales of Ziagen, an antiviral drug used to treat AIDS. These royalties could exceed $300 million. "With such amounts at stake, [experts] wonder if universities can police themselves, or effectively oversee investigators when the interests of both are in parallel," Dr. Coleman said.

Panelists during this session talked about the regulations governing the exchange of research materials and the technology transfer tools available to researchers in the public and private sectors.

At the end of the day, Myrl Weinberg, president of the National Health Council, presented the public perspective of scientific partnerships. The NHC recently concluded a survey of individuals with chronic diseases and/or disabilities and their families to determine what and how they think of genetics research. "Their major concerns about genetics research have to do with 'playing God' in cloning or genetic engineering, and confidentiality of their genetic information," said Ms. Weinberg. "In particular, they are concerned that insurance companies will use the information to deny coverage or that employers will use it to deny jobs."

"The Council's research strongly indicates that people are receptive to learning more about genetics research and, with some conditions attached, participating in tissue sample studies to further genetics research," Ms. Weinberg said. "These are important findings because this field has raised huge issues in the areas of confidentiality, privacy, and discrimination. The public does fear that information gathered as part of this research may be misused. Public understanding of genetics research – its capabilities and limitations – is essential and will facilitate realistic expectations and increased opportunities for scientific advances." Along those lines, she said, the Council recommends that when communicating information about genetics research, researchers should:

- Clearly differentiate genetics research for preventing or treating conditions (e.g., personalized medicine, gene therapy) from cloning human beings.
- Use concrete examples, preferably recent successes in prevention and treatment. Information that links genetics research with finding new treatments for illnesses is likely to be attention getting, encouraging, and persuasive.
- Make sure that messages or materials do not inadvertently reinforce peoples' concerns that the benefits of genetics research will be too costly to be available to the uninsured, the elderly, or the poor.

Dr. Hendrix said the conference was "quite interactive and provocative." The agenda and select presentations from the conference can be found on the Web at http://www.faseb.org/opar/news/docs/springconf.pdf.

***Board Meeting**, from page 1*

Complex issues surround the goal of making scientific information accessible, the Board noted. "FASEB encourages debate on how best to improve the electronic publishing of, and access to, peer-reviewed scientific papers.

However, practicing scientists and their representative organizations must be allowed to engage in constructive discussion in an atmosphere that is respectful and free from coercion."

FASEB To Add National Health Council to list of Formal Partners

The FASEB Board voted unanimously to join the National Health Council, a nonprofit, umbrella organization with 112 national health-related organizations as members. The Council's core constituency is comprised of almost 50 of the country's leading patient-based organizations, including the American Heart Association, American Cancer Society, American Diabetes Association and the National Multiple Sclerosis Society.

These organizations represent approximately 100 million people with chronic diseases and/or disabilities. Other Council members include professional and membership organizations such as the American Medical Association, American Association of Health Plans, The Pharmaceutical Research and Manufacturers of America, The Biotechnology Industry Organization, and the Genetic Alliance; business and industry members including Pfizer and Amgen; and, other national organizations with an interest in health such as AARP and the Paralyzed Veterans of America.

"As an umbrella organization for more than 100 patient advocacy groups, NHC brings the consumer perspective to medical research issues in a manner that is consistent with our broad-based support for biomedical research," said FASEB President Mary Hendrix. "This organization will serve as a strong ally for FASEB in addressing the challenges of increased regulatory burden, animals in research, and issues related to Institutional Review Boards."

HHMI President Details Future Plans for Institute

Thomas R. Cech, the president of the Howard Hughes Medical Institute (HHMI), talked to the FASEB board about the future plans for his organization. One of the largest, and a significant departure from prior HHMI activities, is a 10-year, $500 million plan for a biomedical science center that will develop advanced technology for biomedical researchers and provide a collaborative setting where scientists from around the world can create the new tools of biology. The campus will be located on a 281-acre site that HHMI recently acquired just outside Washington, D.C., in Loudon County, Virginia.

Thomas R. Cech.

"In the last 5 to 10 years, biomedical research has changed," Dr. Cech told the board. "Bioinformatics is becoming a much larger part of the enterprise and our investigators are asking for imaging equipment. The cost is not excessive, but trained personnel are in short supply."

HHMI's new campus will develop and share the advanced technology resources needed for the cutting-edge, interdisciplinary scientific work that will characterize the medical research of the future, said Dr. Cech. "Advances in science and technology are occurring at a rapid pace. Breakthroughs in computer science, chemistry, physics and engineering can be critical for developing research tools used in the study of biology and medicine. Adapting these discoveries for use in biological systems or health-related sciences, however, requires state-of-the-art technologies, multi-disciplinary expertise and high-quality research facilities. In establishing the facility, HHMI intends to accelerate this adaptation process," he said.

The new campus will be home to a large, permanent research-and-development program. "At the same time, it will have the space and financial resources to shift rapidly into new areas that show unusual scientific promise," Cech added.

A new approach to promoting collaborations will be possible at the facility, he said. "For the first time, we will have well-equipped laboratories where a group of scientists can come to work together, each bringing a few members of their research group, for periods ranging from a few weeks to several years," he said.

The Institute anticipates that the facilities on the new campus will be available for occupancy in about four years. The scientific staff will eventually number more than 200. For the collaborative activities on the new campus, HHMI will invite proposals from the scientific community at large, as well as from HHMI investigators. HHMI will seek proposals that center on cutting-edge scientific and technological goals, and will give preference to projects that bring together diverse individuals and expertise from different environments. To be successful, proposals will have to demonstrate originality, creativity, and a high degree of scientific risk-taking.

FASEB Board Selects 2002-2003 Officers: A Leading Bone Researcher and Pathologist Chosen as President-Elect; Nutritional Biochemist Tapped to Lead the Federation Think Tank

The FASEB Board of Directors has elected its officers for 2002-2003. Steven L. Teitelbaum, the Wilma and Roswell Messing Professor of Pathology at the Washington University School of Medicine in St. Louis, has been chosen as the President-Elect. Alfred H. Merrill, Jr., a professor in the department of biochemistry at Emory University School of Medicine, was selected as the Vice President-Elect for Science Policy. Both men will assume their duties on July 1, 2002.

Dr. Teitelbaum represents the American Society for Bone and Mineral Research on the Federation's board, and is also a member of two other FASEB member societies: the American Society for Investigative Pathology and the American Society for Clinical Investigation.

"I am honored to have been elected President of FASEB for 2002-2003," said, Dr. Teitelbaum. "FASEB is the nation's largest organization of biomedical researchers and has been a leader in the effort to promote policies that will advance science and improve our lives. Researchers in FASEB's 21 member societies are advancing the frontiers of knowledge in all areas of medicine and life sciences research."

Dr. Teitelbaum's primary goal as FASEB president will be to promote the federal funding of biomedical and life sciences research. "With the tools and knowledge at our disposal, we are poised to make bold and exciting progress in the battle against disease," he said. "Advances made in the last several years have given us the opportunity to understand the most fundamental biological processes. These insights, in turn, present us with exciting new hope for prevention, cures, and treatments. As a nation, we have invested wisely in biomedical research, and we must continue on this course.

"This is an exciting era for biomedical research, and as biologists we have an intimate knowledge of the investments needed. We also appreciate that advances in other fields of science are important to our progress in biomedicine and to our well being as a society. Therefore, I am firmly committed to working with broad coalitions of scientists and others to ensure that our investment in research is sufficient to meet the challenges and opportunities before us."

It addition to funding, he said, there are other policy issues that are important to the advancement of medical research. "As a long time member of the Institutional Review Board at Washington University, I am personally committed to the protection of human research participants," he said. "Progress in biomedical research has led to a huge increase in human subjects research, and we must meet the challenges presented by this growth. New policies and regulations must be carefully crafted so that the resulting system does not substitute rigid bureaucracy for informed oversight. The cost of not doing research must also be appreciated, and the burdens carried by the untreated must be considered."

It would be cruel and unethical, however, to perform research on humans without first conducting research on animals, he said. "Animal research underlies most of the important breakthroughs in biomedical science," Dr. Teitelbaum said. "Unfortunately, the importance of animal research to the advancement of medicine and the protection of human research participants is often misunderstood. One of my goals as president of FASEB is to advance the understanding of animal research and to promote policies that ensure that animal research is not prohibited by well meaning but misguided policies."

He also intends to make medical records privacy a top priority during his term.

The past, present and future. Shown here, from left to right, are Robert R. Rich, who will become president of FASEB on July 1; Mary J.C. Hendrix, FASEB's current president, and Steven L. Teitelbaum, who will assume the presidency on July 1, 2002.

Dr. Teitelbaum, who also serves as a pathologist at Barnes-Jewish Hospital and St. Louis Shriners' Hospital for Children, is an expert on the normal biology and pathology of bone. In the late 1970s, he developed a method of using structural changes in bone to diagnose bone disorders such as postmenopausal osteoporosis. He also showed that vitamin D therapy helps overcome defective bone formation that occurs with kidney failure. In the 1980s, he began studying bone cells called osteoclasts that cause localized destruction of bone during both normal remodeling and disease. He demonstrated that osteoclasts are derived from white blood cells called macrophages and that they develop along a different pathway than cells that rebuild bone.

Dr. Teitelbaum received a medical degree from the Washington University School of Medicine in 1964. After a one-year internship in pathology at the medical school, he completed an internship and residency at New York University and returned to Washington University in 1968 as a clinical fellow in pathology. He served as chairman of Jewish Hospital's Institutional Review Board from 1977 to 1997 and was also pathologist-in-chief at Jewish Hospital from 1987 to 1996. The medical school named a scholarship to honor him as a distinguished alumnus in 1997.

An author or co-author of more than 200 scientific articles, Dr. Teitelbaum also is an associate editor for the *Journal of Cellular Biochemistry* and serves on the editorial boards of many scientific journals. He served as the science advisor on *Bone Builders: Preventing and Treating Osteoporosis*, the most recent article in FASEB's Breakthroughs in Bioscience series.

"We look forward to working with Dr. Teitelbaum," said FASEB Executive Director Sidney H. Golub. "He has been a

leader in FASEB activities, including our governance committee and as science advisor for a superb article in the FASEB Breakthroughs series communicating to the public the important progress in osteoporosis research. He is greatly respected for his experience and knowledge in public affairs, human subjects research, and other key issues. Furthermore, his skills at building consensus and his collegial style are well matched to the challenge of the FASEB Presidency."

Three generations of leaders. Shown here, from left to right, are Sue P. Duckles, the current Vice President for Science Policy; Alfred H. Merrill, Jr., who will assume that position in July 2002; and incoming VP for Science Policy, Bettie Sue Masters.

Dr. Merrill represents the American Society for Nutritional Sciences on the Federation's board. He is also a member of another FASEB Society: the American Society for Biochemistry and Molecular Biology.

The Science Policy Committee serves as a think tank for FASEB, examining science policy issues and recommending courses of action for the Federation. "As VP for Science Policy, I will continue the current areas of emphasis of the Science Policy Committee, which include human subjects and bioethics; animal subjects, training and career opportunities, NIH issues such as peer review, the Breakthroughs in Bioscience series, and an ongoing dialog about the future of biomedical science," said Dr. Merrill. In addition, he said, he hopes to explore mechanisms to better educate and empower scientists regarding the decision-making groups that influence science, and to increase participation of scientists in the science policy process.

Dr. Merrill received a Ph.D. in biochemistry from Cornell University in 1979 and, after a post-doctoral fellowship at Duke University, joined the faculty of the Department of Biochemistry at Emory in 1981. He was promoted to full Professor in 1992. He received the Emory Williams Teaching Award for Natural Sciences (1985), the Outstanding Teacher Award in Biochemistry from the Emory University Medical Class of 1993, and helped found the Emory University Center and Graduate Program in Nutrition and Health Sciences, which promotes multidisciplinary training and research beginning with a strong foundation in the basic sciences.

His research has helped characterize the metabolism and biological functions of a diverse family of compounds called sphingolipids. Sphingolipids influence cell growth and other behaviors, including the "programmed" pathways for cell death (called apoptosis). In collaboration with scientists at the U.S. Department of Agriculture, Dr. Merrill has established that diseases caused by a food contaminant (fumonisins) are due to disruption of sphingolipid metabolism. His lab has also shown that naturally occurring sphingolipids (in food) as well as synthetic analogs can be used to inhibit the development of colon cancer.

His contributions have been recognized by the Mead-Johnson Award (1989) from the American Institute of Nutrition (AIN), a Pew Faculty Scholarship (1989), Achievement Awards from the National Aeronautics and Space Administration (1989 and 1991), a Focused Giving Award from Johnson and Johnson Foundation (1995), and the Osborne-Mendel Award for Basic Accomplishments in Nutrition from the AIN (1996). He became a Fellow of the American Association for the Advancement of Science in 2000.

He has served or is serving on the editorial boards of Biochimica *Biophysica Acta: The Journal of Biochemistry* (Tokyo) and *The Journal of Biological Chemistry*, and has been a Contributing Editor of *Nutrition Reviews* and an Associate Editor of *The Journal of Nutrition*. In addition, he has written more than 170 primary research publications and reviews. He has served on numerous committees and grant review panels, including the Metabolic Pathology Study Section of the National Institutes of Health (1986-1991), the grants review panel of the American Institute for Cancer Research (1985-1992), the External Advisory Committee of the Research Infrastructure for Minority Institutions (RIMI) Program at Spelman College in Atlanta (as Chair, 1997-present), and as a Member (and Co-Vice Chair) of the Food and Nutrition Board of the Institute of Medicine (1999-2001).

"Dr. Al Merrill will be a superb Vice-President for Science Policy," said Dr. Golub. "His thoughtful and analytical approach, coupled with a wide-ranging knowledge of contemporary biomedical research, makes him perfectly suited to lead our science policy think tank."

UPCOMING FASEB EVENTS

Press Event

On July 11, 2001, Robert R. Rich, FASEB's President-Elect, will present his 2001-2001 priorities at a press conference. The event will run from 8:30 to 11 in the Zenger Room of the National Press Club, 529 14th Street, N.W., Washington, D.C. For more information, contact Paulette W. Campbell at Campbell@opa.faseb.org.

Fall Policy Conference

In October, FASEB's Science Policy Subcommittee on the Future of Biomedical Science will host a fall conference, "Corporate Financing of Academic Research: Inherent Conflicts of Interest." The one-day conference will be preceded by an evening reception, keynote address and dinner in conjunction with the Science Policy Committee's annual face-to-face meeting. The date and location will be announced in the August *FASEB News.* For more information, contact Tamara Zemlo at tzemlo@opa.faseb.org.

What We've Been Doing

FASEB, Advocacy Partners Announce Launch of National Accrediting Entity for Human Research Protection

On May 23, FASEB, joined by six advocacy organizations, announced the launch of the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The new organization, AAHRPP, is currently developing a voluntary, peer-driven accreditation program, using a site visit model that will make use of a rigorous set of performance standards and outcome measures to ensure the integrity of human research programs.

"AAHRPP has come into existence because the key stakeholders – researchers, patients, medical schools and research universities – felt that we had to do something proactive to make sure that clinical research was being performed in an appropriate and safe way and that it would continue and flourish," said FASEB President Mary J. C. Hendrix. "We at FASEB are proud to participate in the founding of AAHRPP. As an organization of investigators, we expect to bring an important perspective to this process. Our goal is to insure that human subject research is performed with proper attention to the rights and safety of the subjects while simultaneously promoting society's interest in having the benefits of high quality biomedical research."

Along with FASEB, the founding member organizations of the AAHRPP are the Association of American Universities, Association of American Medical Colleges, Consortium of Social Science Associations, National Association of State Universities and Land-Grant Colleges, National Health Council, and Public Responsibility in Medicine and Research. "We look forward to working with our partner organizations in making AAHRPP a success," said Dr. Hendrix.

FASEB President Testifies on Behalf of Department of Defense Life Sciences Research

On May 23, Mary Hendrix testified before the Senate Appropriations Subcommittee on Defense. In its annual funding report to Congress, FASEB recommended a $50-million increase to the Department of Defense's Basic Research budget for the Life Sciences for fiscal year 2002. This increase should be for the designated purpose of providing an increase to the Army, Navy and Air Force Defense Research Science Programs, the University Research Initiatives, and the Chemical and Biological Defense Program. "This agency supports a major basic research program in the Life Sciences that has produced significant benefits to the nation," Dr. Hendrix said. "Today, for instance, military personnel are protected from epidemic hepatitis as a result of knowledge gained from basic research on the biology and immunology for the hepatitis-A virus. Additionally, basic research supported by the DoD, into the physiology of body temperature control has produced procedures that are used at Army Ranger training sites to protect trainees from hypothermia, and this has also been adapted for civilian use."

But this agency's Life Sciences research effort, as well, has been threatened by a decline in funding. "DoD's budget for basic research in the life sciences has declined by 25 percent from 1993 to 1998 (in inflation-adjusted dollars). According to FASEB's funding report, "These cutbacks have compromised basic biomedical research at a time when the potential to have a larger impact on military readiness is greater than it has ever been. As the pace of technology quickens, it has become obvious that new funding and research opportunities for the DoD Basic Research Program are critical if the U.S. military is to maintain its technological superiority. Therefore, it is imperative that the level of support for this area be substantially increased to realize this potential."

Hendrix Meets with Biotech Industry Reps

On May 17, Mary Hendrix met with representatives of the Biotechnology Industry Organization (BIO) to discuss potential areas of collaboration. "We should work closely on areas of common interest such as research policy, training, and regulatory policy," Dr. Hendrix told Carl Feldman, president of BIO. "There are many issues where we can stand shoulder to shoulder, and in the process we will also learn to be more sensitive to the areas of individual concern."

Dr. Hendrix talked also of FASEB's priorities, which include completing the National Institutes of Health doubling campaign; ramping up support for the National Science Foundation; advocating for better treatment and pay of postdoctoral students; and, keeping tabs on increasing regulatory burdens in the areas of compliance costs, animals and human subjects protections.

FASEB President-Elect Gives Talk on Federal Regulations

On April 30, Robert R. Rich, who will assume the FASEB presidency on July 1, talked about the state of federal regulations governing the use of animal in research at "At the Crossroads," a meeting sponsored by the National Association of Biomedical Research (NABR). Dr. Rich opened his talk with a description of the extraordinary scientific opportunities available. But, he cautioned, as the number of research animals continues to increase, particularly genetically modified rodents, so will the cost of maintaining and caring for those animals. Duplicate federal agency oversight, unnecessary paperwork and documentation, redundant or meaningless reporting requirements and other rules that do not contribute directly to animal care and well-being will merely drive costs much higher. More than creating frustrations for researchers and animal care professionals, he said, such provisions divert time and attention from their scientific work as well as from real animal welfare efforts.

At that same meeting, Janet L. Greger, University of Wisconsin professor and chair of the NIH Working Group on Regulatory Burden Subcommittee on Animal Use, echoed these themes and described what the congressionally mandated NIH project has been doing to solve the problems. Dr. Greger is a member of FASEB's Science Policy Subcommittee on Animals in Research.

Hendrix Talks to Association of Graduate Schools

On April 19, Mary Hendrix delivered the keynote speech to the 57th Annual Meeting of the Midwestern Association of Graduate Schools. She pointed out that the research community

has proposed several important recommendations to improve the graduate and postdoctoral experiences. "In recent years, FASEB's recommendations to Congress have called for a substantial increase in the base salaries of trainees supported by the National Research Service Award (NRSA) training and fellowship program," Dr. Hendrix said. "FASEB is committed to working for higher stipends and improved benefits for graduate students and postdocs, and will be making this a significant part of our advocacy program." In addition, she said, improvements in postdoctoral training are needed to keep careers in biomedical research attractive and desirable; a clear distinction should exist between postdoctoral fellows who are in the process of being trained and other valuable research workers; and, trainees should be made aware of a broad range of career options as early as possible and given placement assistance. The entire text of her speech, "Ethical Challenges for Graduate Education," can be found on the web at www.faseb.org/opar/Graduate.Education.html.

FASEB Increases Advocacy for NSF Doubling Effort

In an email alert sent April 4 to more than 32,000 biomedical researchers, Dr. Hendrix asked her colleagues to contact members of Congress and urge them to increase funding for the National Science Foundation (NSF). "Once again, Senators Christopher "Kit" Bon (R-Mo.) and Barbara Mikulski (D-Md.) are circulating a 'dear colleague' letter to Senate Majority Leader Trent Lott and Democratic Minority Leader Thomas Daschle advocating a doubling of the NSF budget over five years," Dr. Hendrix wrote. "We must support this effort now!"

President Bush has proposed a $4.47 billion budget for the NSF in FY 2002. This request represents a 1.3 percent increase in the foundation's budget; research activities would decline by 0.5 percent. In its annual report to Congress, FASEB recommended the NSF budget for FY 2002 be increased by at least 16 percent, (to $5.1 billion). That report is online at http://www.faseb.org/opar/fund2002/fedfund02.pdf. Dr. Hendrix's testimony to Congress on behalf of the NIH can be found at www.faseb.org/opar/ppp/nsf_test.html.

FASEB Approves Policy Statement on Postdoctoral Training

FASEB has released a statement on postdoctoral training which says, among other things, that postdocs need higher stipends; there should be a distinction between postdoctoral fellows who are in training and other research workers; and, scientists and educators should make trainees aware of a broad range of career options as early as possible and provide placement assistance. The full statement can be found at www.faseb.org/opar/train_pol.html.

FASEB Praises NIH Statement on NAS Training Report

Last year, the National Academy of Sciences released *Addressing the Nation's Changing Needs for Biomedical and Behavioral Scientists*, the 11th in a series of reports on the national needs of biomedical and behavioral scientists. On March 26, the National Institutes of Health (NIH) announced its intention to support and execute selected recommendations from the Biomedical and Crosscutting sections of the NAS report.

FASEB supported the NIH view that more information is needed on students supported on research grants. The Federation also endorsed NIH's plan to implement higher stipends, in accord with the NAS recommendations. FASEB also strongly backed the NIH view that there should not be limitations placed on the number of students entering science programs. The NAS report can be found at www.nap.edu/books/0309069815/html/. The NIH statement can be found at http://grants.nih.gov/training/nas_report/NIHResponse.htm. FASEB's letter can be found at www.faseb.org/opar/Graduate.Education.html.

Hendrix Distributes FASEB Cloning Article to Press

Recent media attention has focused on the latest proposals to clone human beings. From FASEB's perspective, cloning human beings is an irresponsible and misguided act. A clear distinction should be made, however, between reproductive human cloning and cell cloning techniques since these techniques have tremendous therapeutic potential to treat human disease and repair damaged tissues or organs. To educate the public about the value of this cloning technology, FASEB published the "Cloning: Past, Present, and the Exciting Future", as part of its *Breakthroughs in Bioscience* series.

In an April letter accompanying a reprint of the report, Mary Hendrix told journalists: "We hope this article, written by one of the pioneers in animal cloning, Dr. Marie A. Di Bernardino, will serve as a valuable reference as you write about human cloning and cloning technologies."

The article, which can be found on the Web at www.faseb.org/opar/cloning/, explains the history of cloning and potential therapeutic uses of these techniques. "The article was published in 1999, demonstrating FASEB's ongoing commitment to educating the public about current biomedical issues," Dr. Hendrix notes. "Since that time, additional evidence has mounted showing the enormous risks associated with animal cloning. In species where cloning has been attempted, most clones do not survive to term or die at birth, and those that live have severe health problems. Furthermore, recent evidence suggests that these abnormalities may be due to defects in genetic reprogramming, the process through which the nucleus from the donor body cell "resets" its genetic makeup once it is inserted into a recipient egg cell whose own nucleus has been removed. While this process gives the cell the potential to develop into many different cell types, it may also result in genes being turned on or off at inappropriate times [see Rudolf Jaenisch and Ian Wilmut's article (March 30, 2001): *Science* 291: 2552]. It is crucial that scientists and the public maintain an open and informed dialogue about the discoveries from this research."

Hendrix Addresses FASEB Society Councils at EB 2001 Meeting

Mary Hendrix attended the council meetings of several FASEB societies during the Experimental Biology 2001 meeting in Orlando, Fla. to talk about FASEB's public policy priorities. Among the societies visited were the American Physiological Society, American Society for Biochemistry and Molecular Biology, American Society for Investigative Pathology, American Society for Nutritional Sciences, American Association of Immunologists, and American Association of Anatomists. FN

19 FASEB Society Members Elected to the Academy

Nineteen FASEB Society members were among the 72 scientists and 15 foreign associates who were elected May 1 to the National Academy of Sciences (NAS) in recognition of their distinguished and continuing achievements in original research. Election to membership in the Academy is considered one of the highest honors that can be accorded a U.S. scientist or engineer. The FASEB Society members among the newly elected are:

Bjorkman, Pamela J.; investigator, Howard Hughes Medical Institute, and professor, division of biology, California Institute of Technology, Pasadena, Calif. (AAI, Protein).

Brugge, Joan Siefert; professor, department of cell biology, Harvard Medical School, Boston, Mass. (ASBMB).

Cantley, Lewis C.; professor, department of cell biology, Harvard Medical School, and chief, division of signal transduction, department of medicine, Beth Israel Deaconess Medical Center, Boston, Mass. (ASBMB).

Cresswell, Peter; investigator, Howard Hughes Medical Institute, and professor, department of biology, Yale University, New Haven, Conn. (AAI).

Exton, John H.; investigator, Howard Hughes Medical Institute, and professor of molecular physiology and of pharmacology, Vanderbilt University, Nashville, Tenn. (APS, ASBMB).

Fearon, Douglas T.; Wellcome Trust Research Professor of Medicine, School of Clinical Medicine, Addenbrookes Hospital, University of Cambridge, Cambridge, U.K. (AAI, ASCI).

Glazer, Alexander N.; director, Natural Reserve System, and professor, division of biochemistry and molecular biology, department of molecular and cell biology, University of California, Berkeley (ASBMB).

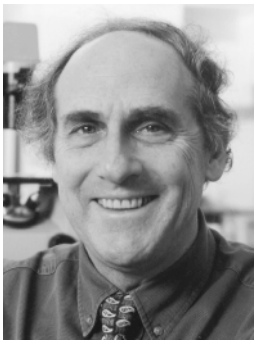
Gordon, Jeffrey I.; Alumni Professor and head, department of molecular biology and pharmacology, and director, division of biology and biomedical sciences, Washington University School of Medicine, St. Louis, Mo. (ASBMB, ASPET, ASNS, ASCI).

Ingram, Lonnie O'neal; Distinguished Professor, department of microbiology and cell science, University of Florida, Gainesville, Fla. (ASBMB).

Kuriyan, John; investigator, Howard Hughes Medical Institute, and Patrick E. and Beatrice M. Haggerty Professor, Laboratories of Molecular Biophysics, Rockefeller University, New York (ASBMB, BPS, Protein).

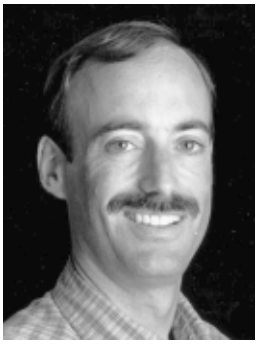
Landmesser, Lynn T.; professor and chair, department of neurosciences, Case Western Reserve University, Cleveland, Ohio (APS, SDB).

Sommer, Alfred; professor of epidemiology and international health and dean, Johns Hopkins University School of Hygiene and Public Health, Baltimore, Md. (ASNS).



Steinman, Ralph Marvin; senior physician and Henry G. Kunkel Professor, Rockefeller University, New York (AAI, ASCI).

Taylor, Edwin W.; Louis Block Professor of Molecular Genetics and Cell Biology and professor, department of molecular genetics and cell biology, University of Chicago (BPS).



Vale, Ronald D.; associate investigator, Howard Hughes Medical Institute, and William K. Hamilton Distinguished Professorship of Anesthesia, department of cellular and molecular pharmacology, University of California, San Francisco, Calif. (BPS).

Foreign Members

Allende, Jorge E.; professor and director, Institute of Biomedical Sciences, Faculty of Medicine, University of Chile, Santiago, Chile (ASBMB).

Honjo, Tasuku; dean, Kyoto University Faculty of Medicine, Japan (AAI).

Maclennan, David; J.W. Billes Professor, Banting and Best Department of Medical Research, University of Toronto, Canada (ASBMB, BPS).

Yanagimachi, Ryuzo; professor of anatomy and reproductive biology, department of anatomy and reproductive biology, John A. Burns School of Medicine, University of Hawaii, Honolulu, Japan (SSR).

The National Academy of Sciences is a private organization of scientists and engineers dedicated to the furtherance of science and its use for the general welfare. The Academy was established in 1863 by a congressional act of incorporation, signed by Abraham Lincoln, that calls on the Academy to act as an official adviser to the federal government, upon request, in any matter of science or technology. Additional information about the institution is available on the Internet at http://national-academies.org. A full directory of NAS members can be found online at http://national-academies.org/nas.

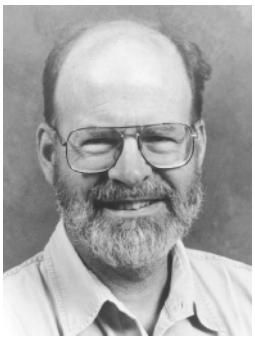
Society News

Deadline Nears for Abstracts for APS Meetings

Call for Abstracts booklets are now available for the 2001 American Physiological Society (APS) Conferences. The abstract deadline is June 8. Upcoming meetings include the "Cellular and Molecular Physiology of Sodium-Calcium Exchange," to be held Oct. 10-14, in Banff, Alberta, Canada; and, "Genome and Hormones: An Integrative Approach to Gender Differences in Physiology," Oct. 18-20, in Pittsburgh, Pa. Please contact the APS Meetings Office (301-530-7171; meetings@aps.faseb.org) to request your booklet. Complete details can be found on our web page at: www.the-aps.org/meetings/aps/mtg_confern.htm

Janeway Receives AAI Lifetime Achievement Award

On April 3, Charles A. Janeway was presented with the American Association of Immunologists (AAI) Lifetime Achievement Award in recognition of distinguished scientific accomplishment and exemplary service to the AAI. In addition to innumerable contributions to the field of immunology, he also served as AAI Councillor and President from 1992 to 1999. Dr. Janeway is professor of imm-unology at Yale University and an investigator at the Howard Hughes Medical Institute.



Charles A. Janeway

Biophysical Society Discussions

The Biophysical Society will hold a "Discussions" meeting, in Asilomar, Calif., on April 19-22, 2002. The meeting will focus on "Frontiers in Structural Cell Biology: How Can We Determine the Structure of Large Subcellular Machines?" Discussions are small meetings that focus on cutting-edge or emerging topics in biophysics. Plenary sessions consist of five-minute presentations by speakers, followed by a 25-minute discussion. In addition, there are shorter presentations and poster sessions. The meetings are limited to 200 participants, and last two-to-four days. The Discussions call-for-papers will appear in the Biophysical Society's September/October Newsletter.

Fallon Becomes AAA President; McCuskey Next in Line

John F. Fallon, professor of anatomy at the University of Wisconsin-Madison, moved up to become president of the American Association of Anatomists (AAA) at the close of Experimental Biology 2001 meeting, while Robert S. McCuskey, professor and head of cell biology and anatomy at the University of Arizona, became president-elect. Dr. McCuskey will be AAA president from 2003-2005.

AAA Developmental Biology Award Named for H.W. Mossman

A new AAA award named for Harland Winfield Mossman will honor outstanding achievements of young scientists in all aspects of developmental biology – ranging from the level of the gene and molecule to that of the whole organism – and have demonstrated remarkable promise of future accomplishments.

Dr. Mossman, a member of the University of Wisconsin Medical School Anatomy Department from 1926 to 1968, was an international authority on fetal membranes and comparative reproduction. He was the first to describe "counter current" mechanisms in a circulatory system and to show its efficiency in the exchange of nutrients and waste between mother and fetus.

The first award – a certificate and a $500 honorarium – will be presented at the AAA Annual Meeting at EB 2002 in New Orleans, where the recipient will give a special lecture. Eligibility is restricted to individuals who have completed their doctorate degree within the past 12 years. Nominations, due Sept. 15, should include the nominator's letter; the *curriculum vitae* of the nominee; and, several representative papers. For additional information on the award nomination process, go to www.anatomy.org/anatomy/nawards.htm.

Protein Society Meeting Attracts Hundreds

More than 750 people attended The 4th European Symposium of The Protein Society at the Institut Pasteur. The space available limited attendance to this number. Various speakers emphasized the role of protein scientists in the next major biological thrust, namely, the unraveling of the role of individual and interacting proteins in molecular and cellular biology. This includes such topics as bioinformatics, proteomics, imaging, and drug design. A report of the symposium appears on the web site of biomednet.

ASBMR Reports Meeting Highlights

To highlight current issues in bone and mineral research, from basic to clinical and translational, the 2001 ASBMR Program Committee has added a new element to the ASBMR 23rd Annual Meeting this fall: State-of-the-Art Lectures. These lectures will feature focused presentations by senior scientists on specialized topics. The meeting is scheduled for Oct. 12-16 in Phoenix, Ariz.

Another novel feature of the 2001 ASBMR Annual Meeting is the ASBMR/Orthopaedic Research Society (ORS) Joint Symposium entitled "Mechanical and Metabolic Properties of the Skeleton." This symposium will be on Oct. 12, from 9:30 a.m. to 12:00 noon. The moderators for the joint symposium are Drs. Edward Puzas and Marie Demay. For more information about the Annual Meeting, visit the ASBMR web site at www.asbmr.org. ASBMR Comm-issions Membership Survey. In a continuing effort to learn more about its members and ensure that its programs are meeting member needs, ASBMR is surveying all members. Results will help the ASBMR Council plan future programs and products. ASBMR Council Activities. ASBMR will hold its Summer Council Meeting and Strategic Retreat on June 28-29, 2001, in Sonoma, California. For condensed minutes of ASBMR Council Meetings, and other updates, visit the ASBMR web site at www.asbmr.org.

Teratology Society to Hold 41st Annual Meeting in Montréal

The 2001 Annual Meeting of the Teratology Society will be held at Le Centre Sheraton Hotel in Montréal, Canada on June 23-28. Highlights of the program include the March of Dimes Symposium on scientific advances in male-mediated developmental toxicity and the Wiley-Liss Symposium on pluripotent stem cells in and out of the

embryo. Symposia will also be presented jointly with the Neurobehavioral Teratology Society on genetic pathways of neurodevelopment and with the Organization of Teratogen Information Services on teratogenic effects of obstetrical procedures. There will be workshops on recent advances in our understanding of teratogenic exposures in humans, the role of redox regulation in teratogenesis, and food borne infections during pregnancy. The full program and other information about the meeting are available on the Teratology Society web site at www.teratology.org/meetings/2001/prog2001.htm.

Radiation Research Society Holds Annual Meeting in San Juan

The annual meeting of the Radiation Research Society (RRS) was held at the Caribe Hilton hotel in San Juan, Puerto Rico on April 21-25. More than 750 participants attended a wide variety of refresher courses, symposia, and workshops and shared their own research through more than 400 posters. Three plenary lectures focused on the theme of molecular targets and featured Joe Gray, University of California, San Francisco, (Genome Evolution in Solid Tumors: Clinical Correlations and Therapeutic Targets); Dan Kenan, Duke University, (Designer Ligands for Molecular Targets) and Edison Liu, National Cancer Institute, (Therapeutics in the Genomic Era).

A highlight of the meeting was a special symposium on Space Radiobiology that featured Ellen Baker, a National Aeronautics and Space Administration shuttle astronaut. A veteran of three space flights, Dr. Baker has logged over 686 hours in space including two missions on Atlantis and one on the Columbia. Her presentation dealt with the issue of radiation exposure during space missions. The entire meeting schedule with abstracts can be viewed on the Radiation Research Society web page (www.radres.org).

EMS 2001–A Science Odyssey

The 2001 Program Committee of the Environmental Mutagen Society (EMS) assembled an accomplished group of speakers and a wide range of interesting topics and activities to make the 32nd annual meeting in San Diego, Calif., an informative experience. The plenary session opened with keynote speaker, Stephen J. Gould, one of the leading scientists in the field of evolution as well as an historian and social commentator. His many articles and books have explored a diversity of topics in biology, with an emphasis on the impact of science on society.

Each day had a theme: Cancer Genetics; Genomics, Proteomics, Toxicogenomics, and Bioinformatics; Animal Models and Ethics; The Mechanisms of Mutagenesis and Carcinogenesis. Sir Alec Jeffreys, who developed DNA fingerprinting, provided a plenary talk on the mutagenicity of repeated DNA sequences in humans and mice.

The conference closed with a symposium on the potential genotoxic effects of perinatal exposure to antiretroviral drugs to treat HIV infection. This comprehensive symposium presented all facets of this important scientific development, which has far-reaching social/political policy implications. FN