President’s Message
Barbara Mounho, Ph.D.

BTSS Happenings and Updates

It is hard to believe that the summer is over and fall is upon us! I am sure many of you are asking the same question “where does the time go?”

Much has happened over the summer for the BTSS. The BTSS now has a student and a post-doctoral representative. Our student representative is Fanny Casado-Pena, who is a doctoral candidate at the Department of Environmental Medicine at the University of Rochester Medical Center in Rochester, NY; our post post-doctoral representative is Holly Mortensen, who is conducting post-doctoral research at the National Center for Computational Toxicology in the Office of Research and Development at the US EPA. Please read more information about Holly and Fanny under the student and post-doctoral representatives piece in this newsletter (see page 4). If you are interested in being a student or post-doctoral representative for the BTSS in the future, please contact Andrea Weir at Andrea.Weir@crl.com.

We had incredible participation in the Program Committee this year, with 5 proposals submitted, 2 of which were accepted for the 2011 Annual Meeting. Janet Clarke provides insights into the quick work undertaken by the Program Committee (see page 3). If you are interested in participating in this committee, please contact Janet Clarke at Janet.clarke@biogenidec.com.

The BTSS website is up and running! There is lots of information available on the website, so, please take time to browse. The BTSS council would like to thank Tim MacLachlan for his continued efforts; if you would like to be involved in the BTSS website, please contact Tim at Tim.MacLachlan@genzyme.com.

The BTSS now has 4 awards! Awards are now open, and are described in this newsletter (see page 5). If you are interested in nominating someone for any of the 4 awards, please contact Hanan Ghantous at hanan.ghantous@fda.hhs.gov.

The BTSS membership continues to grow (we have over 100 members now!). If you are interested in becoming a member of the BTSS, just go to the SOT website, or contact Barbara Mounho at bmounho@amgen.com. There are still many opportunities to get involved in the BTSS, so spread the news!
BTSS Council - Open Positions for 2011

There are two positions on the BTSS Council that will be open in 2011: Vice President Elect and Councilor. If you would like to nominate yourself or a colleague, please contact Barbara Mounho at bmounho@amgen.com for more information.

2011 Annual Meeting

The 2011 Annual meeting will in Washington D.C., March 6 – 10th, which will be the 50th year anniversary for SOT! There are several activities planned for the 2011 Annual Meeting in celebration of the 50th year anniversary, including commemorative posters and an Anniversary Book that will feature many of the significant events and people that have contributed to the SOT over the years. For more information on the Anniversary Book, go to http://www.toxicology.org/AI/MEET/2011/index.asp. For more information on the activities that will be held at the 2011 Annual meeting in celebration of the 50th year anniversary, go to the SOT website. SOT expects high attendance for the 2011 meeting, and hotels are filling up fast. Make sure you reserve your room soon!

2011 Annual Meeting - BTSS Reception

The BTSS reception will be on Monday, March 7th for the 2011 meeting. Please mark your calendar! There will be updates on the BTSS, opportunity to interact with other BTSS members (some of them hopefully will be new members!), food and drink, and the BTSS council is also planning to have a guest speaker for the reception. Stay tuned!

BTSS Website:

http://www.toxicology.org/isot/ss/btss/index.asp

Thanks to Tim MacLachlan
The first program committee for the BTSS got off to a hard working start in 2010. Faced with an SOT deadline of April, the committee had 5 weeks to solicit, review and rank proposals for sponsorship and endorsement at the 2011 SOT meeting!

More than twenty people volunteered for the program committee, many of whom participated in brainstorming sessions to generate ideas for proposals in this short time-frame. Several members spearheaded preparation of some proposals in record time and a hardy program committee then met to review, advise and later rank submissions. The final result; the BTSS program committee facilitated 5 proposals of which 2 were accepted for the 2011 annual meeting. This was consistent with the overall acceptance rate for submissions this year, which was highly competitive, SOT received a record high of 202 submissions for 71 sessions. Congratulations to the chairs and speakers involved in the following proposals which were accepted by SOT and sponsored by BTSS;

**Roundtable:**
“Current uses and understanding of the tissue cross reactivity assay” Chairs: Jeanine Bussiere and Michael Leach

**Workshop:**
“Risk assessment for proteins introduced into genetically modified crops” Chair: Bruce Hammond

Thanks also to the Program Committee:
Scott Burchiel
Janet Clarke
(Chair)
Kaushik Datta
Hanan Ghantous
(Vice-Chair)
Daland Juberg
Barbara Mounho
(BTSS President)

Some lessons we learned from our first shot at this;
- start earlier
- submit a range of proposal types (ie a mix of symposia, workshops, roundtables etc), SOT allows the section to rank only 3 of a given proposal type
- let the program committee know as early as possible of a proposal for sponsorship. This allows us to provide advice, ensure diversity of proposal type, be aware of duplicative proposals and generally shepherd the proposal through the SOT system.

We will be starting in October to solicit, encourage, and “nag” for proposal ideas, with a goal to have BTSS sponsored proposals completed and ranked by the time of the SOT annual meeting in March. If you submitted a proposal this year and were rejected, don’t give up! Please consider adapting and resubmitting the proposal again as we received many interesting and novel ideas that there just wasn’t enough time to develop fully the first time around. Please contact me, Janet Clarke (janet.clarke@biogenidec.com) Program Committee chair, or Hanan Ghantous (hanan.ghantous@fda.hhs.gov) if you have questions or ideas for a proposal for 2012; it’s not too early to start planning.
Post-Doctoral and Student Representative Update
Submitted by Andrea Weir

We are pleased to announce that we have added a post-doctoral and student representative to BTSS since the June newsletter. Our post-doctoral representative is Holly Mortensen. Holly obtained her Ph.D. in human genetics at the University of Maryland in College Park, MD. Currently, she is conducting post-doctoral research at the National Center for Computational Toxicology (NCCT) in the Office of Research and Development at the US EPA. Holly is especially interested in the implementation of biotechnology, and related tools, to understanding toxicity that results in human disease. Our student representative is Fanny Casado-Pena. She is a doctoral candidate in the Department of Environmental Medicine at the University of Rochester Medical Center in Rochester, NY. Fanny’s interest in developing adequate tools to assess the safety of biotechnology-derived products led her to further her education in toxicology.

Both Holly and Fanny have been active in SOT. Holly has been a post-doctoral member of the society since 2008 and has attended and presented her research at two meetings. She will co-chair an accepted symposium at the 50th Anniversary SOT meeting in 2011 entitled “Human Variability in Susceptibility to Environmental Toxicants”.

Since becoming a student member of SOT in 2007, Fanny has attended and presented her research at 3 meetings and was the recipient of the Graduate Student Support (2009) and Student Travel Award (2010) from the Hispanic Organization of Toxicologists. Additionally, she is an active member of the BTSS Newsletter Committee, and has volunteered in Continuing Education and as a Peer Mentor for the SOT Undergraduate Education Program.

Their positions with BTSS should provide Holly and Fanny with the opportunity to interact with toxicologists with established careers in different areas of biotechnology, including agricultural and biopharmaceutical and to learn about career paths for toxicologists in the biotechnology field. Please welcome Holly and Fanny.

Membership Update
Submitted by Andrea Weir

Our membership has grown slightly since spring of this year. We now have 110 members compared to 104 in April. As indicated in the June 2010 edition of our newsletter, most of our members are from the biopharmaceutical area. Expanding our membership in other areas of biotechnology, such as agriculture, biobased fuels and environmental health and sciences, remains one of our primary goals. Please encourage your colleagues from these other areas to join BTSS!
**Awards Update**  
*Submitted by Hanan Ghantous*

It is not too soon to start thinking about submitting a nomination for the various BTSS Awards to be recognized at the 2011 SOT Annual Meeting. Nominations are open. Detailed descriptions of all the awards can be found on the SOT-BTSS website at: [http://www.toxicology.org/isot/ss/btss/index.asp](http://www.toxicology.org/isot/ss/btss/index.asp).

The following award categories will be considered, please submit nominations to Hanan Ghantous at hanan.ghantous@fda.hhs.gov before December 1st, 2010.

<table>
<thead>
<tr>
<th>Award</th>
<th>Description</th>
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<tr>
<td>Career Achievement in Biotechnology Award</td>
<td>Awarded to a Senior Investigator whose body of work represents an outstanding achievement in or contribution in the evolution of scientifically relevant approaches to and interpretation of toxicological aspects that are unique to biotechnology-derived products.</td>
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<tr>
<td>Outstanding Young Investigator Award</td>
<td>Awarded to the Young Investigator who has made a significant contribution to the evolution of scientifically relevant approaches to and interpretation of toxicology aspects unique to biotechnology-derived products.</td>
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<tr>
<td>Student Achievement Award</td>
<td>Awarded to two graduate students who are presenting a poster at the Annual SOT Meeting and whose work exemplifies the mission of the Biotechnology Specialty Section.</td>
</tr>
<tr>
<td>Best Paper Award</td>
<td>Awarded to the authors of the best paper in the area of biotechnology, published in a peer-reviewed scientific journal.</td>
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**Financial Report**  
*Submitted by Theresa Reynolds*

Member’s dues and all donor contributions have been booked to the BTSS (see table for details). As you can see, the costs from the inaugural BTSS SOT reception in Salt Lake City have booked, and we are in the black and ready to plan for the 2011 Reception in Washington, DC. Once again, thanks to our generous 2010 donors: Aclairo, Charles River, Genentech, Pfizer and William Brock.

We invite you or your organization to make a contribution that will be used to create awards, support receptions, and underwrite the activities of the section, as it continues to grow.

Donations for the 2011 calendar year can be made any time from July 1, 2010 – June 30, 2011. This means that checks written in 2010 can be applied to 2011, for those of you with extra budget to spend this year. Checks should be made out to Society of Toxicology, and ‘Biotechnology Specialty Section’ should be written on the check to ensure that it is posted to our account. If you require an invoice from SOT in order to get the process started, email Kim von Brook, Kimberly@toxicology.org, and she can provide one for you.
Society of Toxicology
Biotechnology
For the Twelve Months Ending June 30, 2010

### Ordinary Income/Expense

#### Income
- Contributions: 10,500
- Dues: 1,575
- Misc. Income: -
- Registration: 846
- Interest: 582

**Total Income**: 13,504

#### Expense
- Awards - Sections: -
- Plaques: -
- Contributions: -
- Executive Meetings: -
- Miscellaneous: -
- Newsletter: -
- Reception: 3,777
- Symposia: -
- Web Development: -

**Total Expense**: 3,777

#### Excess (Deficiency) of Revenue over Expenses

**Excess (Deficiency)**: 9,727

### Net Assets

- Net Assets Beginning of year: -
- Transfers from General Fund: 2,500
- Net Assets After Transfers: 2,500

**Net Assets End of Year**: 12,227
Health Care Reform Legislation:  
Changing the Landscape for Biosimilars in the United States  
Submitted by Andrea Weir and Barbara Mounho

Biosimilars are a new class of recombinant therapeutic proteins which are follow-on versions or attempted copies of approved protein products. The question of whether and/or on what basis to approve biosimilars in the United States has been an important topic of discussion and debate for a number of years. On March 23, 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act (PPACA), which contains the Biologics Price Competition and Innovation Act (BPCIA). The legislation creates an abbreviated approval pathway in the United States for biosimilar products that are demonstrated to be highly similar (biosimilar) to a protein product previously approved as a Biologics License Application (BLA) under the Public Health and Services Act (PHSA), and includes general information on the standards and data needed for determining biosimilarity. The statute defines biosimilarity as “the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components (42 U.S.C. 262 (i)(2)(A)); and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency of the product” (42 U.S.C. 262 (i)(2)(B)).

While the law provides general standards to demonstrate biosimilarity to the innovator product, Congress has authorized the Food and Drug Agency (FDA) to define the scientific standards and extent of the analytical, preclinical, and clinical data needed to determine biosimilarity. To date, FDA has not issued any regulatory guidance documents for biosimilars. However, as part of their ongoing effort to address biosimilars, FDA established a Biosimilars Implementation Committee (BIC), which is co-chaired by Dr. Janet Woodcock (director of Center of Drug Evaluation Research or CDER) and Dr. Karen Midthun (acting director of the Center for Biologics Evaluation Research or CBER). This committee is evaluating the law and working on the necessary steps towards implementing the approval of biosimilars. (www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm) The BIC plans to hold public meetings and seek comments from experts in the field, patients, and key stakeholders. Two Biosimilar Review Committees have also recently been chartered. These committees will consist of members from both CDER and CBER and will be chaired by Dr. John Jenkins and Dr. Robert Yetter, respectively. The goal of these groups is to address product-specific issues associated with scientific methodology. Additionally, FDA/CDER has appointed Dr. Leah Christl as acting Associate Director for Biosimilars in its Office of New Drug’s (OND) Dr. Christl will be coordinating OND’s implementation of the new biosimilar pathway (www.fda.gov/AboutFDA/CentersOffices/CDER/ucm217641.htm). FDA will also be developing procedures and staff training to consistently regulate the approval of biosimilar products.

While currently there are no biosimilars approved under the new law in the U.S., a legal and regulatory pathway has existed for biosimilars in Europe (and other countries) for a number of years (since 2005/2006). In order to define the regulatory expectations for the approval of biosimilar products, the European Medicines Agency (EMA) has issued a number of guidelines, including product specific guidelines. For example, the Guideline on Similar Biological Medicinal Products (CHMP/437/04) introduces the concept of biosimilars, outlines the basic scientific principles to be applied

After being a topic of discussion for a number of years, a legal pathway for the approval of biosimilars in the U.S. has been laid out in the health care reform law. Next steps will be the issuing of regulatory guidance and/or regulation for biosimilars by the FDA. However, the timing for issuing guidance is unknown. Likewise, the scientific standards and content of such standards have not yet been revealed by the agency. Undoubtedly, the upcoming public meeting held by FDA will be of great interest and an informative event to gain a better understanding in the agency’s expectations for approval of biosimilars.

Useful References Related to Biologic Compounds as Pharmaceutical Agents

Submitted by Katie Sprugel

The successful registration of more than 25 biologic molecules as therapeutics over the last 10-15 years has enabled us as a field to establish some general principles for good development practice. While specific development programs will always be case-by-case, there are now a number of review articles and books which provide information about specific aspects of biologic drug development, regulatory experience with these molecules, ongoing challenges, refinements in study design and interpretation, and specific molecule examples. Below is a potpourri of papers and books published in the last 5 or so years on these topics which may be of interest to you.

It has been suggested that we include an ongoing newsletter column highlighting interesting books or papers recently published. Additional topics to consider as a focus: biosimilars, agricultural biotechnology, member publications. Please send additional suggestions and/or citations to Katie Sprugel.


Chamanza R, Marxfeld HA, Blanco AI, Naylor SW, Bradley AE. Incidences and range of spontaneous findings in control cynomolgus monkeys (Macaca fascicularis) used in toxicity studies. Tox Path 38: 642-657, 2010.


