

Regulatory and Safety Evaluation Specialty Section

ANNUAL REPORT: 2017-2018

May 1, 2017 to April 30, 2018

I. Officers/Committees:

<u>Officers</u>	<u>2017-2018</u>	<u>2018-2019</u>
President:	Edward V Ohanian	Marie C Fortin
Vice President:	Marie C Fortin	Anne E. Loccisano
Vice President-Elect:	Anne E. Loccisano	Amy L Roe
Secretary/Treasurer:	Amy L Roe	April O'Connell
Past President	Michael L Dourson	Edward V Ohanian
Councilors:	April O'Connell	Norman Kim
	Norman Kim	Haitian Lu
PDA Representative:	Gregory J Smith	Gregory J Smith
GSLC Representative:	Monique Williams	Brett Winters
Proposal Review Committee Chair	Liz Vancza	Bob Budinsky

Committees:

Ad hoc group for webinars – Norman Kim, Edward Ohanian, April O'Connell

Ad hoc group for Risk Assessment publication monitoring-Edward Ohanian

Ad hoc group for new RSESS Mentoring Activities – Monique Williams and Marie Fortin

II. Activities:

The 2018 SOT Annual Meeting RSESS Reception was held in San Antonio, TX.

Approximately 200 people in attendance.

Dr. Edward Ohanian presided over the meeting which began at 6:00 PM on March 12th, 2018 and the executive committee proceeded with the business portion of the meeting.

Several awards were given to graduate students, postdoctoral scholars, and one award was given for the best paper of the year award:

Postdoctoral Awards

1. **Dr. Miao Li**, Kansas State University. Application of Population Physiologically-Based Pharmacokinetic Model for Penicillin G in Dairy Cows to Facilitate Food Safety Assessment. 3174: Poster Board – P 813 (March 14th 1:30-300 PM)
2. **Dr. Rui Xiong**. US FDA/NCTR. Evaluating Mode-of-Action of Acrolein Toxicity in an In Vitro Human Airway Tissue Model. 3323: Poster Board – P 104 (March 15 8:30-11:30 AM)

3. **Dr. Samantha Faber** University of North Carolina at Chapel Hill. Diesel Exhaust Particles Downregulate PI3K/Akt/mTOR Signaling and Mitochondrial Bioenergetics in a Novel Organotypic Model of the Airway Microenvironment. 1216: Poster Board – P306 (March 12 9:15-10:45 AM)

Student Travel Awards

4. **Mr. Yu-Syuan Luo** Texas A&M University. Comparative Analysis of Toxicokinetics and Toxicodynamics of Perchloroethylene in Cytochrome P450 2E1 Knockout and Humanized Transgenic Mice. 1709: Platform CC Room 304 (March 12 2:49-3:05 PM)
5. **Ms Jalissa Nguyen Wynder** University of Wisconsin-Madison. Evaluating the Applicability of Read-Across Tools and High-Throughput Screening Data for Food Relevant Chemicals. 1613: Poster Board – P853 (March 12 10:45-12:15 PM)
6. **Ms. Eva Vitucci.** University of North Carolina-Chapel Hill. A Cellular Game of Telephone: Trans-Cellular Reprogramming in Responses to Toxic Stimuli. 1918: Poster Board – P251 (March 12 – 3:00 PM – 4:30 PM)

Best Published Paper Award

Title: A quantitative comparison of points of departure between 28-day and 90-day repeated dose studies with a proposed extrapolation factor. *Regulatory Toxicology and Pharmacology* 92(2018) 189-200.

Authors: **Dr. Bradley J. Lampe**, Emily Fuller, Senthilkumar P. Kuppusamy.

Reception Debate

“*The Great Debate*” followed the awards ceremony. This year’s debate topic was:

“Relevance and Predictability of Animal Toxicity Studies to Human Toxicity?”

The debater on the Pro side was Dr. David Herr, Ph.D., U.S. Environmental Protection Agency.

The debater on the Opposing side was Dr. Michael DeVito, PhD., National Institute of Environmental Health Sciences.

Excellent feedback and questions from the audience led to a great, well rounded discussion.

2017 SOT Annual Meeting Breakfast Regulatory Seminar

At 6:30 AM on 14 March 2018 at the SOT Annual Meeting in San Antonio, TX. Speaker Scott Jordan, Ph.D., gave an overview and case studies on the topic of OTC drugs and dietary supplement regulation at Health Canada.

Challenges on the safety assessment of these products and changes in regulation were discussed with excellent feedback from the audience.

This is the 5th annual “Global regulatory toxicology event” where a non-US regulator was invited by SOT through RSESS to present global regulatory perspectives. Approximately ~20 individuals attended this session.

2018 SOT Annual Meeting Courses/Sessions:

The RSESS 2018 Proposal Review Committee Reviewed 50/126 Total Proposals Submitted to SOT: 40% review rate

Of the 50 RSESS reviewed proposals 19 were accepted (38%). All 19 accepted proposals were pre-reviewed by the RSESS committee.

2/11 Symposia (18% acceptance rate) were accepted by RSESS

9/23 Workshops (9% acceptance rate that includes a guaranteed session for the RSESS “Pilot Year” program)

2/4 Roundtables were accepted (50% acceptance rate)

-Others (education, regulatory, informational session proposals) 6/12 accepted (50% acceptance rate).

Endowment Fund Details: Fund in “spend-down” mode.

Newsletters: Two newsletters were distributed to our membership: one in 2017 and spring 2018 prior to the Annual SOT meeting in San Antonio, TX.

Webinars

The webinar "**Updates to FDA’s GLP Regulations**" with Mark Seaton Ph.D., US FDA was hosted by Norman Kim and held on Friday, September 29, 2017 at 11:30 am EST. There were 760 registrants and the webinar was extremely well attended.

GSLC-RSESS Joint Webinar “**Finding your Dream Job in Regulatory Toxicology**” with RSESS Panelists Edward Ohanian, Amy Roe, Anne Loccisano was held October 31st, 2017. There were 108 registrants and the webinar was extremely well attended.

Other Specialty Section 2017-2018 Activities:

RSESS SOT Mentoring Event

For the 57th Society of Toxicology Annual Meeting, the RSESS sponsored its first Lunch and Learn mentoring event. This new initiative was designed to provide trainees (e.g., students and postdocs) with an opportunity to learn about careers in regulatory and safety evaluation through small group discussion with a toxicologist experienced in this field. This event was a success and had a total of 17 mentors and 22 mentees that attended and participated. This event facilitated networking and mentoring of young professionals by experienced toxicologists that will develop into lasting professional relationships that will benefit both the mentors and mentees. The “*Lunch and Learn Mentoring Event*” was held at the historic Menger’s Hotel near the Convention Center on Wednesday, March 14th at 11:30 AM. RSESS looks forward to continuing this networking event for years to come.

Ad hoc group for Risk Assessment Publication Monitoring

Edward Ohanian (RSESS 2017-18 president), in his new role as an Associate Editor of Toxicological Sciences Journal, promoted awareness and visibility of the field of risk assessment and regulatory toxicology by encouraging RSESS members to submit articles to Toxicological Sciences Journal. Specifically, the main objective was to increase publications related to risk assessment in Toxicological Sciences Journal. An RSESS poster was assembled by postdoctoral representative Gregory J. Smith and graduate student rep Monique Williams with current RSESS SOT 2018 meeting activities and events which was displayed in the gallery area of the SOT Exhibitor Hall during the Annual SOT Meeting in San Antonio.