

# REGULATORY AND SAFETY EVALUATION SPECIALTY SECTION

## ANNUAL REPORT: 2007-2008

May 1, 2007 to April 30, 2008

### I. Officers:

	<u>2007-2008</u>	<u>2008-2009</u>
President:	James D. Green	Frank D. Sistare
Vice President:	Frank D. Sistare	James C. Lamb
Vice President-elect:	James C. Lamb	Brian Short
Sec/Treas/News Letter	Suzanne Fitzpatrick	Vicki Dellarco
Councilors:	Vicki Dellarco	David Jacobson-Kram
	David Jacobson-Kram	Cynthia Afshari
<i>Past-President</i>	James T. MacGregor	James D. Green
SAC Representative:	Jaishree Bankoti	Jaishree Bankoti

### II. Activities and Notable Actions

#### Fall 2007 Annual Officers Meeting and March 2008 Officers SOT Breakfast Meeting

The Fall meeting of the Executive Committee of the Regulatory and Safety Evaluation Specialty Section (RSESS) of the Society of Toxicology (SOT) was held September 27, 2007 at the Government Affairs office of Biogen Idec, Inc. in Washington, D.C. Minutes of this meeting are attached. An Executive Committee meeting was held on March 17, 2008 at the SOT annual meeting in Seattle. Minutes of this meeting are also attached.

#### RSESS Sponsored Workshop

RSESS contributed sponsorship support to an education workshop on the mode of action human relevance framework held at RTP, NC on February 12, 2008.

#### Student Representative

Jaishree Bankoti, University of Montana was elected to continue to serve on the 2008-2009 RSESS Council.

#### RSESS Reception at Annual SOT Meeting, Annual RSESS Membership Meeting, and Student Awards

The RSESS reception and annual membership meeting was held March 18, 2008 in Seattle, WA. Approximately 120 people were in attendance. Dr. Green, RSESS President, called the meeting to order and reviewed the following business items: introduction of the officers and Councilors present, a sincere thank you to outgoing Past President Jim Macgregor and outgoing

Sec/Treas Suzy Fitzpatrick, presentation of the student awards, and discussion of recent activities of the Section.

Incoming President Frank Sistare presented four student travel awards, based on the quality of their applications and presentations at the annual SOT meeting. These awards are to be used for travel and lodging for the SOT Annual Meeting. These were:

Venkatesh Hegde, Dept. of Pathology, Microbiology and Immunology, University of South Carolina School of Medicine, Advisor: Prakash Nagarkatti, *Attenuation of experimental autoimmune hepatitis by exogenous and endogenous cannabinoids: Involvement of regulatory T cells*

RSESS Travel Award \$2000

Binu Philip, Dept. of Pharmacology and Toxicology, Indiana University School of Medicine, Advisor: James Klaunig; *Role of Kupffer Cell in Wyeth-14,643-Induced Hepatocyte Proliferation in Naïve C3H Mice*

RSESS Travel Award \$2000

Jennifer Phillips, Dept. of Pharmacology and Toxicology, Michigan State University, Advisor: Jay Goodman; *Phenobarbital Alters the methylation status of key genes during early phases of tumorigenesis*

Merck RSESS Travel Award \$2000

Vikrant Vijay, Center for Chemical Toxicology Research and Pharmacokinetics, College of Veterinary Medicine, North Carolina State University, Advisor: Ronald Baynes; *Solvatochromatic Interactions Influencing Dermal Permeation of Biocides in commercial cutting fluids*

Burdock Travel Award \$500 plus RSESS Travel Award \$1500

A highlight of the meeting was the annual “Great Debate” on the topic: “*MTD: Is testing to the MTD unnecessary animal use or necessary to assure human safety?*”

Frank Sistare moderated the discussion. Speakers included:

Pro MTD Position: Dr. Jack Reynolds

Con MTD Position: Dr. Bob Osterberg

### **2009 Annual Meeting Program Recommendations**

Proposals for the 2008 SOT annual meeting program were reviewed and ranked by the RSESS Scientific Program Committee, which was chaired by Dr. Harry Olsen. These recommendations were submitted to the Executive Committee for review and final decision. Frank Sistare posted the SS recommendations to the SOT website on May 7, 2008.

### **Financial Summary**

Financial information is available to members at:  
([http://www.toxicology.org/script/ss\\_financials2.asp](http://www.toxicology.org/script/ss_financials2.asp)).

From June 2007 – June 2008, our Section had \$20,356 income and \$22,583 expenses. We now have a fund balance of \$61,971.

### **2009 Objectives**

RSESS Executive Committee seeks to drive sponsorship of at last one scientific forum for engaging regulatory discussion on a key important topic of common interest to regulatory, academic and industry scientists in 2008/2009.

### **Attachments:**

**Minutes of 9-27-07 officers meeting**

**Minutes of 3-17-08 officers meeting**

Minutes: 9/27/07 RSESS Executive Committee Meeting

**Minutes**  
**Regulatory and Safety Evaluation Specialty Section**  
**September 27, 2007**  
**Washington, DC**

The Fall meeting of the Executive Committee of the Regulatory and Safety Evaluation Specialty Section (RSESS) of the Society of Toxicology (SOT) was held September 27, 2007 at the Government Affairs office of Biogen Idec, Inc. Attendees were as follows:

Jim MacGregor, Past President  
Jim Green, President  
Frank Sistare, Vice-President  
Jim Lamb, Vice-President Elect  
Suzy Fitzpatrick, Secretary-Treasurer and Newsletter Editor  
Harry Olsen, Chairman of RSESS science advisory group  
Marcia Lawson, SOT HQ (partial)

Not able to attend:  
Vicki Dellarco, Councilor  
David Jacobson-Kram, Councilor  
Jaishree Bankoti, Student Representative

**1. RSESS Annual Report**

Jim Green reminded the committee of the specialty sections responsibility to complete an annual report. The 2007 report content was briefly reviewed for content and format. The preparation of the 2008 report is the responsibility the current Vice-President Elect. A copy of the 2007 report is attached (Attachment 2).

**2. RSESS Budget Status**

Suzy Fitzpatrick reviewed the current funds available as reported through June 2007. The RSESS has \$55,125.00 available for use. Various spending options were discussed. It was agreed that RSESS will fund travel support for the RSESS Student Representative, Jaishree Bankoti to attend the 2008 SOT

Annual Meeting/RSESS March Business Mtg, and to the 2008 Fall RSESS Business Meeting.

### **3. Discussion of the August 2007 Face-to Face Meeting of Specialty Section Officers**

Jim Lamb, who represented the RSESS at this meeting, summarized important issues that were discussed; handouts from the meeting were previously distributed to committee members and were reviewed. Jim's opinion is that the meeting was very worthwhile and that a similar meeting should be held every year. Jim Green, who attended last year's meeting on behalf of RSESS, felt the same after that meeting. Marcia Lawson has been notified that our Section endorses continuation of these meetings on an annual basis. In addition, Jim noted that the Specialty Sections are being encouraged to use SOT-supported tele-seminars. The officer group discussed potential topics that might be considered for RSESS to sponsor. It was decided that we would highlight this capability in our next newsletter and solicit the membership for topic ideas. Furthermore, since this meeting was viewed as particularly useful for new officers, the committee decided that we should send two RSESS representatives to next years meeting. SOT-HQ covers the expenses of one committee member; therefore, the committee agreed to fund the costs associated with the additional committee member to attend.

### **4. Scientific Program Committee: Specialty Section 2008 ranking process for workshops, symposiums and roundtables**

Harry Olson reported on the activities of our newly established standing Science Program Committee. A major activity of this committee this year was conducting the primary review of symposiums, workshops, roundtables and CE courses in which RSESS had been identified as the primary endorser. Overall, the executive committee acknowledged that under Harry's leadership the committee did an excellent job; clear rankings were provided for the executive committee to consider. One important issue that was identified related to the timing of the committee's review relative to when SOT-HQ expected the final rankings to be submitted. It was emphasized that more time was needed for thoughtful reviews to be completed before the SOT-imposed deadline. Furthermore, it was decided that the committee review should not commence until the authors have submitted the information to SOT in the proper format for inclusion in the overall SOT roll-up. In this way, the committee would only review those submissions that have been properly submitted according to SOT

determined deadlines and not waste time on reviews of submissions in which we have not been properly designated as the primary review group.

The committee discussed the issue of term of service for the chair and committee members. Harry Olson agreed to serve in the Chair position for one more year. In addition, he agreed to propose a process by which committee members can be rotated to foster additional RSESS member involvement and to ensure the continuity of the review process. For 2008, the review committee will again be asked to perform the primary review and ranking of the proposals submitted for consideration at the 2009 annual meeting. The final ranking will be communicated to Frank Sistare for sharing with the executive committee. Frank will then submit the sections final ranking to SOT-HQ as required.

## **5. RSESS Process for Considering non-SOT Requests for Financial Support**

The process by which the EPA proposal submitted by Vicki Dellarco was reviewed for adequacy. It was decided that the following procedure would be followed for any new proposals that requested RSESS funding support:

- 1 – Proposal sponsor will notify RSESS president of proposal and funding request.
- 2 – RSESS president will circulate proposal information, requested funding amount to executive committee and scientific advisory committee chairman for review. Reviewers will be asked to respond to RSESS president whether or not they approve, disapprove or require further information.
- 3 – Within one week of proposal being circulated to reviewers, the RSESS president will schedule a one hour telecom in which the proposal request can be discussed if necessary.
- 4 – Based upon majority consensus as determined by the RSESS president, a decision will be made to support or not support the proposal. If the proposal is supported, SOT-HQ will be notified so that the requested funds can be made available. The RSESS president will notify the sponsor of the committee's decision.

## **6. Newsletter**

Suzy Fitzpatrick led a committee discussion regarding potential topics for our next series of newsletters. In addition, the timings for the next two newsletters were decided. Topics to be included in the upcoming newsletter will include:

- President's message
- Research Triangle Proposal Sponsorship
- Available student awards
- Essay topics
  - o Next steps on ILSI activities regarding Animal/human toxicity concordance
  - o Evidence based toxicology
  - o ACSA: Agricultural Safety Assessment
- Future topics identified
  - o Nanotoxicology
  - o ICH safety updates
  - o Computational toxicology
  - o REACH
  - o Threshold level of concern

It was decided that we would publish a winter and spring newsletter. The due dates for contributions for the winter and spring newsletters is 10/31 and 2/15, respectively.

## **7. Annual Meeting Topics**

### **Student Awards**

It was decided that the RSESS would again offer 4-5 student awards this year and that the award amount would be increased to \$2,000.00. Frank reported that Merck has indicated that it will again sponsor a student award.

Furthermore, since last year's Merck Award winner had to withdraw, the funds from last year's Merck award are also available so there will be two Merck Awards this year. Jim Green will ask Frank Sistare to contact the Burdock Group to determine if the Burdock Award will be funded this year. Suzy Fitzpatrick indicated that the award availability will be prominently announced in our winter newsletter. The committee decided that a similar announcement would be included on our web site. It was noted that Frank Sistare will be the contact point and the individual responsible to coordinate selection of the 2008

award winners. In addition, Marcia Lawson reported that SOT-HQ has assumed responsibility to assure that duplicate awards are not given to the same submission/student as has occurred in previous years.

### **Great Debate at 2008 Annual Meeting**

Possible topics for the next “Great Debate” were discussed and a selection was made. The next debate will be:

*“MTD: Is testing to the MTD unnecessary animal use or necessary to assure human safety?”*

Frank Sistare agreed to moderate the discussion at the SOT meeting.

Proposed speakers were identified as follows:

Introduction/Background: Frank Sistare (accepted)

Pro MTD Position: Drs. Jack Reynolds

Con MTD Position: Dr. Bob Osterberg

Harry Olson agreed to contact Jack and Bob to ascertain level of interest.

Other potential debate topics discussed, but not selected for the current debate, were:

- Threshold level of concern

- DNT vs. DIT

- US vs. Canada Use of Safety Factors

- Biomarker use as a ‘mechanistic’ safety factor

- Does a new technology like ‘nano’ require new testing paradigms?

### **Specialty Section Meeting at 2008 Annual Meeting Time**

The committee decided that it would contact SOT-HQ to strongly indicate that our section meeting be held during one of the scheduled evenings and not during the lunch period. Post-meeting note: This request has been communicated to SOT-HQ.

## **8. Nomination for the Next RSESS Officer Election**

Nominees for the next election were discussed and selected. Those selected, alternates, and those proposed (who might be considered in the future), along with the individual who agreed to contact the nominees, are:

### **Vice-President Elect**

MaryEllen Cocenza, Amgen (Jim Green) — Declined

Mike Holsopple, ILSI (Suzy Fitzpatrick) — Accepted

1<sup>st</sup> Alternate: Kerry Deerfield (Jim Lamb) - Accepted

2<sup>nd</sup> Alternate: Bern Schwetz, USHHS (Suzy Fitzpatrick)

3<sup>rd</sup> Alternate: Brian Short, Allergan (Jim Green)

### **Councilor**

Cindy Afshari, Amgen (Frank Sistare) — Accepted

Bob Krieger, UC Davis (Jim Lamb) — TBD

1<sup>st</sup> Alternate: P. Goehring (Suzy Fitzpatrick)

2<sup>nd</sup> Alternate: John Thomas, IUSMed (Suzy Fitzpatrick)

3<sup>rd</sup> Alternate: Laura Andrews, Genzyme (Jim Green)

Others suggested: Kerry Dearfield, Michele Embry

## **8. AOB**

No new business items were raised.

The committee adjourned at 2:00 PM.