

# The Teratology Society

## Newsletter

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### Strategic Planning Meeting Results

**Christina Chambers and Melissa Tassinari**

The Teratology Society's third Strategic Planning Session was held in San Diego, California, on April 18-20, 2007. Following a pre-conference web-based membership survey, 24 Society members participated in the two-and-a-half day planning session, led by a team of professional facilitators. This session was designed to build on the work accomplished through previous Strategic Planning Sessions and was focused on 3 areas: 1) scientific excellence and leadership, 2) membership recruitment and retention, and 3) outreach and partnerships. The 2007 workshop looked at Society strengths as the base for change and generated a great deal of excitement about opportunities for the Society to explore in moving forward during the next five years. During the session, specific themes for strategic emphasis were identified by the participants. These include: improved visibility of the Society, communication, a shared scientific identity, the design of the annual meeting, and membership. Core working groups focused on each of these themes were established, and will carry on this work in collaboration with Council and the Society

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### Survey Says....

**Deborah Hansen**

A twenty-four question survey was distributed to members of the Teratology Society about a month before the Strategic Planning Meeting. The survey was designed by the facilitators for the meeting. Its purpose was to take the pulse of the membership in 3 areas: the strategic focus of the Society, how the Society operated, and their point of view of the Society. While only 17% of members responded to at least some of the questions, the total number of responses was 116, which is a reasonable rate for this type of survey.

A large majority of respondents agreed that the Society's mission is relevant for the next five to ten years. However, a large proportion was not sure that they clearly understood the Society's strategic goals, and only about half thought that we were choosing the right area on which to focus. The strategic focus areas for the Society were identified as scientific excellence and leadership, recruitment and retention of members, communication (both internal and external) and outreach. These were also the main focus areas identified by Council and the other participants in the Strategic Planning Meeting.

It was also clear from the survey that we need to do a better job of communication regarding our Committees. About half of the respondents didn't understand the purpose and objective of some of our Committees, and a large proportion weren't sure if there was overlap between Committees.

The results of the survey were discussed at the Strategic Planning Meeting and will be used in helping us to identify our goals and action items. ■

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**To learn more about the Strategic Plan,  
Please join us at the Issues Forum on  
Tuesday, June 26 at 5:00 PM**

membership to further delineate the activities necessary to achieve the identified goals, and the action steps required for implementation. A detailed presentation of the planning session and the initial outputs from the work groups will be made at the Issues Forum at the annual meeting in Pittsburgh, on Tuesday, June 26, beginning at 5:00 PM. Members are urged to attend to learn more about this exciting event and to find out how they can be involved in the process of shaping the future of the Society. ■

## Member News

*Drugs During Pregnancy & Lactation*, 2nd Edition. Written by world renowned experts Christof Schaefer, Paul Peters and Teratology Society Past President Richard K. Miller, it provides conclusive information on the prevention of birth defects through the safe use of drugs before pregnancy, as well as during pregnancy and lactation. The latest edition is *the* resource for any practicing OB/GYN, family physician, midwife, or pharmacist who prescribes medicinal products to or evaluates environmental or occupational exposures in women who are or may become pregnant. *Receive a 20% discount when you ORDER NOW at <http://books.elsevier.com> using offer code 89022 at checkout.*



## Public Affairs Committee Update

### Janine Polifka

The Public Affairs Committee is pleased to announce that a Community Outreach Event on Fetal Alcohol Syndrome/Fetal Alcohol Effects is planned at the University of Pittsburgh prior to the Society's annual meeting. Jointly organized by Megan Adamson, Tina Chambers and Janine Polifka, it built upon a planned joint OTIS/NBTS/TS symposium on FASD. Local collaboration with Dr. Elizabeth Gettig who is the Director of the Genetic Counseling Program at the University of Pittsburgh helped to locate a venue at the University of Pittsburgh and to recruit genetic counseling students for the course. Dr. Sylbia Kunst, a principal at the Pioneer Education Center in Pittsburgh, was contacted to help recruit special education teachers and other education professionals to attend the workshop. Since the workshop falls into a week of professional development, Dr. Kunst plans to extend a district wide invitation that will also include social workers, school nurses, and building administrators.

The program will begin with a continental breakfast for participants followed by opening remarks presented by Dr. Sylbia Kunst. Dr. Nancy Day will present an overview of FASD which will include the causes and characteristics of FASD, the diagnostic criteria for FASD and how to obtain services for children and adults with FASD. Kathleen Mitchell will then discuss the lifelong effects of FASD on individuals and families. Elizabeth Parra Dang will then discuss educational curricula and media materials that are available from the CDC. And last, but not least, Drs. Kathy Sulik and Marianne Meeker will discuss "Better Safe than Sorry: Preventing a tragedy". The workshop will conclude with lunch and an opportunity for participants to network.

The FAS/FAE workshop will be held on Tuesday, June 26, 2007 between 7:30 AM-Noon in Parran Hall at the University of Pittsburgh. Registration for the workshop is free. Anyone who is interested in attending the course should contact Janine Polifka at [polifka@u.washington.edu](mailto:polifka@u.washington.edu). ■

## From the President's Desk

**Elaine Faustman**

It has been an exciting year, and this annual meeting will be special for me as your President. I invite you to enjoy and learn as we come together in Pittsburgh. I do want to call your attention to several items as we move towards our meeting time.

### **Dr. Ann Streissguth is the 2007 Warkany Lecturer**

I am pleased to announce that Dr. Ann Streissguth is our 2007 Warkany Lecturer. The title of her talk will be "Fetal Alcohol Spectrum Disorders from Teratology to Public Health" and will reflect her longstanding, highly productive research career and personal commitment to public health. Dr. Streissguth is a Professor emeritus at the University of Washington in the Department of Psychiatry and Behavioral Sciences. Her MS training was in child development from the University of California Berkeley and her doctoral degree is in Clinical Psychology from the University of Washington.

Dr. Streissguth and her research and clinical colleagues have been actively involved in research on the prevention of FAS and FAE since 1974. She is the recipient of numerous awards including a NIH Merit Award, the International Jellinek Memorial Award for Advancement in the Field of Alcohol Studies, the Silver Key award from the National Council on Alcoholism and Drug Dependence and was a recipient of New York State's "Women of the Century" Awards (to name just a few). When I had the pleasure to contact Ann and tell her that she had been nominated as the Warkany Lecturer, she immediately described some of her new research on brain imaging. She also, in the same breath, mentioned that one of the FAS kids from the first years of her longitudinal study had just re-contacted her and was asking for advice. This need to "be there for her kids" and to continue to "be there for her kids" is a wonderful reflection of personal commitment to help these affected children and their families. This blend of

highly relevant and significant scientific research along side with a public health commitment to prevention and intervention is why she was chosen as this year's Warkany Lecturer. She recounted to me her visits with Dr. Joe Warkany when he would spend his summers in Seattle.

I invite you to celebrate her career and hear about her new research on Monday, June 25 at 8:15 AM at the Teratology Society meeting. To learn more about Ann's research and see interviews with her, we encourage you to visit her website at <http://depts.washington.edu/fadu/Ann.Streissguth.bio.html>. ■

### **2007 Warkany Lecturer: Dr. Ann Streissguth**



## “Mentor Core” for Teratology

**Elaine Faustman**

Those of you who are fans of NPR “Story Core” interviews with family members and friends will enjoy a new feature at our 2007 annual meeting. We welcome you to interview your mentor and/or distinguished colleagues at the annual meeting. We will be compiling a series of video clips to document the roles that our long-standing Teratology members have played in the history and future of our Society.

If you would like to do one of these interviews, there will be a sign-up sheet to schedule “booth” time to run a 5–7 minute interview. We will provide some example questions that you may want to use to focus these interviews. Groups are welcome as well as one-on-one interviews. Please join us in this new activity to celebrate our members! We will be trying this on a trial basis and will be interested in hearing your feedback as we work on this project over the next few years. ■



*Dr. Narsingh Agnish at the 2006 Annual Meeting.*

### **Career Placement Opportunities**

We invite our members and colleagues to advertise job opportunities at the annual meeting. There will be a designated poster for posting these ads in Pittsburgh. You may also submit a posting for the website after the meeting by sending it by email to [tshq@teratology.org](mailto:tshq@teratology.org).

## Updates on US Pediatric Legislation

**Melissa Tassinari**

This is a busy time in the U.S. Congress. Two key pieces of legislation concerning the conduct of pediatric clinical trials are up for re-authorization; the Best Pharmaceuticals for Children’s Act (BPCA) and the Pediatric Research Equity Act (PREA). The combined effect of these laws has resulted in over 800 studies, more than 47,000 patients studied and more than 129 new labels with information to treat children<sup>1</sup>. Right now, the Senate has passed its version of the re-authorization and the House has taken up the Bills for debate. The 2 laws provide a ‘stick’ and a ‘carrot’ for the pharmaceutical industry. The ‘stick’ is PREA which mandates a study in pediatric populations for the approved adult indications for that medicine. BPCA is the ‘carrot’ which allows for an added 6 months patent extension in return for work done under a plan issued by the FDA called a Written Request. While both laws are expected to be reauthorized, and must be by October 1, 2007, the challenge is in the proposed modifications to the current laws. In particular, the length of the exclusivity award, and the means to determine how that exclusivity is awarded is under intense debate. Recent publications have indicated that any reduction of the incentives for conducting pediatric studies would likely result in a decline in the number of studies and areas of pediatric disease that are studied.<sup>2,3</sup> The cost, complexity and time that these pediatric program take has risen significantly over the 10 years that these laws have been in force.<sup>4</sup> If some of the new provisions are enacted, the FDA will be expected to change the way it handles the many pediatric programs that it oversees in ways that are, in some respects, redundant to the functioning process already in place. These laws are important and have worked well, let’s hope that they are renewed without language that reduces their effectiveness in delivering much needed information to the health care providers and parents of the children who need it.

1. US FDA: [www.fda.gov/cder/pediatric](http://www.fda.gov/cder/pediatric) (May 2007)
2. Li, JS et al.: JAMA. 2007;297:480-488
3. Schachter, AS and Ramoni MF: [www.nature.com/reviews/drugdisc](http://www.nature.com/reviews/drugdisc) (June 2007)
4. Tufts CSDD Impact Report vol. 9, no. 2, March/April 2007 ■

# Latest News on the National Children's Study

## Carole Kimmel

Many of you are probably aware that full funding for the NCS was part of the fiscal year 2007 budget continuing resolution passed by Congress. However, a Congressional request for NCS funding is required each year. Efforts are currently underway in Congress to add \$14 billion to the FY 2008 Labor-HHS-Education budget that would fund vital health and education programs, including the National Children's Study. The 2008 funding need for the NCS is \$111 million.

**BACKGROUND.** The National Children's Study (NCS) is a large longitudinal study designed to examine the effects of environmental influences on the health and development of more than 100,000 U.S. children from before birth to age 21. The goal of the Study is to improve the health and well-being of America's children. The NCS is designed to examine many aspects of children's lives, from family genetics; to the constructed world of neighborhoods and schools; to chemical exposures linked to the atmosphere, food or

water supplies; to the social and behavioral environment in which children grow and develop. The ability to examine multiple exposures and link them in cause-effect relationships with multiple outcomes is the defining characteristic of the National Children's Study, and the focus of the Study Plan. Children's health outcomes to be examined and improved through the use of data generated by the Study include pregnancy outcomes, growth, obesity, diabetes, neurobehavioral and cognitive development, asthma, injury, and reproductive development and function. The repository of biological and environmental samples to be collected in the Study will provide material for additional questions to be addressed for decades to come. A significant amount of effort and resources have gone into laying the groundwork for the Study over the past 7 years. This major interagency collaboration (NICHD, NIEHS, CDC, EPA) has included over 2500 scientists and community members from academia, industry, professional organizations, and advocacy and public interest groups. Much more information about planning for the Study can be found on the NCS website ([www.nationalchildrensstudy.gov](http://www.nationalchildrensstudy.gov)).

In 2005, the initial seven Centers, or Vanguard Centers, and the Coordinating Center for the NCS were funded. The Vanguard Centers have been assisting in refining the protocol and will be conducting pilot testing of the protocol in advance of the full Study. The Coordinating Center is the central processing group that will provide scientific, technical, and logistical support to all Study Centers and is responsible for information management, statistical sampling, data collection and analysis, and quality control. A repository as well as analytical laboratories are currently being planned.

**CURRENT EFFORTS.** The Research Plan, which will be reviewed by the National Academy of Sciences, is being completed and there will be an opportunity for public comment. The Research Plan will describe the general plan for the Study, the hypotheses and the exposure and outcome measures to be included. A more detailed protocol and operations manual are also under development.

With the 2007 funding, an RFP was released in early March to fund approximately 15-20 new Centers to cover up to 30 sites for the Study. These Centers will be selected and funded by the end of FY 2007. It is expected that an additional wave of Centers will be funded in subsequent years to complete the total of approximately 40 Centers and 105 sites for the Study.

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## Membership Engagement

### Elaine Faustman

### Please let us know how you would like to be involved in the Society: Call for Member input and interest welcome

The Teratology Society is graced with tremendously generous and insightful members who help to keep our scientific and professional programs vital. As we all prepare for the Annual Teratology Meeting we would like to welcome your input and interest in becoming more involved in our Society. As you know every year at this time the Teratology Society establishes our yearly priorities. This year we had a Strategic Planning Session so input directly from our members and from our committee's was especially useful. As we implement many of these proposals please let us know if you or one of your associates would like to volunteer or has input for our Society activities. One of the suggestions from the Strategic Planning Session was to formalize this input and volunteer forms. You may access the form through the Web site, your input will go directly to our headquarters office. Thank you in advance for all your efforts on behalf of the Teratology Society. ■