Regulatory and Safety Evaluation Specialty Section — Newsletter

of the Society of Toxicology
Winter 2011

President's Message

by Brian Short, DVM, PhD, DACVP

Brian Short,
2010 RSESS President

SOT's 50th Anniversary is fast approaching and I hope you will be able to attend and enjoy celebrating this historic occasion for our society, engage in the many scientific presentations and discussions, and reconnect with colleagues and friends. RSESS Executive Council has been working hard the past year to help plan the best meeting we can.

Firstly, our RSESS Reception and meeting Monday March 7 on Capitol Hill featuring the Great Debate attended by Senator Johnny Isakson (R-GA) and congressional staffers interested in hearing opposing views regarding underlying principles that may help guide the direction of reform of bills that will amend and reauthorize the Toxic Substances Control Act (TSCA). Our two outstanding speakers, Dr. George Gray of George Washington University and Dr. Lorenz Rhomberg of Gradient Corporation, are sure to make this a memorable event and I urge you to read more about our Great Debate in this newsletter. Speaking of TSCA, I want to thank the RSESS members who volunteered to serve on the TSCA Reform SOT task force, including Past President Jim Lamb who summarized the importance of this working group in our newsletter by Nancy Beck.

One of my goals the past year was to promote the involvement of RSESS members in helping SOT address regulatory policy issues. Although this is a small step forward, I am confident that SOT leadership will continue to move in this direction and eventually develop a more concerted effort and process to have a greater impact on regulations, guidelines, and policies that influence interaction between government, academia, and industry. For example, FDA is soliciting response on wide ranging proposals to revise Good Laboratory Practice for Nonclinical Laboratory Studies (Docket No. FDA-2-10-N-0548; edocket.access.gpo.gov) to more completely address how nonclinical studies are conducted. Several other groups (International Consortium for Innovation and Quality in Pharmaceutical Development, Society of Quality Assurance, Society of Toxicologic Pathology, and Biotechnology Industry Organization) have stepped up to provide comments on this important initiative.

I have other goals for the RSESS Executive Committee to achieve this year, including recognizing Program Chair, Graduate Student and Postdoctoral roles, which need further discussion that may merit changes to our by-laws.

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RSESS MISSION

The mission of the Regulatory and Safety Evaluation Specialty Section (RSESS) of SOT is to promote the development of sound governmental policies and regulations based on contemporary scientific knowledge arising from the disciplines encompassed by toxicology. RSESS provides a forum for the interaction of SOT members to discuss the impact of regulations, guidelines, and guidances on the practice of toxicology and the safety evaluation of food additives, nutraceuticals, therapeutic drug products and environmental, industrial and household chemicals, and other products of concern.

President's Message (cont'd from page 1)

Once again the specialty section is sponsoring a large number of sessions under the guidance of Susan Hart, our Program Chair, and her Program Committee. This group worked hard to help us endorse the strongest programs as listed in this newsletter. Planning for 2012 is underway, and I hope you will be a part of that. I am happy to announce that this year we will be providing timely guidance, review, and feedback from SS leaders for program submission proposals before the April 30th deadline and also feedback from the SOT Program Committee in the summer to submitters of unsuccessful proposals. Please review Susan's article regarding the 2012 Program and the Program Committee in this Newsletter. We need your help by volunteering to serve on the program committee.

We reviewed many high quality abstracts for Graduate Student and Postdoctoral Student Awards and will be presenting 6 awards at our reception on Monday, March 7th after the Great Debate, so please come support these great young scientists and their advisors. Our specialty section is financially strong and we are happy to support new and emerging scientists in this way.

I am also pleased to announce our new Graduate Student representative, Marcy McNamara, from University of Montana, and our Postdoctoral representative, Michael Boyle, DVM, DACVP, from NIEHS in Research Triangle Park, NC. This is the first time we've had 2 representatives as we move forward to increase input from this vital contingent of our organization. I also thank our departing Graduate Student representative, Tom Simones, for his contribution the last year. We wish Tom well on his newly elected position as Chair-elect for the student advisory council (SAC).

In May our Past-President Jim Lamb will become Past-Past President (i.e. "Out to Pasture President"), a position we have yet to officially recognize. His service the last 4 years has been exemplary; including his organization of what may be 'The Greatest' Debate on Capitol Hill as his crowning achievement as he departs our group. Thanks so much, Jim. We also lose our Councilor/Secretary/Treasurer and Newsletter Editor, Cindy Afshari. We appreciate her service and she will be missed as well. We had a great ballot this year for VP Elect and Councilor and we will be announcing our new officers at the reception. I am looking forward to seeing all of you at SOT.

Great Debate 2011 is Shaping Up to be an Event to Remember

by Jim Lamb, PhD, DABT

The Regulatory Safety Evaluation Specialty Section Meeting and Reception is taking on new dimensions for SOT's 50th Annual Meeting and ToxExpo. This year, we are combining forces with the SOT Communications Committee and hosting our Great Debate on Capitol Hill to take advantage of being in Washington. Senator Johnny Isakson (R-GA) will be the honorary host for the evening's festivities, which will start at 5 p.m. on Monday, March 7, 2011. Sen. Isakson was the SOT Congressional Science Leadership Award recipient in 2010 and he has graciously agreed to act as the host for this special event. Senator Isakson was selected for the award for his vision and leadership in sponsoring and supporting legislation that advances sound science as a basis for effective decision-making. The Senator has been a staunch supporter of stem cell research through legislation he sponsored, the HOPE bill, which was designed to accelerate research that would lead to a treatment for SMA. He serves on the Commerce Science and Transportation Committee, the Health, Education, Labor and Pensions Committee and the Foreign Relations Committee. He supported the Food Safety legislation and has been a consistent advocate of legislation to provide adequate for those agencies charged with conducting research for the nation. You'll learn more about the Senator when you attend the event, which will be held from 5 p.m. – 6:30 p.m. on Monday, March 7, 2011. Just a note, we are changing the time of our event this year to accommodate the Senate's busy schedule in the hope that our Great Debate will be a draw and attract lots of Hill staffers.

The event is being held in the Kennedy Caucus Room, which is Suite 325 of the Senate Russell Office Building. The room itself holds lots of history and class. It is one of the grandest and most historic rooms in the Nation's Capitol. The room, as the name implies, was originally intended for party caucuses or meetings where members of the same party decided on their candidates, policies and legislative matters. The Caucus Room was also the site of many famous investigations including the sinking of the Titanic, the Teapot Dome scandal, Pearl Harbor, the Kefauver Crime Committee, the Army vs. McCarthy, the Vietnam War and Watergate. The Office Building itself is named after Richard Brevard Russell, Jr., a Democrat from Georgia who served from 1933-1971.

The debate will be moderated by RSESS Past-President Dr. James Lamb of Exponent. He has set up a classic debate between two outstanding speakers. The proposition being debated is: *Hazard information provides an adequate basis for restricting chemical use.* This topic is timely considering that the U.S. Congress is currently considering bills to restrict certain chemicals, and also considering bills that will amend and reauthorize the Toxic Substances Control Act (TSCA).

Through a top-secret flip-of-the-coin, Dr. George Gray of George Washington University will speak in favor of the proposition. Dr. Lorenz Rhomberg of Gradient Corporation will speak in opposition. They have both promised to faithfully, even aggressively, defend their assigned perspective to the end. Each debater will be allowed to present their viewpoint and then be rebutted as least once. A vote will be taken at the end on the audience's position as well. George and Lorenz are excellent and entertaining speakers. They are extremely well informed on the subject.

The long and short of our reception is that it will be an event worthy of the SOT 50th anniversary!

Because of the logistics involved in getting to and from the Hill, the SOT Communications Committee has offered to provide bus transportation for everyone. Space is limited and we will be loading buses sharply at 4 p.m. on the L Street entrance of the Convention Center. We will have to walk a ways to the building and go through security before finally getting to the Caucus Room. Please bring photo ID. You will be going through an airport-like scanner, so don't wear metal if at all possible.

SOT TSCA Task Force

by Nancy Beck, PhD, DABT

The Society's Toxic Substances Control Act Task Force (TSCA TF) was formed 6 months ago and is comprised of 10 members including Drs. Dennis Devlin, William Farland, Ron Filler, Michael Gallo, George Gray, Daland Juberg (Chair), Mark Lafranconi, James Lamb, Nancy Rachmann, and Robert Skoglund. Martha Lindauer, SOT Director of Communications, serves as the liaison and support to this TF.

The stated Mission of this TSCA TF is to review science-based provisions of proposals for TSCA reform and to develop a communication outreach strategy with two targeted audiences. One audience is the SOT membership who will need to be informed about the impact of TSCA reform on many facets related to regulatory toxicology (e.g., toxicity testing, research needs, risk assessment approaches). Communications to SOT members will be forthcoming in 2011. The other audience is Congressional Staff who have previously conveyed to the Society the need for technical information about provisions of the former proposed bills (HR 5820 and S 3209) and including future legislation that may emerge in the current Congress.

To date, the TSCA TF has met monthly by phone and will hold a face to face meeting in late January 2011. The TSCA TF has reviewed the former bills and identified example areas where it believes it can provide Congressional Staff with in-depth insight, education, and clarification on language and/or issues that fall within the realm of toxicology and risk assessment. The TSCA TF does not advocate for specific issues or positions, but rather intends to provide assistance so that Congressional staff and lawmakers become comfortable in using current scientific principles to support legislative goals.

In advance of its January meeting and so that the TSCA TF can gain in-depth insight into areas whereby the Society can provide the most value, a subset of the TSCA TF is meeting with up to 6 Congressional Committees (both Republican and Democratic Staff) in January to gain direct insight and input which will leverage its work and communications to SOT members and Congressional Staff going forward. The TSCA TF intends to continue its work in the months ahead, in step with the stated Mission, while remaining cognizant of the pace of future TSCA legislation and being mindful of the stated needs of Congressional Staff.

ARA: Beyond Science and Decisions Workshop Series

by Nancy Beck, PhD, DABT

As part of an initiative to continue and broaden the discussion set forth by the National Academy of Science's (2009) report on Science and Decisions: Advancing Risk Assessment, the second of a series of workshops was held in October, 2010 in Crystal City, Virginia, under the auspices of the Alliance for Risk Assessment (*ARA*) (http://www.allianceforrisk.org). The goal of the workshop series, currently sponsored by 40 different organizations, is to build consensus among participants and develop a practical, solution-oriented, human health risk assessment methods compendium.

The workshops are focusing on human health risk assessment methods to address specific problem formulations. Held in Austin, Texas, the first workshop was devoted to presentations from leaders of ongoing risk assessment-related activities, and brainstorming and selection of case studies to evaluate proposed dose-response assessment techniques and their utility for different applications. The emphasis of the second workshop was on discussion of the methods as illustrated through the case studies, led by an Expert Science Panel. The purpose of the case studies was to provide illustrative information on dose-response methods that can be carried forward into a methods compendium. While some case studies have focused on specific chemicals for illustrative purposes, the charge of the Panel related only to utility of the method. The second workshop also included several presentations of ongoing activities related to risk assessment methods.

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Pathology Peer Review

by Brian Short, DVM, PhD, DACVP

Pathology peer review is considered essential for improving accuracy and quality of pathology diagnoses and interpretations, which is a cornerstone for making risk-based determinations for safety of a compound in humans. Recently this process has been under scrutiny by regulatory agencies world-wide and their concern with proliferation of contract laboratory studies and the responsibility sponsor in ensuring the highest quality data without perception of bias. Recently, recommendations for pathology peer review have been published that describe the state of the art at the current time (Morton et al., Toxicologic Pathology 38: 1118-1127, 2010). Some of the recommendations are"

1. For pathology peer review conducted before study completion, the peer review pathologist reviews sufficient slides and pathology data to assist the study pathologist in refining pathology diagnoses and interpretations.
2. Materials to be reviewed are selected by the peer review pathologist.
3. Consultations with additional experts or a formal (documented) pathology working group may be used to resolve discrepancies.
4. The study pathologist is solely responsible for the content of the final pathology data and report, makes changes resulting from peer review discussions, initiates the audit trail for microscopic observations after all changes resulting from peer review have been made, and signs the final pathologist's report.
5. The peer review pathologist creates a signed peer-review memo describing the peer review process and confirming that the study pathologist's report accurately and appropriately reflects the pathology data.
6. The study pathologist also may sign a statement of consensus.
7. It is not necessary for the study pathologist to archive working notes created during the peer review process

This article is a significant step in documenting the current practices of pathology peer review and will also stimulate additional discussion within regulatory agencies and industry.

ARA: Beyond Science and Decisions Workshop Series (cont'd from page 4)

This series of workshops has been organized by the *ARA*, a collaboration of nonprofit organizations that fosters the development of technical chemical risk assessment products and services, utilizing a team effort of specialists from organizations dedicated to protecting public health by improving the process and efficiency of risk assessment. The *ARA* is expected to increase the capacity for developing risk values to meet growing demand. Consistent with the goals of the *ARA*, the workshop series has included several different ways for involvement from multiple sectors. The workshop series has been developed and supported by a large number of people and broad range of organizations, including federal and state government agencies, scientific societies, private companies, and NGOs (see http://www.allianceforrisk.org/ARA_Dose-Response_Sponsors.htm for the full list). The Expert Science Panel was designed to be balanced and reflective of a range of affiliations and perspectives, as well as types of expertise (biology, risk assessment, modeling). Particular effort was made to include people from the NAS Science and Decisions panel and environmental NGOs. See http://www.allianceforrisk.org/Workshop/Panel.htm for the list of panel members and biographical sketches. The broader risk assessment community was invited to submit case studies on specific methods for consideration in the workshop; 26 organizations are represented as coauthors on case studies. Reflecting these multiple opportunities for involvement, more than 135 scientists from a broad range of organizations participated in the second workshop, either in person or via webinar. The workshop was held in tandem with the Federal-State Toxicology and Risk Analysis Committee (FSTRAC) annual meeting, with one overlapping session.

The third workshop will be held May 4, 5 and 6 in Falls Church, VA. At this workshop, the Expert Science Panel will review additional case studies, and seek consensus on a methods compendium highlighting key considerations for applying dose-response techniques for common risk assessment applications. See http://www.allianceforrisk.org/ARA_Dose-Response.htm for more information and meeting registration.

Program Committee Review and Selection Process for SOT 2012

by Susan Hart

Even though the 2011 SOT Meeting is still a week or so away, it's not too soon to start thinking about submitting a proposal for the 2012 SOT Scientific Program. The deadline for proposal submissions (April 30th) comes up incredibly fast following the meeting, with an even faster deadline (usually within the first two weeks of May) for the Executive Committee of each Specialty Section to review its assigned proposals and make its decisions on endorsement, sponsorship and prioritization for each proposal.

For a large Specialty Section like RSESS, the sheer number of submission to be reviewed makes the process even more challenging. For example, in 2010 a total of sixty proposals for the 2011 meeting were submitted to RSESS for review (representing approximately 1/3 of the total number of proposals submitted for the entire meeting!). In addition to the "formal" proposals received through the SOT online submission process, a number of "informal" proposals were submitted to one or more of the RSESS officers in the weeks between the SOT meeting and the proposal submission deadline, many of which never ended up being submitted formally through the SOT website. While it's not possible to track the "proposed but not submitted" programs, a reasonable estimate is that these have accounted for an additional 15 to 25 submissions per year on average. This adds up to an incredible commitment of time and effort on the part of the RSESS EC and Scientific Program Committee over a period of six to eight weeks following each SOT meeting.

The sheer volume of submissions received by RSESS and the timelines imposed by the SOT Program Committee makes it impossible for RSESS to handle the review of proposals as the other Specialty Sections do. For this reason, the RSESS EC, in its wisdom, delegated the job to a Scientific Program Committee (the 2011 members are Vicki Dellarco, Lori Dostal, Ron Gerson, Denise Robinson-Gravatt, Haitian Lu, Tao Wang, and yours truly as the Chair). The Committee does the bulk of the work in reviewing each session proposal and submits a recommendation to the RSESS EC on each one, but the final decision ultimately resides with the EC. We have been working hard over the past three years to try and streamline the process but it's still a work in progress and has resulted in much confusion and frustration from would-be session chairs who are expecting definitive decisions regarding endorsement or sponsorship by RSESS in advance of the submission deadline. For that reason, a few additional modifications to the process for 2012 have been made to try and improve the service to RSESS members submitting proposals (which is to be encouraged!).

For starters, there are two levels of support that can be provided by a given Specialty Section (SS) – Sponsorship and Endorsement. A proposed session can be endorsed by as many SSs as the proposer chooses to solicit, but there is only one SS sponsor for each program. Sponsorship requires more rigorous review by the SS, because in addition to agreeing to serve as a session's sponsor, SOT requires that the sponsoring SS to select the top five proposals within each session type and provide a 1-5 ranking for each of the chosen five (for example, if we decide to sponsor seven CE Courses, we need to choose the top five and rank them 1-5). So we not only have to decide if the proposal is worthy of sponsorship but also to determine how it stands up to the others in its class – this takes the bulk of the discussion time on the Committee's part. Proposals for which only endorsement is requested of RSESS are not ranked; only a "yes" or "no" decision is required. As a general rule, only proposals which are clearly outside the objectives of RSESS, are incomplete or which do not conform to the session type proposed are rejected for either Sponsorship or Endorsement.

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Program Committee Review and Selection Process for SOT 2012

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The guidelines for proposal submission and submission deadline will be available on the SOT website at https://www.toxicology.org/ms/SciSess_proposal.asp soon after the 2011 meeting is complete. Anyone interested in submitting a session proposal for the 2012 meeting should start here for the basic guidelines on the process. The modifications for RSESS specifically are as follows:

- The "Submitting a Proposal Guide" posted on the website encourages submitters to provide the draft submission to the appropriate Sponsor or Endorsing SS prior to online submission, for review, assistance with fine tuning and "pre-approval" before formally submitting the proposal online. Due to the sheer volume of submissions received and the fact that all submissions go through the Committee, RSESS has not been able to do this consistently in the past; however, for 2012, each informal proposal will be assigned to a member of the Scientific Program Committee for a preliminary assessment, comment and suggestions in advance of online submission. This will not guarantee an ultimate decision for sponsorship or endorsement by the full Committee but will provide some needed guidance on strength of the proposal, "goodness of fit" to the session type and advice on improving the chances of acceptance.
- Proposals for informal review may be submitted to any RSESS officer, member of the Scientific Program Committee or, for fastest service, directly to me (shart@intrexon.com) for assignment to a committee member for a preliminary assessment. Submission of complete and detailed program proposals from the beginning will markedly improve the value of this interaction (as will submitting them as early as possible, preferably before April 15).
- Official review of the proposals can only occur after they have been submitted (and are finalized) on line. Again, the earlier this is completed the better the chances of a thorough and favorable review by the Scientific Program Committee (including a window of opportunity for Program Chairs to be contacted for clarification and additional suggestions to strengthen the proposals). If our request to SOT for earlier access to the online submissions is honored this year (keep fingers crossed!), an updated spreadsheet listing all completed submission will be circulated to the Program Committee members on a weekly basis starting the second week of April to allow additional time for review.
- Within 24 hours after the submission deadline, a final spreadsheet listing all of the proposals submitted to RSESS is collated and circulated to the Scientific Program Committee members (the actual proposals are supplied as embedded Word or .pdf files within the spreadsheet). The spreadsheet serves as each Committee member's ranking ballot for Sponsored proposals and "yes or no" ballot for endorsed proposals. The ballots and Committee member comments are collated by the Scientific Program Committee Chair onto a Master Spreadsheet, which is circulated to the RSESS EC following final decisions by the Committee on the submitted proposals.

RSESS Program Sponsored and Endorsed Sessions

Monday 3/7 AM: Integration of Toxicological and Epidemiological Evidence to Understand Human Risk (Sponsor)

Monday 3/7 Afternoon: Reforming the Toxic Substances Control Act (TSCA): Challenges, Opportunities, and Timing (Sponsor); The International Cooperation on Alternative Test Methods (ICATM): Translating Science to Provide Improved Public Health Safety Assessment Tools (Endorsed); Human Variability in Susceptibility to Environmental Toxicants (Endorsed)

Tuesday 3/8 AM: Risk and Risk Management of Potentially Toxic Compounds Formed by Cooking Food (Endorsed)

Tuesday 3/8 Afternoon: Integrating Alternative Test Methods in the Federal Regulatory Framework (Endorsed); Nonclinical to Clinical Abuse Liability Assessment of Drugs: Current Practices, Challenges, and Impact of Recent Regulatory Guidance (Sponsor)

Wednesday 3/9 AM: The Application of the Threshold of Toxicological Concern Concept to the Preclinical Safety Assessment of Non-Pharmaceutical Medical Products, Including Medical Devices and Combination Drug -Device Products (Endorsed); Approaches for Incorporating Non-Chemical Stressors into Cumulative Risk Assessments (Endorsed); Understanding the Implications of Preclinical Seizures for Clinical Drug Development (Sponsor)

Wednesday 3/9 Afternoon: Current and Changing Perspectives on Mycotoxins and Their Potential Health Risks Worldwide (Endorsed); Assessment of Nanoparticle Exposure in Occupational Settings and in Inhalation Toxicology Studies: Is There a Best Dosemetric to Use? (Endorse); Toxicological Considerations of Pharmacotherapy during Pregnancy (Endorsed)

Thursday 3/10 Morning: Beyond Science and Decisions: From Problem Formulation to Dose-Response (Endorsed); Bringing Toxicology to the Decision-Makers Table: Opportunities for Science Policy Positions in Washington DC (Endorsed); Vascular Injury: A Figment of Your Inflammation (Sponsor); Are We There Yet? Attrition in the Pharmaceutical Industry and Impactful Strategies for Reducing Failure (Endorsed); Role of Biomarkers in Assessing Tobacco Harm Reduction: A Toxicological Perspective (Sponsor)

Workshop Ads

The following upcoming workshops may be of interest to RSESS Members:

- "Nonclinical and Clinical Strategies in First in Human Dosing of Large and Small Molecules" DIA meeting, April 4-6, 2011. www.diahome.org.
- American College of Toxicology: "Toxicology for Industrial and Regulatory Scientists," May 16 – 20, 2011, http://www.actox.org/Education/ToxicologyforIndustrialandRegulatoryScientist/ToxCourseRegistration/tabid/6183/Default.aspx
- DIA/FDA Quantitative Structure-activity Relationship (Q)SAR Approaches to Assessing Genotoxic Impurities in Pharmaceuticals, April 7, 2001, Rockville, MD. www.diahome.org.

White House Scientific Integrity Developments

by Nancy Beck, PhD, DABT

The Obama Administration's strong commitment to ensuring information quality has been recently reinforced in a variety of contexts. The President's March 9, 2009 Memorandum on Scientific Integrity[1] refers to the need for each Federal Agency to:

- have appropriate rules and procedures to ensure the integrity of the scientific process within the agency;
- use scientific and technological information that has been subject to well-established scientific processes such as peer review when considered in policy decisions;
- appropriately and accurately reflect scientific and technological information in complying with and applying relevant statutory standards; and
- make available to the public the scientific or technological findings or conclusions considered or relied upon in policy decisions.

On December 17, 2010, John Holdren, the Assistant to the President for Science and Technology and Director of the Executive Office's Office of Science and Technology Policy (OSTP) issued a Memorandum to the Heads of Departments and Agencies[2] that provides further guidance to Executive Branch leaders as they implement Administration policies on scientific integrity. This implementing guidance reiterates that "the accurate presentation of scientific and technological information is critical to informed decision making by the public and policymakers." This implementing guidance focuses on four areas:

1. Ensuring foundations of scientific integrity
   In addition to fostering a culture of scientific integrity, including many of the aspects mentioned above, agencies are tasked to:
   "Communicate scientific findings by including:
   - a clear explication of underlying assumptions;
   - accurate contextualization of uncertainties; and
   - a description of the probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios where appropriate."

2. Public Communications
   - This section tasks agencies with developing communication policies which promote and maximize openness and transparency with the media and the public. The memo directs agencies to develop policies to expand and promote access to scientific and technical information by making it available online in open formats. Where appropriate, this should include data and models underlying regulatory proposals and policy decisions.

3. Use of Federal Advisory Committees
   - Agencies are encouraged to develop policies to ensure the integrity of those providing scientific advice to the government and the guidance lays out some selection criteria and information that may be useful. Agencies must ensure that data and research used to support policy decisions undergo independent peer review by qualified experts, where feasible and appropriate, and consistent with law, including setting clear standards governing conflicts of interest.

4. Professional Development of Government Scientists and Engineers
   - This section focuses on the establishment of policies that promote and facilitate professional development of government scientists and engineers.

For further information about these initiatives please see the memorandums referenced above, as well as the OSTP blog[3].

[1] Available at: http://www.whitehouse.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09

[2] Available at: http://www.whitehouse.gov/sites/default/files/microsites/ostp/scientific-integrity-memo-12172010.pdf

[3] Available at: http://www.whitehouse.gov/blog/2010/12/17/scientific-integrity-fueling-innovation-building-public-trust-ostp