

## Board advises NTP on critical issues

By Robin Mackar

NTP received both praise and input about how to move forward on several important topics, including systematic review, Tox21, and several cancer listings, June 25 at its Board of Scientific Counselors (BSC) [meeting](http://ntp.niehs.nih.gov/?objectid=720164F2-BDB7-CEBA-F5C6A2E21851FoC4).  
(<http://ntp.niehs.nih.gov/?objectid=720164F2-BDB7-CEBA-F5C6A2E21851FoC4>)

New BSC Chair [Melissa McDiarmid, M.D.](http://medschool.umaryland.edu/occupational/who.asp), from the University of Maryland, started the meeting with a report from NIEHS and NTP Director Linda Birnbaum, Ph.D. Birnbaum updated the board on recent activities, including the NIEHS strategic plan, budget, science findings, and some recently launched big data initiatives, including the [NIEHS-NCATS-UNC DREAM Toxicogenetics Challenge](#) that had more than 60 people signed up the first week.

### NTP monograph

Kembra Howdeshell, Ph.D., from the [NTP Office of Health Assessment and Translation \(OHAT\)](#),  
(<http://ntp.niehs.nih.gov/?objectid=497C419D-E834-6B35-8AF15D389859AF07>)

provided an overview of the NTP [Monograph](#)  
([http://ntp.niehs.nih.gov/NTP/OHAT/Cancer\\_Chemo\\_Preg/CCPmonograph\\_PrepubCopy\\_508.pdf](http://ntp.niehs.nih.gov/NTP/OHAT/Cancer_Chemo_Preg/CCPmonograph_PrepubCopy_508.pdf))  
on Developmental Effects and Pregnancy Outcomes Associated with Cancer Chemotherapy Use During Pregnancy. Howdeshell made her presentation by phone, since she was also presenting the monograph in a symposium on cancer and pregnancy at the Teratology Society annual meeting, co-chaired by Howdeshell and Michael Shelby, Ph.D., also of OHAT.

Howdeshell said that 457 observational studies were included in the evaluation, which was developed to serve as a tool for physicians and patients making clinical decisions about cancer treatment during pregnancy.

McDiarmid, who served as the BSC liaison during the peer review of the monograph in [October 2012](#), told the board that NTP did a good job given the limitations of the data. NTP and the board identified the need for greater participation in registries, and improvements in the quality of reporting in case reports.

### Contracts approved

The BSC also unanimously approved two contract concepts — [quality assessment support](#)  
([http://ntp.niehs.nih.gov/NTP/](http://ntp.niehs.nih.gov/NTP/About_NTP/BSC/2013/June/QASupportContractConceptFINAL_508.pdf)

[About\\_NTP/BSC/2013/June/QASupportContractConceptFINAL\\_508.pdf](http://ntp.niehs.nih.gov/NTP/About_NTP/BSC/2013/June/QASupportContractConceptFINAL_508.pdf))

### Highlights of NTP Roadmap progress

The NTP associate director's report focused on progress made by NTP since it laid out its [roadmap](#)  
([http://ntp.niehs.nih.gov/NTP/About\\_NTP/NTPVision/NTProadmap\\_508.pdf](http://ntp.niehs.nih.gov/NTP/About_NTP/NTPVision/NTProadmap_508.pdf))  
in 2004. Bucher framed his talk around three of the main areas addressed in the plan, with a heavy emphasis on [Tox21](#):  
(<http://www.niehs.nih.gov/assets/file417691.pdf>)  
(642KB)

- Refine traditional toxicology assays
- Develop rapid mechanism-based predictive screens for environmentally induced diseases;
- Improve the overall utility of NTP products for public health decision making

Bucher talked about how, in Phase II of Tox21, a 10,000-compound library had been tested across a set of nuclear receptor and stress response pathway assays, in a small number of assays. He showed data where compounds with similar biological activity patterns, across the different assays, were linked in a connectivity network.

“Using this kind of plot helps us determine if some of the associations we are seeing make sense,” Bucher said. “We are just at the beginning stages, but eventually we hope to get to a point where the Tox21 data can be used to better predict the potential for hazard and, thus, protect public health.”

A lively discussion followed the presentation, with encouragement from BSC to continue to move forward with testing in human cells. “In every case we can, we’re using human cells,” Bucher said.

and [global pathology support](#).

([http://ntp.niehs.nih.gov/NTP/About\\_NTP/BSC/2013/June/GlobalPathSupportConcept\\_508.pdf](http://ntp.niehs.nih.gov/NTP/About_NTP/BSC/2013/June/GlobalPathSupportConcept_508.pdf))

## Report on Carcinogens

Ruth Lunn, Dr.P.H., director of the [Office of the Report on Carcinogens \(RoC\)](#) shared where NTP was in the development of the next RoC. After presenting a [schematic](#)

(<http://ntp.niehs.nih.gov/?objectid=3756DEOC-FA7A-404B-3F72194C30ABD961>) of how the NTP reaches its level of evidence conclusions, she focused on the substances 1-bromopropane and cumene, which were [peer reviewed](#) at a public meeting in March 2013. Lunn summarized the comments from the panel and shared NTP's response. The peer review panel concurred with NTP to list both substances as reasonably anticipated human carcinogens.

BSC member Dale Hattis, Ph.D., of Clark University, who served as BSC liaison for the peer review meeting, commented on how thorough he felt the discussions were at the meeting and how receptive NTP was to the comments provided.

## Systematic review

Andrew Rooney, Ph.D., deputy director of OHAT, presented on the implementation of systematic review and evidence integration for literature based health assessments. Rooney focused his attention on some areas that have received the most input and questions during public comment periods and webinars recently hosted by NTP, including study quality and risk of bias. He discussed how NTP planned to approach these topics and how the public comments would inform these issues moving forward.

OHAT Director Kristina Thayer, Ph.D., then presented next steps for the systematic review process. "We expect to complete our [case studies](#) (<http://ntp.niehs.nih.gov/?objectid=960B6F03-A712-90CB-8856221E90EDA46E>) during the next calendar year. These will help us better assess the performance of our methodology and fine tune our processes," Thayer said.

Given the public interest, Thayer said, NTP is helping support the development of a free software tool that will facilitate harmonization of information collected on studies included in systematic reviews. "We're pretty excited about what this tool will do," Thayer said. Beta testing begins this summer.

## Draft concept

The final topic discussed at the meeting was something rather new for NTP — getting input on how to define an exposure, light at night, that has been nominated for study.

"We want to define this so it is meaningful to public health," said NTP Associate Director John Bucher, Ph.D. Lunn walked the BSC through the [draft concept, shift work at night, light at night, and circadian disruption](#).

([http://ntp.niehs.nih.gov/NTP/About\\_NTP/BSC/2013/June/DraftShiftworkConcept\\_508.pdf](http://ntp.niehs.nih.gov/NTP/About_NTP/BSC/2013/June/DraftShiftworkConcept_508.pdf))

She pointed out that those nominating the exposure were concerned that light at night may be a cause of breast cancer among women, and noted that the International Agency for Research on Cancer has classified shiftwork, involving circadian disruption, as a probable carcinogen.

The Board concluded that NTP was in the best position to address this very broad, important topic, but urged it to proceed with caution, consult technical experts, and try to narrow its focus.

(Robin Mackar is the news director in the NIEHS Office of Communications and Public Liaison, and a frequent contributor to the Environmental Factor.)



Lunn, who leads the RoC effort, made two presentations to the board — one focused on a new draft concept, and the other on progress of two RoC candidate substances. (Photo courtesy of Steve McCaw)



Board member Miguel Fernandez, M.D., of University of Texas Health Science Center, served as a reviewer and discussant for the draft concept on light at night. He said health care workers are an important target audience for this kind of study. (Photo courtesy of Steve McCaw)



David Dorman, D.V.M., Ph.D., of North Carolina State University, provided scientific advice on how to address mechanisms of action in reports and processes. (Photo courtesy of Steve McCaw)



*McDiarmid, left, seemed right at home taking on her new role as BSC chair, shown with Mary Wolfe, Ph.D., director of the NTP Office of Liaison, Policy, and Review. (Photo courtesy of Steve McCaw)*



*Thayer, who leads OHAT, talked about next steps for systematic review. (Photo courtesy of Steve McCaw)*



*OHAT deputy director Rooney addressed some of the ways NTP is revising its systematic review process based on public input. (Photo courtesy of Steve McCaw)*



*Bucher encouraged the board to share their thoughts about how the NTP should be moving forward. (Photo courtesy of Steve McCaw)*

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