STP Liaison Report: ACT

Liaison: Laura Dill Morton

Date: 03/31/06

1. 3nd Annual ACT/STP "Pathology for Non-Pathologists" Course planned:
    a. May 8-11, 2006
    b. Mitretek Systems, Inc., Falls Church, VA
    c. Topics: Cardiovascular Systems & Female Reproductive System
    d. 43 registrants as of March 31, 2006.
2. 26th Annual ACT Meeting, NOVEMBER 5 - 8, 2006, Renaissance Esmeralda Resort & Spa, Indian Wells (Palm Springs Area), CA (www.actox.org)
    a. No STP symposium has been proposed to the ACT for this year's meeting.
    b. Abstract deadline: August 18th, 2006 – Abstracts can be submitted via e-mail abstracts@actox.org

STP Liaison Report: ACVP, PHARMA, etc

Liaison: Hugh E. Black, D.V.M., Ph.D.

Date: 01-20-2006

3. High level topic: The IFSTP/ IATP Facilitates the Establishment of the STP of Latin America

In October 2005, a delegation of pathologists representing Japan, (Dr. Konishi – President of IFSTP and Dr. Shoji Fukushima), Europe (Dr. Johannes Harleman and Dr. Robert Ettlin) and North America (Dr. Charles Capen and Dr. Hugh Black [Secretary General – IFSTP]) traveled to Recife and Natal, Brazil and gave presentations at the 14th Congress of the Brazilian Society of Toxicology (Recife) and at the 25th Congress of the Brazilian Society of Pathology (Natal). The trip culminated from contacts made at the joint meeting of the IFSTP and the JSTP held in 2004 in Kobe, Japan between the IFSTP and Joao Lauro Viana de Camargo, MD, PhD from the Universidale Estabual Paulista, Botucatu, SP Brazil.

Presenters at the Toxicology Congress were Dr. Harleman and Dr. Fukushima. All members of the group gave presentations at the Congress of Pathology. Copies of all the presentations were left with our Brazilian colleagues for their review and study. The presentations can be reviewed in their entirety on the IFSTP website.

Costs associated with travel by Drs. Capen and Fukushima were paid for by IFSTP from the Society's funds. All other participants paid their own costs. . Novartis made a generous donation to help defer costs associated with local meeting arrangements.

Following the all day session on toxicologic pathology at the Congress of Pathology, the Brazilian pathologists held a long session at which they reviewed a draft constitution for their society and elected their first executive committee.

4. High level topic: The IFSTP and the Globalization Committee of STP Develop Plans for WebCast of Presentations to Brazilian Pathologists/Regulators

At the IFSTP sponsored meeting in Brazil Dr. de Camargo identified to those of us in attendance that there is a significant need for individuals working in their regulatory agencies to have a better understanding of toxicologic pathology. Was there anything that we could do to meet that need?

Since November the members of the Globalization subcommittee of STP have been discussing this issue identified by IFSTP and how to address it. To date we have provided Dr. de Camargo with a list of possible presentations on subjects in toxicologic pathology. These presentations have been given previously to regulatory agencies in the USA and Canada. The idea of using a webcast has been proposed as the medium by which to make the presentations. This has been accepted by our Brazilian colleagues. Presently it is our goal to have a "test" webcast in the second quarter of 2006 to determine the feasibility of using this system for disseminating information to other regions of the world.

STP Liaison Report: ILSI

Liaison: Gary Cockerell

Date: 19 January 2006

5. International Life Sciences Institute (ILSI)/Health Environmental Sciences Institute (HESI) Highlights

    a. A Nanomaterial Toxicity Screening Working Group report, *"Principles for characterizing the potential human health effects from exposure to nanomaterials: elements of a screening strategy"* was the focus of a public program sponsored by the Woodrow Wilson Center for Scholars on October 20, 2005. The program is available as a webcast at www.wilsoncenter.org and in an online journal at http://www.particleandfibretoxicology.com/content/2/1/8. The report contains recommendations for developing toxicity screening strategies.

    b. A workshop on Framework Approaches to Risk Assessment attended by scientists from HESI member and non-member companies, academic institutions, and national and international government agencies was held November 14-16, 2005, in Nice, France. Session topics included "DNA Adducts in Risk Assessment", "Rodent Liver Tumors as Predictors of Human Cancer Risk?", and "Framework for Agricultural Chemical Safety Assessment."

    c. ILSI's First International Conference on Nutrigenomics – Opportunities in Asia, was held in Singapore, December 6-9, 2005. Plenary session topics included molecular epidemiology, nutrient-gene interactions and nutrigenomics in relation to cancer.

    d. ILSI-HESI hosted the Annual Seminar on Advanced Pathologic Techniques, in conjunction with the Annual Meeting of the ACVP/ASVCP in Boston, MA, on December 3, 2005. The title of the Seminar was "Current Issues in Neuropathology. A review paper including extended abstracts of each speaker's presentation is being prepared for publication in *Toxicologic Pathology.*

    e. Financial constraints prevent HESI from continuing to sponsor the annual ILSI-HESI Seminar on Advanced Pathologic Techniques. ACVP Council has asked the Investigative Toxicologic Pathology Interest Group (ITPIG)

to take responsibility for creating a new seminar series. A Planning Committee, consisting of Jim Moe, Chuck Qualls and Mark Cartwright, was formed to determine next steps.

f. A workshop on "New" Reproductive Endpoints will be held on March 27-28, 2006, in Crystal City, VA. The objective is to use the results from a database-level analysis to determine the utility of the new endpoints added to the U.S. EPA Reproductive and Fertility Effects Test Guideline in 1998 (OPPTS 870.3800, and later, the OECD 416 guideline adopted in 2001) and will evaluate the performance of the new endpoints by examining trends across all submitted studies, with respect to correlations among and between endpoints.

g. ILSI-HESI's Development of Methods for a Tiered Approach to Assess Bioaccumulation of Chemicals Subcommittee and the Society of Environmental Toxicology and Chemistry (SETAC) will jointly host a workshop March 3-4, 2006 to explore the range of in vitro techniques which may be applied to evaluate the bioaccumulation potential of chemicals.

h. Additional details of these and other ILSI/HESI activities can be found at http://hesi.ilsi.org/ and *ILSI News* (Volume 23, Number 4).

i. EC action required: None

6. Risk Science Institute (RSI) Highlights

a. Project on the Evaluation and Interpretation of Neurodevelopmental Endpoints for Human Risk Assessment. The goal is to assess the lessons learned to-date from the implementation of standardized tests for developmental neurotoxicity in experimental animals and the subsequent application of test results to human health risk assessment. A steering committee initially framed the specific objectives and scope of the project. An Expert Panel was subsequently formed and is now preparing to publish results of their finding in five manuscripts: (1) Application of developmental neurotoxicity testing to public health protection; (2) Undertaking a positive control study as part of a developmental neurotoxicity testing procedure; (3) Identification and interpretation of treatment-related effects in developmental neurotoxicity testing; (4) Determining normal variability for endpoints measured in a developmental neurotoxicity test; (5) Statistical issues and techniques appropriate for developmental neurotoxicity testing.

b. Additional details of these and other ILSI-RSI activities can be found at http://rsi.ilsi.org/.

c. EC action required: None

STP LiaisonReport: National Toxicology Program

Liaison: Ron A. Herbert, DVM, PhD

Date: 04/21/06

1. **Dr. Allen Dearry Assumes Post as Interim Associate Director of the NTP**

   Allen Dearry, Ph.D., who most recently served as the Director of the NIEHS Division of Research Coordination, Planning, and Translation, is acting as the Interim Associate Director of the NTP. Dr. Dearry assumed this post in January when Dr. Christopher Portier was appointed NIEHS Associate Director for Risk Assessment. Dr. Dearry is promoting the goals set forth in the NTP Roadmap and is working closely with NTP Director Dr. David Schwartz and other leaders in the NTP to carry out the roadmap's activities.

2. **Upcoming Events**

   a. NTP Board of Scientific Counselors Technical Reports Subcommittee Review of Draft Technical Reports

   The NTP Technical Reports Review Subcommittee of the NTP Board of Scientific Counselors is scheduled to convene two meetings during 2006. The first is scheduled for June 12, 2006, at the NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC. The subcommittee will peer review the findings and conclusions from four draft NTP Technical Reports. The draft reports tentatively scheduled for review are:

   TR-539: Genistein (multigeneration)
   TR-540: Methylene blue trihydrate
   TR-543: alpha-Methylstyrene
   TR-545: Genistein (2 year)

   The subcommittee is also scheduled to meet on August 28, 2006, at NIEHS, 111 T.W. Alexander Drive, RTP, NC to peer review the findings and conclusions from five draft NTP Technical Reports in which genetically modified mice strains were used. The draft reports tentatively scheduled for review are:

   GMM-07: Allyl bromide
   GMM-08: Benzene
   GMM-09: Dicyclohexylcarbodiimide
   GMM-12: Phenolphthalein
   GMM-13: Glycidol

   Details about these meetings will be announced in the *Federal Register* and posted on the NTP website (*http://ntp.niehs.nih.gov* select *Advisory Committees and Board*) or can be obtained by contacting the Executive Secretary, Dr. Barbara Shane. These meetings are open to the public and public comment, both written and oral, is welcome on any report. *Contact Information: Dr. Barbara Shane, NTP Liaison and Scientific Review Office, NIH/NIEHS, P.O. Box 12233, MD A3- 01, Research Triangle Park, NC 27709; T: (919) 541-4253; FAX: (919) 541-0295; shane@niehs.nih.gov*

b. ***NTP Board of Scientific Counselors Meeting***

The NTP Board of Scientific Counselors (BSC) will meet June 13, 2006at the NIEHS, 111 TW Alexander Drive, Research Triangle Park, NC. Tentatively, on the agenda for discussion are a summary of the NIEHS' Strategic Plan, an update of NTP Roadmap activities, information about a new NTP program on host susceptibility, and two concept reviews for NTP research proposed through a contract mechanism. The NTP will also seek input from the BSC on testing recommendations for substances nominated to the NTP for study. Items for discussion may be added or modified as the agenda is finalized. Details about this meeting, as available, will be announced in the *Federal Register* and posted on the NTP website (*http://ntp-server.niehs.nih.gov*) or can be obtained by contacting the Executive Secretary, Dr. Barbara Shane. This meeting is open to the public and public comment, both written and oral, is welcome on any agenda topic. *Contact Information: Dr. Barbara Shane, NTP Liaison and Scientific Review Office, NIH/NIEHS, P.O. Box 12233, MD A3-01, Research Triangle Park, NC 27709; T: (919) 541-4253; FAX: (919) 541-0295; shane@niehs.nih.gov*

c. ***NTP Workshop Scheduled for May 2006***

The workshop, "Hormonally Induced Reproductive Tumors: Relevance of Rodent Bioassays," is scheduled for May 22-24, 2006, at the Marriott Raleigh Crabtree Valley, 4500 Marriott Drive, Raleigh, NC 27612. The workshop's goal is to determine the adequacy and relevance to human disease outcome of rodent models for four types of hormonally induced reproductive tumors: ovary, mammary gland, prostate, and testis. The format includes both plenary talks and four breakout groups. Topics for discussion include:

- Dose-response for tumor induction
- Predictiveness of rodent pre-neoplastic events for humans
- Importance of the inclusion of *in utero* exposure in the etiology of specific tumors
- The concept of "additivity to background" when normal hormones are present with homeostatic control mechanisms

This meeting is open to the public, but registration is limited to 100 people. Time will be set-aside during the plenary session on the first day for public comment. Information about the workshop and on-line registration are available from the NTP website *http://ntp.niehs.nih.gov/* select *Meetings and Workshops*). *Contact Information: Dr. Paul M. Foster, Toxicology Operations Branch, NIH/NIEHS, P.O. Box 12233, MD EC-34, Research Triangle Park, North Carolina 27709; T: (919) 541-2513; FAX: (919) 541-4255; foster2@niehs.nih.gov*

d. ***Satellite Symposium at the Annual STP Meeting: Pathology of the Immune System***

The NTP will sponsor an interactive pathology satellite symposium on Saturday, June 20 in conjunction with the Society of Toxicologic Pathology (STP) being held June 18-22, 2006, in Washington, DC. The NTP hosts these symposia annually as opportunities to provide continuing education on interpreting pathology slides and generate lively and productive conversation. This year's NTP satellite symposium will focus on Pathology of the Urinary System. The symposium is organized by Dr. Susan Elmore and is intended to provide continuing education on interpreting pathology slides and using standardized terminology. This session is free to meeting attendees, but due to limited space, registration is required.

3. The NTP Testing Program

a. ***Request for Study Nominations***

With a broad mandate to provide toxicological characterizations for chemicals and other agents of public health concern, the NTP accepts nominations for new toxicological studies at any time. Labor unions, academic scientists, federal and state agencies, industry, and the general public are welcome to make nominations for specific substances or for general issues related to potential human health hazards of occupational or environmental exposures. As available, a rationale for study should accompany the nomination along with background information describing sources of

exposure and possible adverse health effects or concerns associated with exposure, the chemical name and the Chemical Abstract Service (CAS) registry number. Details about the nomination process are available on the NTP website (*http://ntp.niehs.nih.gov* select *Nominations to the Testing Program* under *Testing Information*) or by contacting the NTP Office of Chemical Nomination and Selection (contact information below).

Current areas of focus in the NTP's testing program include potential hazards associated with nanoscale materials, perfluorinated compounds, herbal dietary supplements, photoactive chemicals, brominated flame retardants, certain complex occupational exposures, dioxin-like compounds, contaminants of finished drinking water, and endocrine-disrupting substances, and methods for assessing potential cardiac toxicity.

All nominations undergo several levels of review before being selected by the NTP for study. These steps of review help to ensure that the NTP's testing program addresses toxicological concerns pertinent to all areas of public health and helps maintain balance among the types of substances and issues evaluated. Studies are initiated on selected nominations as time and resources permit.

b. Study Nominations Currently in Review

A *Federal Register* notice published on April 11, 2006 (71FR18341) formally solicits comment on the 10 new nominations and corresponding study recommendations listed below [available on the NTP website at *http://ntp.niehs.nih.gov/go/21134*]. The NTP Board of Scientific Counselors meeting will review these nominations at its June 13, 2006. The NTP website also provides access to electronic versions of supporting documents for each nomination and further information on the NTP Study Nomination Review and Selection Process. The NTP invites interested persons or groups to submit written comments to Dr. Scott Masten (contact information below). Persons submitting comments and information are asked to include their name, affiliation, mailing address, phone, fax, e-mail address and sponsoring organization (if any) with the submission. Written submissions will be posted electronically on the NTP website as they are received and distributed to the NTP Board and NTP staff.

Arbutin: Recommended studies - *In vitro* and *in vivo* metabolism and disposition studies; *in vitro* and *in vivo* genotoxicity studies; emphasis on understanding gastrointestinal metabolism and disposition, identifying experimental animal model representative of humans, and development of appropriate biomarkers.

tert-Butylacrylamide: Recommended studies - Metabolism and disposition studies; subchronic toxicity studies; mammalian genotoxicity studies; coordinate with voluntary data development activities of the Extended HPV Program.

Ceric Oxide: Recommended studies - Toxicological characterization including chemical disposition and toxicokinetics; comparative inhalation toxicity studies of microscale and nanoscale forms; dermal penetration studies.

Diazonaphthoquinone derivatives [Sodium 1,2- naphthoquinone- 2-diazide-5-sulfonate; 2,3,4-Trihydroxybenxophenone tris(1,2-naphthoquinonediazide-5- sulfonate; 2,3,4-Trihydroxybenzophenone 1,2- naphthoquinonediazide-5-sulfonate]: Recommended studies *In vitro* toxicity studies evaluating genotoxicity, immunotoxicity and phototoxicity; dermal penetration studies.

3-Dimethylaminopropyl methacrylamide: Recommended studies - Metabolism and disposition studies; genotoxicity studies; subchronic toxicity studies; coordinate with voluntary data development activities through the Extended HPV (EHPV) Program.

***Flame Retardants*:**

Antimony trioxide: Recommended studies - Chronic toxicity studies (oral route); consider studies

of nanoscale form if used in or released during flame retardant applications.

Decabromodiphenyl oxide: Recommended studies - Developmental neurotoxicity studies; studies only to be performed if adequate private sector study not identified or planned.

Tris(chloropropyl)phosphate, mixture of four isomers:
Recommended studies -Subchronic and chronic toxicity studies (oral route); studies to focus on commercial mixture or major isomers present in commercially used mixtures.

Phosphonic acid, (3-((hydroxymethyl)amino)-3- oxopropyl)- dimethyl ester: Recommended studies - Subchronic and chronic toxicity studies (oral route); dermal absorption studies.

Tris(hydroxymethyl)phosphine oxide: Recommended studies - Subchronic and chronic toxicity studies (oral route); dermal absorption studies.

Aromatic Phosphates [tert-Butylphenyl diphenyl phosphate; 2-Ethylhexyl diphenyl phosphate; Isodecyl diphenyl phosphate; Phenol, isopropylated, phosphate (3:1); Tricresyl phosphate; Triphenyl phosphate]: Recommended studies - For one or more representative aromatic phosphates, subchronic and chronic toxicity studies (oral route); neurotoxicity and/or developmental neurotoxicity studies; coordinate with U.S. EPA to pursue additional testing by manufacturers.

Gypsum, natural and synthetic forms: Recommended studies - Short-term pulmonary toxicity studies; comparative studies of intratracheal vs. inhalation routes of administration; studies are of relatively low priority given low suspicion of toxicity.

N-methyl-3-oxobutanamide: Recommended studies - *In vitro* and *in vivo* genotoxicity studies; include structurally-related diketene compounds and N-phenyl derivative.

Phenoxethyl acrylate: Defer study pending voluntary data submission through the Extended HPV Program.

Trifluoromethylbenzene: Defer study pending review of (1) production data through the 2006 Toxic Substances Control Act Inventory Update Rule, and (2) Organization for Economic Cooperation and Development Screening Information Data Sets program output

Contact information: Dr. Scott Masten, Office of Chemical Nomination and Selection, NIH/NIEHS, P.O. Box 12233, MD A3-07, 111 TW Alexander Dr., Research Triangle Park, NC 27709; T: 919-541-5710; masten@niehs.nih.gov

STP Liaison Report: PhARMA-DruSafe

Liaison: Darrell Tuomari Date: 11 APR 06

7. Cancer Hazard Identification Strategies (CHIS), which is a collaborative effort with HESI.

a. CHIS is an effort to review data from 3- to 12-month studies (emphasis on the 3-month) to see if these shorter-term studies had signals that were predictive of the outcome of the 2-year rodent studies. Controversial, since a recent paper from FDA-personnel (Jacobs, A., et. al, Tox. Sci. 2005, 88: 18-23) "blasted" the idea of looking at short-term signals.

b. The central hypothesis of CHIS is that key events of carcinogenic potential can be identified in short-term assays, and used with PK data to reliably predict human cancer hazard identification. They are focusing on 4 organs: Liver, Lung, Kidney, and Urinary Bladder. The current effort has been focused on reviewing the NTP database, but this is too highly focused on industrial chemicals rather than drugs. Merck is beginning to review their database, and they are trying to recruit other companies.

c. Current emphasis is on review of the data for 3-month studies. In addition, this assessment will include ways to improve the predictive value of the 3-month studies (e.g. potentially adding BrDU labeling to identify proliferating cells). Potential future steps could include the evaluation of 6- to 12-month data, in a tiered-approach.

d. The major pitfall is that the predictive value is based on comparison to the outcome of the 2-year rodent bioassay as the "Gold Standard" for identifying potential human carcinogens. However, at this time there are no reliable alternatives.

e. It is obvious that the toxicologic pathologist will play a critical role the identification of the signals of concern, the assessment of the data from various studies, and the compilation of the "Weight of Evidence" approach to human cancer hazard identification. Therefore, STP is encouraged to ask its member to participate in the CHIS effort.

ACTION ITEM: Interested members should directly contact Dr. James MacDonald (Executive Vice President of Preclinical Safety at Schering-Plough) at the following e-mail address: james.macdonald@spcorp.com.

8. **Drug-Induced Phospholipidosis, an FDA safety concern.**

    a. PhRMA-DruSafe formed an ad hoc committee that has sent comment to the FDA in response to their request for data on compounds associated with non-clinical and clinical phospholipidosis signals.

    b. The FDA had requested information about drug-induced phospholipidosis, and how could it be monitored in human patients. The FDA may draft a guidance document for industry and regulatory reviewers. This is part of the ongoing phospholipidosis biomarker activities at the Critical Path Institute (C-Path) in Arizona, requested by the FDA. Phospholipidosis appears to becoming an important drug safety issue for the FDA.

    c. Currently, there is no concurrence on how to approach this issue.

9. **Animal Rights Activities, a mutual concern of PhRMA and STP.**

    a. PhRMA-DruSafe is working to enhance its collaboration with the National Association for Biomedical Research (NABR), to address animal rights activist's threats and concerns. (www.nabr.org)

10. **EMEA Draft Guideline on Juvenile Animal Toxicity Studies**

    a. PhRMA-DruSafe has a Technical Group that is compiling a set of comments on this draft guideline that will be sent to the EMEA in late April.

11. **Biosafe Joint Meeting on product safety testing**

    a. PhRMA-DruSafe has a joint meeting with Biosafe in late April. Biosafe is an organization associated with the development of biological pharmaceutical products.

12. **STP Pathology Image Position Paper**

    a. PhRMA-DruSafe was the group that initially asked STP to write a position paper on pathology images. DruSafe was disappointed with the progress on this position paper. They hoped that the raw data issues raised by the Society of Quality Assurance could be resolved.

STP Liaison Report: PhARMA-Preclinical Safety Leadership Committee (DruSafe)

Liaison: Darrell Tuomari Date: 23 MAY 06

13. **Drug-Induced Phospholipidosis, an FDA safety concern.**

a. During a teleconference today, PhRMA-DruSafe discussed the FDA's request for company data on drugs that were associated with phospholipidosis, both marketed as well as drugs "killed" early in development. The FDA would then data mine this database and look for areas of commonality and for potential discriminators between drugs associated with "good" phospholipidosis (not associated with toxicity) versus "bad" phospholipidosis that was associated with adverse effects. This effort is controversial because even if a killed drug was associated with phospholipidosis, it is very unlikely that the drug was killed because of the phospholipidosis. Thus, some thought it is doubtful that this effort will show clear distinctions between "good and bad" phospholipidosis.

b. A second potential step would be special studies (e.g. genomics assays) to look for potential biomarkers that could be used to monitor clinical studies for the development of phospholipidosis. This is part of the ongoing phospholipidosis biomarker activities at the Critical Path Institute (C-Path) in Arizona, requested by the FDA.

c. Eventually based on the requested information about drug-induced phospholipidosis, and potential biomarker on how could it be monitored in human patients; the FDA would then draft a guidance document for industry and regulatory reviewers.

d. However, at this time DruSafe is still discussing how best to respond to the FDA drug data request and how this effort should move forward.

14. **Biosafe Joint Meeting on product safety testing**

a. PhRMA-DruSafe in late April had a meeting with Biosafe, an organization associated with the development of biological pharmaceutical products, to discuss the regulatory uncertainty about what should be done for drug development for a biological pharmaceutical product.

b. There are three main areas of concern/activity:
   i. The interpretation of preclinical safety studies.
   This is the major area of concern for DruSafe.
   ii. Quality issues that could impact product safety, such as changes in the manufacturing process, and what needs to be done to characterize the drug product.
   BioSafe has played a major role in trying to address this area.
   iii. Regulatory influence and uniformity across various geographical areas.
   DruSafe has no activity planned in this area at this time.

c. There appears to be too much uncertainty at this time to define any specific areas where STP could collaborate with DruSafe on this issue.

15. **Potential ICH Topics for Harmonization**

a. DruSafe is currently trying to prioritize various topics that could become ICH harmonization topics. This includes potentially re-opening some previous harmonized guidelines: in particular S-2 (genotoxicity), S-6 (drug safety) and M-3 (metabolites). Again, these are areas of interest for biological pharmaceutical products.

b. Some EU countries, in particular Germany, are pushing to make the photosafety an ICH topic.

c. DruSafe will discuss these issues further at their business meeting on June 26th.

STP Liaison Report: Society of Toxicology (SOT)

Liaison: Darlene Dixon, D.V.M., Ph.D.

Date: 05/25/06

1. 2006–2007 Councilors and Committee Members

SOT President:
James A. Popp
popp@stratoxon.com

Vice President:

George B. Corcoran
corcoran@wayne.edu

Vice President -elect:
Kenneth S. Ramos
kenneth.ramos@louisville.edu

Treasurer:
Norbert Kaminski
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Treasurer-elect:
William Slikker, Jr.
wslikker@nctr.fda.gov

Secretary:
Janice E. Chambers
chambers@cvm.msstate.edu

Councilors:
Scott W. Burchiel
Elaine V. Knight
Bruce Fowler
Michael Holsapple

2. Nominate for SOT Officers by August 1

The Nominating Committee will prepare a slate of nominees for the 2007 elected officers and elected standing committees this fall. The offices of President, President-elect, Treasurer-elect, Secretary-elect, and Councilors will be on the ballot. Positions on the Awards, Membership, Education, and Nominating Committees will also be on the ballot. Please send your candidate recommendations to SOT Headquarters (sothq@toxicology.org) by August 1.

3. Communicating with SOT Leadership — Council Meeting and Conference Call Schedule

The Council conference call and meeting dates are listed for reference by members and Committee Chairs. If you are interested in having an item included in the Council agenda, please contact Shawn Lamb (shawnl@toxicology.org) via e-mail at SOT Headquarters at least 3 weeks before the scheduled conference call.

May 2006
Conference call Thursday, May 25 (10:00 AM-1:00 PM)
Tuesday, May 30 (2:00 PM-9:00 PM)
Wednesday, May 31, (8:00 AM-4: 30 PM)

August 2006
Conference Call, Tuesday, August 14 (10:00 AM-1:00 PM)
Wednesday, August 16 (8:00 AM-6:00 PM)
Thursday, August 17 (8:00 AM-3:00 PM)

September 2006
Conference call September 28 (10:00 AM-1:00 PM)
Wednesday, October 4 (12:00 Noon-9:00 PM)
Thursday, October 5 (8:00 AM-3:00 PM)

November 2006
Conference call Tuesday, November 21 (10:00 AM-1:00 PM)
Tuesday, November 28 (8:00 AM-6:00 PM)
Wednesday, November 29 (8:00 AM-3:00 PM)

January 2007
Conference call Wednesday, January 10 (10:00 AM-1:00 PM)
Tuesday, January 16, 2007 (8:00 AM-6:00 PM)

Wednesday, January 17, 2007 (8:00 AM-6:00 PM)
Thursday, January 18, 2007 (8:00 AM-3:00 PM)

March 2007
Wednesday, March 20 Conference Call (10:00 AM-1:00 PM)
Saturday, March 24 (8:00 AM-12:00 Noon)

4. SOT Expands Media Outreach for 2006

At the request of the new SOT Communications Strategy Committee, SOT Council retained an experienced communications consultant to help strengthen SOT media outreach for the 2006 Annual Meeting. A number of press releases were distributed that highlighted scientific sessions, awardees, and SOT outreach activities and special events. Visit the Press Release section on the SOT Web site.

5. Redesigned Toxicological Sciences Web Site Provides More Member Benefits

A key benefit of SOT membership is on-line access to Toxicological Sciences. Oxford University Press has recently revamped the journal Web site as part of a major redesign initiative at Oxford Journals. The journal site now incorporates a new URL, new look, new content, and new functionality. The new site complies with accessibility legislation for persons with disabilities and is rich in new features. *Toxicological Sciences* accepts submissions online. *Toxicological Sciences* Manuscript Central (ToxSci MC) is located at http://toxsci.manuscriptcentral.com.
E-mail: toxsci@bms.com

6. Call for Authors for NLM ToxLearn Modules

The ToxLearn Work Group of the SOT Education Committee is soliciting applications from potential authors for Modules 4-6 of the Web tutorial replacing the National Library of Medicine (NLM) ToxTutor.

Potential authors will provide the following information:

a) An expression of interest in the project indicating which one or more modules you are interested in authoring.
b) A writing sample consisting of about 250 words, highlighting a relevant toxicology concept, and aimed at undergraduate students. Ideally, it would incorporate graphic images. A PowerPoint or Web-based presentation, which fulfills or complements these requirements, could also be submitted.
c) Personal resume of no more than 3 pages.

These items will be sent electronically to **Betty Eidemiller** (bettye@toxicology.org) at SOT Headquarters, no later than **June 15, 2006**. The authors selected for the modules will receive:

a) Outline of content to be developed
b) Module production template
c) Author Agreement; timeline includes receipt of module draft by September 1, 2006
d) **$3,000 per module** for the author or team of authors upon completion

7. Call for SOT Award Nominations—Deadlines are Approaching

Now is a good time to begin preparations for nominating SOT members—or yourself—for one of the many SOT Awards. The application **deadline is October 9**, with an earlier deadline for one student award (see below). Each year at the annual meeting the Society recognizes its distinguished toxicologists and students with several prestigious awards at a special Awards Ceremony. For SOT Awards, a sponsor and a seconder, who are full members of SOT, must submit a nomination using the Award Nomination Form available through the Awards Nomination On-Line system beginning July 1.

8. Teaching Toxicology to the Public: TEF Foundation Debuts Award-Winning Video

"Is it Safe? Evaluating Chemical Risks" is a video produced by the Toxicology Education Foundation (TEF) and co-sponsored by the U.S. National Institute of Environmental Health Sciences (NIEHS). TEF is a non-profit organization dedicated to encouraging, supporting, and promoting charitable and educational activities that increase the understanding of toxicology. The video is aimed at giving people a clearly explained and engaging look at the basics of toxicology and risk assessment. It offers guidance on determining what chemicals may be causes for concern and, more importantly, under what circumstances. Fundamental concepts, such as "The dose makes the poison" and prevention are enhanced by the visual format. In April 2006, this video received a Platinum "Best of Show" Aurora award in the Instructional/Educational/Training programs category. The Aurora Awards is an international competition designed to recognize excellence in the film and video industries.

9. Society of Toxicology On-Line Membership Application and Dues renewal:

The SOT offers membership application and dues submission on-line (www.toxicology.org).

10. New Colgate-Palmolive Grants for Alternative Research: for Scientists at any Stage of their Career—Deadline October 9, 2006.

The Colgate-Palmolive Grants for Alternative Research will identify and support efforts that promote, develop, refine, or validate scientifically acceptable animal alternative methods to facilitate the safety assessment of new chemicals and formulations. Scientists at any stage of career progression may submit a proposal.

High priority will be given to projects that:

Use in vitro or non-animal models
Reproductive and Developmental Toxicology
Neurotoxicology
Systemic Toxicology
Sensitization
Acute toxicity

Deadline for applications is October 9, 2006.

Applications can be for a single year or multi-year, and candidates can re-apply for additional funding each year. The maximum award in any one-year will not be greater than $40,000. Awards are made as a single lump payment. An expert panel from the SOT In Vitro Specialty Section will recommend a prioritized list of applicants for funding, with the final awards designated by the SOT Awards Committee.

11. Colgate-Palmolive Traveling Lectureship in Alternative Methods in Toxicology Award

The Colgate-Palmolive Company sponsors the Colgate-Palmolive Traveling Lectureship in Alternative Methods in Toxicology Award annually through the Society of Toxicology. This award covers expenses for an individual scholar to visit institution(s) for the dissemination of knowledge and for stimulating research that takes advantage of modern in vitro toxicology approaches. The overall goal of this program is to make scientists aware of the benefits of modern in vitro toxicology approaches and to simulate research for the replacement, reduction or refinement of currently used animal models. The scholar may be asked to make a special presentation at the SOT Annual Meeting.

Lecturing scholars should be established, mid-career through late-career scientists who are members of SOT and who are developing collaborative relationships with scientists at other institutions.

Requests for funds can be made by the individual scholar or by an organization such as universities, colleges, SOT Specialty Sections and SOT Regional Chapters, and other toxicology organizations that are interested in inviting the scholar. Up to $15,000 is available. The Awards Committee reviews the

applications, which must be accompanied by a statement of the applicant's experience, a brief overview of the techniques to be discussed in the lecture and a letter from the hosting institution(s) indicating their interest in serving as host and the potential benefits to the institution.

Available for nomination through Awards Nomination On-line (Closed: Deadline Oct. 9)

12. 46th Annual Meeting--March 25–29, 2007

Charlotte Convention Center, Charlotte, North Carolina
On-line abstract submission period: August 1-October 3, 2006.
(www.toxicology.org).

13. Upcoming SOT Sponsored Conferences and Events:

• Society of Toxicologic Pathology (STP) Annual Meeting, **June 18–22, 2006**, Fairmont Hotel, Vancouver. Full meeting details are found on the STP Annual Meeting Web site.

• Institute of Neuroscience and Biomedical Research (INBR) announces a Neuroscience Congress entitled "Environment and the Developing Brain", **July 10–13, 2006**, Owerri, Nigeria. For more information download the Meeting Preliminary Program.

• International conference "Frontiers of Pharmacology and Toxicology,"

August 26-30, 2006, Renaissance Hotel in Chicago, IL. See Conference

Information for more details.

•RASS XI: The Eleventh Risk Assessment Summer School to be held

September 2-10, 2006, at See hotel Hoeri, Bodensee, Germany. See

event Program and Application for more details.