

NAME OF SPECIALTY SECTION Dermal Toxicology

ANNUAL REPORT: 2014-2015

May 1, 2014 to April 30, 2015

I. Officers/Committees:

<u>Officers</u>	<u>2014-2015</u>	<u>2015-2016</u>
President:	Jens Thing Mortensen	Jeffrey Yourick
Vice President:	Jeffrey Yourick	Doug Learn
Vice President-Elect:	Vacant	Zbigniew Wojcinski
Secretary/Treasurer:	Jill Harvilchuck	Jill Harvilchuck
Past President	John S Graham	Jens Thing Mortensen
Senior Councilor:	Adrienne Black	Neera Tewari Singh
Junior Councilor:	Neera Tewari Singh	Margaret Kraeling
PDA Representative:	E Chepchumba "Chep" K Yego	Shuxi Qiao
GSLC Representative:	Shuxi Qiao	Carrie Mae Long
Vice GSLC Representative:		Laila Al-Eryani

Committees: If applicable. N/A

II. Activities:

2015 SOT Annual Meeting Reception was held in San Diego, California on Wednesday, March 25, 2015. Approximately 60 people were in attendance. Dr. Mortensen called the meeting to order at 6:15 PM on Wednesday, 25 Mar 15.

Business Meeting Speaker: Dr Mortensen made some general announcements regarding DTSS business and upcoming events. Dr. Yourick solicited for DTSS member support to contribute to the upcoming 2016 program proposals. The Meeting Minutes are attached (see Attachment I).

Awards:

The awards were presented by Dr. Adrienne Black (Councilor):

DTSS Sinclair Student Award: Laila Al-Eryani

Al-Eryani, Laila; Pan, Jianmin; Rai, Shesh N.; States, J. C. MICRORNA PROFILE CHANGES IN IMMORTALIZED HUMAN KERATINOCYTES AFTER LOW ARSENIC EXPOSURE

DTSS Stratacor Postdoctoral Award: Changzhao Li

Li, Changzhao, Srivastava, Ritesh K.; Weng, Zhiping; Chaudhary, Sandeep C; Afaq, Farrukh; Athar, Mohammad. ROS-MEDIATED INDUCTION OF UPR SIGNALING UNDERLIES PATHOGENESIS OF LEWISITE-INDUCED SKIN LESIONS.

DTSS Annual "Paper of the Year" Award: Yoke-Chen Chang

Therapeutic potential of a non-steroidal bifunctional anti-inflammatory and anti-cholinergic agent against skin injury induced by sulfur mustard Yoke-Chen Chang, James D.Wang, Rita A. Hahna, Marion K. Gordon, Laurie B. Joseph, Diane E. Heck, Ned D. Heindel, Sherri C. Young, Patrick J. Sinkoe, Robert P. Casillas, Jeffrey D. Laskin, Debra L. Laskin, Donald R. Gerecke. Toxicol. Appl. Pharm. 280:236-244, 2014.

Battelle Research Awards: Carrie Long and Dongxi Xiang

Carrie Long: Increased Expression and Immunoregulatory Potential of microRNA 210 in a Murine Model of Dermal TDI Sensitization

Dongxi Xiang: A New Paradigm in Drug Development for Targeting Tumourigenic Cells

2015 SOT Annual Meeting Courses/Sessions: none were sponsored

Endowment Fund Details: DTSS does not have an Endowment Fund and there was no discussion related to an Endowment Fund at this time.

Newsletters: Fall DTSS 2014 Newsletter (see attached)

Teleseminars: N/A

White Papers: N/A

Contributions to SOT website: N/A

Other Specialty Section 2014-2015 Activities:

Meeting Minutes: Officer's Business meeting, Monday, March 23, 2015

Agenda:

1. Plan DTSS member reception Wednesday: Agenda and sharing of roles
 - a. DTSS awards – Recipients, certificates, cheques, stand-up performances
 - b. Student/Post Doc raffle - MB Research sponsored prize

- c. Officers rotating off
- 2. Other activities at the SOT meeting
 - a. DTSS poster attendance Monday 11:45am-12:15pm
 - b. Event “Meeting the Leaders” Tuesday 3-4pm
 - c. Skin poster session Tuesday 1-4:30pm
- 3. Finances
- 4. Sponsorship from Charles River Laboratories – How do we put it to good use?
- 5. Dermal toxicology session proposals for SOT Annual Meeting 2016
- 6. Election result, new DTSS officers and student/postdoc representatives 2015-16
- 7. Any other business (old or new)

ATTACHMENT 1

Dermal Toxicology Specialty Section Reception - Minutes

SOT 54nd Annual Meeting

Wednesday, March 23, 2015 6:00 – 7:30 pm

Welcome and Introduction of Current Officers – Jens Thing Mortensen

Jens Thing Mortensen (President), Jeff Yourick (Vice President), Jill Harvilchuck (Secretary-Treasurer), Neera Tewari-Singh (Junior Councilor), Adrienne Black (Senior Councilor), Amy Sharma, Anil Jain (Post-Doctoral Representatives), Shuxi Qiao (Student Representative), John Graham (Past-President)

Thanks to Retiring DTSS Officers – Adrienne Black, John Graham

Jens thanked the outgoing officers for their past service: Adrienne Black as Senior Councilor and John Graham as Past President/Councilor.

Introduction of New 2016 DTSS Officers – Jens

Jeff Yourick (President), Doug Learn (Vice President), Zbigniew Wojcinski (Vice President-Elect), Jill Harvilchuck (Secretary-Treasurer), Neera Tewari-Singh (Councilor), Margaret Kraeling (Councilor), Jens Thing Mortensen (Past President/Councilor)

Financial update – Jill Harvilchuck

The net assets at the end of the year are \$12,916. This amount includes \$14,096 carried over from the previous year and income received. The income included contributions of \$2500 and registration fees of \$1300. The cost of the DTSS reception at the 2014 Annual Meeting was \$3129 and the cost of the awards and plaques was \$1850.

Scientific Program Proposals for 2016 – Jeff Yourick

Jeff announced that the deadline for proposals, symposia, workshops, and CE courses for the 2015 meeting is April 30, 2015 and asked that anyone with an idea for one of these programs to contact him as soon as possible. In addition, DTSS will have an incentive program for DTSS members that successfully get a program proposal accepted for the 2016 SOT meeting.

Awards – Adrienne Black

The awards were presented by Dr. Adrienne Black (Councilor):

DTSS Sinclair Student Award: Laila Al-Eryani

Al-Eryani, Laila; Pan, Jianmin; Rai, Shesh N.; States, J. C. MICRORNA PROFILE CHANGES IN IMMORTALIZED HUMAN KERATINOCYTES AFTER LOW ARSENIC EXPOSURE

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Student/Mixer Raffle: George DeGeorge

The Graduate Student/Post-doc mixer was held Sunday, March 22, from 7:30 – 9:00 pm. Attendees of the mixer entered into a raffle for a Kindle Fire, with the drawing to take place at the DTSS reception. Students also had a chance to enter the raffle if attending the DTSS reception. The student had to be present at the reception to win the prize. The winner of the drawing was presented with the Kindle.

Closing and Thank you – Jens Thing Mortensen

DTSS Officer Meeting Minutes

9 December 2014

Attendees: Jens Thing Mortensen, Doug Learn, Adrienne Black, Jeff Yourick, Jill Harvilchuck

Absent: Neera Tewari-Singh, Shuxi Qiao, Anil Jain, Amy Sharma

1. Locate willing candidates for next year's DTSS officer group (please, think of suitable DTSS members who might volunteer)

- Need candidate for councilor and VP Elect
 - o Councilor: Jens contacted (and will contact) people that may be potentially interested; Jeff Yourick knows someone who would be willing to run as well, Doug will reach out to a few people to see if they are interested
 - o VP Elect: Doug will reach out to a few people
 - If we don't get a VP Elect, Jens will ask SOT to send out an email to all of DTSS members

2. Promote generation of dermal topics for future SOT annual meetings. Specific topics? Incentives to be active?

- All will begin thinking of topics for future meetings
- Doug: incentives to be active for submitting an idea that gets accepted – maybe give free membership to specialty section for submitting viable idea for topic and if gets accepted maybe give them a year's membership for SOT
- First five people who submit viable idea we support their DTSS membership
- Jeff: Promoting special recognition at DTSS reception for viable proposals that get submitted at SOT – give them certificate (for those that submit early)
- Need to advertise it to the DTSS members (Jens and Doug will put something together)

3. Advertise the DTSS awards, so we will get as many applicants as possible.

- Adrienne put together draft sent to everyone this morning (Attachment 1 below)
- Adrienne will send out to the DTSS membership if don't hear comments back from DTSS officers
 - o Will send out shortly (before the holidays)
 - o Will send out repeat email after holidays if still don't have entries for post-doc award
- To date, received one entry for the post doc award to date

Attachment 1 (per Adrienne Black)

Dear DTSS members,

REMINDER: The DTSS award deadlines for the 2015 Annual SOT meeting are on January 31, 2015.

Please consider submitting an entry for the student, postdoctoral, Best Paper of the Year or Battelle Research awards.

Descriptions and requirements are provided below.

Student and Postdoctoral Awards:

These awards recognize outstanding graduate student and postdoctoral candidates for their contribution to advancing the understanding of skin toxicology and pharmacology. The awards consist of a plaque and check. The winners will be announced at the DTSS reception at the SOT Annual Meeting.

- Graduate student: \$500 award
- Postdoctoral: \$500 award

To apply: please submit a copy of the abstract in electronic form (Word doc) accepted by the SOT for presentation at the Annual Meeting

Best Paper of the Year Award

The DTSS Annual Paper of the Year Award is in recognition of an exceptional recent publication in the field of skin toxicology and pharmacology. To be eligible, paper must have been published or in press in a peer reviewed journal during the period of August 1 to July 31 and first-authored by an SOT member. The winner will be announced at the DTSS reception at the SOT Annual Meeting.

- Authors: \$500 award

To apply: please submit a copy of the publication in electronic form.

Battelle Student Research Award:

This award, sponsored by Battelle, presents a check for \$2500 to each of two students for use in research projects involving dermal toxicology. The winners will be announced at the DTSS reception at the SOT Annual Meeting.

- \$2500/per student – 2 awardees

To apply: please submit the title of the project, specific aims of the project, approach to be used in the project, and anticipated outcome and impact of the project.

For additional information or submissions, please contact Adrienne Black, DTSS Senior Councilor (adrienne159@gmail.com).

Meeting minutes.

DTSS officer group meeting – Tuesday, October 7, 2014 (telecon).

Present: Jeff Yourick, John Graham, Doug Learn, Adrienne Black, Neera Tewari-Singh, Anil Jain, Jens Thing Mortensen.

Apologies: Jill Harvilchuck, Shuxi Qiao.

Agenda:

1. Newsletter Fall 2014 (Jeff)
2. Awards (Adrienne)
3. Preparation for DTSS members' meeting at SOT 2015 (Jens)
4. Finances (Jill)
5. Potential scientific activities, incl. session proposals for future SOT meetings (All)
6. Student/postdoc activities (Anil)
7. AOB

Re 1:

Jeff has received parts of input for the Fall 2014 newsletter from DTSS members and from DTSS officers.

Action: **Jeff** intends to collate and distribute the newsletter within the next week or two. **DTSS officers** who may not yet have delivered according to Jeff's email (Sep 18, 2014), please deliver material to Jeff, including any photos you may have from the DTSS member meeting at SOT 2014 in Phoenix.

Re 2:

Adrienne has been in contact with our sponsors, including new contact person at Sinclair. Our award sponsors intends continue their sponsorship, although we need final confirmation from Sinclair. If this does not come through, DTSS will finance the 500\$ DTSS Sinclair student award. There were no applications for the Battelle student research awards in 2014, so there is still 2x2500\$ available. The future of this sponsorship is uncertain due changes in Battelle organization and policy.

Action: **Adrienne** will advertise the awards in the DTSS newsletter and by email blast to the DTSS members in December/January to prompt as many applications as possible.

Re 3:

The specialty sections have to submit the budget sheet for the officers' meeting and members' meeting at SOT 2015 in San Diego by Oct 24. We decided for a 10-person round table setting for the officers' meeting (Monday, March 23, 2015 at 6:30-8:00AM) and to budget for approximately 65-70 people for the members' meeting (Wednesday, March 25, 2015 from 6:00-7:30PM, "California dreamin' " menu (mixed meat/vegetable buffet, bartender shared with other specialty sections, microphone in room, award certificates/plaques to be procured from "Carol Sabourin's surce").

Action: **Jens** to fill in and budget sheet and submit to Raul at SOT before Oct 24, after checking financial implication with **Jill**.

Re 4:

Nothing to report.

Re 5:

No specific session suggestions from the DTSS officers at this time. Preparation of session proposals should be started early, despite deadline is April 30, 2015 after SOT 2015. Doug suggested off-line after telecon to create a DTSS award for best/successful dermal session proposal for next year's SOT program. To be considered

Action: **All DTSS officers** to start/continue thinking. **Jeff** to try to include a boxed blurb or similar in the DTSS Fall 2014 newsletter under preparation if possible.

Re 6: Nothing to report.

Re 7: After the telecon it occurred to me that we must soon to look for candidates for next year's DTSS officer group (we need two candidates: Vice president-Elect and Councilor) to run for election before end of 2014.

Action: **All** to think of and propose suitable DTSS member candidates we could encourage to run for election.

Next DTSS officer meeting/telecon: End January/beginning February 2015 when we know about applications for the 2015 DTSS awards, etc.

Jens Thing Mortensen
October 10, 2014

DTSS Officer Meeting Minutes (teleconference) – Tuesday, February 24, 2015

Present: Jeff Yourick, John Graham, Doug Learn, Adrienne Black, Neera Tewari-Singh, Anil Jain, Jens Thing Mortensen, Shuxi Qiao, Amy Sharma, Jill Harvilchuck

Absent: NA

Agenda Items:

Awards, Plaques, Certificates, Checks

- Award winners finalized (Student, Post-Doc, Paper of the Year, Battelle Research Award)
 - o Winners determined by either general consensus of rankings among DTSS officers or if rankings were different, the average was taken
 - o Adrienne will contact winners on behalf of DTSS to see if they will be attending the meeting and to give a short (3 min) talk on their research (no slides).
 - o Jill will get the plaques/certificates made and will see if we can get the checks presented at SOT for the winners.
- Informa award
 - o Adrienne talked to Wally Hayes and he will take care of the award.
- Sinclair award
 - o Jill to find out who and where to send the check to
- Raffle Prize
 - o George DeGeorge will support raffle award again this year, but he doesn't know what it will be yet
 - o Adrienne will contact George again to see if the prize can be added to the DTSS poster. If so, Adrienne will let Shuxi know.

Specialty Section Poster

- Raul asked if we want to have a poster to advertise DTSS. Officers have the opportunity to be present at the poster in the afternoons of the meeting.
- Shuxi has the poster from last year and Shuxi and Anil have volunteered to put the poster together for this year. The poster will also be used for the student/post-doc mixer.
- Officers not on poster from last year need to send title/name to Shuxi for inclusion.
- Doug can get poster printed, if needed.
- Jens will send out an email for officers to volunteer to be present at the poster during the specified times (afternoons and Mon 1145-1215).

Officer meeting

- DTSS Officer meeting scheduled for 0630 Monday 23 March, CC Room 25
- At the officer meeting, scientific session proposals for next year's SOT will be discussed.

DTSS Evening Reception

- Reception is set for ~70 people, with a bartender.
- Jens will have Raul send out an email reminder to members of the time/place for the DTSS reception (~2 weeks prior to the meeting).
- Would be a good idea to have a designated person to take pictures at the reception for the subsequent newsletters (e.g. awardees, etc.)

Officer election results

- VP Elect and Councilor positions were determined. Both have been contacted and the new Councilor will be in attendance at the meeting.
- Need to get certificates for those rotating off of DTSS this year – Jill will get these pulled together

Scientific Session proposals for next year

- There should be an emphasis on promoting session proposals for next year since DTSS had none of this year
- Doug had proposed that we should make an incentive for proposals that are successful for DTSS
 - o Jeff sent an email to Raul last week to be sent to DTSS members discussing incentives, but it has not gone out yet.

Additional Items

- Doug has secured CRL sponsorship for DTSS. Total contribution is still being determined, but funds will be general funds, not tied to a specific item/award.

Executive Council

President

Jens Thing Mortensen, DVM,
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Vice President

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Vice President-Elect

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Past President

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Postdoctoral Representative

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Student Representative

Shuxi Qiao, PhD
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In this Issue:

President's Message.....	p.1
The Mission of DTSS.....	p.3
ICH Photosafety Guidelines.....	p.4
Upcoming Conferences & Events.....	p.6
Membership and Award Opportunities.....	p.9
DTSS Financial Report.....	p.10
DTSS Awards at 2014 SOT Annual Meeting.....	p.11
DTSS Member Publications.....	p.12
Photos from 2014 DTSS Reception.....	p.13



The President's Message

Fellow DTSS members,

We are now just about halfway in the annual cycle of DTSS, delimited by SOT annual meeting 2014 in Phoenix, and the upcoming SOT annual meeting in San Diego March 22-26, 2015. The SOT annual meeting is also the venue for our annual DTSS members' meeting. This is an occasion for toxicologists with an interest in the toxicology of the skin to meet scientific colleagues and friends and to discuss both scientific and general topics. This year the DTSS annual meeting will be on Wednesday 25 March, so all DTSS members, please mark your calendars.

Lots of things are happening in the field of dermal toxicology, both on a scientific and regulatory level: A new ICH S10 guideline on Photosafety evaluation of pharmaceuticals has recently reached ICH Step 4 and is under implementation in the various regions. This guideline is obviously relevant for drugs applied to the skin. The SOT 2014 annual meeting had an interesting session on phototoxicity testing of pharmaceuticals without the use of animals, organized by Lew Kinter and Abigail Jacobs and co-sponsored by DTSS, where different strategies for mainly in vitro-based testing for phototoxic potential of both dermal and systemically applied pharmaceuticals were presented. Generally, as judged from the presentations and posters on dermal toxicology at the SOT meetings it is evident that new and improved in vitro-based methods play an increasing role in the safety evaluation of drugs

The DTSS President's Message, cont.

or chemicals that come in contact with the skin, be it methods to assess transdermal penetration, local skin (or eye) irritation, or phototoxicity. Also, in vitro methods that could provide a realistic assessment of chemicals for allergic skin sensitization potential are being researched. In the European Union the safety of cosmetic products is now being assessed without the use of animal testing, and safety evaluation of chemicals under the European Union's REACH process intends to use as few laboratory animals as possible. Members of DTSS are clearly taking part in this research for such new methods.

When this newsletter is published, the deadline for submission of abstracts for SOT 2015 has just passed. I hope that many DTSS members have submitted abstracts, so there will be a good selection of dermal toxicology posters and presentations at the upcoming SOT 2015. Please note: The Late Breaking Abstract submission period will be from December 5, 2014 to January 12, 2015. I also strongly encourage all members to consider generating scientific session proposals with dermal toxicology content for future SOT meetings, since this would clearly increase the value of the SOT meetings for the DTSS members. The next deadline for submitting session proposals is 30 April 2015 but it is probably not too soon to start putting your ideas and speakers together. Finally, I would like to draw your attention to the awards that are given out by DTSS in collaboration with our sponsors at the annual DTSS member meeting. Please, visit the DTSS website for further details about the various awards and submit your application by 31 January 2015.

I would like to use this occasion to thank my fellow DTSS officers for the work they are doing for our members: John Graham as Past President and Councilor, Jeff Yourick as Vice President, Doug Learn as Vice President-Elect, Jill Harvilchuck as Secretary/Treasurer, Adrienne Black and Neera Tewari-Singh as Councilors, Shuxi Qiao as student representative and Anil Jain as post-doc representative.

Thank you for your continued support of DTSS and I look forward to seeing everyone in San Diego!

Sincerely,
Jens Thing Mortensen, DVM, DABT, ERT
President 2014-15, Dermal Toxicology Specialty Section

Dermal Toxicology

Specialty Section

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 Jens Mortensen or any of the other Officers by e-mail.

DTSS Activities include:

- Presents/sponsors programs and educational activities;
- Acts as a resource to the SOT in dermal toxicology;
- Relates developments in dermal toxicology to SOT activities; and
- Stimulates growth in the science of dermal toxicology.



ICH HARMONISED TRIPARTITE GUIDELINE PHOTOSAFETY EVALUATION OF PHARMACEUTICALS S10

Having reached Step 4 of the ICH Process at the ICH Steering Committee meeting on 13 November 2013 this guideline is recommended for adoption to the three regulatory parties to ICH.

Excerpt from the document related to dermal routes:

Please refer to the complete document for more detail (http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Safety/S10/S10_Step_4.pdf)

Recommendations for Pharmaceuticals Given via Dermal Routes 5.2.1 Assessment of Phototoxicity Potential

If the active substance and excipients do not have MEC values greater than 1000 L mol⁻¹ cm⁻¹ (between 290 and 700 nm), no further photosafety testing is recommended and no phototoxicity is anticipated in humans. For compounds with MEC values of 1000 L mol⁻¹ cm⁻¹ or higher, negative photoreactivity test results (e.g., a ROS assay) can support a decision that no further photosafety assessment is warranted (see Note 5 for exception). If further assessment is warranted, available data on the phototoxicity of chemical class-related compounds should be evaluated, as this could inform on the approach to be taken.

Tissue distribution is not a consideration for the phototoxicity of dermal products. Dermal products are administered directly to the skin and hence, unless they are applied to areas not usually exposed to light, are assumed to be present in light-exposed tissues.

5.2.2 Experimental Evaluation of Phototoxicity and Photoallergy

The 3T3 NRU-PT can be used to assess individually the phototoxicity potential of the API and any new excipient(s), provided that appropriate testing conditions can be achieved (e.g., test concentrations not limited by poor solubility, relevant UVB dose can be applied). In cases where no phototoxic component has been identified in vitro, the overall phototoxicity potential of the clinical formulation can be regarded as low. (continued on next page)

Continued



ICH HARMONISED TRIPARTITE GUIDELINE PHOTOSAFETY EVALUATION OF PHARMACEUTICALS S10

Some properties of the clinical formulation that could influence the potential phototoxic response (e.g., penetration into skin, intracellular uptake) cannot be evaluated using the 3T3 NRU-PT alone. Therefore, confirmation of the overall negative result in an evaluation using the clinical formulation and/or monitoring during clinical trials can still be warranted. Reconstructed human skin models can be used to assess the phototoxicity potential of clinical formulations. Under adequate test conditions (see Section 3.3), a negative result in a reconstructed human skin assay indicates that the direct phototoxicity potential of the formulation can be regarded as low. In this case, generally no further phototoxicity testing is recommended (see Note 5 for exception).

If an appropriate in vitro assay is not available, the initial test could be an in vivo phototoxicity test on the clinical formulation. A negative result in an appropriately conducted in vivo animal phototoxicity study would be sufficient evidence that the formulation is not directly phototoxic and no further phototoxicity testing is recommended (see Note 5 for exception). Alternatively, the phototoxicity potential can be assessed in the clinical setting.

For dermal products where the API or any new excipient has a MEC value greater than 1000 L mol⁻¹ cm⁻¹ at any wavelength between 290 and 700 nm, a photoallergy assessment is generally warranted in addition to phototoxicity testing. As the predictivity of nonclinical photoallergy tests is unknown, this would typically be a clinical assessment using the to-be-marketed formulation and conducted during Phase 3.

Photosafety evaluation of the clinical formulation delivered via dermal patches can follow the above described principles for clinical dermal formulations. For transdermal patches, the principles for both dermal and systemic drugs should be applied. In addition, the intended clinical use (e.g., skin area recommended for use, duration of application) and the properties of the patch matrix (e.g., being opaque to UV and visible light) should be considered for the overall risk assessment.

Upcoming Conferences & Events

Mar 20-24, 2015: *American Academy of Dermatology 73rd Annual Meeting*, San Francisco, CA USA (www.aad.org/meetings/2014-annual-meeting)

Mar 22-26, 2015: *SOT 54th Annual Meeting & ToxExpo™*, San Diego, CA, USA (<http://www.toxicology.org/AI/MEET/am2015/am.asp>)

January 31, 2015: Deadline for *Early Bird Registration* for SOT meeting

February 19, 2015: Deadline for *Housing Registration* for SOT meeting

February 28, 2015: Deadline for *Standard Registration* for SOT meeting

After February 28, 2015: *Final Registration* period for SOT Meeting

May 6-9, 2015: *Society of Investigative Dermatology 2015 Annual Meeting*, Atlanta, GA, USA (<http://www.sidnet.org/2015annualmeeting>)

June 8, 2015: *Satellite meeting: International Society for Biophysics and Imaging of the Skin*, Vancouver, Canada (<http://isbs2015.doodlekit.com/>)

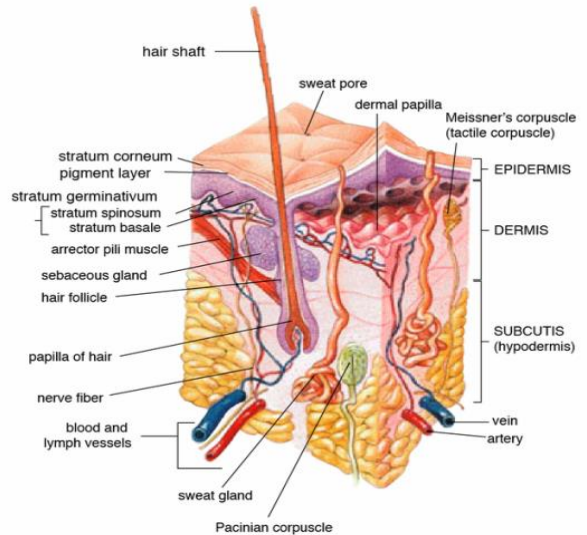
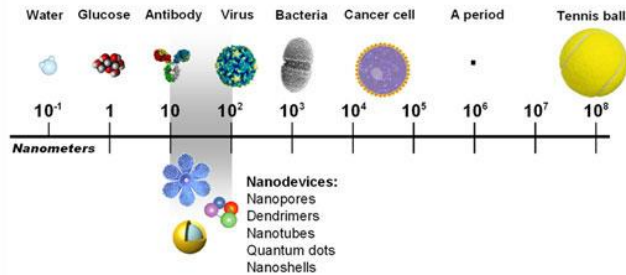
August 16-21, 2015: *Barrier Function of Mammalian Skin: Defining, Investigating and Surmounting the Barrier*, Gordon Research Conference, Waterville Valley, NH, USA (<http://www.grc.org/programs.aspx?id=10945>)



54th Annual Meeting and ToxExpo™
March 22-26, 2015

Safety of Nanomaterials in Cosmetic Products

FDA Guidance for Industry



Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
Guidance for Industry
Safety of Nanomaterials in Cosmetic Products
June 2014

CFSAN Finalized this Guidance for Industry in June 2014. There is plenty of dermal/skin application in this guidance that might be of interest to DTSS members:

Summary of Recommendations

In summary, nanomaterials can have chemical, physical, and biological properties that differ from those of larger scale particles with the same chemical composition, and the use of nanomaterials in cosmetic products may raise questions about the safety of the product for its intended use. As with any cosmetic product that has new or altered properties, data needs and testing methods should be evaluated to address any unique properties and function of the nanomaterials used in the cosmetic products as well as the questions that continue to remain about the applicability of traditional safety testing methods to products that involve nanotechnology. We recommend that the safety assessment for cosmetic products using nanomaterials should address several important factors, including:

- the physicochemical characteristics,
- agglomeration and size distribution of nanomaterials under the conditions of toxicity testing and as expected in the final product,
- impurities,
- potential routes of exposure to the nanomaterials,
- potential for aggregation and agglomeration of nanoparticles in the final product,
- dosimetry for *in vitro* and *in vivo* toxicology studies, and
- in vitro* and *in vivo* toxicological data on nanomaterial ingredients and their impurities, dermal penetration, potential inhalation, irritation (skin and eye) and sensitization studies, mutagenicity/genotoxicity studies.

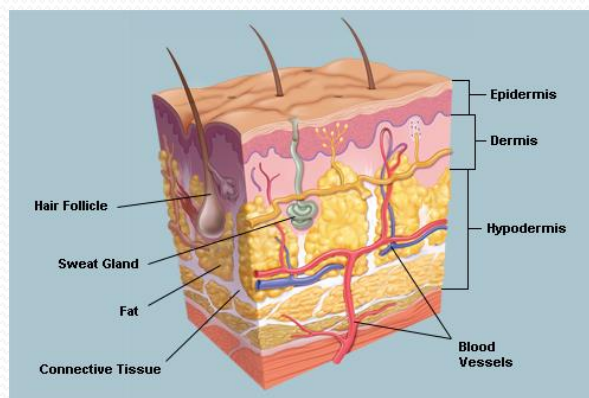
We expect that the science surrounding nanomaterials will continue to evolve and be used in the development of new testing methods.

Safety of Nanomaterials in Cosmetic Products Guidance for Industry, cont.



The safety of a cosmetic product should be evaluated by analyzing the physicochemical properties and the relevant toxicological endpoints of each ingredient in relation to the expected exposure resulting from the intended use of the finished product. If you wish to use a nanomaterial in a cosmetic product, either a new material or an altered version of an already marketed ingredient, we encourage you to meet with us to discuss the test methods and data needed to substantiate the product's safety, including short-term toxicity and other long-term toxicity data, as appropriate. We welcome your questions relating to the use of nanomaterials in cosmetic products.

(disclaimer: Guidance documents represent FDA's current thinking on a topic. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. Manufacturers can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations.)



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:

jnsthing@gmail.com

Thank you to our sponsors:

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Experience and Innovation



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 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 2015 award winners will be announced at the 2015 SOT Annual Meeting in San Diego.



The Society of Toxicology is committed to creating a safer and healthier world by advancing the science of toxicology.

DTSS Financial Report:

Society of Toxicology
TOTAL SECTIONS
For the Eleven Months Ending May 31, 2014

	Dermal Toxicology <u>70-812-0</u>
Ordinary Income/Expense	
Income	
Contributions	-
Membership Dues	-
Misc. Income	-
Registration	967
Interest	-

Total Income	967

Expense	
Awards - Sections	850
Plaques	162
Contributions	-
Executive Meetings	-
Mentoring Activities	-
Miscellaneous	74
Newsletter	-
Reception	3,609
Symposia	-
Travel	-
Web Development	-

Total Expense	4,695

Excess (Deficiency) of Revenue over Expenses	(3,728)

Net Assets Beginning of year	14,617
Transfers from General Fund	-
Net Assets After Transfers	14,617

Net Assets End of Year	10,890

The net DTSS assets as of August 2014 are \$14,096. This amount includes our budget after clearing all expenses from the 2014 Annual meeting. The balance still includes \$5000 received from Battelle in 2013 for the Battelle Research Student Awards. The cost of the DTSS reception and Officer's meeting at the 2014 Annual Meeting was \$3,608.52. The cost of the 2014 awards and plaques was \$1086.02.

The May 2014 summary is included to show DTSS's annual meeting expenses.

Dermal Toxicology Specialty Section

2014 Awards

DTSS awards given out at the DTSS Reception at the 2014 SOT Annual Meeting in Phoenix, AZ:

The ***DTSS Best Paper of the Year award*** went to **Yunan Tang** (University of Louisville School of Medicine, Louisville, Kentucky) for the paper: Tang Y, Zhang M, Hellmann J, Kosuri M, Bhatnagar A, Spite M. 2013. Proresolution therapy for the treatment of delayed healing of diabetic wounds. *Diabetes*. 62: 618-617.

The ***Sinclair Student Award*** was given to **Shuxi Qiao** (University of Arizona, Tucson, AZ) for the work: “Repurposing the aminophenol-antimalarial amodiaquine for autophagy-directed anti-melanoma intervention.”

The ***Stratacor Post Doctoral Award*** went to **Satya Achanta** (Yale University School of Medicine, New Haven, CT) for the work: “TRPA1 inhibitors counteract inflammation and edema in a mouse model of CS tear gas agent-induced cutaneous injury.”

Please, visit the Dermal Toxicology Specialty Section website for information about awards available for 2015:

- 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, Adrienne Black, and to whom applications for all awards should be sent (adrienne159@gmail.com). The deadline for all applications is January 31, 2015.

In addition, a Kindle Fire HD was awarded as a door prize from contact information submitted during the 2014 Student-Postdoc Mixer. This prize was sponsored **by MB Research Labs**.

Recent DTSS Member Publications


The following is a list of publications self-reported by DTSS members that were published in 2014:

M.E. Kraeling, W. Zhou, P. Wang, O.A. Ogunsola. *In vitro* skin penetration of acetyl hexapeptide-8 from a cosmetic formulation. *Cutaneous and Ocular Toxicology*. April 22, 2014 (doi: 10.3109/15569527.2014.894521).

W. Jo, M. Glynn, H. Nejishima, H. Sanada, K.Minowa, B. Calvarese, H.Senda, R.Pillai, L. Mutter. Nonclinical safety assessment of efinaconazole solution (10%) for onychomycosis treatment. *Regul Toxicol Pharmacol*. Oct: 70(1):242-53, 2014. (doi: 10.1016/j.yrtph.2014.07.012).

V. Ciaravino¹, D. Coronado¹, C. Lanphear³, I. Shaikh⁴, W.Ruddock⁴, S. Chanda². Tavorole, a novel boron-containing small molecule for the topical treatment of onychomycosis is noncarcinogenic in 2-year carcinogenicity studies. *Int J Toxicol*. Sep.Oct: 33(5)419-427, 2014. (doi: 10.1177/1091581814545245). ¹Anacor Pharmaceuticals Inc., Palo Alto, CA, USA, ³MPI Research, Inc., Mattawan, MI, USA. ⁴ITR Laboratories Canada Inc, Baie d'Urfe, Quebec, Canada.

T.B. Zanoni, M. Tiago, F. Faiao-Flores, S.B.M. Barros, A. Bast, G. Hageman, D.P. Oliveira, S.S. Maria-Engler. Basic Red 51, a permitted semi-permanent hair dye, is cytotoxic to human skin cells: Studies in monolayer and 3(D) skin model using human keratinocytes (HaCaT). *Toxicology Letters*, 227:139-149, 2014.



**Please forward this
newsletter to your
colleagues that might be
interested in becoming a
member of DTSS!**

Pictures from 2014 DTSS Reception



George DeGeorge (Past DTSS President)
Jill Harvilchuck (DTSS Secretary/Treasurer)
Mike Babin (DTSS Councilor)



Stratacor Post Doctoral Award

Satya Achanta
Bill Reifenrath (Past DTSS President)



**George DeGeorge (MB
Research Labs)**
presenting a Kindle Fire HD
as a door prize) to
Anand Ravindran



Wally Hayes
**Jim Riviere (Past
DTSS President)**