The President’s Message

Fellow DTSS Members:

Our specialty section continues to do well as evidenced by the number of members and annual awards. What a great turnout at the 2013 Annual Meeting (I’m sorry travel restrictions prevented me from attending)! I hope to see you all in Phoenix in March.

During the last annual meeting our specialty section organized and presented a CE course entitled, “The REACH Regulation and Safety Assessment Approaches for Chemical that Come in Contact with the Skin,” co-chaired by Jens Thing Mortensen and Jon Heylings. Many thanks to their hard work, and to the speakers. Thanks also to the members, students and post-docs for attending the DTSS reception in San Antonio this year (75 attendees). Students and post-docs represent the future of dermal toxicology and our specialty section. I’m asking DTSS members to do their best to recruit more members so we can continue to grow.

I would like to take this opportunity to thank Carol Sabourin for her dedicated leadership as DTSS President this past year. Carol now transitions to Past-President and remains actively involved in the DTSS leadership. Many thanks to the retiring executive committee officers for their time and effort throughout the year; John Harbell as Senior Counselor, Chep Yego as Postdoctoral Representative, and Swetha Inturi and Anand Ravindran as Student Representative. Finally, we thank our award sponsors, Battelle, Sinclair Research, Stratacor, and MB Research Laboratories. Thanks also go out to George DeGeorge for heading up the membership Committee.

Sincerely,

John S. Graham, Ph.D., M.B.A., DABT
President, Dermal Toxicology Specialty Section
The Past President’s Message

The 52nd anniversary SOT meeting in San Antonio drew attendees from across the globe. Our specialty section reception was well attended by members including a number of students and post-docs.

I am delighted to have served as President of our Specialty Section this past year and appreciate all the support of my fellow officers. I look forward to an exciting year with John Graham as our new President and Jens Mortensen as Vice President. We had an excellent slate of officers and are joined by Frank Barile as our new Vice-President Elect and Adrienne Black as our new Councilor. Congratulations and welcome to both of you. Many thanks to Councilor John Harbell for his service over the past two years; Mike Babin will continue as Senior Councilor and will coordinate awards. He is joined by our newly elected Councilor, Adrienne Black. We are fortunate to have Jill Harvilchuck continue as Secretary-Treasurer. In addition, I want to thank our Post Doctoral Representative, Chep Yego and Student Representatives, Swetha Inturi and Anand Ravindran for preparing the poster and brochure for the annual meeting; excellent work! Special thanks to Jeff Yourick, my predecessor, who served as Past-President and Councilor this past year.

I would also take this opportunity to acknowledge our award sponsors: Battelle for providing $5,000 for two student research awards, Stratacor for providing $500 for the graduate post-doctoral abstract award, Sinclair for providing $500 for the student abstract award, and MB Research Laboratories for providing a Kindle Fire to the winner at the student reception. We appreciate their past and continued support. There were many excellent proposals and nominations for awards this year; please submit those applications in January.

Finally, and most importantly, the DTSS would not exist without the continued support of our members. Presentation of your original research at our sponsored sessions provides an opportunity to showcase your work. I look forward to seeing all of you again in next year.

Carol Sabourin
DTSS Past-President

The Mission of DTSS

The objectives of the Dermal Toxicology Specialty Section (DTSS) are to provide a forum for the interaction of individuals involved in risk assessment, pharmacokinetics, dermal penetration/absorption, hypersensitivity and dermal toxicity, regulatory issues, basic skin biology and other professionals working in the field of dermal research. Members who wish to receive more information on the specialty section should contact John Graham or any of the other Officers by e-mail.
Upcoming Conferences & Events

Nov 3-6, 2013: American College of Toxicology 34th Annual Meeting, San Antonio, TX, USA
www.actox.org/am/am2013/index.asp


January 31, 2014: Deadline for Early Bird Registration for SOT meeting
February 20, 2014: Deadline for Housing Registration for SOT meeting
February 28, 2014: Deadline for Standard Registration for SOT meeting
February 28, 2014: Deadline for Cancellations for SOT Meeting

April 23-26, 2014: Perspectives in Percutaneous Penetration, 14th International Conference, La Grande Motte, France (www.pppconference.org)


June 2-4, 2014: International Meeting of International Society for Biophysics and Imaging of the Skin, Mystic, CT, USA (www.i-s-b-s.org)

Aug 24-28, 2014: 9th World Congress on Alternatives and Animal Use in the Life Sciences, Prague, Czech Republic (www.wc9prague.org)
Thank you to our sponsors:

Membership and Award Opportunities

DTSS Members – Would you like to become more active in DTSS?

If you have any suggestions or recommendations on how to make our specialty section better or better able to serve your needs, please email your suggestions to:

john.s.graham1.civ@mail.mil

Membership Drive and Award Opportunities

As always, we encourage you to apply for membership at this website: http://www.toxicology.org/ISOT/SS/dtss/membership.html. DTSS members have the opportunity to apply for a number of DTSS sponsored awards. The Best Paper Award is awarded in recognition of an exceptional recent peer-reviewed publication in the field of dermal toxicology and pharmacology. The Sinclair Student Abstract Award and the Stratacor-Port Royal Postdoctoral Abstract Award recognize outstanding student and postdoctoral candidates for their contribution to dermal toxicology. Two Battelle Student Research Awards are awarded to graduate students for use in research projects involving dermal toxicology. The DTSS 2013 award winners will be announced at the 2013 SOT Annual Meeting.
Please forward this newsletter to your colleagues that might be interested in becoming a member of DTSS!

Graduate Student Report

Thank you to everyone who stopped by the DTSS Historical Highlights poster during the Student/Postdoctoral Mixer at the 52nd Annual Meeting. We enjoyed discussing the benefits of obtaining DTSS membership with all of you.

DTSS provides a wonderful opportunity for young scientists not only to get exposed to the cutting-edge research in the field of dermal toxicology but also build connections with leading skin researchers from academia, industry and government. Most of all, DTSS sponsored a list of awards for graduate students in recognition of their outstanding research.

Students and postdocs with accepted abstract for presentation at the 2014 Annual Meeting are eligible to apply for the DTSS Student and Postdoctoral Awards. With a goal of providing funds for projects involving dermal toxicology, two research awards sponsored by Battelle are also available exclusively for students. Apart from these specific student awards, all DTSS members are encouraged to apply for the DTSS Annual “Paper of the Year” Award.

We would like to thank all graduate students and postdoctoral fellows that submitted their abstracts and proposals for the DTSS awards this year. We strongly encourage you to submit your best work for 2013 award season!

For more information in the award description and deadlines for submission, please visit the DTSS website at http://www.toxicology.org/ISOT/SS/dtss/awards.asp

To find information on becoming a member or to renew current membership of DTSS, please visit http://www.toxicology.org/ISOT/SS/dtss/membership.html

Graduate Student Representative
Shuxi Qiao (qiao@pharmacy.arizona.edu)
Treasurer’s Report:
By Jill Harvilchuck

The net assets as of May 2013 are $11,521. This amount includes $15,198 carried over from the previous year, income received and $5000 received from Battelle for the Battelle Research Award. The income included 2013 meeting registration specialty section allocation of $981 (2013 dues and interest are not yet included). The cost of the DTSSS reception at the 2013 Annual Meeting was $2745 and the cost of the awards and plaques was $6581.

<table>
<thead>
<tr>
<th>Ordinary Income/Expense</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Income</td>
<td></td>
</tr>
<tr>
<td>Contributions</td>
<td>5,000</td>
</tr>
<tr>
<td>Membership Dues</td>
<td></td>
</tr>
<tr>
<td>Misc. Income</td>
<td></td>
</tr>
<tr>
<td>Registration</td>
<td>981</td>
</tr>
<tr>
<td>Interest</td>
<td></td>
</tr>
<tr>
<td>Total Income</td>
<td>5,981</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Expense</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Awards - Sections</td>
<td>6,350</td>
</tr>
<tr>
<td>Plaques</td>
<td>231</td>
</tr>
<tr>
<td>Contributions</td>
<td></td>
</tr>
<tr>
<td>Executive Meetings</td>
<td>158</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>175</td>
</tr>
<tr>
<td>Newsletter</td>
<td></td>
</tr>
<tr>
<td>Reception</td>
<td>2,745</td>
</tr>
<tr>
<td>Symposia</td>
<td></td>
</tr>
<tr>
<td>Travel</td>
<td></td>
</tr>
<tr>
<td>Web Development</td>
<td></td>
</tr>
<tr>
<td>Total Expense</td>
<td>9,658</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Excess (Deficiency) of Revenue over Expenses</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(3,677)</td>
</tr>
</tbody>
</table>

| Net Assets Beginning of year                | 15,198 |
| Transfers from General Fund                 |   |
| Net Assets After Transfers                  | 15,198 |
| Net Assets End of Year                      | 11,521 |
DTSS awards given out at the DTSS Reception at the 2013 SOT Annual Meeting in San Antonio:

The DTSS awards ceremony was organized by Mike Babin and Carol Sabourin.


The Sinclair Student Award was given to **Anand Ravindran** (The Pennsylvania State University, PA) for the work: Ultraviolet Radiation (UVB)-Induced migration of Skin Dendritic Cell subsets is mediated through TGF-β Signaling.

The Stratacor Post Doctoral Award went to **Daniela M. Leme** (FACULDADE DE CIÊNCIAS FARMACÊUTICAS DE RIBEIRÃO PRETO (FCFRP/USP), RIBEIRÃO PRETO-SP/BRAZIL) for the work: The use of 3D human dermal equivalents to assess genotoxicity of textile dyes.

The Battelle Student Research Awards were presented by Dr. Carol Sabourin to two students:

**Amy M. Sharma** (Pharmacy, University of Toronto, Ontario, Canada): Nevirapine-induced skin rash is caused by a reactive sulfate metabolite formed in the skin.


**DTSS Awards available for 2014:**
Please, visit the Dermal Toxicology Specialty Section website for information about available awards for 2014:

- Dermal Toxicology Specialty Section Annual “Paper of the Year” Award
- Dermal Toxicology Specialty Section Sinclair Student Award
- Dermal Toxicology Specialty Section Battelle Student Research Award
- Dermal Toxicology Specialty Section Stratacor Post Doctoral Award

Further information can be obtained from DTSS Councilor Mike Babin, to whom the applications should also be sent. Deadline for the applications are January 31, 2014.
2014 SOT Annual Meeting
Advanced Continuing Education Course Endorsed by DTSS

Photosafety Evaluation of Pharmaceuticals without Testing in Animals

Chairpersons:
Lewis B. Kinter, AstraZeneca Pharmaceuticals
Abby Jacobs, US Food and Drug Administration

Advances in understanding of photochemistry, photoreactivity, and phototoxicity of pharmaceuticals offer for the first time the opportunity to appropriately evaluate the potential for photosafety risk in humans while minimizing or eliminating phototoxicity testing in animals. Only compounds that absorb light in the visible and UV ranges pose photosafety risk. Photoreactivity assays to detect generation of reactive oxygen species (ROS) and in vitro bioassays to detect phototoxicity (3T3-NRU and 3D-skin assays) offer high sensitivity (e.g. few false negatives) but lower selectivity (higher numbers of false positives) with which to predict phototoxicity potential in humans. However, to support an integrated assessment strategy, it is most important these assays show high sensitivity, because negative assay results are usually conclusive and do not warrant further photosafety evaluation, and it is not essential that positive assay results always predict a clinically relevant phototoxic response. Further, the fact that these assays measure entirely different endpoints lowers the probability of multiple ‘false positive’ findings. Finally, compounds that both absorb in the relevant spectrum and test positive in chemical and/or in vitro assays can be evaluated for photosafety in clinical trials with proper precautions, without intermediate in vitro or animal testing if the sponsor chooses (ICH M3(R2) 2010). The session will be of broad interest to academic, industry, regulatory, and consultant toxicologists concerned about current status of photosafety testing and/or advances in nonclinical safety assessment that reduce or replace animal testing (e.g. 3Rs).

1. Abigail Jacobs, US Food and Drug Administration

Presentation Title: Introduction

Presentation Description: The presentation will provide the scientific and regulatory background underpinning the principles of modern photosafety assessment for pharmaceuticals, and will introduce the subsequent speakers and their topics.

...continued on page 9.
2. Satomi Onoue, Ph.D., Department of Pharmacokinetics and Pharmacodynamics, School of Pharmaceutical Sciences, University of Shizuoka; 52-1 Yada, Suruga-ku, Shizuoka 422-8526, Japan

Presentation Title: Chemical Methods for Detection of Photoreactive Pharmaceuticals

Presentation Description: The initial consideration for assessment of photoreactive potential is whether a compound absorbs wavelengths between 290 and 700 nm. Absorption with a molar extinction coefficient (MEC) less than 1000 L mol⁻¹ cm⁻¹ is not considered to result in a photosafety concern. Excitation of molecules by light can lead to generation of reactive oxygen species (ROS), including superoxide and singlet oxygen via energy transfer mechanisms. Although other mechanisms for phototoxicity are known (e.g., formation of photoadducts or cytotoxic photoproducts), even in these cases, it appears that ROS are typically generated as well. Thus, photoabsorption and ROS generation following irradiation with UV or visible light are critical indicators of phototoxic potential. Validation of a ROS assay to detect photo-induced ROS generation will be presented.

3. Roderick Todd Bunch, Bristol-Myers Squibb

Presentation Title: In Vitro Methods for Detection of Phototoxic Pharmaceuticals

Presentation Description: The most widely used in vitro assay for phototoxicity is the “in vitro 3T₃ Neutral Red Uptake Phototoxicity Test” (3T₃ NRU-PT) for which a guideline is available. This is currently considered the most appropriate in vitro screen for soluble compounds that are not exclusively UVB absorbers. Although the formal ECVAM validation exercise conducted on this assay indicated a sensitivity of 93% and a specificity of 84%, experience within the pharmaceutical industry suggests a much lower specificity. The original OECD protocol was not validated for pharmaceuticals specifically. Thus, some modifications to the original OECD protocol have been proposed to address the low specificity observed with drug substances. The sensitivity of the 3T₃ NRU-PT remains unquestioned, and if a compound is negative in this assay it would have a very low probability of being phototoxic in humans. The presentation will focus on current in vitro methods for phototoxicity assessment including standard assay conditions (per OECD guidelines) and proposed revised testing methods for assessment of pharmaceuticals. In addition, the strengths and weaknesses of the available methods and their predictivity will be reviewed.

...continued on page 10.
4. Helena Kandarova, MatTek In Vitro Life Science Laboratories, Mlynské Nivy 73, 821 05 Bratislava

Presentation Title: In Vitro 3-Dimensional Skin Models for Testing Phototoxic Potential of Dermal Formulations

Presentation Description: Reconstructed human skin models, with the presence of a stratum corneum, permit testing of various types of topically applied materials ranging from neat chemicals to final clinical formulations. The models developed to date measure cell viability in the tissue preparation with and without irradiation. While such models appear to be capable of detecting known human dermal phototoxicants, the sensitivity of some models with respect to the dose eliciting a positive response can be lower than in the in vivo human situation. Consequently, it is important to understand the sensitivity of any model selected and, if appropriate, to adjust the assay conditions accordingly (e.g., testing higher strength formulations, increasing exposure time). The presentation will focus upon current 3-D skin models for the assessment of the phototoxicity potential of dermal formulations. The presentation will describe the protocols and the strengths, weaknesses, and predictivity of the various models.

5. Hon Som Ko, US Food and Drug Administration

Presentation Title: Evaluation of Phototoxicity of Pharmaceuticals in Clinical Trials

Presentation Description: There are various options for collecting photosafety date in humans, if warranted, ranging from standard reporting of adverse events in clinical studies to a dedicated clinical photosafety study. The precise strategy is determined on a case-by-case basis. The presentation will focus upon systemically administered drugs and topically applied drug formulations for evaluation of photoirritation and photoallergy reactions in humans in the presence of UV or visible light, and provide details on strategy and clinical protocol options.

6. Lewis B. Kinter, AstraZeneca Pharmaceuticals

Presentation Title: Concluding Remarks
The following is a list of publications self-reported by DTSS members that were published in 2012-2013:


Corsini E, Galbiati V, Nikitovic D, Tsatsakis AM. Role of oxidative stress in chemical allergens induced skin cells activation. Food Chem Toxicol 2013 Feb 27.


...continued on page 12.


Xu G, Hughes-Oliver JM, Brooks JD, Yeatts JL, Baynes RE. Selection of appropriate training and validation set chemicals for modeling dermal permeability by U-optimal design. SAR QSAR Environ Res 2013, 24(2):135-156.
Carol Sabourin (DTSS President)  
Marc Tayman (Sinclair Research)  
Anand Ravindran  

Sinclair Student Award

---

Carol Sabourin  
Daniela Leme  
Mike Babin (Senior Counselor)  

Stratacor Post Doctoral Award

---

Carol Sabourin  
Amy M. Sharma  
Mike Babin  

Battelle Student Research Award 2013
Carol Sabourin
Shuxi Qiao
Mike Babin

Battelle Student Research Award 2013

George DeGeorge
Neera Tewari-Singh

Swetha Inturi

Battelle Student Research Award 2012

DTSS Best Paper of the Year 2013
Vincent Ramirez
Battelle Student Research Award 2012

Jens Thing Mortensen
DTSS Vice President

Marc Tayman
(Vice President, Business Development, Sinclair Research) with past DTSS President Jeff Yourick