

# REGULATORY AND SAFETY EVALUATION SPECIALTY SECTION-NEWSLETTER

of the Society of Toxicology

Autumn 2003

## President's Message

### Greetings

I hope that you all have had an enjoyable summer and are ready to hear about past, current and pending RSESS activities. The Council has been busy and we are about to get busier. We have wrapped up issues from SOT 2003, are actively working on SOT 2004 and have just been asked to think about SOT 2005!! Here is what's new:

### Membership

Our membership is the highest of the specialty sections and continues to grow. Statistics:

2001 – 317 members

2002 – 333 members

2003 – 350 members

We appreciate your support and hope to meet your needs and see continued growth.

As part of our student focus, and to enhance our growth, we have decided to offer section membership to our student travel award winners. So, our 2003 membership will grow to 354 with this addition. Please welcome award winners who are also SOT members: Elmarie Bodes, University of North Carolina; Yoonkyung Do, Medical College of Virginia; Rebecca Watson, Michigan State University; Jennifer Yauck, Medical College of Wisconsin.

### Student Travel Awards

Once again, we will be offering student travel awards for the 2004 SOT meeting. An application form is on the SOT website and we will be sending notices/reminders to all of the universities listed in the SOT directory. Please encourage any students you know to make a presentation at the SOT meeting and to apply for our award. Ron Gerson, our Vice President, will be coordinating the awards this year.

### Life as a Toxicologist

Ron Gerson will be having a very busy year. We have just received formal acceptance for this course, which he and Denise Robinson (our 2002-2003 secretary treasurer) will co-chair at the 2004 SOT meeting. The idea for this program was generated by a discussion session at last fall's RSESS Council meeting, when several of us were talking about the need to give students a better idea of "life beyond the lab." As we shared some of the culture shock we had

encountered at our first "real" jobs, it became apparent that this would be a great idea for a program. Thus, "Life as a Toxicologist" was born. Ron and Denise have done all of the leg-work, paper-work, brain-work and telephone-work to make this happen and the results look terrific! The course will be held on Saturday night and will include speakers from the pharmaceutical, chemical/agrochemical and CRO industries and from regulatory agencies (FDA and EPA). Please encourage any students you know to sign up.

### RSESS Council Meeting/Nominations for Next Year

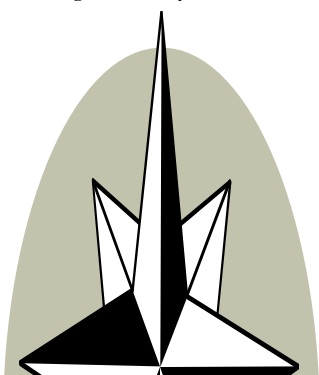
The RSESS Council will have our fall "face-to-face" meeting at SOT headquarters in November. One agenda item will be nominations for 2004 Council members. Harry Olson, our Past President, will chair this effort. We plan to continue to maintain a balance of industry (pharmaceutical, chemical, CRO and others), government and academia on the Council (and we'll work on that gender thing also!). Please contact Harry, or any Council member, if you are interested in serving or if you have a suggestion. Other issues we will be addressing (and on which we would like your input), include:

### The Great Debate

We plan to continue our series of mini-debates on contemporary issues at our RSESS reception at SOT. Previous topics have been "Transgenics: Should Transgenic Models "Knock Out" the Traditional Mouse Bioassay?" (2003) and "Alternatives to Animal Testing: 20 Years of Fertility or Futility?" (2002). The current lead idea for 2004 is GMO Foods, a really hot topic in Europe. Other possibilities are children's health issues and endocrine disruptors. Let us know what you think

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The mission of the Regulatory and Safety Evaluation Specialty Section (RSESS) of SOT is to promote the development of sound governmental policies and regulations based on contemporary scientific knowledge arising from the disciplines encompassed by toxicology. RSESS provides a forum for the interaction of SOT members to discuss the impact of regulations, guidelines, and guidances on the practice of toxicology and the safety evaluation of food additives, nutraceuticals, therapeutic drug products and environmental, industrial and household chemicals, and other products of concern.

about these and if you have any suggestions for speakers and/or other topics.

It's hard to believe that it's time to start thinking about 2005...but it is! We have just received a request from the SOT Program and Continuing Education Committees to contribute ideas for symposia, workshops, roundtables and continuing education courses for the 2005 meeting. Proposals (with topics and speakers designated) are due to SOT on April 30, shortly after the 2004 meeting. Anyone who has put a proposal together knows what a big job this is. So, please start thinking about this now. Let us know if you have ideas or questions and if you need assistance or advice in preparing proposals relevant to regulatory toxicology and/or safety assessment. There were a large number of excellent proposals for 2004 and we look forward to a continuing high level of proposals for 2005.

As always, we would like to hear from you!! Let us know how we are doing and how we can best meet your needs. ....looking forward to hearing from you, and to seeing you in Baltimore in March!!

Best regards, Carol

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## Student Travel Awards Available.....

Are you, or do you know, a student who will be submitting a poster or making a presentation at the 2004 SOT meeting?

If so, you should know that the RSESS Specialty Section plans to continue our practice of providing travel awards to students with presentations applicable to regulatory toxicology or safety evaluation. In the past, awards of up to \$500 have been presented to up to 4 students each year.

Applications consist of an application form, a copy of the abstract of work to be presented and a recommendation by the student's academic advisor. Both undergraduate and graduate students are eligible.

If you, or a student who is interested, need additional information, please contact:

Ron Gerson

Vice President, RSESS  
gerson.ronald@endo.com

You can find more information regarding the application process as well as an application form on the SOT web site at:

[http://www.toxicology.org/Information/AwardsFellowships/awards\\_SS.html#specialtystudent](http://www.toxicology.org/Information/AwardsFellowships/awards_SS.html#specialtystudent)

**Just scroll down to the section for the Regulatory and Safety Specialty Section.**

We are looking forward to your applications !!!

## ILSI HESI ACT Workshop on the Utility of Transgenic Assays for Risk Assessment

On February 20, 2003, the ILSI Health and Environmental Sciences Institute's Alternatives to Carcinogenicity Testing (ACT) Technical Committee hosted a workshop on "The Utility of Transgenic Assays for Risk Assessment," at the Hamilton Crowne Plaza Hotel in Washington, D.C. This workshop was held in conjunction with another sponsored by the National Toxicology Program (NTP) on February 21, 2003, on "Genetically Modified Rodent Models for Cancer Hazard Identification: Selecting Substances for Study and Interpreting and Communicating Results."

Dr. James MacDonald (Schering Plough Corporation), chair of the ILSI HESI ACT Committee, opened the workshop by providing background on the development and use of various transgenic assays for risk assessment and by reviewing the workshop objectives, which were two-fold: (1) to reach an understanding of how data from transgenic models are considered by different regulatory bodies, and (2) based on this understanding, to identify areas in which more experimental work may be needed to increase the utility of these assays.

Dr. Christopher Portier (NIEHS) presented results of a recent evaluation by NTP examining the ability of transgenic assays to predict human carcinogenic potential. This evaluation indicated that, although transgenic assays missed some known/suspected carcinogens, their results generally showed a higher level of concordance with IARC/NTP RoC calls than did the standard rodent bioassay.

Drs. Abigail Jacobs (US FDA Center for Drug Evaluation and Research), Jan Willem van der Laan (National Institute of Public Health and the Environment, The Netherlands), and Tohru Inoue (National Institute of Health Sciences, Japan) offered workshop participants regulatory perspective on the use of data from transgenic assays for risk assessment. Dr. Jay Goodman (Michigan State University) summarized these perspectives by highlighting some areas of agreement and disagreement. He indicated that all three presenters considered the p53<sup>+/-</sup> and RasH2

models useful in providing data for regulatory purposes. In addition, the Tg.AC model was considered helpful in evaluating products intended for dermal application.

The afternoon sessions were devoted to discussion of issues associated with the use of transgenic assays for risk assessment. Specifically, assay selection, protocol, and data integration issues were discussed. A special thanks goes out to Drs. Douglas Keller (Sanofi-Synthelabo), Peter Kasper (Federal Institute for Drugs and Medical Devices, Germany), Richard Storer (Merck Research Laboratories), Frank Sistare (US FDA Center for Drug Evaluation and Research), Jef French (NIEHS), Bruce McCullough (Aventis Pharmaceuticals), Gerald Long (Eli Lilly and Co.), and Ronald Gerson (Endo Pharmaceuticals) for co-chairing the afternoon sessions. Potential areas in which more experimental study could be of value towards increasing the utility of transgenic assays for risk assessment were identified. These include an evaluation of the criteria by which specific assays are selected; expansion of the historical control database; further examination of influence of study duration, number of animals/study, and age of animals at study initiation on assay results; and further development of positive controls for these assays.

As a follow-up to this highly successful event, the ACT Committee is publishing proceedings from the workshop. Please look for these in an upcoming issue of *Toxicological Sciences*. For more information about this workshop and the ILSI HESI ACT Committee, please contact ILSI HESI at hesi@ilsi.org.

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