# National Capital Area Chapter  
Society of Toxicology Newsletter  
Electronic Edition  

**September 2015**  

**Issue No. 38**  

*Gertrude-Emilia Costin, Editor*

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CHAPTER MISSION STATEMENT

The National Capital Area Chapter of the Society of Toxicology (NCAC-SOT) was established to provide a regional focus for scientists of all disciplines interested in toxicology. The Chapter acts to:

- Sponsor and co-sponsor symposia on current issues in toxicology
- Provide annual awards to an outstanding student and post-doc in toxicology to assist in attending the annual meeting of the SOT
- Maintain communication with the National SOT regarding current toxicology and regulatory concerns
- Sponsor Regional Chapter events at the SOT Annual Meetings

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MESSAGES FROM THE NCAC-SOT EXECUTIVE BOARD MEMBERS

President’s Message

Dear NCAC-SOT Fellow Members,

We are planning a full year of engaging activities, interactive seminars, symposia, networking and social events. We are counting on your active participation to continue building upon our previous successes.

We will hold a Fall Webinar on September 18th on the current status of the Endocrine Disruptor Screening Program and are planning a Winter Symposium in early January, 2016. I would like to hear from you regarding the topic(s) to be developed for the symposium. Additionally, there are two national meetings in November-December which will be held locally and we encourage our membership to take advantage and participate. We will send you more information regarding social-networking events for NCAC-SOT members at these meetings. Please refer to a mini-guide of events that you can find on pages 13-16 of this newsletter and mark your calendars.

SRC, Inc., a not-for-profit research and development company, is supporting NCAC and SOT to conduct outreach activities especially STEM (Science, Technology, Engineering, and Math)-related activities. We are devoting efforts to properly plan members’ participation in different events that include serving as a judge for Regional Science Fairs in 6 counties (Loudoun, Prince Williams, Fairfax, Prince George, Montgomery and Howard), the District of Columbia and the Baltimore Science Fair that includes Baltimore City, and Baltimore, Carroll, Cecil, Harford and Howard Counties; NCAC-SOT volunteers will select a research project related to toxicology and present a $100 award at each Regional Science Fair. In addition, the K-12 Outreach Activities Committee will coordinate members’ participation at the AAAS Family Day and the USA Science and Engineering Festival. There will also be plenty of opportunities for mentoring high school students from NCAC to participate in person or in virtual High School Poster Exposition at the New Orleans SOT meeting on March 2016. More information on these activities will be sent by the Chair and Co-Chair of the Education and K-12 Outreach Activities Committee, Drs. Gladys Erives and Gopala Krishna.

Plenty of opportunities are also available for participation at the SOT Domestic ToxScholar Program visits funded by the SOT-Education Committee and the Committee on Diversity Initiatives.
You can make a difference visiting undergraduate education institutions to promote the field of toxicology. Please refer to the article on page 12 of this newsletter and apply.

At the NCAC-SOT, we like to celebrate our members’ accomplishments highlighting the ground-breaking research and publications more specifically of graduate students and postdoctoral fellows. Please contact our newsletter Editor Emilia Costin for more information on how to let other members know about your publications.

This is your SOT chapter, and it should support and reflect your vision. Please feel free to contact me at pedro.delvalle@fda.hhs.gov or any other Board member with your comments, ideas and suggestions. Please invite your colleagues to join the NCAC; they do not need to be SOT members. The membership fees remained unchanged and will fund our symposium each year and support a myriad of student activities, including student awards, travel supplements, and K-12 outreach.

I am excited about all the activities we can develop together during this operational year and look forward hearing from you and your active participation at the different events to advance and stimulate the field of toxicology for the general public, students and professionals.

Warm Regards,

Pedro L. Del Valle, PhD
NCAC-SOT President

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Graduate Student Representative’s Message

Greetings NCAC-SOT Students,

We hope you are interested in our upcoming webinar, “Looking forward after 19 years of the Endocrine Disruptor Screening Program”, on September 18th. We will be holding a winter meeting in early January 2016. This is a great opportunity to present your research in the form of a poster or student platform presentation and receive feedback from experts. The 55th SOT Annual Meeting and ToxExpo will be on March 13-17th, 2016 in New Orleans, LA. Abstract submission is open until October 7th and information for awards can be found at http://www.toxicology.org/awards/sot/awards.asp. Deadlines for some travel awards can be as early as October, so be sure to check which ones you are eligible to apply for.

The Graduate Student Leadership Council (GSLC) will host a webinar as well as the annual YouTox Media Challenge. Emails with details for these activities will be sent out closer to the event dates. Your participation in NCAC-SOT will give you the opportunity to network with professionals from academia, government, and industry as well as apply for NCAC-SOT awards. We can help you find the specialty sections and special interest groups you are interested in. If you have any questions about how to get more involved with the NCAC-SOT regional chapter contact us at sot.ncac.officers@gmail.com. You can also find us on ToXchange and comment on our Facebook group (SOT National Capital Area Chapter). We look forward to hearing from you!

Sincerely,

Georgina Harris
NCAC-SOT Graduate Student Representative
Post-Doctoral Representative’s Message

Dear NCAC-SOT Postdoctoral Scholars,

Participation in NCAC and national SOT events provides a great opportunity for you to share your work and network with other toxicologists.

Abstract submission and registration is open for SOT’s 55th Annual Meeting and ToxExpo in New Orleans, LA on March 13-17, 2016. During registration, please remember to sign up for the postdoc-specific activities, including the Student/Postdoctoral Mixer (3/13 – No registration fee), the In Vitro Lecture and Luncheon (3/14 - $10 registration fee), and the Postdoctoral Luncheon (3/15 - $10 registration fee). Other events and activities at the SOT Annual Meeting for postdoctoral scholars include the Poster Tours for Trainees and the Chat with an Expert program which allow postdocs to participate in informal mentoring experiences.

Numerous awards and fellowships are available for postdoctoral scholars including national SOT, Regional Chapter, Specialty Section, and Special Interest Group awards. Postdocs may apply for multiple awards, so make sure you take advantage of these opportunities! The Postdoctoral Assembly is currently accepting applications for the Best Postdoctoral Publication Awards (BPPA). These awards recognize outstanding postdoctoral researchers who have recently published exceptional papers in the field of toxicology. The deadline for the BPPA application is October 1 and the award will be presented at the PDA Luncheon at the annual meeting this spring. Further information and application may be found at the following link: http://www.toxicology.org/application/af/awards_details.aspx?id=96.

For postdoctoral scholars interested in serving in a leadership role in SOT, there are numerous postdoctoral representative leadership positions still available within various regional chapters, specialty sections, and special interest groups. More information on available positions may be found at the following link: https://www.toxicology.org/groups/postdoc/groupReps.asp. In addition, there will be a call for nominations in November for candidates for PDA Officers, including Vice Chair, Treasurer, and Councilor positions. These are great opportunities for postdocs to gain leadership experience and interact with their fellow postdocs and SOT members.

The National Postdoctoral Appreciation Week (NPAW) will be September 21-25, 2015. This is sponsored by the National Postdoctoral Association which is a non-profit organization that supports the postdoc community. The SOT PDA-sponsored webinar for NPAW will be held on Monday, September 14th at 11 AM ET and is entitled “Increasing Your Visibility and Participation in SOT as an Early Career Toxicologist”. The webinar will be hosted by PDA Vice Chair Kathryn Page and will include a diverse panel of speakers. There will also be a postdoc-themed blog series all week written by recently transitioned postdocs in academia, government, and industry on the topic “Advice from the Other Side: Reflections of the Postdoctoral Experience”. Please visit the following website for information on more NPAW events in the area: http://www.nationalpostdoc.org/news/246634/National-Postdoc-Appreciation-Week-Celebrates-Postdoctoral-Scholars.htm.

For more information and resources for postdoctoral scholars, please look out for the Fall 2015 Post-y PDA Newsletter which will be available in the upcoming weeks. If you have any questions or comments, please feel free to contact me (Shelby.Skoog@fda.hhs.gov).

Sincerely,

Shelby Skoog
NCAC-SOT Postdoc Representative

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Message from the Outgoing Newsletter Editor

Dear NCAC-SOT members,

It has been my pleasure being the Newsletter Editor for this chapter for the past 3 years. Being an editor for a small part of my career made it fun to put together the newsletters for you. Without the help of other officers (past and present), the previous outgoing newsletter editor, and members, this newsletter wouldn’t have been possible, and I thank you. I know that Emilia Costin will do a wonderful job taking over the reins, and I look forward to keeping up with what the chapter is doing through her eyes. I have enjoyed getting to know the officers, assisting in planning events, and meeting members at Annual Meetings and our chapter events. Seeing and being part of what goes on behind the scenes for events to occur for such a large group has been helpful and has been used in other parts of my career.

If you have ever thought about being an NCAC-SOT officer, please look for emails later this year with instructions. It is a great experience (both professional and personal) that you will not regret. Thank you again and I hope to see you soon!

Melanie Biggs, Ph.D.
Consumer Product Safety Commission
301-987-2593
mbiggs@cpsc.gov

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Message from the Incoming Newsletter Editor

Dear NCAC-SOT Members,

It is my pleasure to introduce myself as the new Editor of the Chapter’s Newsletter. My transition to this assignment was thus far very smooth thanks to Dr. Melanie Biggs, outgoing Newsletter Editor, and to the Chapter’s Board members. I had the chance to interact with the officers and started to learn about their respective assignments and tasks through our regular monthly conference calls, so I am now up to speed with the Chapter’s current projects.

Coming to this assignment while still the Editor of another Newsletter (of the PanAmerican Society for Pigment Cell Research), it is very exciting to learn now about NCAC-SOT’s Newsletter, its content, formatting and goals. Following discussions during the Chapter’s Board meetings, we agreed upon starting a new series in the Newsletter with the intent to open the dialogue between Chapter’s members at large and to get to know each other better and our areas of expertise. Our new series is entitled “What’s New in Toxicology?” and our first contributor is Dr. Erik Janus, NCAC-SOT Vice President, who will discuss the newest projects he is working on. We hope you will enjoy the columns included in the current number and will wish to contribute as well to the upcoming newsletters.

As for me, I enjoy working on Newsletters because this activity provides me with the enjoyment of connection, being always informed first-hand about what is new and exciting in our field and with the pleasure to inform the members further. I have worked in the area of in vitro toxicology for the past 8 years at the Institute for In Vitro Sciences (IIVS) where we use exclusively in vitro testing systems for safety assessment of a wide variety of products: pharmaceutical, personal care and cosmetic, chemicals, etc. As a non-profit contract lab, it is our mission at IIVS to outreach and train others in the uses of in vitro assays for toxicology. I hope to share more about my activities with the members of NCAC-SOT in the future.

I hope you enjoy this number. Please contact me with suggestions and comments about the Newsletter content. If you would like to contribute a column for our newly started series, please do not hesitate to send me an email at ecostin@iivs.org. Thank you,

Gertrude-Emilia Costin
NCAC-SOT Newsletter Editor
TREASURER’S REPORT

NCAC-SOT Treasurer's Report – August 4, 2015
By Nancy Beck, Treasurer

Account activity since last report
(Dated Feb 16, 2015 in March Newsletter)

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<td>Graduate Student Travel Award to Suzanne Martos</td>
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<td>NCAC Travel Award to Sanah Vohra</td>
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<td>6/26/15</td>
<td>Reimbursement from NC SOT chapter for joint reception in March 2015</td>
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Balance: $10,624.91

June 30, 2015* (Closing balance)
*Most recent bank statement in our possession.

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NCAC-SOT MEMBERSHIP

Details
Did you remember to renew both your SOT and NCAC memberships this year? Annual membership fees for NCAC-SOT remain unchanged this year and are only $25 for regular memberships and $10 for full-time students. These negligible fees are used to fund our symposium each year and to support a myriad of student activities, including student awards, travel supplements, and K-12 outreach. If you have not yet renewed your regional chapter membership, please do so today! You can do so online at http://www.toxicology.org/script/loginredirect1.asp?page=dues, or just fill out and mail in the membership application form on the next page. It’s never too late to renew your NCAC-SOT membership for 2015!
MEMBERSHIP APPLICATION

Name: ______________________________________________________

Affiliation: ___________________________________________________

Address: _______________________________________________________

______________________________________________________

City: ____________________________

State: _____ Zip Code: __________

Area Code: _____ Phone: _______________ FAX: ____________________

E-mail: ______________________________________________________

Membership Type ______ Full Member ($25) ______ Student ($10)

Please check the most appropriate responses:

SOT Member Yes No

Highest Degree Attained A.S. B.A. B.S. B.V.M. D.V.M. D.V.M./Ph.D. M.D. M.D./Ph.D.

M.P.H. M.S. M.A. Ph.D. Sc.D. V.M.D. V.M.D./Ph.D.

Type of Affiliation Academia Consulting Contract Lab Government Industry- Chemical/Petroleum Industry- Pharmaceutical Industry- Other Other-

Please complete the information above and send with a check, money order or credit card (payable to National Capital Area Chapter SOT, no POs) to the address below. The NCAC SOT will review your application, and you will be notified within 30 days. Those not accepted will receive a full refund. Current RC members: please do not use this form since your renewal dues are billed annually through SOT.

Payment Type: Money Order______ Check ______ Credit Card ______

Credit Card # _____________________________ Exp date ________

Name on Card ______________________________________

Signature ___________________________________________

Please send form as a pdf to: Nancy Beck, Treasurer
Nancy_Beck@americanchemistry.com

If paying by check, please send to: Society of Toxicology, ATTN: Ashley Pomper
1821 Michael Faraday Drive, Suite 300, Reston, VA 20190
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<tr>
<th>Position</th>
<th>Name</th>
<th>Institution/Contact Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>President</td>
<td>Pedro L. Del Valle (2015-2016)</td>
<td>U.S. Food and Drug Administration 301-796-2111 <a href="mailto:pedro.delvalle@fda.hhs.gov">pedro.delvalle@fda.hhs.gov</a></td>
</tr>
<tr>
<td>Vice President/President-elect</td>
<td>Erik Janus (2015-2016)</td>
<td>M³ Technical &amp; Regulatory Services 304-839-2276 <a href="mailto:erik@mcubedservices.com">erik@mcubedservices.com</a></td>
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<tr>
<td>Past President/Councilor</td>
<td>LCDR Mark Miller (2015-2016)</td>
<td>National Institute of Environmental Health Sciences 919-541-7758 <a href="mailto:mark.miller2@nih.gov">mark.miller2@nih.gov</a></td>
</tr>
<tr>
<td>Secretary</td>
<td>Kelly Brant (2015-2018)</td>
<td>U.S. Food and Drug Administration 301-796-7917 <a href="mailto:Kelly.Brant@fda.hhs.gov">Kelly.Brant@fda.hhs.gov</a></td>
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<tr>
<td>Councilors</td>
<td>Gertrude-Emilia Costin</td>
<td>Newsletter Editor (2015-2018) Institute for In Vitro Sciences, Inc. 301-947-6524 <a href="mailto:ecostin@iivs.org">ecostin@iivs.org</a></td>
</tr>
<tr>
<td></td>
<td>David Szabo</td>
<td>Website Coordinator (2013-2016) Reynolds American Inc. 336-741-4435 <a href="mailto:szabod@rjrt.com">szabod@rjrt.com</a></td>
</tr>
<tr>
<td></td>
<td>Susan A. Laessig</td>
<td>Student Liaison (2013-2016) US Environmental Protection Agency 202-564-5232 <a href="mailto:laessig.susan@epa.gov">laessig.susan@epa.gov</a></td>
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<tr>
<td></td>
<td>Gladys Erives</td>
<td>Education and K-12 Outreach Activities Committee Chair (2014-2017) US Food and Drug Administration 240-402-3066 <a href="mailto:Gladys.erives@fda.hhs.gov">Gladys.erives@fda.hhs.gov</a></td>
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<tr>
<td>Postdoctoral Representative</td>
<td>Shelby Skoog (2015-2017)</td>
<td>U.S. Food and Drug Administration 301-796-2800 <a href="mailto:Shelby.Skoog@fda.hhs.gov">Shelby.Skoog@fda.hhs.gov</a></td>
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<tr>
<td>Graduate Student Representative</td>
<td>Georgina Harris (2015-2016)</td>
<td>John Hopkins University 410-614-4916 <a href="mailto:gharri27@jhu.edu">gharri27@jhu.edu</a></td>
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**NCAC-SOT ACTIVITIES UPDATE**

**Awards**

**President Service Award**: Dr. Bruce Fowler for his service and leadership as President-Elect, President, and Past-President of the National Capital Area Society of Toxicology 2012-2015.

**SOT K-12 Travel Award**: With assistance of NCAC K-12 liaison Dr. Gopala Krishna, high school student Mayur Krishna (Centennial High School, Ellicott City, MD), worked with Dr. Saryu Goel (Supernus Pharmaceuticals) on a toxicological project related to BPA entitled “Bisphenol A: Comparative Mutagenic and Carcinogenic Risk Prediction Using Multiple Structure Activity Relationship Software”. Mayur Krishna was awarded with NCAC K-12 travel award with a congratulatory note and cash amount of $500. In the photo below Mayur is making a poster presentation at the National SOT meeting in San Diego, CA, during March 2015.
“Looking forward after 19 years of the Endocrine Disruptor Screening Program”

In the 1990s, a variety of chemicals were suspected of disrupting the endocrine system in animals. Based on scientific evidence, Congress approved the Food Quality Protection Act and Safe Drinking Water Act (SDWA) Amendments in August 1996 requiring the U.S. EPA to initiate the Endocrine Disruptor Screening Program (EDSP) to screen pesticides, commercial chemicals and environmental contaminants for their potential effect on the endocrine systems of humans and wildlife. EDSP is a two-tiered screening process aimed at identifying chemicals and determining their potential to disrupt the endocrine systems of mammals, birds and fish.

Tier 1: EPA will identify chemicals that have the potential to interact with the endocrine system.

Tier 2: EPA will determine the endocrine-related effects caused by each chemical and obtain information about effects at various doses to enable subsequent risk assessments for each chemical.

EPA announced the initial list of chemicals to be screened for their potential effects on the endocrine system (or Tier 1 testing) on April 15, 2009, and in November 2010, EPA issued a finalist (“List 1”) of chemicals for screening as well as draft policies and procedures for the EDSP. The second list of chemicals (as well as related policies and procedures) for screening under the SDWA (“List 2”) was issued on June 14, 2013 (with minor revisions in May 2014); however, EPA currently does not have authorization from the White House Office of Management and Budget (OMB) to collect these data. On June 18, 2015, EPA announced a plan for incorporating validated high-throughput assays and a computational model into the EDSP to screen chemicals for their ability to interact with the endocrine system. This proposed new method would serve as an alternative for three of the eleven current assays in the EDSP Tier 1 screening battery (estrogen receptor binding, estrogen receptor transactivation, uterotrophic). On July 30, 2015, EPA released its reviews of the Tier 1 screening assay results for the first 52 pesticide chemicals (active and inert ingredients) in the EDSP, representing a major milestone of achievement for the almost 20-year-old program.

This webinar provides a great opportunity to hear about the current status of the EDSP program from stakeholders involved with the program as well different perspectives on the future directions of the program.

A diverse panel of speakers is aligned for the webinar. The complete schedule of the webinar will be provided closer to the event’s date by posting on ToXchange and on NCAC-SOT web-page (https://www.toxicology.org/groups/rc/ncac/index.asp).

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Outreach Activities

The NCAC-SOT Education and K-12 Outreach Activities Committee

Chair, Gladys Erives, PhD
Email: Gladys.erives@fda.hhs.gov

Co-Chair, Gopala Krishna, PhD, MBA, DABT, FATS
Email: gkrishna@supernus.com

We invite all NCAC members to actively participate in the activities listed below. Bring a colleague who is not aware of these opportunities and promote his/her participation as well. Contact us for more information on these events.

Guide for K-12 Outreach Activities

<table>
<thead>
<tr>
<th>2015</th>
<th>ACTIVITY</th>
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<tbody>
<tr>
<td>September - December</td>
<td>Register as NCAC volunteer – include County of residence</td>
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<td></td>
<td>Reach out to STEM (Science, Technology, Engineering, Math) Teachers of your High School of preference - Serve as Judge in the school and/or District Science Fairs</td>
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<td></td>
<td>Collaborate with local High Schools and make a case for Toxicology careers via short presentations</td>
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<table>
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<td>January-March</td>
<td>Mentor High School students from NCAC area to participate in person or in virtual High School Poster Exposition at the New Orleans SOT Meeting</td>
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<tr>
<td>January –December</td>
<td>Collaborate with local High Schools and make a case for Toxicology careers via short presentations</td>
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<tr>
<td>February 11-15</td>
<td>AAAS 2016 Family Science Days – booth, display &amp; fun toxicology hands-on activities</td>
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<tr>
<td>April 16-17</td>
<td>USA Science and Engineering Festival – booth, display &amp; fun toxicology hands-on activities</td>
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Regional Science Fairs

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<td>February 13-14</td>
<td>Howard County</td>
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<tr>
<td>March 11-12</td>
<td>Montgomery County</td>
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<td>March 11-12</td>
<td>Prince William County - Manassas</td>
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<td>March 16-17</td>
<td>Loudoun County</td>
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<td>March 18-19</td>
<td>Prince Georges County</td>
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<td>March 18-20</td>
<td>Fairfax County</td>
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<td>March 19-20</td>
<td>Baltimore – includes Baltimore City, and Baltimore, Carroll, Cecil, Harford and Howard Counties</td>
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<tr>
<td>March 27-28</td>
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The SOT Domestic ToxScholar Program

The SOT Domestic ToxScholar Program visits are an opportunity to:

- introduce a scientific discipline and career options that are frequently unknown at the undergraduate level,
- connect faculty and undergraduates to Regional Chapter meetings and activities,
- encourage applications for SOT undergraduate programs,
- recruit regional students to graduate programs, and
- to discover ways that research opportunities for undergraduates can be increased.

It will all start with the commitment of a toxicologist to make a visit to an institution. We have developed a list of primarily undergraduate institutions organized by areas covered by Regional Chapters. For some of these institutions we have names of potential faculty contacts - sponsors of applications for SOT undergraduate programs or perhaps a department chair name. Perhaps you or other Regional Chapter members are alums of these institutions or already have connections. This is not an inclusive list; you may have connections to other institutions that may be sites for worthwhile visits. The contact name may also be out-of-date. However, we anticipate that this information will make it easier for a potential ToxScholar visitor to identify a starting point.

The Education Committee has a modest amount of funding to support travel and miscellaneous costs (flyers, room rentals, refreshments, etc.) for ToxScholar visits; the Committee on Diversity Initiatives has funding for visits to institutions that have a high proportion of students from groups under-represented in the sciences. Up to $500 can be requested for a visit. Both share the same application.

Whether or not funds are needed for these visits, it is required that we receive visit reports including attendee lists. These allow us to measure the level of activity, to reinforce connections to these schools, and to publicize SOT programs directly to participants. Previous reports are available for reference. See Education ToxScholar and CDI ToxScholar reports.

More information is found on the ToxScholar web page (http://www.toxicology.org/awards/gf/toxscholar.asp), including the application. Please be in touch with Rachel Woodson if you have any questions.

We really appreciate your willingness to help SOT strengthen communication with undergraduates and undergraduate institutions and reinforce SOT efforts in shaping the future of toxicology.

Tom Lewandowski, PhD, DABT, ATS
Coordinator, Domestic ToxScholar Program
SOT Education Committee
Meetings of Interest

USDA Office of Risk Assessment and Cost-Benefit Analysis and National Capital Area Chapter of the Society for Risk Analysis,
SCIENCE, POLICY AND RISK FORUM
September 15, 2015
1:30 – 3:00 pm
Room 4433, U.S. Department of Agriculture South Building

On Objective Risk

Dr. Dima Yazji Shamoun, Research Fellow, Regulatory Studies Center, Mercatus Center, George Mason University

Objectivity in the science of risk plays a monumental role in the projection of the benefits from health and safety regulations, which constitute the majority of total reported benefits of all federal regulations. Claims concerning the accuracy of regulatory risk assessments have been un-testable so far in that they focus on whether a risk assessment over- or underestimates the risk of exposure to certain hazards; yet such claims rely on an implication that the true level of risk can be known. This presentation proposes moving the debate from the realm of the un-testable to the realm of the testable "process objectivity" of the science of risk. Consistent adherence to a process should yield objective results. There is a sizable body of guidelines and recommendations on sound risk assessment practices produced by the federal government and by various scientific bodies. The proposed process incorporates these guidelines and recommendations and is testable, objective, and - if adhered to consistently - has the potential to shed light on the accuracy of the benefits calculus of major federal health and safety regulations.

Attend via webinar: Reserve your Webinar seat now at: Registration URL:
https://attendee.gotowebinar.com/register/4483415161835866882
Webinar ID: 148-082-435

Attend in person: Please register by contacting Jennifer Lohr at jlohr@oce.usda.gov or 202-720-8024.

USDA employees may enter the building at the Wing 1 entrance, located directly above the Smithsonian Metro station. All others must bring a valid government picture ID and enter through Wing 3, located on Independence Ave, between 12th and 14th Streets. When exiting the Smithsonian Metro station turn left, the Wing 3 entrance is half way down the block. For escort to the forum, please have guards call Teresa Pickett Wade at 202-720 8022. For further information, contact Linda Abbott 202-690-6056 or mail to: labbott@oce.usda.gov.

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Trends in Reported Foodborne Illness in the United States; 1996 - 2013

Mark Powell, Office of Risk Assessment and Cost-Benefit Analysis, U.S. Department of Agriculture

Retrospective review is a key to designing effective food safety measures. The analysis examines trends in the reported incidence of U.S. foodborne illness using both a conventional generalized linear model and penalized B-spline regression. B-spline regression is a semi-parametric, locally-controlled method that makes no assumptions about the form of the trend. To address the sensitivity of B-spline regression to choices about the number and location of join-points called knots, penalized B-spline regression imposes a “roughness” penalty on differences among neighboring B-spline regression coefficients. The optimal degree of smoothing is determined based on statistical model selection criteria (e.g., generalized cross-validation). The result is a flexible, smooth curve that avoids over-fitting the data, while providing a statistical test for trend. The findings indicate a lack of evidence for continuous reduction in foodborne illnesses in the U.S. during 1996-2013.

Attend via webinar: Reserve your Webinar seat now at: https://attendee.gotowebinar.com/register/8601960319600971778
Webinar ID: 114-452-323

Attend in person: Please register by contacting Jennifer Lohr at jlohr@oce.usda.gov or 202-720-8024.

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Workshop: Interindividual Variability: New Ways to Study and Implications for Decision-Making, September 30 – October 1, 2015, Washington DC

The workshops sponsored by NIEHS (National Institute of Environmental Health Sciences) bring together participants from government, industry, nongovernmental organizations, and the academic community to explore the potential for new methods and approaches to advance our understanding of environmental impacts on human health. The free workshops are held in Washington DC (and webcast) twice per year and consist of presentations from leading researchers and policy experts, interactive panel discussions and Q&A sessions, and networking opportunities over lunch and at breaks.

The next workshop sponsored by NIEHS will take place on September 30 - October 1 and will focus on Interindividual Variability: New Ways to Study and Implications for Decision-Making. Within any population, factors such as heritable characteristics, stress, body weight, and genetics can influence the type and degree of response that people may have to environmental stressors. Accounting for this interindividual variability is a challenge for decision makers tasked with setting chemical safety regulations. Presentations, panel discussions, and Q&A sessions will focus on topics such as:

- *in-vitro* toxicology methods using highly diverse cell lines;
- *in-vivo* methods using highly diverse animal populations;
- epidemiologic analytical approaches which explore mediators within the causal pathway.

The workshop will take place in Washington DC and will be webcast. For more information and to register, please visit: [http://nas-sites.org/emergingscience/meetings/interindividual-variability/](http://nas-sites.org/emergingscience/meetings/interindividual-variability/).

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FutureTox III, November 19 – November 20, 2015, Arlington, VA

FutureTox III is focusing on building the high throughput risk assessment paradigm, taking the science of *in vitro* data and *in silico* models forward. Thus, the conference will explore the central question: What progress is being made to address challenges in applying and implementing the emerging “big data” toolbox for risk assessment and regulatory decision-making?

The overarching objectives of this meeting are toward:

- Advancing the cornerstones for high-throughput risk assessment through exploration and discussions with multiple stakeholders
- Taking 21st century toxicity testing (TT21C) *in vitro* and *in silico* models forward while reducing reliance on animal testing
• Exploring progress and identifying challenges in implementing the emerging “big-data” toolbox for risk assessment and regulatory decision-making.

The conference will include plenary sessions by invited speakers, a poster session, and topical breakout groups. For more information, to submit an abstract, and to register, please visit the FutureTox III website (http://www.toxicology.org/events/shm/cct/futureToxIII.asp).

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Society of Risk Assessment Annual Meeting, December 6 – December 10, 2015, Arlington, VA

The theme of the meeting is “Empires of Risk Analysis: Science, Policy, and Innovation”. There are many fantastic opportunities planned, some new and some that we enjoy every year. The preliminary program, registration form, pre-conference workshops, and program schedule will be posted on the society’s website (http://www.sra.org/events/sra-2015-annual-meeting) as they become available. Nancy Beck and Pamela Williams (NCAC-SOT) will chair Session T4-C, a Joint SRA/SOT Roundtable: Discussion on TSCA Reform on Tuesday, December 8, Room C 3:30 – 5:00 PM.

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WHAT’S NEW IN TOXICOLOGY?

Commentary: AOPs are crucial to the ongoing paradigm shift in toxicology

By Erik R. Janus
President, M³ Technical & Regulatory Services
Vice President, National Capital Area Chapter

There’s no question that the field of toxicology is currently undergoing a paradigm shift that will modify the way that “conventional” testing approaches are utilized to demonstrate safety profiles for chemicals and finished goods in the marketplace. This paradigm shift has been made possible by technical advances in bioinformatics, molecular & systems biology, toxicogenomics and computational & cellular toxicology and “envisioned” by the seminal 2007 report from the National Research Council (NRC 2007). This shift is moving the focus towards understanding “pathways of toxicity” by characterizing a chemical’s mode-of-action (MOA) through the identification of key events at the molecular, cellular, and tissue/organ level – perturbation of which leads to some undesired, “adverse” outcomes. This modern approach is very different from the current approach to toxicity testing, which relies on identifying observable effects through a complex assembly of study types using whole animals, where some change in pathology or clinical indicator is assumed to be representative of
some undesired, “adverse” state (i.e., as NRC says, “indicative of a disease state”). As such, it is necessary to capture MOA data in a clear fashion that is amenable to the identification of key events that can be then tested empirically (using existing or yet-to-be-developed methods) to demonstrate the quantitative relationship between said events and adverse outcome and eventually develop predictive toxicology models. Such efforts are referred to as MOA frameworks.

Examples of MOA frameworks found in the literature include the MOA/Human Relevance Framework (Meek et al., 2003; Boobis et al., 2006; Boobis et al., 2008), developed jointly by the International Program on Chemical Safety and the International Life Sciences Institute (ILSI), the Key Event Dose-Response Framework (also developed by ILSI) (Julien et al., 2009), “Pathways of Toxicity” as described by Kleensang et al. (2014), and the Adverse Outcome Pathway approach as described by Ankley et al. (2010) and widely embraced in Europe by the OECD (See Figure 1 for an easy visualization of how they compare). It is this latter approach that appears to have the greatest potential for internationally harmonized use, as evidenced by the young, but slowly growing, AOP-Knowledgebase (https://aopkb.org/).

The AOP-KB is actually an information hub that not only includes a repository for AOPs (AOP-Wiki) and a graphical interface to explore them (AOP Explorer). Also under development is a tool to use quantitative AOPs (Effectopedia) as well as the “intermediate effects” database that promises to place AOP information in a regulatory context. At current moment, only the AOP-Wiki is operational, where completed, in progress and draft AOPs awaiting public comment are stored. An example of an AOP for estrogen receptor antagonism is shown in Figure 2.

OECD became the primary driver for the development of the AOP-KB in 2012, when the program was announced. In order to add information to the AOP-Wiki, a proposal is sent to the OECD Secretariat and these proposals are then vetted and managed by the European Advisory Group on Molecular Screening and Toxicogenomics in coordination with the IPCS Mode of Action workgroup activity. Proposals are reviewed and accepted twice a year and collaborations across industry, academia and government are encouraged (See http://www.oecd.org/chemicalsafety/testing/adverse-outcome-pathways-molecular-screening-and-toxicogenomics.htm for more information on submitting AOP proposals, including a flow chart and guidance documentation).

In order to populate AOP-Wiki with a sufficient amount of pathways and data in order to enable its functionality as an international research and analysis tool, it is imperative that practitioners get involved in collaborative projects. In essence, this a clarion call for members of the various scientific disciplines to “roll up their sleeves” and get involved in establishing AOPs in their field of expertise.

![Figure 1](http://alttox.org/mapp/emerging-technologies/pathway-based-toxicology/)

Figure 1. Graphical depiction of the various available MOA frameworks. Courtesy of AltTox.org
Figure 2. An example of an AOP from the AOP-Wiki (“Estrogen receptor antagonism leading to reproductive dysfunction”). Reproduced from: https://aopkb.org/aopwiki/index.php/Aop:30.

Citations:


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MEMBERS ACCOMPLISHMENTS CORNER (March through August, 2015)

At NCAC-SOT we like to acknowledge the accomplishments of our members. The Newsletter Editor will send an email to the members asking to share their publications, presentations and other accomplishments from the last number of the newsletter to date to be included in the next number. We are happy to spread the word of your successes, so please take advantage of this opportunity to share them with your colleagues.

Publications and Presentations

Presented in alphabetical order based on the author who is member of the NCAC-SOT (underlined)

Book chapters


Manuscripts


**Poster presentations**
Irwin, W., Liccione, J. Organelle Imaging Toxicology. 54th Society of Toxicology Meeting, March 2015, San Diego, CA.

**Lectures**
Costin, G.-E. 21st Century Methods – Assessing Acute Toxicity While Avoiding Animals. Western Plant Health Association Summer Regulatory Conference, July 2015, Sacramento, CA, USA.

**Courses**

**Ph.D. Thesis Defense**

Our colleague, Shelby Skoog, NCAC Postdoctoral Representative, successfully defended her PhD dissertation in July 2015. Shelby conducted her research at the FDA’s Center for Devices and Radiological Health, Division of Biology, Chemistry and Materials Science. Her dissertation was titled “In Vitro Biocompatibility Assessment of Microstructured and Nanostructured Surfaces for Medical Device Applications.” Shelby received her Ph.D. from the UNC-Chapel Hill-NC State University’s Joint Program in Biomedical Engineering under the mentorship of Professor Roger Narayan; Peter Goering of FDA-CDRH served as co-mentor. Dr. Skoog is continuing at CDRH as a postdoctoral fellow for a research project designed to assess the biological impacts of degradants evolving from biodegradable polymeric medical device materials. Congratulations to Shelby!

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