

Message from the President

J.M. Friedman

It has been a bustling spring for the Teratology Society. We are getting ready for our Annual Meeting, implementing a new Strategic Plan, revitalizing and expanding our journal and website, and moving forward in several other areas.

I hope to see you at our 42nd Annual Meeting in Scottsdale, Arizona, on June 22-27, 2002. Highlights of the meeting will include an outstanding Education Course on integrative risk assessment, the Warkany Lecture by Ken Jones, and special addresses by Bern Schwetz, Acting Principal Deputy Commissioner of the FDA, and José Cordero, Director of CDC's new National Center on Birth Defects and Developmental Disabilities. Please see Bill Slikker's article on the meeting in this Newsletter and the Program Agenda <http://teratology.org/meetings/2002Agenda.pdf> on our website for more information.

Our second Strategic Planning Session was held in Nashville, Tennessee, on March 14-15, 2002. A summary of the discussions <http://teratology.org/members/sps2002.htm> is posted on the website. Six areas of emphasis were identified that are most important to our future. These include:

- The annual meeting;
- Scientific issues related to public policy;
- Our website;
- The journal;
- Our educational activities; and
- The management of our Society and communication with our members.

An action plan was initiated in each of these areas, and we will be reporting our progress to you on a regular basis.

Rich Miller's Editor Selection Committee is interviewing candidates for the editorship for Part B of our new journal, *Birth Defects Research: Developmental and Reproductive Toxicology*. Negotiations are now in progress regarding the editorship of Part C, the review section. We hope to announce both of these appointments in July. The new editors will work closely with Phil Mirkes, who will be the new editor of *Birth Defects Research: Clinical and Molecular Teratology*, to re-launch the journal in 2003. The activities of all three parts of *Birth Defects Research* will be coordinated and overseen by a reconstituted Publication Committee.

These changes to the journal and the Publication Committee, as well as a number of other changes that are necessary to bring our Society more fully into the Information Age, are the subject of a set of amendments to the Teratology Society Constitution and Bylaws. Please review the proposed amendments that are posted on our website http://teratology.org/members/Proposed_Changes.pdf. The changes will be discussed at our Business Meeting in Scottsdale and voted on shortly thereafter.

While you are visiting the website, notice the improvements that are occurring there as well. There is new content, with frequent additions and updates. Finding what you need on the website is easier, too, with the addition of a Google search feature.

Your Council and Public Affairs Committee are continuing to work with the FDA and CDC on public policy initiatives to prevent birth defects and improve the recognition of teratogenic exposures. This has been an exciting spring for us, and there are lots of opportunities for the Teratology Society and its members to make a real difference. Please contact me at frid@interchange.ubc.ca if you would like to become more involved with your Society.

See you in Scottsdale!

Jan Friedman, MD, PhD
President, Teratology Society

Pack Your Saddlebags and Head Out West
Submitted by William Slikker, Jr.

Come to Scottsdale and be an active participant in the largest gathering of Teratologists in 2002. Hear the latest research in either platform or poster formats. Enjoy the presentations of your peers in eight different symposia. Listen to the views of well-positioned colleagues: *Bernard Schwetz*, Acting Principal Deputy Commissioner, FDA and *Jose Cordero*, Director National Center on Birth Defects and Developmental Disabilities, CDC. Sign up for a one-day and/or mini-educational course. Judge for yourself the outcome of the “Great Debate: Is there an all or none phenomenon in Teratology?” Take note of the significant scientific contributions of the Warkany and Wilson Publication award winners. All these opportunities and more await you at the Annual Teratology Meeting in Scottsdale, AZ, June 22-27, 2002 (see the preliminary program at our web site: www.Teratology.org).

The members of the Program Committee: Judy Buelke-Sam, Mildred Christian, Michael Cunningham, Donna Farmer, Deb Hansen, Tony Machado, Rich Miller, Phil Mirkes, Janine Polifka, Shelly Tyl and Patrick Wier, have made all this possible. Please join me in thanking them. I also thank the membership at large for their contributions to the Program content. Before last year’s Annual Meeting, we asked for symposium proposals and the Program Committee was blessed with many fine ideas, suggestions and requests. Input was not only received from our own membership but also from that of our sister Societies. The working relationships with MTA, MARTA, NBTS, OTIS, etc. are vital to us and we will continue to foster our fruitful collaborations.

Two new sources of scientific information to look for this year, both during the poster sessions, are the Late-Breaking Abstract posters and presentations for our Sister Societies. We have prevailed upon the leadership of our Sister Societies to present posters describing their Society membership, planned activities and meeting/publication highlights. With our call for Late-Breaking Abstracts we were able to boost our abstract number by 9% and add some new participants to our meetings. I hope you look for these two new features as you enjoy our Joint Poster Sessions on Monday and Tuesday from 5 to 7:30 p.m.

In order to provide more time to interact with our colleagues in an informal setting, we have reintroduced the continental breakfast on Monday through Thursday mornings. I hope you will enjoy the convenience of coffee and assorted pastries before our morning sessions, and use this time to get acquainted with new and current members of all the Societies.

So come to Scottsdale and immerse yourself in the blue water of the pools, the green of the golf course, the beauty of the Fairmont Scottsdale Princess Resort, the cutting-edge science and the warmth of renewed friendships in the Arizona sun.

See you in Scottsdale—Bill

Enlighten Yourself: Take an Educational Course and Learn from the Best

Submitted by William Slikker, Jr., Ph.D., Donna Farmer, Ph.D., and Deborah Hansen, Ph.D.

Knowledge is a wonderful thing and you can have an opportunity to learn plenty by attending two education course offerings at this year's Annual Teratology Meeting. Both the traditional one-day course and the new mini-course have an excellent set of instructors and a detailed syllabus.

The Education Committee, chaired by Donna Farmer, has selected the timely topic of *Mechanisms, Biomarkers, Data Interpretation: An Integrative Risk Assessment using Developmental Neurotoxicity as a Model*, for this year's course. The eight course instructors will review current risk assessment and integrated risk assessment approaches, using developmental neurotoxicity to provide a framework for application of these concepts. These topics were chosen in response to numerous Teratology Society member requests for courses in these areas. The course begins on Saturday afternoon, June 22, with an overview of risk assessment. In health, safety and environmental policy issues, the tools of risk assessment provide the essential foundation for risk analysis. Steps currently used in conducting health risk assessments will be discussed, as well as steps being considered to improve this process. Such steps include incorporation of biological information and mechanistic events at multiple levels to provide a more comprehensive evaluation of potential risk. Thus, several presentations will follow on the development of the nervous system, molecular and functional aspects of nervous system development and developmental neurotoxicity, to set the stage for consideration of this information in a risk assessment paradigm. These will begin with an overview of the pre- and postnatal development and function of the nervous system. The last two presentations on Saturday will address current and future methods/approaches available for evaluating abnormal development of the nervous system from subcellular to the organism. First a discussion of molecular markers of nervous system development followed by structural and functional outcomes already recognized to result from teratogens and how these effects are related to time of exposure and time of testing.

The presentations on Sunday morning, June 23, will focus on developmental neurotoxicity testing, results and data interpretation. The potential neurotoxicity, including developmental neurotoxicity, of exogenous substances is currently evaluated in a variety of ways including new studies mandated by regulatory agencies. The first presentation will focus on the practical and logistical considerations of conducting developmental neurotoxicity studies, the data interpretation and challenges. The results of studies examining effects of the pesticide, chlorpyrifos, on developmental processes of the nervous system at multiple levels will be described next. The final presentation will pull together concepts introduced in previous talks as they pertain to the use/application of Biologically-Based Dose-Response Models in an integrated risk assessment framework for developmental toxicants. The course will wrap up with a panel discussion on status and issues in identifying and understanding mechanisms of developmental neurotoxicants, and evaluating risk.

For the first time, the Teratology Society will include a mini-course as a part of our Annual Meeting. The purpose of the mini-course, organized by Deborah Hansen, is to cover a topic in more detail than is possible during a platform presentation and to get practical insights from experts in the area. The first mini-course will be held on Tuesday morning, June 25, before other programming and cover issues of ***Experimental Design and Biostatistics***. Dr. Woody Setzer will present basic statistical analysis for prenatal reproductive and developmental toxicity studies - such as appropriate tests for various endpoints, situations with unequal N's, and whole litter versus using representative fetuses from a litter. Dr. Paul Foster will compare and contrast prenatal versus post natal evaluations (especially with regard to number of animals evaluated) with an emphasis on what we've learned from looking at endocrine active chemicals that might influence study design. This may include issues of culling, the value of sexually dimorphic indicators of maturity as well as issues concerning microarray analysis of fetal tissues.

**Vice President-Elect's Report
Submitted by Rochelle Tyl**

The site selection process for future Annual Meetings is underway. Currently we are exploring locations for 2004. Under consideration are Monterey, California; Palm Springs, California; Hawaii; and Vancouver, British Columbia, Canada.

Besides trying to locate the next annual meeting on the West Coast, Council is trying to identify ways to energize the Annual Meeting in order to build attendance. In addition to building attendance we are looking to broaden recognition of the Society and the scientific contributions made by our members. In order to facilitate this attempt, we are requesting that you complete a survey to provide this information. There will be a form, available at the Annual Meeting. The surveys should be returned to staff at the registration desk.

Please take advantage of the opportunity to provide this information, as your feedback is important to the Society.

Secretary's Report
Submitted by George Dearlove

Reporting from the Strategic Planning Session in Nashville

A number of items were discussed at this meeting (see review elsewhere) and one item that came up requires further research before we can properly address the concerns.

The possibility of continued membership concerns (with the direction the Society was taking, with the apparent lack of Society responsiveness to individual members' various concerns and/or any other issues that the membership felt were not getting adequate deliberation) were still issues that need to be discussed. To adequately address these concerns, Council needs to find out what they are. Subsequently, George Dearlove volunteered to be the contact person to collect this information for presentation to Council.

In order to fulfill this commitment, I am asking for input from the membership and am offering you several ways to respond. If you have any concerns or suggestions regarding anything about the Society, you may send them to george.dearlove@criver.com, mail them to Teratology Headquarters (attention suggestion box), or bring them to the annual meeting and place them in a locked suggestion box that will be situated near the meeting registration desk. The latter two options will permit members to submit their suggestions/concerns without identifying themselves.

I will compile one or more lists of the membership concerns, suggestions, and even accolades for presentation to Council for future discussions. The results of these discussions will be featured in future issues of the newsletter. Council may not get to all of the issues at one time, but they will all be addressed. Individuals who identify themselves with their concerns will receive personal notification from me of what action Council has taken.

Note: No member will be identified with any suggestion being presented to Council for discussion unless that member specifically requests that Council be informed of their identity.

Treasurer's Report
Submitted by John M. Rogers

The purpose of this report is to transmit to the membership the final approved 2002 Budget for the Society and to update you on other matters concerning our finances. There is both good news and bad news on the financial front. The good news is, first, that we continue to be in sound financial condition, and second, that it appears that last year's net income was greater than \$70,000, due in large part to a very successful (scientifically and financially!) Annual Meeting in Montreal. Over a quarter of this comes from the hotel "commission" paid back to the Society, and this money (\$20,750) will be used to defray costs (i.e., reduce registration) for this year's meeting in Arizona. Instituting this commission as part of our contract with the host hotel each year has been very profitable since its inception. The bad news is that our projected budget is in deficit for FY2002, and sustaining memberships and contributions are coming in more slowly than expected. While I don't think either of these items is a critical problem for us this year, there are some things that all members can do to help. These include attending the annual meeting and making hotel reservations as soon as possible (to make our room block and maximize the commission), paying outstanding individual membership dues, and working to get sustaining members dues and contributions paid in full. If the annual meeting is again very successful and contributions don't fall, we can still end up in the black. Of course, any and all ideas for additional income or contributions are always welcome!

The reason that Council approved a deficit budget for this year was the recognized importance of the Strategic Planning Committee meeting that was held before the SOT meeting in Nashville. We budgeted \$25,000 for this meeting, without which our budget would have been positive. Because the Society has had strong positive cash flows for several years now, I feel that the investment in the Strategic Planning meeting was a wise one, and one which we could afford. The outcome of that meeting will be reported in detail separately.

Here is the itemized FY2002 budget. AM is Annual Meeting, G&A is General and Administrative. One FAQ concerns the meaning of "Credit Card Fees;" this represents fees paid so that we can accept credit cards for payments, not interest paid on credit card debt.

Income		Expenses					
Awards	15000	Abstracts-AM	5000	Fax	500	Printing	8000
CE Course	28360	A/V-AM	4844	Finan. Serv-G&A	4500	Public Affairs	1000
Contributions	64173	Audits	4500	Food, Bev, RmsAM	56900	Signage	500
Dues Memb	40000	AwardStudent-AM	15000	Insurance	2700	Site Visits	1000
Dues Sustain	40000	Ballots	2000	Journals-Memb/Pub	40000	Speakers	29450
Exhibits	12000	Bank/Lockbox	1800	Legal Fees	500	Staff Time AM	9382
Interest	12000	Banquet-AM	30000	Mailing/Labels	400	Staff Time AM/year	28000
Journal Subs	40000	CE Course-AM	19841	Mgmt Fee-G&A	14156	Staff Travel AM	5748
Minicourse	2375	Council	10000	Minicourse	1900	Steno/Clerical	35700
Misc	2000	Credit Card Fees	5500	Misc G&A	5000	Strat Plan Comm	25000
Registration	101195	Digital Project-AM	2780	Misc AM	3550	Supplies	1000
TOTAL	357103	Display Booth	1000	Newsletter	500	Telephone	1200
		Dues and Fees	6300	Postage	3500	Website	1500
		Exhibits- AM	2400	Posters-AM	2250	Xerox	180
						TOTAL	394981
						revenue-expense	-37878
						2001 hotel commission	20,750
						Net cash flow	-17,128

Our current investments are the same as reported at the Annual Meeting in Montreal.

I would be glad to answer any questions or receive any comments about the budget or other financial matters. My e-mail is rogers.john@epa.gov.

COMMITTEE REPORTS

Publication Committee Update Submitted by Rochelle Tyl

James G. Wilson Publication Award Selection

Process: The Journal Section Editors and Editor-in-Chief were asked to nominate no more than five papers each (rank ordered out of 51) published in *Teratology* from January 1 – December 31, 2001 for the 2002 Wilson Award. The Publications Committee Chair then ranked the over 20 nominated papers by the number of times each was nominated and by its rank order from each nominator. The top five nominated papers (in alphabetical order by first author) were then presented to the Publications Committee members with the request that the members rank the papers. The five top papers were all excellent; the award will be presented for the following paper:

Title: Multifactorial Genetics of Exencephaly in SELH/Bc Mice

Authors: D.M. Juriloff, T.M. Gunn, M.J. Harns, D.G. Mah, M.K. Wu, and S.L. Dewell

Location: Department of Medical Genetics, University of British Columbia, Vancouver, BC, V6T, 1Z3, Canada

Citation: *Teratology* 64(4), 189-200 (October 2001)

None of this could have been done without the superb support and assistance of Ms. Phyllis Dennehy, Editorial Assistant to Lew, or without the participation and cooperation of the Section Editors, the Editor-in-Chief, and the members of the Publications Committee.

Student Affairs Committee Update Submitted by Janet Uriu-Adams, Ph.D.

The annual Teratology Society meeting is an excellent opportunity for graduate students and postdoctoral fellows to present their work and interact with interested scientists. Continuing student participation and contribution are absolute keys to the future of the society.

The James C. Bradford Memorial Award will be given to a student for best paper in the poster competition. The Wilson Presentation Award will be given to two students (predoctoral/postdoctoral) for best paper in the platform competition. The presentations with their research will be made during the special student plenary session on Monday, June 24 (10 a.m. to 12 p.m.). There will be no concurrent sessions so as to give the

students maximum visibility and recognition of their achievements. Judging will be by the Student Affairs Committee based on the following criteria:

- 1) Clarity of introduction, background and hypothesis to be tested
- 2) Experimental design, methods, and level of innovation
- 3) Scientific impact of results
- 4) Conclusions based on presented data
- 5) Clarity of visual presentation (figures and tables) and overall organization of presentation
- 6) Clarity of verbal communication, overall knowledge of topic and ability to answer questions

A limited number of Young Investigator Travel Awards will also be provided to eligible graduate students and postdoctoral fellows to help defray a portion of the cost of attending the meeting. The Marie W. Taubeneck Memorial Award recognizes a graduate student or postdoctoral fellow for scholarship in teratology and service to the Society. Students will receive a ballot with the candidate's names prior to the meeting and will vote for the candidate of their choice at the meeting. The final decision will be made by the Student Affairs Committee. All student awards will be announced at the James G. Wilson and F. Clarke Fraser Awards Luncheon on Thursday, June 27 (11:45-1:00 p.m.). We hope you will join us in recognizing the student's achievements.

Several student events are being planned for this year's meeting. Following the March of Dimes Symposium (organized by Patrick Wier and Karen Augustine), there will be a special session to provide students the opportunity to meet with the MOD Symposium speakers (Sunday, June 23; 5:00-6:00 p.m.). Donald Mattison will be the moderator for the session. On Monday evening (June 24; 7:30-10:30 p.m.), MARTA and MTA will host a dinner and interview skills workshop for all graduate students and postdoctoral fellows (see announcement below). This will be a fun opportunity to meet your fellow students, and to interact with scientists representing all facets of the Society. In addition, Michael O'Hara will be organizing a special student outing. Potential activities include horseback riding or mountain biking (details will be forthcoming). Students who are interested in finding out more can contact Michael at mfo001@jefferson.edu.

The 2002 Student Affairs Committee members are: Jan Uriu-Adams (chair), Jack Bishop, Bruce Buehler, Michael O'Hara (student member), and Bill Slikker (Council liaison).

MARTA/MTA Student Career Event:

Attention ALL Pre and Postdoctoral Students! On Monday, June 24, from 7:30 – 10:30 PM the Middle Atlantic Reproduction and Teratology Association (MARTA) and Midwest Teratology Association (MTA) will host a Student Career Event for all students attending the joint annual meetings of the Teratology Society, Neurobehavioral Teratology Society (NBTS) and the Organization of Teratology Information Services (OTIS). You will be treated to plenty of food and drink while being offered information on interviewing do's and don'ts in preparation for that next phase in your professional

career. In addition to the brief interviewing skills component of the evening, you will have plenty of opportunity for one-on-one interactions with scientists representing Academia, Industry, Contract Organizations, Consultants, and the Government who have agreed to make themselves available. You will be invited to discuss these various career paths, your future, and to make some valuable contacts all while being treated to dinner. This event has been overwhelmingly well received by students in past years and we hope to see you there. The organizing committee for this event (Theresa Fico, Utpal Gupta, Mary Giknis, Sandra Wood, Ben Fisher, Steve Harris, Jeff Pitt, and Gary Chmielewski), would like to acknowledge the generous financial support received from Pfizer, Aventis, Pharmacia, and Covance making this event possible.

**F. Clarke Fraser New Investigator Award Committee
Submitted by Martha Werler, Sc.D.**

This award honors F. Clarke Fraser, one of the founding members of the Teratology Society, for his many contributions to the field of developmental toxicology. The award will be presented at the Wilson Luncheon held on Thursday, June 27 at the Annual Meeting in Scottsdale, Arizona.

To be eligible to receive this award the individual must be active in the Teratology Society and demonstrate a successful independent research career, as evidenced, for example, by high quality publications in peer-reviewed journals, obtaining funding for research endeavors, have an established teaching program with active graduate students, and/or by being generally recognized as an expert in the field. Individuals working in academia, government, and industry are equally eligible to compete for this award. Candidates must be within ten years of the date their doctoral degree was conferred or their last formal postdoctoral training program was completed and must be nominated by a current member of the Teratology Society.

The committee pleased to announce Jeffrey M. Peters as this year's awardee. Dr. Peters is on the faculty at Penn State University, is the current Chairperson of the Membership Committee and was in charge of coordination of the Teratology Society recruitment booth at the 2002 SOT Annual Meeting in Nashville, TN.

**Public Affairs Committee
Submitted by Christina Chambers, MPH**

The Public Affairs Committee worked with Council to prepare a response to the FDA draft guidance for reviewers document ("the wedge") which was sent to the FDA within the open comment period.

The text of this document was posted to the TS website for members to read. A subcommittee headed by Patte Bittner has been working on press coverage for the upcoming annual meeting. Carole Kimmel and Jane Adams have put together an excellent symposium on methylmercury for this year's meeting.

Pregnancy Label Revision

Following the symposium presented at the Montreal meeting in June, the Public Affairs Committee developed a letter to the Secretary of Health and Human Services regarding the FDA's progress on the pregnancy label revision. This letter has been approved by Council and has been sent on behalf of the Society. The text of this letter is printed below. Members of the Society as individuals may wish to communicate to their legislators on this important issue as well.

Tommy G. Thompson
The U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Thompson:

The Teratology Society, a multidisciplinary scientific society founded in 1960, is dedicated to understanding the causes and biological processes leading to birth defects and their prevention. Among its many activities, the Teratology Society addresses public health issues regarding the causes and prevention of birth defects. We are writing to call your attention to an important issue that we believe deserves to be given a high priority for action.

Numerous studies in the United States have shown that medications are frequently prescribed to pregnant women. As a result, each year hundreds of thousands of pregnant women and their health care providers seek information regarding the potential risks of these medications to the developing embryo or fetus. The most easily accessible and most commonly used source of this information is the pregnancy portion of the FDA-approved product label. Although other resources are available, the pregnancy section of the product label is perceived by pregnant women and clinicians as being authoritative.

However, we believe that the ABCDX system that the FDA currently uses to label drugs with respect to pregnancy safety is confusing, incomplete and, in some cases, inaccurate. This can lead to misperceptions of risk and mismanagement of pregnancies.

In response to these concerns, the FDA Pregnancy Labeling Task Force has invested a considerable amount of effort in exploring alternatives to the current system over the last several years. Despite the formidable challenges involved in revising such a complex and far-reaching set of rules, we believe that the Task Force has made substantial progress in developing an acceptable plan. We applaud this work; however, we are frustrated that the progress toward implementation of these revisions seems to have come to a halt. We view revision of the FDA use-in-pregnancy labels to be a matter of urgency because it impacts the health and well-being of numerous pregnant women and their children. We urge you to move forward in the regulatory process for this important initiative as soon as possible. As members of the Teratology Society, we would be pleased to assist in any way possible.

Draft Guidance on Preclinical Testing of Drugs for Reproductive Toxicity

In response to the call for public comment on the Draft Guidance document ("the wedge") posted by the FDA on November 16, 2001, the Public Affairs Committee has developed a response letter. Following approval by Council, this letter will be submitted as the official position statement of the Teratology Society. For Society members who have not read the document or who wish to independently submit comments to the FDA, the draft guidance is located at <http://www.fda.gov/cder/guidance/4625dft.pdf>.

News from ETS

The European Teratology Society (ETS): A call for collaboration. Submitted by Asher Ornoy, President of ETS

The European Teratology Society (ETS) was established in September 1969, as several prominent teratologists from Europe gathered together to establish the society. The first conference of the society was held in Cardiff, Wales in 1971. The first president was Prof. Tuchmann-Duplessis and the first secretary/treasurer was Prof. K. Sune-Larsson. Today there are over 400 members from 34 European countries and from countries worldwide including USA and Canada. The present president of the ETS is Asher Ornoy, Israel, the secretary is Lindsay Aveyard, UK and the treasurer is Frank Ross, UK ; The society has good connections with other Teratology societies and is a member of the IFTS. The annual meeting is usually held at the beginning of September in different European countries. The 2002 annual meeting will be held in Hannover, Germany, in September 7-11. The meeting starts on Saturday with a 2 days symposium on "Adverse effects of endocrine disrupters" co-organized with the section of Toxicology of the German Pharmacology -Toxicology Society and will continue with workshops, symposia (i.e. Standards and new testing procedures of endocrine disrupters; Folates and the prevention of disease coorganized with the Teratology Society, molecular pathways in normal development and dysmorphogenesis) and free communications as well as poster sessions. The meeting will end on Wednesday by an "Overview of the activities in the 6th framework program of the EU", including grant writing. This year, the ETS award lecture in the meeting "Epidemiology of congenital malformations- achievements and hope" will be given by Elizabeth Robert, Lyon, France. Prof. Heinz Nau, Past ETS president is the Chair of the Organizing Committee.

The ETS web site (www.etsoc.com) is operated by Graham Copping since 1998 and is updated periodically. One year ago *Reprod. Toxicol.* became the official journal of the society.

ETS members have interest in the same issues that are of interest the TS members. Our members are looking for research collaboration with teratologists from other societies as well with clinicians that have similar interest. In the name of the ETS members I extend an invitation for collaboration and invite urge that wishes so, to become a member of our Society.