

HESI History: Highlights

- 1978** The International Life Sciences Institute, ILSI, founded by Dr. Alex Malaspina.
- 1989** HESI is founded as the global branch of ILSI.
- HESI's first Chair is Dr. Louis Lasagna (Tufts University), a globally recognized leader in clinical trial methodology and the placebo effect, often referred to as the 'Founder of Clinical Pharmacology'.
- Nine sponsor companies participate.
- HESI convenes 14 scientists for its first workshop on the human relevance of mouse liver tumors.
- 1990** HESI's first President is Dr. Peter N. Britton (Johnson & Johnson).
- 1992** The first HESI technical committees are formed.
- Dr. Denise Robinson is appointed HESI's first Scientific Director in Fall 1992.
- 1993** The HESI Emerging Issues Committee is formed – setting the stage for an ever growing and current scientific portfolio.
- 1997** Dr. Denise Robinson promoted to HESI Executive Director.
- 1999** HESI celebrates 10 years of science with 48 participating companies and dozens of academic and government scientific participants.
- 2001** HESI is independently incorporated as a 501c3 nonprofit, and becomes an independent, branch of ILSI.
- 2002** Dr. Michael Holsapple is hired as HESI's second Executive Director on October 1st.
- 2005** HESI achieves a landmark 100 publications.
- 2011** HESI holds its first annual meeting in Europe.
- Syril Pettit, M.E.M., becomes HESI's third Executive Director on November 21st.
- 2013** The FDA Director for the Center for Drug Evaluation and Research (CDER), Dr. Janet Woodcock, and HESI Executive Director, Syril Pettit, MEM, sign a Memorandum of Understanding (MOU) committing to partnership to enhance drug development and drug safety evaluation through shared research, education, and collaboration.
- 2014** The number of HESI Sponsor companies grows to over 60.
- The HESI Scientific Portfolio includes 13 scientific committees and more than 60 distinct projects.
- Over 260 HESI publications are cited almost 5,000 times in over 1,000 scientific peer reviewed journals.
- Syril D. Pettit, MEM, (HESI Executive Director) leads a staff of eleven.

HESI HISTORY

HESI Chairs and Presidents

1989

Chair, Louis Lasagna, Tufts University
Interim President, Alex Malaspina, The Coca-Cola Company
Vice President, Gordon V. Loewengart, Hoechst Celanese Corporation

1990 -1996

Chair, Louis Lasagna, Tufts University
Vice Chair, Anthony D. Dayan, St. Batholomew's Hospital Medical College
President, Peter N. Britton, Johnson & Johnson
Vice President, Gordon V. Loewengart, Hoechst Celanese Corporation

1997

Chair, Louis Lasagna, Tufts University
Vice Chair, Anthony D. Dayan, St. Batholomew's Hospital Medical College
President, R. Michael McClain, Hoffman-La Roche, Inc.
Vice President, Gordon S. Hassing, The Procter & Gamble Company

1998

Chair, Anthony D. Dayan, St. Batholomew's Hospital Medical College
Vice Chair, Curtis D. Klaassen, University of Kansas Medical Center
President, R. Michael McClain, Hoffmann-La Roche Inc.
Vice President, James E. Gibson, Dow AgroSciences

1999

Chair, Anthony D. Dayan, St. Batholomew's Hospital Medical College
Vice Chair, Curtis D. Klaassen, University of Kansas Medical Center
President, James E. Gibson, Dow AgroSciences
Vice President, Jack H. Dean, Sanofi Pharmaceuticals Inc.

2000

Chair, Curtis D. Klaassen, University of Kansas Medical Center
Vice Chair, Jay I. Goodman, Michigan State University
President, James E. Gibson, Dow AgroSciences
Vice President, Jack H. Dean, Sanofi-Synthelabo Research

2001

Chair, Curtis D. Klaassen, University of Kansas Medical Center
Vice Chair, Jay I. Goodman, Michigan State University
President, Jack H. Dean, Sanofi-Synthelabo Research
Vice President, Lewis L. Smith, Syngenta Ltd.

2002

Chair, Jay I. Goodman, Michigan State University
Vice Chair, Helmut Greim, Technical University of Munich
President, Jack H. Dean, Sanofi-Synthelabo Research
Vice President, Lewis L. Smith, Syngenta Ltd.

2003

Chair, Jay I. Goodman, Michigan State University
Vice Chair, Helmut Greim, Technical University of Munich
President, Lewis L. Smith, Syngenta Ltd
Vice President, William T. Robinson, Novartis Pharmaceuticals Corporation

2004

Chair, Helmut Greim, Technical University of Munich
Vice Chair, Samuel M. Cohen, University of Nebraska Medical Center
President, Lewis L. Smith, Syngenta Ltd
Vice President, William T. Robinson, Novartis Pharmaceuticals Corporation

2005

Chair, Helmut Greim, Technical University of Munich
Vice Chair, Samuel M. Cohen, University of Nebraska Medical Center
President, William T. Robinson, Novartis Pharmaceuticals Corporation
Vice President, James S. MacDonald, Schering-Plough Research Institute

2006

Chair, Samuel M. Cohen, University of Nebraska Medical Center
Vice Chair, Alan R. Boobis, Imperial College London
President, William T. Robinson, Novartis Pharmaceuticals Corporation
Vice President, James S. MacDonald, Schering-Plough Research Institute

2007

Chair, Samuel M. Cohen, University of Nebraska Medical Center
Vice Chair, Alan R. Boobis, Imperial College London
President, James S. MacDonald, Schering-Plough Research Institute
Vice President, Marc S. Bonnefoi, sanofi-aventis

2008

Chair, Alan R. Boobis, Imperial College London
Vice Chair, Kendall B. Wallace, University of Minnesota School of Medicine
President, James S. MacDonald, Schering-Plough Research Institute
Vice President, Marc S. Bonnefoi, sanofi-aventis

2009

Chair, Alan R. Boobis, Imperial College London
Vice Chair, Kendall B. Wallace, University of Minnesota School of Medicine
President, Marc S. Bonnefoi, sanofi-aventis
Vice President, Dennis J. Devlin, Exxon Mobil Corporation

2010-2011

Chair, Kendall B. Wallace, University of Minnesota School of Medicine
Vice Chair, Ronald N. Hines, Medical College of Wisconsin
President, Marc S. Bonnefoi, sanofi-aventis
Vice President, Dennis J. Devlin, Exxon Mobil Corporation

2011-2012

Chair, Kendall B. Wallace, University of Minnesota School of Medicine
Vice Chair, Ronald N. Hines, Medical College of Wisconsin
President, Dennis J. Devlin, Exxon Mobil Corporation
Vice President, Laurie A. Hanson, Pfizer Inc.

2012-2013

Chair, Kendall B. Wallace, University of Minnesota School of Medicine
Vice Chair, Herman N. Autrup, University of Aarhus
President, Dennis J. Devlin, Exxon Mobil Corporation
Vice President, Laurie A. Hanson, Pfizer Inc.

2013-2014

Chair, Kendall B. Wallace, University of Minnesota School of Medicine
Vice Chair, Herman N. Autrup, University of Aarhus
President, Laurie A. Hanson, Pfizer Inc.
Vice President, Timothy P. Pastoor, Syngenta Crop Protection, Inc.



First HESI President
Peter Britton, PhD
Director of Community Environmental
Development
Johnson & Johnson

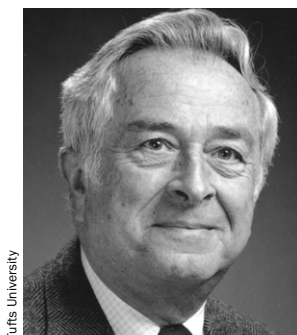


First HESI Chair of Board
Louis Lasagna, MD
Dean of the Sackler School of Biomedical
Sciences, Tufts University School of Medicine
"Father of Clinical Pharmacology"

ILSI Founder: Dr. Alex Malaspina



Obituary



Tufts University

Louis Lasagna

Clinical pharmacologist, investigator of the placebo effect, proponent of stricter rules for drug approvals. Born in Queens, New York, USA, in 1923; died Aug 8, 2003, aged 80, from a lymphoma.

Louis Lasagna's career included groundbreaking studies on the methodology of clinical trials, analgesics, hypnotics, medical ethics, and the placebo effect. Perhaps not surprisingly, the work that brought him his widest audience was research into the psychological responses to drugs. The first results appeared in his landmark 1954 paper, "A Study of the Placebo Response", published in the *American Journal of Medicine*. The implications for the development and assessment of the effectiveness of drugs raised by the idea that the act of taking a substance, even one with no active ingredients, could cause a response in patients rumble on today. Lasagna became an early proponent of the need for a randomised, placebo-controlled trial before any drug received approval.

Lasagna trained in medicine at Columbia University, New York, before becoming a clinical research fellow in anaesthesia at Harvard University. That was followed by 16 years at The Johns Hopkins University School of Medicine, Baltimore, where he taught and started the first academic group devoted solely to clinical pharmacology. He became professor of pharmacology, toxicology, and medicine at the University of Rochester, New York, in 1970, before establishing the Centre for the Study of Drug Development, now affiliated with Tufts University. His successor as director of the centre, Dr Kenneth Kaitin, told *The Lancet* "Lou Lasagna's strong belief that the public is best served when policy debates are conducted in the presence of solid, academic research, led, in 1976, to his founding of the Center". Lasagna's final academic appointment was as Dean of the Sackler School of Biomedical Sciences, Tufts University School of Medicine, Boston.

Lasagna had an important role in reshaping the pharmaceutical industry. Kaitin said he was "a remarkable force in the fields of clinical trial methodology and medical ethics. He was the first to demonstrate the necessity of placebo-controlled clinical trials in studying drug effects". A supporter of stricter rules on drug approvals, Lasagna testified before Congress on several occasions, most notably at the 1962 Kefauver hearings on drug pricing. His evidence helped establish new rules for the use of controlled clinical trials in proving a drug's effectiveness.

According to Kaitin, "his testimony in Congress at the 1962 Kefauver hearings was instrumental in establishing the efficacy requirement for new drugs in the Food, Drug, and Cosmetic Act".

Lasagna's extensive research on drug development in the USA showed that although most biopharmaceutical products originated in the USA and began clinical trials there, they were usually marketed first in Europe. As a result of the longer time required for clinical studies in the USA, together with lengthy and stringent product review processes, fewer new drugs were introduced in the USA than anywhere else except Norway. By contrast, Lasagna said other industrialised countries regulated drug prices and pharmaceutical industry profits much more strictly than did the USA. He was a member of the Commission on the Federal Drug Approval Process that examined the drug development and approval process and reported its findings to Congress in April, 1982. He served on the General Accounting Office's Health Advisory Committee and was chairman of the National Committee to Review Current Procedures for Approval of New Drugs for Cancer and AIDS.

A constant scrutiniser of the high cost of drug development and of flawed prescribing, Lasagna criticised misleading drug advertisements and medical fads, and questioned the ethics of the pharmaceutical industry and the gullibility of some doctors and the media. He wrote, in *The New York Times*, that "most of us are amenable to suggestion, and the ability of sugar pills or water injections to alleviate all kinds of real or imagined ills has often been demonstrated in clinical experiments—and just as often forgotten by physicians in their enthusiasm for new remedies".

In his books *The Doctors' Dilemma* (1962) and *Life and Death and the Doctor* (1968), Lasagna addressed the ethics and role of being of doctor. His popular writings ranged from medical education to the philosophical basis of euthanasia. He also called for a worldwide competition for an updated Hippocratic oath. His own revised version of the Hippocratic oath, subsequently adopted by many medical schools, emphasised doctors' responsibilities to emphasise prevention over cure, to ask for help when needed, and to keep in mind the psychological aspects of disease.

His wife, Helen, their three sons, four daughters, and eight grandchildren survive him.

Pearce Wright

e-mail:
pearce.wright@dial.pipex.com

HESI Committee Portfolio Development

1989

- ❖ Rodent Liver Tumor Workshop

1999

12 Committees, ~20 projects

- ❖ Alternatives to Animal Testing for Eye Irritation
- ❖ Alternative Methods for Carcinogenicity Testing
- ❖ Developmental and Reproductive Toxicology
- ❖ Immunotoxicology
- ❖ Predictivity of Toxicity in Humans from Animal Studies
- ❖ Water Quality
- ❖ Aggregate Exposure Assessment
- ❖ Insect Resistance Management
- ❖ Genomics and Proteomics in Risk Assessment
- ❖ Use of Mechanistic Data in Risk Assessment
- ❖ Criteria for Evaluation of Epidemiology Studies
- ❖ Structure Activity Relationships Database

2014

13 Committees, ~80 projects

- ❖ Animal alternatives in environmental risk assessment
- ❖ Application of genomics to mechanism-based risk assessment
- ❖ Biomarkers of nephrotoxicity
- ❖ Cardiac Safety
- ❖ Developmental and reproductive toxicology (DART)
- ❖ Development of methods for a tiered approach to assess bioaccumulation of chemicals
- ❖ Genetic toxicology
- ❖ Immunotoxicology
- ❖ Protein Allergenicity
- ❖ Risk assessment in the 21st century (RISK21)
- ❖ Sustainable chemical alternatives
- ❖ Use of imaging for translational safety assessment
- ❖ Translational biomarkers of neurotoxicity

(Plus new Emerging Issues to be initiated in Fall 2014)

ILSI and ILSI-NF Annual Meetings Attract 180; Members Updated on ILSI Programs, EC Harmonization

Some 180 member company representatives, public members, scientific advisors, lecturers, and staff gathered in the Bahamas this January for what participants agreed was one of the best ILSI/ILSI-NF annual meetings ever. Present at the meetings were representatives from all four ILSI branches—Australia, Europe, Japan, and North America — and their member companies.

ILSI now has a total of 166 member companies worldwide, up from 145 at the end of 1988, ILSI president Dr. Alex Malaspina told the ILSI/ILSI-NF Joint Board of Members Meeting on January 20. Discussions are taking place to form possible branches in Latin America, where interest from Mexico, Brazil, and Argentina is especially strong. ILSI, by uniting the efforts of government, academia, and industry, can make an important contribution toward ensuring the safety of the world's food sup-

ply and assuring the public of that safety, he said.

Prof. Michel Fondu, scientific director of ILSI Europe, updated members on developments in the European Community as they affect foods, additives, and packaging (see article on page 2). Safety issues involving potential toxicants were reviewed from the worker's perspective by Mr. Ronald Haigh, who is in charge of a unit responsible for the EC Commission's action on industrial medicine and hygiene.

The EC is working to harmonize worker health and safety standards throughout the community, which is "no small task" in light of the very different social, industrial, and political structures of member states, Mr. Haigh said. One component of this initiative is the creation of a system to develop and distribute safety data information on dangerous substances and preparations, possibly by year-end. The EC Council of Ministers, he said, has stressed

continued on page 6

ILSI Health and Environmental Sciences Institute Hosts Workshop on Mouse Liver Tumors

Future Research Directions Suggested

Fourteen scientists from university, government, and industry laboratories and other facilities described their current research findings on mouse liver tumors at a November 14-15 workshop sponsored by the ILSI Health and Environmental Sciences Institute (HESI). The workshop, the first scientific forum convened by the recently established HESI, was held to assist HESI in developing a research agenda and to foster collaborative research programs in this important field of research.

Mouse liver tumors as endpoints in carcinogenicity testing have generated a great deal of scientific discussion, with emphasis on interpretation of such endpoints for assessing human risks. The workshop, participants agreed, set the stage for progress in this and other areas.

A wide range of research activity was described, including studies involving chemoprevention, genetic susceptibility, oncogenes and protooncogenes, genotoxic

and nongenotoxic carcinogens, and such compounds as polycyclic aromatic hydrocarbons, ethylenethiourea, and phenobarbital. Studies of the histologic characteristics of chemically induced versus spontaneous tumors were also described, as were two-year studies, "stop" studies, and experiments using different strains of mice. At the workshop, investigators discovered some areas of common interest and expressed a willingness to discuss future collaborative projects.

Scientists from the Environmental Protection Agency and the Food and Drug Administration also spoke on mouse liver tumors from the regulatory perspective. They noted that mouse liver tumors are considered appropriate endpoints for evaluating human hazards. Risk assessment for carcinogens, and guidelines used for such assessments, they said, may be modified to accommodate the concept of threshold

continued on page 7

INSIDE

- Lead Toxicity Examined by Panel at Annual Meeting, p. 2
- Members Updated on EC Food and Packaging Harmonization, p. 2
- Draft IFBC Report Calls for Adaptation of Traditional Safety Testing for Biotech Foods, p. 3
- Vitamin A Research and Intervention Programs Reviewed at XIII IVACG Meeting, p. 4
- Health Effects of Indoor Air the Topic of Upcoming RSI-EPA Workshop, p. 6

HESI Hosts Tumor Workshop

continued from page 1

doses if new information becomes available.

The regulators also recognized that there is no single answer to the many questions relating to the use of mouse liver tumors as regulatory endpoints in toxicity testing. They stressed the need for consensus within the scientific community on how mouse liver tumor data should be interpreted to assess human risk, and suggested that collaborative research could help provide decision makers with information on which to base appropriate decisions.

In the lively debate at the conclusion of the workshop, consensus emerged in the following areas:

- Additional research is needed on the dose-response aspect of tumor induction to better characterize maximum tolerated doses and doses for which no effects are observed. The research should focus on alteration of gene expression, benign versus malignant tumors, the role of genetic susceptibility in tumor induction, and the histologic classification of hepatic nodules and tumors.

- There is a need for descriptive information and standardization of pathology and nomenclature in mouse liver tumor studies. The use of standardized methods in all such research would ensure that information gained from one experiment

could be interpreted in evaluating results from another experiment.

- A common data base should be established using the CD-1 and B6C3F1 strains of mice, which have been used to differing degrees by the pharmaceutical and chemical industries. Chemicals known to induce mouse liver tumors in one strain could be used to enhance knowledge in the other strain. Chemicals that are known peroxisome proliferators, genotoxic and nongenotoxic compounds, enzyme inducers, cell proliferators, and those capable of altering gene expression would be appropriate candidates for such studies.

There is a need for consensus on how mouse liver tumor data should be interpreted to assess human risk.

- A comprehensive approach should be taken to identify known chemicals and mechanistic events that are thought to be important in mouse liver carcinogenesis. A matrix could be developed for use in identifying data gaps and inconsistencies. Collaborative research programs could then be developed to address the complex issues involving mouse liver tumors.

The workshop was the natural follow-up to a 1988 conference that reviewed and ana-

lyzed the available information on mouse liver tumors induced by chemicals and environmental factors.

The objective of that conference was to improve understanding of the mechanisms of carcinogenesis in mouse liver and their relative importance to other species, including humans.

The establishment of an ILSI institute for the study of environmental issues was approved in principle by ILSI's Board of Trustees at its meeting in early 1989. The ILSI Health and Environmental Sciences Institute was officially established on September 21, 1989, to provide a mechanism for companies from the chemical, petrochemical, pharmaceutical, automotive, and other consumer product industries to address scientific issues of mutual interest. Using the ILSI model, HESI will employ a balanced and cooperative approach to its activities by seeking scientific input and participation from academia, government, and industry.

To date, HESI member companies have identified six topics of interest: mouse liver tumors, solid waste/recycling, chemical-specific risk assessments, immunotoxicology, animal-to-human extrapolations, and international harmonization. A meeting to discuss HESI's role in solid waste/recycling will be held March 16 in the ILSI office. Interested members of ILSI-NF and the other ILSI branches are encouraged to attend. For further information, call Ms. Gretchen Bretsch at the ILSI office. □

James Bond Receives 1990 Kenneth Morgareidge Award

Dr. James A. Bond was named winner of the 1990 Kenneth Morgareidge Award for his work on the metabolism and molecular dosimetry of chemical toxicants, particularly polycyclic aromatic hydrocarbons. Through his work, Dr. Bond has broadened the understanding of mechanisms by which reactive intermediates produce toxicity, thereby augmenting low-dose extrapolations to human populations and promoting rational risk assessments.

The award, consisting of \$5,000 and a plaque, was presented by ILSI president Dr. Alex Malaspina during the 1990 annual meetings. Following the presentation, Dr. Bond described research on DNA adduct formation in rat respiratory tissue he conducted while at the Lovelace Inhalation Toxicology Research Institute, Albuquerque, NM. He recently joined the staff of

the Chemical Industry Institute of Toxicology, Research Triangle Park, NC.

Kenneth Morgareidge was an outstand-

ing research toxicologist who contributed importantly to ILSI's scientific programs until his death in 1982. □

James A. Bond, left, receives Morgareidge Award from ILSI president Alex Malaspina



Environmental Issues, Proposed Projects Reviewed at HESI's Annual Meeting

As the issue of human health has dominated the decade of the 1980s, its logical extension, environmental health, will dominate the decade of the 1990s, said Dr. Peter Britton, of Johnson & Johnson, in opening remarks at the annual Board of Members meeting of ILSI's Health and Environmental Sciences Institute (HESI). Dr. Britton is president of HESI's board, which heard several scientific presentations at its January 16 meeting in the Bahamas. HESI met in conjunction with ILSI-Nutrition Foundation, ILSI Risk Science Institute, and ILSI Research Foundation.

Solid waste management is a subject in which HESI members have shown a strong interest, said Mr. Toshio Mekaru, of Borden, Inc., who reported on a HESI proposal for an in-depth review of health considerations posed by consumer packaging in solid waste management. An abstract

and outline have been developed to serve as a basis for discussions with regulatory and industry scientists, he noted, as well as to determine the interest of HESI and ILSI-NF members in supporting the review.

Environmental health will dominate the 1990s: HESI president.

The 17-year-old "Garbage Project" was described by Dr. William Rathje, HESI trustee and archeologist at the University of Arizona whose work has received wide media attention. Dr. Rathje and a team of students have been excavating landfills

around the country to determine the proportions of different kinds of garbage deposited in them and to analyze the changes, many of them surprisingly slight, that have occurred in the composition of the garbage over time.

The Product Lifecycle Assessment — an initiative to quantify energy and material requirements, air emissions, water discharges, and solid waste through the life cycle — was reviewed by Mr. William Franklin of Franklin Associates, Ltd., Prairie Village, Kansas. Mr. Franklin also described a database on the energy and environmental impacts of materials and products found in municipal solid waste.

Dr. Michael McClain, of Hoffmann-La Roche, chairman of HESI's Mouse Liver Tumor Group, reviewed the group's three 1990 meetings as well as its 1989 and 1990 workshops. The second workshop, he noted, held November 14-15, continued the dialogue begun at the first to identify areas of research that can be done on a collaborative basis by different laboratories.

continued on page 2

INSIDE

- NCI Official Describes Program to Reduce Cancer Risks, p. 2
- Inhalation Symposium Postponed, p. 2
- NAS President Speaks at Brookings on Global Effort to Mitigate Effects of Natural Disasters, p. 3
- 1991-1992 Future Leaders Named, p. 3
- Food Security in Developing Countries the Subject of ILSI-Smithsonian Colloquium, p. 4
- ILSI Research Foundation Announces 1991 Research Award Recipients, p. 5

ILSI Europe Responds to Growing Interest in Novel Foods

As the European Community gathers information for a project on directives for novel foods, ILSI Europe has undertaken an evaluation of the scientific basis for possible directives.

"Novel foods" are defined by ILSI Europe as "all foods or food ingredients which are the result of innovation (other than a recipe change) introduced at any stage of their conception." ILSI Europe recommends, in a discussion paper prepared by its Technical Committee on the Assessment of Novel Foods, that such foods "be thoroughly and logically assessed in order to assure the safety of the consumer."

The assessment procedure requires, at the least, a thorough search of the scientific

literature relating to a novel food. The literature search may show that a novel food carries no anticipated risk and therefore will not require nutritional or toxicity testing. Depending on the case, chemical analysis, animal studies, and, where necessary, studies in people may need to be undertaken. This protocol, the paper notes, "must apply to every new product for food safety purposes."

The discussion paper was made available at the September 24-25 ILSI Europe Workshop on the Assessment of Novel Foods. A panel convened six weeks later by the World Health Organization and the Food and Agriculture Organization of the United Nations, in which ILSI Europe

continued on page 6

NCI Official, Speaking at ILSI-NF Annual Meeting, Describes Program to Study Foods That May Reduce Cancer Risk

Dr. Herbert Pierson, of the National Cancer Institute's Division of Cancer Prevention and Control, described the division's Cancer Preventive Designer Foods Research Project at the ILSI-Nutrition Foundation annual meeting in the Bahamas. Speaking January 22 at the scientific sessions hosted by ILSI-NF's Food, Nutrition and Safety Committee, Dr. Pierson said the project, with an annual budget of \$5 million, is aimed at elucidating the mechanisms by which the consumption of certain fruits, vegetables, and grains may reduce cancer risk.

The initial emphasis of the project will be the development of analytical methods, compliance markers, and pharmacokinetic studies to aid in the evaluation of food components thought to keep healthy people healthy. The first plants to be studied are flaxseed, garlic, licorice root, citrus fruits, and umbelliferous vegetables (e.g., carrots and parsley). Dr. Pierson listed many compounds from these plants for which evidence of antimutagenic or anti-

carcinogenic activity exists. Examples include limonene from citrus fruits, which has been reported to be an anti-breast-cancer agent, alluson from garlic, and isoflavons from legumes.

NCI is contracting with laboratories to test these compounds in free-living populations for effects on metabolic modulation and on drug, steroidal, and prostaglandin metabolism, which are postulated to play a role in cancer prevention. The goal, Dr. Pierson said, is to develop foods designed to have enhanced anticarcinogenic activity which would be tasty and acceptable. Clinical trials with individuals at high risk for cancer will be conducted after the most promising compounds have been identified.

Dr. Pierson's talk was only one of several presentations made at the FNCS's scientific sessions, whose themes this year were "Emerging Issues," "The Influence of Diet Composition on Regulation of Food Intake," "Changing Dietary Patterns—Implications for Childhood Nutrition," and "Toxicology Testing/Regulatory Update."



Dr. Lloyd J. (Jack) Filer, Jr., holds the world in his hands. A crystal globe featuring the ILSI logo was presented to him by Dr. Alex Malaspina, president of ILSI, at the ILSI-NF annual meeting in the Bahamas. Dr. Malaspina praised Dr. Filer, who recently retired as ILSI-NF's executive director, for his help in leading ILSI-NF during the transition period following the merger of ILSI and The Nutrition Foundation in 1985. Dr. Filer will continue to be involved in ILSI-NF as a member of its Board of Trustees.

Environmental Issues *continued from page 1*

Dr. Kimber White, of the Medical College of Virginia and HESI trustee, described a research proposal in immunotoxicology that would improve understanding of how the status of the immune system correlates with immunocompetence of peripheral blood cells (the primary mechanism for evaluating immunocompetence in people). Another objective of this proposal, in which HESI members have shown an interest, would be to shed light on the ability of animal models to predict immunotoxic effects of compounds in man.

The etiology and prevention of birth defects were the subject of a presentation by Dr. Robert Brent, chairman of the Department of Pediatrics at Philadelphia's Jefferson Medical School and HESI trustee. Genetic causes, he said, account for the largest proportion of birth defects for which there is a known etiology, or 20 to 25 percent of all birth defects. A second and more disturbing category, however, are birth defects for which there is no proven cause, which constitute 65 percent of the total. Thus, the clinician, clinical teratologist, or geneticist cannot confidently

ascribe a cause in two out of three birth defects.

The basic sciences and epidemiology are likely to contribute to our understanding of the mechanisms, incidence, and etiology of birth defects, Dr. Brent said, and clinical medicine can help reduce their incidence by limiting exposure during pregnancy. Our greatest challenge, however, is to select from options that have real potential for reducing birth defects, he concluded.

From the other side of the Atlantic, Dr. Ulrich Mohr of Hannover Medical School and Mr. Gerd Morawietz of the Fraunhofer Institute of Toxicology and Aerosol Research explained the workings of the Hannover Tumor REGISTRY. This computerized database is a joint venture between independent research institutions and European chemical and pharmaceutical companies to improve the evaluation and interpretation of the results of long-term studies involving laboratory rodents.

Fifteen companies from the chemical, petrochemical, and pharmaceutical industries have joined HESI since its inception in September 1989. Schering-Plough Corporation was welcomed at the meeting as HESI's newest member.

Inhalation Symposium Postponed

The symposium "Advances in Controlled Clinical Inhalation Studies," originally scheduled to take place in Hannover, Germany, March 6-8, 1991, has been postponed owing to international travel restrictions on some participants brought about by the Persian Gulf crisis. Current plans are to reschedule the meeting in October 1991 or in early 1992.