

Dermal Toxicology Specialty Section

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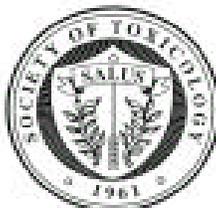
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The *Dermal Toxicology Specialty Section* newsletter is published 3 times/year (March, July, November) in printed and electronic formats. If you would like to share a book review, meeting report, web site, or any other item of general interest to the specialty section, please send it to the editors by the beginning of the month prior to the listed publication dates. We also welcome any comments or suggestions pertaining to overall content or format.

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President's Message

The first year of the Dermal Toxicology Specialty Section was a tremendous success. Most of the success we have had is due in large part to the efforts of our first President, Anna A. Shevedova, who demonstrated great leadership in forming the foundation of our specialty section. As of June, 2001 DTSS has 64 paid members. In just one year, we have established 7 functioning committees and developed a newsletter and website to communicate with our membership. At this year's meeting the DTSS sponsored its first symposium, entitled *Phenolic Compounds: Free Radical Mechanisms of Toxicity, Catalysis, and Protection*. The session was well attended and was successful in elaborating our current understanding of specific free radical mechanisms responsible for different toxic and/or functional roles and pathways of phenolic compounds in cells. All of this in just one year! Again, our sincere thanks to Anna for all her efforts in getting DTSS off to such a great start.

The executive council's number one priority for the coming year is to build the DTSS's membership by at least 50%. Working with Guilin Qiao and others on the Membership Committee, we plan to develop an active recruiting strategy to help build our membership. The membership distribution is currently Industry, 69%; Government, 17%; Academia, 11%; and Other, 3%. A specific goal of the Membership Committee will be to build our membership with scientists from Government and Academia. A number of membership activities will be initiated over the coming year and it is our hope that all DTSS members will help us reach our membership goal.

Another key priority for the coming year is to develop a very active Program Committee. We are pleased to announce that DTSS will be co-sponsoring a symposium entitled, *Altered Gene Expression and Cutaneous Toxicity* at next year's SOT meeting in Nashville, TN. To build a strong presence at SOT, we will need to have a very active and productive DTSS Program Committee. Our goal will be to have this committee start early (late fall) in planning a strong list of potential continuing education courses, symposium and workshops to share with SOT's Program Committee next year in Nashville. There is no doubt that having a successful program committee will be helpful in directly building the reputation and membership of DTSS. Jim E. Riviere, President-Elect, will lead our Program Committee for the coming year. Jim has considerable experience in developing successful SOT programs.

I want to acknowledge the hard work of Mike Robinson and Lisa Ryan who have developed our outstanding DTSS newsletter. The newsletter serves as a source of information on our committee's activities and accomplishments as well as a communication tool on the activities of individual members (e.g., publications, position announcements). This communication tool is critical to our success and I asked each of you to submit information that you think would be valuable to our DTSS membership.

Finally, congratulations to Ian Kimber who was elected DTSS Vice-President Elect for 2001-2002.

I'm looking forward to us having a great year in developing the DTSS to become bigger and stronger. It is my hope that each of you will help us grow DTSS into one of SOT's most successful specialty sections.

G. Frank Gerberick
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Committee Updates

Membership Committee

Submitted by Guilin Qiao

Since the 2001 SOT annual meeting, the Committee and its Chair, Dr. Qiao and the new DTSS president Dr. Gerberick have been working on the enhancement of the membership drive activities. The committee will closely work with the DTSS to maintain a minimum of 50 official members in order to keep the new subspecialty section viable during this critical stage. Additionally, continual effort will be directed towards membership record keeping/updating. Increased energy will be directed at recruitment of DTSS members from the skin toxicology communities in academia and other countries. The committee also wants to encourage DTSS officials/members to play a greater role in the membership drive in the near future. We will develop an electronic version of the DTSS membership list and then update the DTSS webpage information as frequently as possible. As of May 30, 2001, the DTSS has 64 paid members. Membership distribution was characterized as Industry 69%, Federal Government 17%, University 11%, and Others 3%. Some membership applications are still in process and we are expecting an increase in near future.

With the progressing maturity of our DTSS, several issues have required attention. The first is improving communication between DTSS and SOT-HQ with regards to an accurate membership roster. The listing above is our most recent and accurate registered DTSS membership list and we have created an email list for information distribution purposes.

The second issue is expanding our membership. To grow DTSS membership, we are asking all registered members of DTSS to provide the membership committee with the names of potential members along with their email addresses and phone numbers. Our committee will contact these individuals for recruitment into the DTSS. The academic sector is currently under represented. We need your help! So, please think about SOT member colleagues with research interests related to skin and send in their names. We will do the rest.

The third issue relates to the authorized use of the DTSS membership roster. Following discussion among the DTSS president and the chairs of the membership and communications committees, it was decided to recommend an email directory usage policy modified from one proposed by another specialty subsection. The

following guidelines have been recommended.

1. The list shall not be used for job solicitation purposes - either for those seeking employment or those seeking to fill positions.
2. Access to the list shall be limited to only a few Executive Committee Members- this would include the President, Vice-President, and Secretary/Treasurer as well as the heads of Membership and Communications.
3. The list, while not proprietary, will not be made available to non-members for any reason.
4. All messages requested to be mass e-mailed shall first be approved by the President or his/her representative.
5. The list shall, in conjunction with Membership, be maintained by the Communications Chair.
6. All members will be given the opportunity to opt out of the listing.
7. The list shall be used for queries of entire membership (for example, requests by the Program Committee for ideas for presentations at upcoming national meetings) or for dissemination of important information to all (such as upcoming meetings of interest, funding opportunities, newsletter distribution, etc.).
8. Usage of the list by the student representative shall be governed by the same rules as above. All messages requested to be mass e-mailed should be sent to the Communications Chair, who will then forward the requests to the President for approval.

We look forward to your comments on our recommendations.

Lastly, the membership committee welcomes a new member, Cynthia A. Ryan, BS, MT (ASCP) from The Procter & Gamble Company, who will work, as a committee member, with our existing members Guilin Qiao (Chair), NIOSH/CDC, Brian Jones (Co-Chair), Avon Product Inc., and Rick P. Moody (member), Health Canada.

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Continuing Education Committee

Submitted by Nancy Monteiro-Riviere and Diane Heck

The committee met in San Francisco during the March 2001 meeting of the Society of Toxicology. During the meeting, plans for SOT 2002 were discussed including suggestions for potential CE Mini-courses. A course focusing on Models for the Study of Skin-Toxicant Interactions including:

- a) Cell culture based systems
- b) Artificial polymers and hybrid systems
- c) Allograft and other animal models

was discussed. It was decided that proposals for the inclusion of these in the 2002 SOT annual Meeting program would be submitted.

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Communications Committee

Submitted by Michael K. Robinson

The goal of the Communications Committee of the DTSS is to coordinate the collection and dissemination of information relevant to the needs of dermal toxicologists within the specialty section, as well as assisting the Council in outreach to the general toxicology community. We do so through the use of a specialty section newsletter and an SOT-linked web site.

The newsletter is published 3 times each year (currently March, July, and November) and contains reports from the president, committee updates, job postings, member news, member honors and awards, and member publications. The newsletter is sent to all members by email and is posted to the web site. The web site includes postings of the DTSS by-laws, current DTSS membership, current DTSS council members, special announcements, the annual report, a President's Corner, and the current and previous DTSS newsletters.

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Regulatory/Policy Committee

Submitted by James N. McDougal and Robert W. Lange

The purpose of the Regulatory/Policy Committee is to promote awareness of issues, changes or initiatives that affect dermal toxicology in the areas of occupational, environmental and pharmaceutical regulations in the US, Europe and other regions. This committee is looking for individuals in the specialty section and the SOT as a whole who are familiar with regulations and policies of the main regulatory agencies to participate in this committee.

The intent of the committee is to raise the awareness of regulatory policies or issues that would impact on dermal specialty section members. We are also looking for suggestions for workshops or roundtables at the annual meeting that address regulatory topics.

The following is a list of useful regulatory web sites:

International Regulatory Agencies/Organizations for Pharmaceuticals

US Food and Drug Administration
<http://www.fda.gov/>

European Agency for the Evaluation of Medicinal Products
<http://www.emea.eu.int/>

Pharmaceutical and Medical Safety Bureau--Japan
<http://www.mhlw.go.jp/english/org/policy/p13-14.html>

International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
<http://www.ifpma.org/ich1.html>

Interesting FDA Sites

FDA CDER updates (subscribe to receive)
<http://www.fda.gov/cder/cdernew/listserv.html>

CDER freedom of information reading page
<http://www.fda.gov/cder/foi/index.htm>

The Common Technical Document for the Registration of Pharmaceuticals for Human Use: 08-24-00,
<http://www.fda.gov/cder/guidance/4022dfts.htm>

IND content and format for Phase 1 studies 02-16-98,
<http://www.fda.gov/cder/guidance/phase1.pdf>

Impurities in Drug Substances, Guidance Document 06-01-00,
<http://www.fda.gov/cder/guidance/2452fnl.htm>

Summary: Higher or lower threshold levels for qualification of impurities may be appropriate for some individual drugs based on scientific rationale and level of concern, including drug class effects. The Impurities Decision Tree for generic drug substances (Atta

Skin Specific FDA Sites

Chronic Cutaneous Ulcer and Burn Wounds - Developing Products for Treatment

06-27-00,
<http://www.fda.gov/cder/guidance/3226dft.htm>

Topical Dermatological bioequivalence 06-19-98,
<http://www.fda.gov/cder/guidance/2481dft.pdf>

Photosafety Testing 07-05-00,
<http://www.fda.gov/cder/guidance/3281dft.htm>

PTC in Nonclinical Pharmacology/Toxicology 05-06-98,
<http://www.fda.gov/cder/guidance/ptcnclinical.htm>

Summary: This document discusses several nonclinical pharmacology/toxicology issues that are inherent with the development of topical drugs that are intended to prevent sexually transmitted diseases (STD) or with the development of drugs proposed to act as vaginal treatments.

Skin Irritation and Sensitization Testing of Generic Transdermal Drug Products 06-01-00,
<http://www.fda.gov/cder/guidance/2887fnl.htm>

Miscellaneous

U.S. Consumer Product Safety Commission
<http://cpsc.gov/>

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Methods Committee

Submitted by Robert L. Bronaugh

The Methods Committee conducted a survey of DTSS members to determine their interests and experience in the development and validation of methods for dermal toxicity assessment. Nine members responded to the survey with their areas of interest. Skin irritation/mediators of irritation was the most cited area, with mention by five members. Percutaneous absorption and skin sensitization were tied for second place with four votes each. Our committee plans to develop a workshop (speakers - titles of presentations) to aid in the development, standardization and validation of one of the above methods. We would then propose this workshop to the DTSS program committee. We are also exploring the idea of utilizing the SOT web page to promote the sharing of technical expertise of DTSS members.

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Awards Committee

During the past year, the Awards Committee worked with Dr. Anna Shvedova, the president of the DTSS, Avon Products Inc. and Bertek Pharmaceuticals to establish two student awards. The two awards established were for in vitro work (Avon) and in vitro/in vivo work (Bertek). The award notifications, guidelines for application and selection criteria were posted on the DTSS website. Student's participants in the SOT who presented work relevant to dermal toxicology submitted their work that was evaluated by the Awards Committee. The winners of this year's student awards were:

Valescia John: SOT DTSS-Avon Products Inc., 2001 Award for in vitro research

Ashley Murray: SOT DTSS-Bertek Pharmaceuticals 2001 Award for in vitro/in vivo research

Annette Santamaria: SOT DTSS-Bertek Pharmaceuticals 2001 Award for in vitro/in vivo Research

The Awards Committee together with Dr. Shvedova presented two additional certificates that recognized contributions to the administrative aspects of the SOT DTSS, which were especially important in the forming stages of our specialty section.

Sam A. Hart, Jr., 2001: Recognition certificate for outstanding DTSS support
Kelley A. Kathy: Recognition certificate for outstanding DTSS support

The committee prepared a report of its activities for the SOT meeting in March, 2001, San Francisco. Future goals of this committee include maintaining these awards for 2002 and developing a strategy to help share information related to jobs and careers in dermal toxicology.

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Eugenia Harnagea-Theophilus, Co-Chair
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Program Committee

Submitted by James E. Riviere

The DTSS is sponsoring a Symposium entitled "Altered Gene Expression and Cutaneous Toxicity" at the annual 2001 SOT meeting. This Symposium, co-chaired by DTSS officers Drs. G. Frank Gerberick and Ian Kimber will for the first time bring together experts in skin biology and cutaneous toxicity to review how characterization in changes in gene expression are providing new insights into mechanisms of toxicity and opportunities for new approaches to hazard assessment. Speakers include Drs. Rebecca Dearman, Emanuela

Corsini, James McDougal and Dori Germolec. Please be on the lookout for this symposium next year and support your section by making plans to attend.

Our committee has been charged with developing an exciting series of programs for the 2003 SOT meeting. Although it may appear absurd to be thinking about this in the summer of 2001, it is imperative that ideas get formulated now so that we can use the time at the 2002 SOT meeting to finalize programs for submission to SOT. Some ideas that were floated at last year's business meeting included a workshop on validation of a specific dermal toxicology method, and offering an advanced CE course on model systems as a follow-up to the basic CE course offered in 1998. Members should be formulating ideas (and volunteers) on workshops, symposiums and CE courses over the summer. I promise you that our committee will be active in the Fall to insure that DTSS has a dynamic program at the 2003 annual meeting.

James E. Riviere, Chair
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Member Comments/Views

We encourage your enthusiastic involvement and suggestions! Take a moment and send us your comments. – eds.

Member News

The DTSS is proud to recognize its newly elected Vice President, Dr. Ian Kimber, who was the recent recipient of the 9th Annual Robert A. Scala Award in toxicology. The headline from the ECETOC web site reads as follows:

“9th Annual Robert A. Scala Award goes to Professor Kimber (Syngenta)

During a special ceremony and lecture at the Environmental and Occupational Health Sciences Institute in Piscataway New Jersey, Professor Ian Kimber (Syngenta) was presented with the 9th Annual Robert A. Scala Award in Toxicology.

The Robert A. Scala Award and lectureship honours the work of exceptional toxicologists in industry and promotes continued outstanding scientific contributions by industrial organisations. The award honours Robert A. Scala, PhD., former director of the Research and Environmental Health Division at Exxon Corporation, who was one of the foremost toxicologists of our generation.

Professor Kimber has contributed greatly to the ECETOC science programme for many years. Most recently he chaired the ECETOC Task Force on Skin Sensitisation which produced two ECETOC reports (TR No. 78 Skin Sensitisation Testing: Methodological Considerations and Monograph No. 29 Skin Sensitisation Testing for the Purpose of Hazard Identification and Risk Assessment) and external publications. Currently he heads the ECETOC LRI Health Effects Monitoring Team.”

Congratulations, Ian! – eds.

Member Publications

Each newsletter will feature a listing of specialty section member publications (journal articles, book chapters, books) that have appeared in print since the last edition. While the editors will do their best to survey the indexing services relative to the current membership roster, it is likely that some mistakes and omissions will occur. This is particularly true for books and book chapters. If we have inadvertently omitted a recent publication or listed something incorrectly, please advise us by email and we will see that this is corrected in the following newsletter. Also, we welcome your help in this endeavor. Please send us your citations for any recently published articles and books. That will aid us in our literature searching. Thank you - eds.

Recent Publications (DTSS authors in bold):

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