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## **NEW BOSS AT NIEHS**

Linda Birnbaum, a longtime government toxicologist, has been named director of the \$730 million National Institute of Environmental Health Sciences (NIEHS) in Research Triangle Park, North Carolina. Birnbaum succeeds David Schwartz, who left in February amid ethics concerns (*Science*, 22 February, p. [1021](#)).

Birnbaum, who takes over next month, is an expert on the health effects of dioxin and other hormonelike pollutants. She has spent nearly 29 years in government, first at NIEHS and more recently at the Environmental Protection Agency's research lab near NIEHS. Some researchers are worried that Birnbaum might be less supportive of investigator-initiated research than of studies to support regulations. On the other hand, her research has bridged both because "it's been very focused on [biological] mechanisms," says toxicologist David Eaton of the University of Washington, Seattle, who says Birnbaum "is well-prepared to lead NIEHS." Birnbaum says any concerns about a decline in blue-sky basic research are "unfounded" and adds that "it's still going to be extremely important."

Birnbaum sees "a lot of opportunities for improvement" at the institute. For example, she wants to look more closely at whether the trace levels of pollutants in most Americans are harmful.

<http://www.sciencemag.org/cgi/reprint/322/5908/1617c.pdf>

## NIEHS gets new leader

News Blog

Posted by Bob Grant

[Entry posted at 3rd December 2008 05:32 PM GMT]

**Linda Birnbaum**, a toxicologist and former head of EPA's Experimental Toxicology Division, will be the new head of the NIH's **National Institute of Environmental Health Sciences (NIEHS)**, ending a period of turmoil under her predecessor **David Schwartz**, who resigned from the institute early this year amidst allegations of mismanagement.

Raynard Kington, acting head of NIH, announced the appointment today (Dec. 3).



"I look forward to **Dr. Birnbaum** joining us," Kington said in a statement. "She has a long and distinguished career conducting research into the health effects of environmental pollutants, and the cause and effects relationships at pollutant concentrations which mimic those occurring in the environment."

"I am excited about serving as the director of **NIEHS** at a time when integration across disciplines is essential, from molecular biology to pharmacology and physiology to epidemiology. Complex environmental issues require individual and team efforts to address the interactions between the environment and human health," **Birnbaum** said in a statement.

**Birnbaum** will assume leadership of **NIEHS** starting in January, 2009.

<http://www.the-scientist.com/blog/display/55257/>

## New NIEHS leader looks ahead

NewsBlog

Posted by Bob Grant

9th December 2008 04:00 PM GMT]

Researchers at NIH's long-beleaguered **National Institute of Environmental Health Sciences (NIEHS)** are hopeful that the institute's new head, toxicologist **Linda Birnbaum** will be able to right the ship after the rocky tenure of **ex-NIEHS director David Schwartz**.

**Chris Portier**, associate director of NIEHS, said that there are key differences between **Schwartz** and **Birnbaum**. "I'm much more optimistic that she's got management experience of a large group, which **David [Schwartz]** didn't have," he told The Scientist. "She's got governmental experience, which **David** didn't have. It will be a completely different person that steps into that office."

Amid allegations of mismanagement -- including stocking his disproportionately large lab full of former Duke University colleagues -- **Schwartz** resigned from his post earlier this year. One of his most provocative moves was to suggest privatizing and cutting funding for **Environmental Health Perspectives**, NIEHS's open-access, peer-reviewed journal. The proposition raised hackles in Washington, DC and beyond, among members of the environmental health and science community.

When asked about how she plans on correcting any damage that former **NIEHS** director **David Schwartz** may have done to the institute, **Birnbaum** demurred. "I don't focus on the past," she said. "I'm looking ahead."

**Birnbaum** did say that she is in favor of keeping **EHP** publically funded. "I've always been a strong supporter of **EHP**," she told The Scientist. "I feel very fortunate to have it as part of the **NIEHS** portfolio."

**Birnbaum**, who formerly headed the EPA's Experimental Toxicology Division, will be taking over as the director of **NIEHS** in January. She said she will encourage increased interaction between basic and applied scientists, from bench researchers to epidemiologists and physicians, at the institute.

"I'm someone who believes in the synergy that can come from different kinds of science," she said.

**Birnbaum** also said she will focus on both the prevention and treatment of environmentally-mediated diseases and that she'll direct more attention to cutting edge technologies, such as biomarkers to track the early effects of asbestos exposure. "These are things that haven't been addressed a lot that offer us real opportunities," she said.

**Portier**, who also studies systems biology at **NIEHS**, agreed that an integrative approach was essential to the success of the institute. "I agree 100% that we're going to have to do much better integrative science if we're going to address the challenges we're facing now," he said. "[**Birnbaum's**] really quite a perfect choice for the institute."

<http://www.the-scientist.com/blog/display/55271/>

## Toxicologist to Become an NIH Director

By Janet Raloff

Web edition: Wednesday, December 3rd, 2008

Long-time readers of *Science News* will recognize the name [Linda Birnbaum](#). Today, this toxicologist — an expert not only on [dioxins](#) and their kin, but also on [brominated flame retardants](#)— was named the incoming director of the [National Institute of Environmental Health Sciences](#). It's one of the smaller siblings among 27 members of the [NIH](#) family and the only one devoted to understanding environmental causes of disease.

The institute [Birnbaum](#) takes over on Jan. 1 is located in Research Triangle Park, N.C. Well removed from NIH's main campus here in the DC burbs, it's been where [Birnbaum](#) has spent most of her working career — first at [NIEHS](#), and later at the [Environmental Protection Agency](#). Indeed, for 16 years she served as EPA's director of [experimental toxicology](#).

[NIEHS](#) is probably best known as the publisher of [Environmental Health Perspectives](#), an open-access peer-reviewed journal on environmental risks and hazards. But with a \$730 million budget, [NIEHS](#) also funds 1,240 scientific grants. Internal research at the agency has, over the decades, made many of the discoveries that underlie a burgeoning field of science that has come to be known as endocrine disruption — or hormone mimicry by environmental agents.

Active in research, [Birnbaum](#) has been an author on more than 600 peer-reviewed journal articles, book chapters, abstracts, and reports. She's president-elect of the [International Union of Toxicology](#) (an umbrella group of societies in more than 50 countries), a recent president of the [Society of Toxicology](#) (the world's largest professional organization of toxicologists), and former chair of toxicology at the [American Society of Pharmacology and Therapeutics](#). In other words, she has the creds.

I'm more familiar with another side of her professional persona: the communicator.

As a reporter who has worked with [Birnbaum](#) for probably 20 years, I've found her singularly articulate in explaining the often arcane effects and mechanisms by which many environmental agents cause harm. A straight shooter, she won't hazard wild guesses about implications of her data, but she will offer informed speculation. The kind of comments, for instance, she'd share with colleagues at a research conference.

She doesn't look for attention or grandstand, but she will speak up repeatedly to keep colleagues grounded on what the data that they're considering show — or don't show. She also points out what kinds of studies would be required to fill in all those niggling data gaps. These would be the investigations needed to understand whether the chemicals we encounter in the home, workplace and environment are likely to be benign or not — at the doses to which we may be exposed.

Earlier this year, [David Schwartz](#) resigned from his post as [NIEHS](#) director under a very gray cloud. One of his sins: He tried to undertake a quick privatization of [Environmental Health Perspectives](#). Researchers and many Capitol Hill investigators suspected this would effectively kill the publication or keep it from publishing groundbreaking data on issues the Bush administration would prefer not come to light. [EHP](#) remains a wholly owned government-administered entity. But the likelihood it would be sold or materially changed remained touch-and-go for a long time.

[Schwartz](#) also had a distinctly different attitude than [Birnbaum](#) about the news media. He encouraged his staff to shun reporters or to find ways to limit contact with them as much as possible. [Schwartz](#) also had been under congressional scrutiny for alleged ethics violations.

As people look for science to once again hold sway in research agencies, appointments like [Birnbaum](#)'s appear to be a step in the right direction.

[http://www.sciencenews.org/view/generic/id/39012/title/Toxicologist\\_to\\_Become\\_an\\_NIH\\_Director](http://www.sciencenews.org/view/generic/id/39012/title/Toxicologist_to_Become_an_NIH_Director)

## New Director Named for NIEHS

December 05, 2008

The next director of the National Institute of Environmental Health Sciences (NIEHS) will be Linda S. Birnbaum, Ph.D., who is currently a senior adviser with EPA but previously worked at NIEHS for a decade. Dr. Raynard S. Kington, acting director of the National Institutes of Health, announced her appointment Wednesday. Birnbaum will start in January; she previously spent 16 years as director of EPA's Experimental Toxicology Division and was president of the [Society of Toxicology](#) in 2004-05.

NIEHS has a \$730 million budget to fund biomedical research programs, prevention, and intervention efforts. It is located in Research Triangle Park, N.C., and currently is funding more than 1,240 research grants, according to the NIH announcement. "I am excited about serving as the director of NIEHS at a time when integration across disciplines is essential, from molecular biology to pharmacology and physiology to epidemiology. Complex environmental issues require individual and team efforts to address the interactions between the environment and human health," Birnbaum said in that announcement. "Chronic exposures and chronic diseases can have multiple causative factors. A broad array of scientific expertise is needed to understand such problems in order to prevent disease. I am eager to translate the work of the basic scientist and epidemiologist into improvements for the health of our citizens and communities."

Birnbaum is the author of more than 600 peer-reviewed publications who has received numerous awards during her career, including the Women in Toxicology Elsevier Mentoring Award, the Society of Toxicology Public Communications Award, EPA's Health Science Achievement Award and Diversity Leadership Award, and 12 Science and Technology Achievement Awards.

<http://ohsonline.com/articles/2008/12/5-new-director-named-for-niehs.aspx>

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## EPA scientist returns to NIEHS as its director

By Wade Rawlins, Staff Writer

Dr. Linda Birnbaum, a federal scientist who has been a senior adviser at the U.S. Environmental Protection Agency, was appointed Wednesday as director of the National Institute of Environmental Health Sciences, which is in Research Triangle Park.

Birnbaum, 61, succeeds David Schwartz, whose leadership of the agency drew congressional scrutiny over spending and alleged conflicts of interest. Schwartz left in April to take a post as a researcher at the National Jewish Medical and Research Center in Denver, Colo. Birnbaum's appointment was announced by Raynard Kington, acting director of the National Institutes of Health.

NIEHS is a branch of the National Institutes of Health. It has a \$730 million budget and supports research to understand the effects of the environment on human health. About 1,500 federal employees, research fellows, contractors, students and guest researchers work there.

"NIEHS is really the premier organization conducting environmental health research in the world," Birnbaum said in an interview. "I want to ensure we continue to be that organization."

Asked about her predecessor's rocky tenure, Birnbaum said, "I think there were some legitimate concerns. David had a very exciting vision that he was eager to implement. I don't think he was used to working in the government."

After coming under fire for testifying in plaintiffs' lawsuits after he became director and for filing expense reports for items some questioned as excessive, Schwartz stepped aside from his official duties of the NIEHS director in August 2007. Samuel Wilson stepped in as acting director, and Schwartz became a senior advisor for environmental health sciences to the NIH director.

Unlike Schwartz, a pulmonologist who came to NIEHS from Duke University, Birnbaum has worked as a government scientist for nearly 30 years in the Triangle. She and her husband, David Birnbaum, a retired mathematician, live in Chapel Hill.

A native of New Jersey, Birnbaum trained as a microbiologist at the University of Illinois, Urbana, where she earned a doctorate. After a stint teaching in New York and working at a private research lab studying the causes of aging, she moved to North Carolina in 1979 and began work as a senior staff fellow at NIEHS. Her research focused on how environmental pollutants such as dioxins and polychlorinated biphenyls get into humans and how the body handles them.

"My love has been these very persistent chemicals," Birnbaum said.

She moved up the ranks, eventually becoming director of the institute's chemical disposition group. She left NIEHS after 10 years to work at the EPA.

Birnbaum will begin in January.

<http://www.newsobserver.com/news/story/1319926.html>

## **Birnbaum** Picked To Head **NIEHS**

By [David J. Hanson](#)



Cheryl Hogue/C&EN  
Birnbaum

**Linda S. Birnbaum** has been appointed the new director of the **National Institute of Environmental Health Sciences and the National Toxicology Program**. **Birnbaum** is a widely respected toxicologist who has studied the impact of environmental chemicals for almost 29 years at **NIEHS** and **EPA**. **Birnbaum** headed EPA's Experimental Toxicology Division for 16 years. At the announcement of her appointment by NIH Acting Director Raynard S. Kington, **Birnbaum** said she was excited about the job. "Chronic exposures and chronic disease can have multiple causative factors. I am eager to translate the work of the basic scientist and epidemiologist into improvements for the health of our citizens and communities," she said. The appointment will be effective in January 2009.

<http://pubs.acs.org/isubscribe/journals/cen/86/i49/html/8649govc3.html>

Effect Measure

## Key NIH institute gets a new Director

Posted on: December 5, 2008 7:45 AM, by revere

Environmental health researchers got some good news yesterday. The NIH's only institute that focusses almost entirely on public health and environmental science, the **National Institute of Environmental Health Sciences (NIEHS)**, got a new Director after years of chaotic and controversial regime of **former Director David Schwartz**, who left under a cloud of alleged conflicts of interest and mismanagement. For the last year **NIEHS** has been under very capable and stabilizing direction of an **Acting Director, Sam Wilson**, but there were limits on what could be done by a Director and his Deputy who didn't have permanent status. Now the answer as to who will guide this very important NIH institute into the 21st Century, and it is a welcome one. The New Director will be **Dr. Linda Birnbaum**, a highly respected scientist in her own right with a track record of scientific leadership in the profession and someone who knows the ropes of the government science world, having been a researcher at **NIEHS** or EPA for the last 30 years.

NIEHS is not geographically with the other NIH institutes in Bethesda, Maryland, but down in North Carolina's Research Triangle Park area cheek by jowl with Raleigh - Durham. It is situated on a lovely artificial lake, across which one can see the EPA's research facility where **Birnbaum** now works as director of experimental toxicology. In the interests of full disclosure I admit to knowing and being a fan of **Dr. Birnbaum's**, so consider that when judging my optimism for this appointment. While this is not a Presidential appointment, *per se*, like Obama's cabinet and staff appointments it is characterized by high competence and a pragmatic a straightforward character. I know her primarily through scientific relationships, where she is enormously productive of work of high importance in the field. Her specialty involves dioxins and the biology of the dioxin receptor and more recently flame retardants, a growing concern in environmental health. But scientists are usually enthusiastic about other scientists, some of whom turn out to be great leaders and some who don't. So I'll also provide you with an informed non-scientist's view of the new Director, that of science journalist Janet Raloff.

Raloff is one of the best science reporters around (I've been interviewed by her and one quickly learns to tell the good ones from the not so good ones on the basis of the questions alone). Her stories in *Science News* are always top notch). And here is what she said there about **Birnbaum**:

As a reporter who has worked with **Birnbaum** for probably 20 years, I've found her singularly articulate in explaining the often arcane effects and mechanisms by which many environmental agents cause harm. A straight shooter, she won't hazard wild guesses about implications of her data, but she will offer informed speculation. The kind of comments, for instance, she'd share with colleagues at a research conference. She doesn't look for attention or grandstand, but she will speak up repeatedly to keep colleagues grounded on what the data that they're considering show -- or don't show. She also points out what kinds of studies would be required to fill in all those niggling data gaps. These would be the investigations needed to understand whether the chemicals we encounter in the home, workplace and environment are likely to be benign or not -- at the doses to which we may be exposed. [snip]

As people look for science to once again hold sway in research agencies, appointments like **Birnbaum's** appear to be a step in the right direction. (Janet Raloff, [Science News](#))

A step in the right direction. Indeed.

[http://scienceblogs.com/effectmeasure/2008/12/key\\_nih\\_institute\\_gets\\_a\\_new\\_d.php?utm\\_source=sbhomepage&utm\\_medium=link&utm\\_content=channellink](http://scienceblogs.com/effectmeasure/2008/12/key_nih_institute_gets_a_new_d.php?utm_source=sbhomepage&utm_medium=link&utm_content=channellink)

RISK POLICY REPORT - 12/9/2008

## Senior EPA Toxicologist Moves To Head Key Toxics Research Agencies

Long-time senior EPA toxicologist **Linda Birnbaum** is leaving the agency to head the **National Institute of Environmental Health Sciences (NIEHS)** and the **National Toxicology Program (NTP)**, whose toxicological studies EPA often uses in its chemical risk assessments.

**Birnbaum**'s research at EPA has focused on dioxin and endocrine disrupting compounds.

The former EPA scientist will take over the institute and its \$730 million budget that funds multidisciplinary biomedical research programs in January, according to an announcement from the National Institutes of Health, which oversees NIEHS.

**Birnbaum**'s appointment will allow **NIEHS** and EPA to leverage the other agency's research as they have not done effectively before, says a former EPA staffer. **NIEHS** and EPA have not communicated well in the past, though their work often converges, the source says. One example is **NIEHS**' "huge program on endocrine disrupting compounds, which no one at EPA knows about."

**Birnbaum**'s appointment provides an opportunity to "bring these two institutions' research together," the source says, adding that **NIEHS** should be aware of EPA's data gaps.

In the announcement, **Birnbaum** emphasized the need to integrate across disciplines. "Complex environmental issues require individual and team efforts to address the interactions between the environment and human health," she said. "Chronic exposures and chronic diseases can have multiple causative factors. A broad array of scientific expertise is needed to understand such problems in order to prevent disease.

Another source says the appointment could create heartburn for industry officials because **Birnbaum** brings additional muscle to an institution whose work can already spell trouble for some chemicals. If **NIEHS** identifies a chemical as a carcinogen, it "sounds the death knell for the commercial prospects of identified chemicals," the source says. And, the source says, **NIEHS** publishes **Environmental Health Perspectives**, a journal that is viewed as "willing to publish anything that can possibly make a chemical look bad."

"I am excited about serving as the director of **NIEHS** and **NTP** at a time when integration across disciplines is essential, from molecular biology to pharmacology and physiology to epidemiology," **Birnbaum** said.

[http://insideepa.com/secure/docnum.asp?f=epa\\_2001.ask&docnum=RISK-15-50-5](http://insideepa.com/secure/docnum.asp?f=epa_2001.ask&docnum=RISK-15-50-5)

## NIEHS Welcomes Birnbaum as Next Director

January 9, 2009  
By Eddy Ball



NIEHS director Dr. Linda Birnbaum  
Photo by: Steve McCaw

Dr. **Linda S. Birnbaum** will become **NIEHS's fifth director** in its 43-year history this month. Her appointment was announced in December by NIH acting director Dr. Raynard Kington. Birnbaum has most recently been a senior advisor at the Environmental Protection Agency, where she has served for 16 years as director of the Experimental Toxicology Division.

As **director of NIEHS and the National Toxicology Program (NTP)**, Birnbaum will oversee a \$730 million budget that funds multidisciplinary biomedical research programs, prevention and intervention efforts that encompass training, education, technology transfer and community outreach. The institute currently supports more than 1,240 research grants.

"I am excited about serving as the director of NIEHS at a time when integration across disciplines is essential, from molecular biology to pharmacology and physiology to epidemiology," said Birnbaum. "Complex environmental issues require individual and team efforts to address the interactions between the environment and human health."

A native of New Jersey, she earned her M.S. and Ph.D. in microbiology from the University of Illinois, Urbana. She is a board-certified toxicologist and has served as a federal scientist for nearly 29 years—the first 10 of those at NIEHS—first as a senior staff fellow at NTP, then as a principal investigator and research microbiologist and finally as leader of the institute's chemical disposition group.

Birnbaum has received numerous awards, including the Women in Toxicology Elsevier Mentoring Award, the Society of Toxicology Public Communications Award, EPA's Health Science Achievement Award and Diversity Leadership Award and 12 Science and Technology Achievement Awards, which reflect the recommendations of EPA's external science advisory board, for specific publications.

The author of more than 600 peer-reviewed publications, book chapters, abstracts and reports, Birnbaum's research focuses on the pharmacokinetic behavior of environmental chemicals; mechanisms of actions of toxicants, including endocrine disruption; and linking of real-world exposures to effects. She is also an adjunct professor in the School of Public Health, the toxicology curriculum and the department of environmental sciences and engineering at the University of North Carolina, Chapel Hill, as well as in the integrated toxicology program at Duke University.

Birnbaum's appointment has been well received within the scientific community, where she is a highly regarded member. She is currently president-elect of the International Union of Toxicology, the umbrella organization for toxicology societies in more than 50 countries; former president of the Society of Toxicology, the largest professional organization of toxicologists in the world; former chair of the division of toxicology at the American Society of Pharmacology and Therapeutics; and former vice president of the American Aging Association.

## CHEMICAL & ENGINEERING NEWS (C&EN)

February 2, 2009

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### New Leader Takes Over At NIEHS Toxicologist Linda Birnbaum charts course for NIH institute

By Cheryl Hogue



**AS THE NEW ADMINISTRATION** settles in, agencies across the federal government are undergoing transitions. But for one leadership change that took place two days before President Barack Obama took the oath of office, the timing was coincidental.

Linda S. Birnbaum, the new director of the National Institute of Environmental Health Sciences (NIEHS), officially assumed her post on Jan. 18 and now oversees an institute with a \$730 million annual budget. Located in Research Triangle Park, N.C., and part of the National Institutes of Health, NIEHS is home to the National Toxicology Program, which tests chemicals of concern to public health.

Birnbaum, the first toxicologist to head NIEHS, came to the institute from the Environmental Protection Agency. For 16 years, she served as director of EPA's Experimental Toxicology Division. During her last year at EPA, she coordinated efforts across the agency probing the contamination of Libby, Mont., with asbestos from a vermiculite mine.

Raynard S. Kington, acting director of NIH, says Birnbaum "has a long and distinguished career conducting research into the health effects of environmental pollutants." She is an expert in the toxicology of dioxins, brominated flame retardants, and endocrine-disrupting chemicals in general, and she has authored more than 600 peer-reviewed publications, book chapters, abstracts, and reports. She is a former president of the Society of Toxicology.

Birnbaum comes to an institute that was wracked by political turmoil during the tenure of David A. Schwartz, who was NIEHS director from 2005 to 2007. Schwartz was the target of several congressional investigations, including some involving conflict-of-interest allegations about testifying in lawsuits after he took the job at the institute.

In addition, Schwartz slashed the budget for NIEHS's open-access journal, *Environmental Health Perspectives*, by 85% and attempted to privatize it. (In response to this, the American Chemical Society, publisher of C&EN, at one time expressed interest in taking over *Environmental Health Perspectives*.) Schwartz also shifted the institute's funding to emphasize patient care at the expense of NIEHS's traditional focus on preventive programs. The morale of the staff is reported to have fallen significantly during Schwartz's controversial tenure.

**DESPITE ALL** that has happened in the recent past, Birnbaum sees great opportunity at NIEHS. "The institute has a marvelous scientific portfolio. It has a lot of excellent people working very hard doing a lot of important things," she tells C&EN.

Although she diplomatically skirts the question of whether she will flat-out reverse Schwartz's policies, Birnbaum has several changes in mind as she sets an agenda for NIEHS.

"Some of my first challenges are to restore morale and develop a culture of openness and trust at the institute," she says.

Besides making efforts within NIEHS, Birnbaum has her eye on reaching out beyond the institute. For instance, although she's left EPA, Birnbaum is by no means severing ties with the agency. NIEHS is situated across a small lake from a major EPA laboratory where Birnbaum worked for 16 years. Pedestrians can easily walk between the facilities via a scenic footpath. But Birnbaum is keenly aware that scientists at these two government research facilities have had little interaction, even though the work of both programs is connected to the effects from chemicals in the environment. She's intent on building virtual bridges between the two.

In addition, Birnbaum wants NIEHS to strengthen its relationships with those outside the government, including scientific organizations and citizen groups. "I'm very excited and optimistic about opportunities to interact," she says.

One avenue of interacting with those outside NIEHS is *Environmental Health Perspectives*. In contrast to Schwartz, Birnbaum is a strong supporter of the publication.

"I am thrilled to see that *Environmental Health Perspectives* has the highest impact factor of any environmental journal," Birnbaum says. "It has a very wide readership," especially in the U.S., Europe, and China (there is an edition in Chinese). "It attracts people from the basic sciences to the most applied sciences, people doing basic chemistry to people doing epidemiology and clinical medicine as well," she says.

Meanwhile, Birnbaum also wants to strengthen NIEHS's connections with other parts of NIH. She says, "I need to work hard to reestablish close working relationships with our sister institutes in Bethesda," the Maryland town where NIH headquarters is located.

Although she has yet to oversee her first budget at NIEHS, Birnbaum indicates that the types of research that the institute funds may change. Specifically, she says the institute should return to its traditional focus on preventive programs.

"There's clearly a role for clinical medicine at NIEHS," Birnbaum says. "However, I think when we're talking about environmental health, it's not only 'bench to bedside,' it is also 'bench to public health.' We have a major role to play in the betterment of public health in this country."

**ONE CRITICISM** that Birnbaum expects to face involves regulatory decisions on chemicals. The decisions, such as those made by EPA and the Food & Drug Administration, rely on studies like those conducted by the National Toxicology Program in which laboratory animals are given high doses of a substance. Critics say these experiments inappropriately include exposures to chemicals that are far higher than what the public experiences.

"They are missing the point," Birnbaum says of these critics. The amount of a chemical given to a laboratory animal isn't what's relevant in these tests, she explains. "It's what's in the body or in the specific tissue at a specific point in time." In animal studies, she says, "if you actually look at the internal dose, frequently, it's not high."

The key, according to Birnbaum, is finding more sophisticated methods to determine how much of a compound is not just getting into the body but how much is getting into the tissue, where it can adversely affect health.

"I'm willing initially, for incremental improvement, to take what's in the blood" as a surrogate measure of tissue load, Birnbaum says. She notes that for some chemicals, such as dioxins, the concentration of the substance in blood may not be the best measure of tissue exposure inside the body. "At high levels of exposure, it isn't just in blood lipids, there's a heck of a lot of it that's bound up in the liver. So you may underestimate the total amount that's in the body, but it's a lot better than saying how much you were exposed to on a daily basis," she says.

Estimates of how much of a chemical gets to nerves, organs, or other tissue inside a person might also be made using other easily accessible bodily fluids, such as urine. But Birnbaum knows that this line of study—whether involving blood, urine, or other fluids—has limitations.

"Not everybody's eager to give you blood," she says. Plus, some chemicals or their metabolites aren't eliminated in urine. And a single metabolite may have more than one source; the body may transform any of several chemicals into the same end product.

Nonetheless, Birnbaum has hope that new tests based on proteomic or metabolomic technologies will allow researchers to easily study accessible bodily fluids for early signs of toxic responses due to exposure to chemicals. She cautions scientists to keep practicality in mind as they invent this sort of assay, known as an "omic" test. She expresses frustration about new techniques for identifying early signs of toxic response in brain, kidney, and liver cells that fail to heed this caution.

"I don't know too many people who are eager to give you a brain biopsy or a kidney biopsy so you can measure what is going on in that tissue specifically," Birnbaum says. "We have to be able to use easily accessible tissue."

In addition, the omic tests are expensive to carry out, she says, expressing hope that researchers will also develop less costly methods to detect early signs of disease.

High-throughput omic tests for initial toxicity screening of chemicals have captured the attention of the federal government in recent years. The National Toxicology Program is involved in this work, as is EPA through the agency's ToxCast program. While endorsing these new technologies, Birnbaum notes their limitation.

These screening efforts may link some chemicals with health hazards they weren't previously associated with, Birnbaum says. But she worries that results of high-throughput testing may incorrectly indicate that some compounds aren't hazardous when in fact they are.

"I am always concerned about the false negatives," Birnbaum says of the rapid screening. In environmental health, giving a clean bill of health to a substance that came up negative in a rapid screening test could cause public health headaches in the future, she says.

**THOSE CONCERNED** about public health, however, have moved beyond the question about the classic toxicity of a chemical: Will this substance make someone sick and, if so, at what dose? They are increasingly focused on substances that may disturb the body's endocrine functions.

Studies of chemicals suspected of being endocrine disruptors raise complex issues, Birnbaum explains.

"When you're dealing with hormonal activity, context is everything and interaction is everything. A given hormone in a given tissue at a given developmental stage may cause one thing to happen. The same hormone in another tissue or another development stage may cause exactly the opposite kind of thing to happen," Birnbaum says.

Scientific understanding of how the endocrine system works continues to evolve, she points out. "Twenty years ago, we knew that estrogen worked through a receptor. But now we know there isn't one estrogen receptor, there are multiple estrogen receptors," Birnbaum says. Plus, there are interactions. "We know

that the estrogen receptor, for example, doesn't act in isolation but interacts with other hormones and receptors," she explains.

Then there's the issue of hormonal variations among individuals, Birnbaum adds. For instance, if a given exposure to an endocrine-disrupting chemical decreases a man's testosterone by 10%, plenty of men would experience no effects, and their levels of this hormone would remain in the normal range. But this would not be the case for men who, before exposure, have testosterone levels on the lower end of the normal range.

Such complexities feed into public health policy and science policy debates, such as the one over bisphenol A (BPA). This chemical, which is used in polycarbonate bottles and epoxy-based food can liners, is an estrogen mimic. FDA is in the midst of a debate over whether it should allow continued use of BPA in food and beverage containers ([C&EN, Nov. 17, 2008, page 42](#)). In September 2008, the National Toxicology Program deemed BPA of "some concern" for developmental and behavioral effects in fetuses, infants, and children ([C&EN, Sept. 8, 2008, page 28](#)).

"There is not enough around to make a difference at the current levels you see in the human population," Birnbaum says of BPA. Yet BPA is one of more than two dozen chemicals people are exposed to that act as weak estrogen mimics, she continues. "They're all weak, but if you even just use a simple dose addition method, all of a sudden the total estrogenic activity is not insignificant," she adds.

Birnbaum points out that the endocrine system goes beyond the heavily studied estrogens, androgens, and thyroid hormones. "There are many other endocrine systems in our body that we need to consider," she says.

"We have a tendency in science to become experts about something very narrow. We're so focused on minutiae that we miss the big picture," she says. "Our bodies and our integrated systems are not simple. There are all the interactions between the parts."

This sort of understanding about parts integrating into a whole offers insight into how Birnbaum is approaching her post at NIEHS.

"The mission of NIEHS is to reduce and prevent environmental impact on disease," Birnbaum says. "It's not only the disease of the individual." Effects may be subclinical or difficult to detect in a given person, but they may affect the overall health of the population, she explains.

"If we can understand how a certain environmental chemical or environmental stressor causes a disease process," she says, researchers can work to stop progression of health problems, as well as prevent them.

## **Chemicals**

### **Birnbaum On Dioxins' Toxicity, Regulation**

Linda S. Birnbaum, the new director of the National Institute of Environmental Health Sciences, has spent a sizable chunk of her scientific career focused on dioxins, furans, and polychlorinated biphenyls. This family of chlorinated or brominated chemicals is commonly lumped together under the moniker "dioxins."

Birnbaum has witnessed how regulation has virtually eliminated production of these toxic chemicals over the past three decades.

"The major sources that were present in the '60s and '70s are no longer significant sources at all. The processes that created them are no longer being used" commercially, she says. Plus, studies show that the levels of dioxins are dropping both in the environment and in people's bodies.

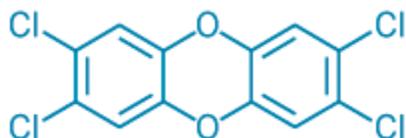
"That's the good news," Birnbaum says. "On the other hand, our continued scientific study of dioxins has revealed that they're much more toxic than we used to believe."

In the past, researchers were concerned about dioxins being lethal after short-term exposure. But nowadays, Birnbaum says, "we are concerned about their subtle developmental effects" and possible long-term cancer risks from exposure.

"For years, with dioxins, nobody really understood that they affected heart development. Well, we knew that it was true in fish, and we knew it was true in birds," she explains, "but nobody had ever really shown that it caused effects during mammalian development or in adults." That's because scientists weren't looking for these outcomes, she says. Now that researchers are probing the possibility of these effects, they are finding them.

In addition, dioxins are linked to an increase in type 2 diabetes. Age and obesity may be more important risk factors for this disease than dioxin exposure, Birnbaum says, but that doesn't make regulation of these substances irrelevant.

"You can't control your age. Many people are not very successful at controlling their weight," she says. "But we as a society can control our dioxin exposure."



INFAMOUS 2,3,7,8-Tetrachlorodibenzo-*p*-dioxin is the most hazardous member of the family of chlorinated and brominated dioxins

To access video clip, refer to article <http://pubs.acs.org/cen/government/87/8705gov1.html>

*Bloomberg.com*  
September 3, 2008  
By Tom Randall

## Chemical in Soda Cans, Baby Bottles May Harm Kids

Exposure to bisphenol A, a chemical used to make plastic for baby bottles and to line soda cans, may harm fetuses and children and needs further study before it is deemed safe, a U.S. government [report](#) found.

Tests in animals showed harmful effects from the chemical, known as BPA, the [National Toxicology Program](#) said today in a report that rated concern about the chemical's risks for children at the middle of a five-point scale. Parents may want to limit family exposure to the substance, said the study's authors, though they didn't recommend changing U.S. safety standards.

The study, the final version of a report issued in draft form in April, underscores differences within the government about the chemical's safety. The staff of the Food and Drug Administration said in a draft [report](#) last month that the agency "has concluded that an adequate margin of safety exists" for bisphenol A when used in products coming into contact with food.

"The possibility that BPA may affect human development cannot be dismissed," said [John Bucher, associate director of the toxicology group](#), in a statement today. "We see developmental changes occurring in some animal studies at BPA exposure levels similar to those experienced by humans."

The [National Toxicology Program](#), part of the Health and Human Services Department, was created in 1978 to provide scientific assessments of the health effects of chemical agents in the environment, according to the program's Web site.

The FDA's staff assessment also recommended more detailed testing, specifically in adult, pregnant and newborn monkeys, to look for effects on nervous system development and behavior. A subcommittee of the FDA's Science Board plans to review the agency's staff report at a Sept. 16 meeting in Rockville, Maryland.

### Industry Response

"There is no direct evidence that exposure to bisphenol A adversely affects human reproduction or development," said the American Chemistry Council, which represents the chemical industry, in an e-mailed statement today. Evidence from animal studies was "limited and inconclusive" and "additional research will be needed to determine if these concerns are relevant," the group said.

In April, Canada became the first country to label bisphenol A as "toxic" and is considering a ban on its use in baby bottles. U.S. lawmakers have considered similar proposals to prohibit use of the chemical.

"We should err on the side of caution and keep this chemical out of children's products," said Senator [Charles Schumer](#), a New York Democrat, in an e-mailed statement today. "Clearly more research is needed."

## Coca-Cola, PepsiCo

Bisphenol A is used to stiffen plastic used to make baby bottles and to seal canned food. [Coca-Cola Co.](#) and [PepsiCo Inc.](#) use it in cans to protect the drink from direct contact with the aluminum and to prevent spoilage, said [Tracey Halliday](#), a spokeswoman for the [American Beverage Association](#), a Washington- based trade group.

Coca-Cola and Pepsi, which referred questions about bisphenol A to the beverage association, don't use the chemical in soft drink and water bottles, Halliday said.

Several companies that produce plastic bottles, such as [Energizer Holding Inc.](#)'s Playtex Infant Care unit and [Thermo Fisher Inc.](#), the maker of Nalgene sports bottles, have stopped using the chemical in their new products because of the concerns.

Average infant exposures are about 2,000 times less than the FDA's safety level, and exposures among adults are 27,000 times lower, that agency's draft report said.

To contact the reporter on this story: [Larry Liebert](#) in Washington at [lliebert@bloomberg.net](mailto:lliebert@bloomberg.net)

[http://www.bloomberg.com/apps/news?pid=20601124&sid=aTt\\_RXITAvUw&refer=home#](http://www.bloomberg.com/apps/news?pid=20601124&sid=aTt_RXITAvUw&refer=home#)

## CHEMICAL & ENGINEERING NEWS

September 3, 2008  
GOVERNMENT & POLICY

### Bisphenol A Assessment Released

**Debate over the safety of low-level exposure to the plastics chemical continues**

[Britt E. Erickson](#)

Current levels of exposure to bisphenol A (BPA), a chemical used in making polycarbonate plastic bottles and epoxy-based canned food liners, are of "some concern" for developmental and behavioral effects in fetuses, infants, and children, according to a final assessment [released](#) on Sept. 3 by the [National Toxicology Program](#). The report comes just weeks after [FDA](#) declared in a draft assessment that the estrogenic chemical is safe in food contact products such as baby bottles and infant formula cans ([C&EN, Aug. 25, page 10](#)).

[NTP's Center for Evaluation of Risks to Human Reproduction](#), an interagency federal research program located on the campus of the [National Institute of Environmental Health Sciences](#) in Research Triangle Park, N.C., has been evaluating since December 2005 the potential for BPA to cause reproductive and developmental effects in humans. Last April, the group expressed its concerns over the chemical in a draft report, which led to an intense debate and a congressional investigation into the safety of BPA in consumer products ([C&EN, June 2, page 36](#)).

The final [NTP](#) assessment reaffirms the earlier concerns and points to the need for more research into the safety of BPA. "There remains considerable uncertainty whether the changes seen in the animal studies are directly applicable to humans, and whether they would result in clear adverse health effects," [NTP Associate Director John R. Bucher](#) said in a statement. "But we have concluded that the possibility that BPA may affect human development cannot be dismissed."

FDA says it will consider the [NTP](#) report as it finalizes its own BPA assessment for regulatory purposes. A public meeting is scheduled for Sept. 16 to discuss FDA's draft assessment.

<http://pubs.acs.org/cen/news/86/i36/8636news3.html>

CNNMoney.com

September 03, 2008: 10:19 AM EST

## **Government Health Experts Concerned BPA Affects Human Growth**

WASHINGTON -(Dow Jones) - Government experts on Wednesday released a final report on the safety of a chemical used in plastic baby bottles, saying they have "some concern" the chemical is linked to health and developmental problems.

The chemical, bisphenol-A, or BPA, makes plastic hard and shatterproof, and is used in hundreds of consumer products from plastic baby bottles to CDs.

The report, released by the Department of Health and Human Services' **National Toxicology Program**, doesn't say BPA should be banned but that more research is necessary to understand how the chemical affects human health.

"There remains considerable uncertainty whether the changes seen in the animal studies are directly applicable to humans, and whether they would result in clear adverse health effects," said **NTP Associate Director John Bucher**, Ph.D." But we have concluded that the possibility that BPA may affect human development cannot be dismissed."

Concerns over the chemical's safety have heightened in recent months, prompting more than a dozen states to consider legislation banning BPA in some children and food products. Concerns about BPA also drove Wal-Mart Stores Inc. (WMT), among other retailers, to say it would stop selling baby bottles containing the chemical. Canada has said it intends to ban the use of BPA in baby bottles.

The Food and Drug Administration said last month, based on current science, that there isn't enough evidence to support banning the chemical from baby and food products. The agency's assessment relied on part of a draft of the report released today.

The FDA is holding a hearing on Sept. 16 to discuss BPA.

The report is similar to a draft the **National Toxicology Program** released in April. There are, however, a few key differences.

The final report says experts have "minimal concern" BPA exposure will affect the development of mammary gland or accelerate puberty in females. The draft said there was "some concern," which is a more elevated concern. Officials lowered the concern after a group of experts reviewing the draft said there wasn't enough evidence to support the earlier level of concern, said **Michael Shelby, an associate director at NTP**.

The **NTP** used a five-level scale of concern, ranging from negligible concern to serious concern. "Some concern" falls in the middle.

The **NTP**'s report relies on a wide-array of research involving numerous laboratory studies, though most of the research was from academia, **Shelby** said.

The program's findings contradict some industry studies that say there is minimal concern BPA affects human development.

-- By Jared A. Favole, Dow Jones Newswires; 202.862.9207; jared.favole@ dowjones.com

[http://money.cnn.com/news/newsfeeds/articles/djf500/200809031019DOWJONESDJONLINE000612\\_FORTUNE5.htm](http://money.cnn.com/news/newsfeeds/articles/djf500/200809031019DOWJONESDJONLINE000612_FORTUNE5.htm)

## ***Environment News Service***

### **Bisphenol A May Affect Brain, Behavior, Prostate in Children**

**WASHINGTON, DC**, September 3, 2008 (ENS) - Two federal government agencies are at odds over the safety of bisphenol A, a chemical used to harden plastic products such as baby bottles and drinking water bottles and for lining food and beverage cans.

A report today by the National Institutes of Health's **National Toxicology Program** finding that bisphenol A may alter brain development and behavior and increase the risk of prostate cancer in children, infants and fetuses is in direct contradiction to last month's assessment by the U.S. Food and Drug Administration that the chemical is safe at current levels of exposure.

Based on 261 scientific publications, the **National Toxicology Program** report contradicts an FDA draft report released in August which found that bisphenol A is safe at current human exposure levels and does not recommend banning the chemical.

Some 93 percent of Americans have detectable levels of bisphenol A in their urine, according to data from the Centers for Disease Control and Prevention on urine samples provided by 2,500 Americans aged six and older for a national health survey in 2003-2004.

The report released today was conducted by the **National Toxicology Program** based on the assessment of an expert panel convened by the **Center for the Evaluation of Risks to Human Reproduction** that evaluated the potential for bisphenol A to cause adverse effects on reproduction and development in humans.

The panel completed its evaluation in August 2007 and the **NTP** assessment also includes scientific information that has been reported since then.

**CERHR Director Dr. Michael Shelby** states in the report that bisphenol A was selected for evaluation because of widespread human exposure, public concern for possible health effects from human exposures, high production volume, and evidence of reproductive and developmental toxicity in laboratory animal studies.

After assessing the evidence, the **National Toxicology Program** said it has "some concern for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A."

The **NTP** has "minimal concern for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children at current human exposures to bisphenol A."

The **NTP** has "negligible concern that exposure of pregnant women to bisphenol A will result in fetal or neonatal mortality, birth defects, or reduced birth weight and growth in their offspring."

The **NTP** has "negligible concern that exposure to bisphenol A will cause reproductive effects in non-occupationally exposed adults and minimal concern for workers exposed to higher levels in occupational settings."



**Shatterproof baby bottles are often hardened with bisphenol A. (Photo by [Wendy Lane](#))**

The **National Toxicology Program** review reflects the findings of dozens of independent scientists from around the world who have raised questions about the chemical's possible dangers for more than a decade.



**These plastic bottles do not contain bisphenol A. (Photo by [Alicia Voorhees](#))**

Richard Wiles, executive director of the nonprofit research organization Environmental Working Group, said today in a statement, "Unlike the FDA, **NTP** has listened to the nation's premier scientists and has concluded that the BPA threat to the brains, bodies and behavior of our children must be taken seriously."

"The agency's stance is measured and courageous in the face of the slick, relentless publicity campaign from the chemical industry, which seems to be following the tobacco industry's playbook," said Wiles.

He points out that the **NTP** reviewed several hundred independent scientific studies before reaching its conclusion, while the FDA relied on three chemical-industry funded reports, which gave the toxic chemical the thumbs up for use in consumer products.

"Consumers deserve straight talk from the government," said Wiles. "The new **NTP** assessment tells us that we are right to be concerned about BPA and the industry's ongoing chemistry experiment on our kids."

The American Chemistry Council, an industry trade group, today said it welcomes the release of the final report on bisphenol A from the **National Toxicology Program**, saying that the findings of the report identified no serious human health concerns.

"The safety of our products is our highest priority," said Steven Hentges, PhD, of the American Chemistry Council's Polycarbonate/BPA Global Group. "An earlier draft of the **NTP** report has already been used by the Food and Drug Administration to support their safety assessment, which confirms that food-contact products made from polycarbonate plastic, including products for infants and children, can continue to be used safely."

The FDA draft report, released August 15, states that based on lab tests in rodents, infants and adults are exposed to bisphenol A levels that are below toxic levels.

"Safe or safety means that there is reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use," but "complete certainty of absolute harmlessness is scientifically impossible to establish," the draft report states.

But Wiles said the FDA report "ignored the nation's top public health scientists, and instead lauded the benefits of a toxic, hormone disruptor found in virtually every infant in America."

<http://www.ens-newswire.com/ens/sep2008/2008-09-03-093.asp>

## **Bisphenol A: Some Concerns Remain**

### **National Toxicology Program** Notes Concerns in Final Bisphenol A Safety Report

By Miranda Hitti

Reviewed by Louise Chang, MD

Government scientists today expressed some concern about the plastic chemical bisphenol A -- but about fewer health topics than they noted last spring.

Bisphenol A, also called BPA, is found in polycarbonate plastic, including some water bottles and baby bottles, and in epoxy resins, which are used to line metal products, including canned foods.

Bisphenol A has been in the media spotlight since April, when the **National Toxicology Program (NTP)** issued a draft report expressing certain concerns about bisphenol A.

Since then, several major companies -- including Wal-Mart, Toys "R" Us, and Babies "R" Us -- have backed away from baby bottles containing bisphenol A, and Nalgene ditched bisphenol A in its consumer bottles.

But the plastics industry has steadily maintained that bisphenol A is safe for people at typical levels of exposure, and an FDA draft report, issued last month, agrees.

Now, the debate has come full circle, with today's release of the **NTP's** final report on bisphenol A. The plastics industry praises the report, saying it identified "no serious human health concerns."

But some **NTP** officials aren't so sure that their report settles all the questions about bisphenol A's safety. And the nonprofit Environmental Working Group continues to voice concern about bisphenol A, calling the **NTP's** report "courageous."

### **Bisphenol A Report**

The **NTP's** final report on bisphenol A notes:

- "Some concern" for effects on the brain, prostate gland, and on behavior in fetuses, infants, and children.
- "Minimal concern" for effects on the mammary gland and an earlier age for puberty for females in fetuses, infants, and children, and for reproductive effects in adults who work with bisphenol A.
- "Negligible concern" for fetal or neonatal death, birth defects, or reduced birth weight and growth in babies born to women exposed to bisphenol A during pregnancy, and also for reproductive effects in adults who don't work with bisphenol A.

In April, the **NTP's** draft report mentioned "some concern" for bisphenol A's effects on mammary glands and early female puberty. In June, an **NTP** advisory panel recommended changing that to "minimal" concern, and the **NTP** followed that advice in its final report.

## **NTP's Lingering Questions**

Much of the research on bisphenol A's safety has been done on animals, and **NTP** officials say it's not clear how that translates to people.

"There remains considerable uncertainty whether the changes seen in the animal studies are directly applicable to humans, and whether they would result in clear adverse health effects," **NTP Associate Director John Bucher**, PhD, says in a news release. "But we have concluded that the possibility that BPA may affect human development cannot be dismissed."

So what does the **NTP** recommend that consumers do?

"Unfortunately, it is very difficult to offer advice on how the public should respond to this information," **Michael Shelby**, PhD, director of the **NTP's Center for the Evaluation of Risks to Human Reproduction (CERHR)**, says in a news release.

"More research is clearly needed to understand exactly how these findings relate to human health and development, but at this point we can't dismiss the possibility that the effects we're seeing in animals may occur in humans. If parents are concerned, they can make the personal choice to reduce exposures of their infants and children to BPA," **Shelby** says.

## **Plastics Industry, Critics Respond**

All along, the American Chemistry Council, a trade group for the plastics industry, has maintained that bisphenol A is safe at typical exposure levels, and that lab tests on animals aren't a good gauge of risk to humans.

That's in line with the FDA's draft report and a separate report by European health officials concluded in July. And in August, California lawmakers rejected a bill that would have limited bisphenol A to trace amounts in products geared to kids aged 3 and younger.

"The safety of our products is our highest priority," Steven G. Hentges, PhD, of the American Chemistry Council's Polycarbonate/BPA Group, says in a news release. "An earlier draft of the **NTP** report has already been used by the [FDA] to support their safety assessment, which confirms that food-contact products made from polycarbonate plastic, including products for infants and children, can continue to be used safely."

Meanwhile, the EWG focuses on the concern mentioned in the **NTP**'s report, calling it a "measured" stance. In a statement emailed to WebMD, EWG Executive Director Richard Wiles is critical of the plastics industry and the FDA, and says "the new **NTP** assessment tells us that we are right to be concerned about BPA."

The **NTP**'s report is about science. It doesn't make recommendations about banning or otherwise regulating bisphenol A; that's up to the FDA. An FDA spokesperson wasn't immediately available to comment on the **NTP**'s final report.

<http://www.webmd.com/news/20080903/bisphenol-a-some-concerns-remain>

*Associated Press*

By Matthew Perrone

September 4, 2008

## ***Plastic chemical still concerns toxicologists***

***The FDA calls bisphenol A safe. Some say it may cause trouble in the brain, hormonal systems.***

WASHINGTON - Government toxicologists have reiterated safety concerns about a chemical used in baby bottles and food containers, just weeks after the Food and Drug Administration declared the substance safe.

A report issued yesterday said there was "some concern" that bisphenol A can cause developmental problems in the brain and hormonal systems of infants and children.

The conclusion from the **National Toxicology Program** repeats initial findings issued in April. The group, with scientists from the National Institutes of Health and other agencies, said bisphenol's risks to humans cannot be ruled out, but acknowledged that its concerns are based on animal studies.

The American Chemistry Council, which represents plastics manufacturers, stressed that studies from animals provided "limited and inconclusive evidence." The group has spent the last year defending the safety of bisphenol from new concerns about the risks to children.

### **'More research'**

Bisphenol A is a plastic-hardening chemical used to seal canned food and make baby bottles. After more than a year of complaints from consumer and parent groups, the FDA has agreed to revisit the chemical's safety. The agency last month said the trace amounts that leach out of food containers were not a threat to children or adults.

The toxicology group said that might not be true.

"More research is clearly needed to understand exactly how these findings relate to human health and development," said **Michael Shelby**, who directed the group's report. "But at this point we can't dismiss the possibility that the effects we're seeing in animals may occur in humans."

The FDA said it would consider the new report as it continued reviewing bisphenol. The agency has scheduled a meeting later this month where its outside advisers will weigh in on the chemical's safety. A final report is expected later in the year.

The toxicology group did back away from one issue raised in its draft. While the group said in April that there was "some concern" the chemical could speed up puberty in girls, the final report states there is now only "minimal concern" about those risks.

The **National Toxicology Program** ranks its conclusions about chemical risks on a five-tiered scale ranging from "negligible concern" to "serious concern."

### **Major retailers**

**Shelby** said it was too early to recommend changes in what consumers buy and eat, but he added that parents who are concerned can avoid buying food containers made from bisphenol.

Several major retailers - including Wal-Mart and Toys R Us - have said they would stop selling baby bottles made with the chemical next year. And smaller companies like Evenflo and BornFree have ramped up production of glass baby bottles as an alternative.

Canada has said it intends to ban the use of the chemical in baby bottles. Lawmakers in several states and in Congress have introduced bills to ban it in children's products.

**WashingtonPost.com**

## **Chemical in Plastic Is Connected to Health Problems in Monkeys**

*By Lyndsey Layton  
Washington Post Staff Writer  
Thursday, September 4, 2008; A02*

Researchers at the Yale School of Medicine have linked a chemical found in everyday plastics to problems with brain function and mood disorders in monkeys -- the first time the chemical has been connected to health problems in primates.

The study is the latest in an accumulation of research that has raised concerns about bisphenol A, or BPA, a compound that gives a shatterproof quality to polycarbonate plastic and has been found to leach from plastic into food and water.

The [Yale](#) study comes as federal toxicologists yesterday reaffirmed an earlier draft report finding that there is "some concern" that bisphenol A can cause developmental problems in the brain and hormonal systems of infants and children.

"There remains considerable uncertainty whether the changes seen in the animal studies are directly applicable to humans, and whether they would result in clear adverse health effects," [John R. Bucher, associate director of the National Toxicology Program](#), said in a statement. "But we have concluded that the possibility that BPA may affect human development cannot be dismissed."

In a study published in the [Proceedings of the National Academy of Sciences](#), the Yale team exposed monkeys to levels of bisphenol A deemed safe for humans by the [Environmental Protection Agency](#) and found that the chemical interfered with brain cell connections vital to memory, learning and mood.

"Our findings suggest that exposure to low-dose BPA may have widespread effects on brain structure and function," the authors wrote. In contrast to earlier research on rodents, the Yale researchers studied monkeys to better approximate the way BPA might affect humans.

"Our goal was to more closely mimic the slow and continuous conditions under which humans would normally be exposed to BPA," said study author Csaba Leranth, a Yale professor of obstetrics, gynecology and reproductive sciences and of neurobiology.

BPA, in commercial use since the 1950s, is found in a wide variety of everyday items, including sports bottles, baby bottles, food containers and compact discs. One recent federal study estimated that the chemical is found in the urine of 93 percent of the population.

The [American Chemistry Council](#), a trade group, maintained yesterday that "there is no direct evidence that exposure to bisphenol A adversely affects human reproduction or development."

The [National Toxicology Program](#), part of the [National Institutes of Health](#), has no power to regulate BPA, but its findings are used by other federal agencies such as the [Food and Drug Administration](#) and the EPA, which set safe exposure limits for chemicals.

The FDA plays a critical regulatory role because it regulates the compound's use in plastic food containers, bottles, tableware and the plastic linings of canned foods.

The agency last month issued a draft report that declared BPA safe for use in food packaging and bottles, based largely on the strength of two studies, both funded by industry.

"Unfortunately the regulatory agency charged with protecting the public health continues to rely on industry-based research to arrive at its conclusions, rather than examining the totality of scientific evidence," [Rep. John D. Dingell](#) (D-Mich.), chairman of the [House Energy and Commerce Committee](#), said in a statement yesterday. His committee is investigating the FDA's handling of BPA.

U.S. manufacturers make about 7 billion pounds of BPA annually. A ban would affect thousands of businesses and perhaps billions of dollars in profit for its largest manufacturers.

Canada has said it intends to ban the use of BPA in baby bottles, and state and federal lawmakers have proposed a variety of BPA bans. [Sen. Charles E. Schumer](#) (D-N.Y.) is sponsoring a bill to prohibit BPA from children's products, while [Rep. Edward J. Markey](#) (D-Mass.) wants to bar it from all food and drink packaging.

"The FDA's assurances of BPA's safety are out of step with mounting scientific evidence to the contrary," Markey said yesterday. "For the sake of the health of every man, woman and child in America, we should ban BPA in food and beverage containers, especially because there are alternatives already available."

Several major retailers, including [Wal-Mart](#) and Toys R Us, have pledged to drop BPA products next year while some makers of baby bottles and sports bottles have switched to BPA-free plastic.

[http://www.washingtonpost.com/wp-dyn/content/article/2008/09/03/AR2008090303397\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2008/09/03/AR2008090303397_pf.html)

September 6, 2008

EDITORIAL

## *That Plastic Baby Bottle*

What do you do when one arm of the government says everything is O.K. and another tells you to watch out? That is what is happening with bisphenol-A — a chemical used in many plastics and epoxy resins now found in baby bottles and liners for canned goods. The answer is a truism in every family rulebook — when in doubt, especially when it comes to children, err on the side of caution. That means it is a good idea to keep the young away from bisphenol-A, or BPA.

The Food and Drug Administration said last month that the small amounts of BPA that leach out of containers and into food or milk are not dangerous. Then this week, the **National Toxicology Program**, the federal agency for toxicological research, reported that their research shows “some concern” about the effects of BPA on the brain development and behavior of fetuses and young children.

A new study by the Yale School of Medicine is cause for even more concern. In tests on primates, researchers found that BPA “causes the loss of connections between brain cells” that could cause memory or learning problems and depression.

**John Bucher, the associate director of the toxicology program**, said there is still considerable uncertainty about whether the changes seen in animal studies are causing the same problems in humans. “But we have concluded that the possibility that BPA may affect human development cannot be dismissed.”

Scientists from the toxicology offer this advice:

- Watch for the numeral 7 on the bottom of plastic containers. That often means they contain BPA.
- Don't microwave plastic food containers made with BPA. Better to use glass or porcelain.
- Watch out for canned foods for children.
- Search for baby bottles and other baby products that are BPA-free.

Some states are considering bills to restrict the use of BPA for the young, and Congress is assessing several possible remedies including a BPA ban in children's products or a ban on BPA in packaging that touches food. The best effort, however, would be the Kid-Safe Chemicals Act. It would require that children's products are proved safe before they are sold, not — as with BPA — the other way around.

<http://www.nytimes.com/2008/09/06/opinion/06sat4.html>



Monday, Sep. 15, 2008

## Concerns About Chemical in Plastics

By Bryan Walsh

For years, a small but growing band of scientists has been raising concerns about the impact on human health of bisphenol A (BPA), a chemical used in plastic that mimics the effect of the hormone estrogen. BPA can be found in a wide variety of products, including some plastic bottles and the lining of aluminum cans, and it can migrate fairly easily into the human bloodstream. That means few of us escape exposure, if in small doses — in one survey, 93% of Americans tested positive for the chemicals. Concerned researchers point to animal studies that indicate that even low-dose exposure to BPA may be associated with a variety of ills, including cancer and reproductive problems. But defenders — most prominently the chemical industry itself — argue that the average dose of BPA is far too low to be toxic, and that in any case, there have never been human studies implicating the chemical as dangerous. So far that argument has carried the day — the Federal Drug Administration (FDA) last month announced that the BPA wasn't dangerous to human health in small doses, and declined to regulate it.

The science may be changing, however. In a study published Sept. 16 in the *Journal of the American Medical Association (JAMA)*, a group of researchers led by David Meltzer of the University of Exeter in Britain reviewed data from the U.S. government's comprehensive National Health and Nutrition Examination Survey, looking for any connections between BPA exposure and health problems. They found more than a few. The *JAMA* study indicates higher levels of BPA in urine — the simplest way to test for the chemical — was associated with higher incidences of cardiovascular disease, diabetes and liver enzyme abnormalities. The article represents the first large-scale study of BPA in a human population — and is sure to add to the controversy surrounding it. "This isn't just any old epidemiological study — this is a national survey," says Frederick vom Saal, a biologist at the University of Missouri and an outspoken opponent of BPA, who wrote an editorial accompanying the *JAMA* study. "This carries greater weight."

Compared with the quarter of the surveyed population (aged 18 to 74) with the lowest levels of BPA, the quarter who had the highest levels were more than twice as likely to report having cardiovascular disease or diabetes. But the study's authors take pains to point out that their research does not prove that BPA can cause these ills, but merely indicates that these disorders seem to occur more often in people with higher levels of the disease. To prove a cause-effect relation would require longitudinal studies that compare the effects of BPA in one group to a control group unexposed to the chemical — hard to do, given BPA's ubiquity. But the *JAMA* study is worrying enough. "The article says that the more of this chemical you have, the greater the risk," says vom Saal. "We understand how BPA causes these problems in animals, and the human study follows that." A recent study by the Yale School of Medicine provides even more cause for concern, showing that tests in primates found that BPA "causes the loss of connections of brain cells" that could lead to memory problems, and even depression.

Though the FDA has ruled BPA safe, not everyone in the government agrees. Earlier this month the **National Toxicology Program (NTP)**, a federal agency that gauges the safety of chemicals, reported that its research shows "some concern" about the effects of BPA on the brain development of fetuses and young children. (Children are considered particularly vulnerable to the chemical, which is thought to interfere with development.) Critics note that the FDA's report relied on a small number of studies funded by industry groups that manufacture BPA, while the **NTP** took in a wider range of science. "The FDA says that their safety standard is that there must be reasonable certainty among competent scientists that a chemical is not harmful," says vom Saal. "So unless they declare the **NTP** scientists incompetent, something is wrong here."

Vom Saal and other scientists will have a chance to have their voices heard on Sept. 16, when the FDA convenes an open meeting to reassess the safety of BPA. Other governments have already moved to regulate the chemical, including Canada, which has considered banning it. For concerned parents, limiting BPA exposure for children isn't that hard. Watch out for the number 7 on the bottom of plastic containers, which often means they contain BPA; avoid canned foods for children; and don't microwave plastic food containers that contain the chemical, as heat can make it easier for BPA to leach. Ultimately, though, it may not even matter what the FDA does — a new report by the Investor Environmental Health Network says that consumers, manufacturers and retailers are already forgoing the chemical, buying and selling BPA-free bottles and other products. Wal-Mart and Toys 'R Us have already announced their intention to shift away from products containing BPA. Which shouldn't be surprising — in America, commerce leaves science and the government in the dust.

<http://www.time.com/time/printout/0,8816,1841441,00.html>



## ***Reassessing the Dangers of BPA in Plastics***

**Sunday, Nov. 02, 2008**

**By Alice Park**

There's no denying that bisphenol A (BPA), the latest headline-making toxin, is ubiquitous — it's in hard plastic water bottles, the lining of food and beverage cans and, most disturbingly, the plastic baby bottles that most parents commonly use. What's less clear, however, is exactly what effect BPA has on human health.

That was the subject of an Oct. 31 daylong meeting of the Food and Drug Administration's (FDA) Science Board. Earlier last week a panel commissioned by the Science Board released its review of the FDA's safety report, which concluded in August that current levels of BPA exposure posed no real health risk. The Science Board convened Friday to discuss the panel's findings — a highly critical 17-page review that deemed the FDA's conclusions flawed — and to hear comments from the public about whether the compound should be banned from food and beverage containers. The board will now forward the review along with the FDA's original safety assessment to FDA chief Dr. Andrew von Eschenbach. The FDA has until February 2009, when the Science Board next meets, to respond.

Why the renewed uproar over plastic? Since the FDA completed its original analysis in August, [additional data on the potential health effects of BPA have emerged](#), linking high levels of BPA exposure to increased risk of heart disease and diabetes and even a decreased sensitivity to chemotherapy in cancer patients. The compound is also linked to developmental and brain effects in infants; BPA is known to mimic the hormone estrogen in the body, which can cause changes in developing fetuses and infants. "There is enough evidence today for the FDA to take the precaution and to certainly get BPA out of infant products," says Urvashi Rangan, senior scientist and policy analyst at Consumers Union. "Even more, consumers should not be ingesting this substance while the science is being figured out."

The FDA's initial assessment — which it has not rescinded — that "an adequate margin of safety exists for BPA at current levels of exposure from food-contact uses, for infants and adults" was based on data available at the time. Back in April, for example, the [National Toxicology Program](#), which is part of the National Institutes of Health (NIH), released a preliminary report expressing "some concern" that according to studies done in animals, BPA could have neural and behavioral effects on fetuses, infants and children at current levels of exposure. Recent surveys by the Centers for Disease Control and Prevention (CDC) had suggested that exposure is widespread, showing that 93% of Americans excrete some BPA in their urine. Still, the weight of the evidence, mostly from animal studies, did not suggest a significant health risk in humans, according to the FDA.

But last week, the reviewing panel disagreed, saying the FDA's analysis excluded several important studies on BPA in animals. The panel also questioned the quality of some of the included studies and found that the FDA did not incorporate enough infant-formula samples in its evaluation. According to the panel review, the FDA's safety report "creates a false sense of security" and the agency's margins of safety for BPA exposure are, in fact, "inadequate." Says Tracey Woodruff, director of the program on reproductive health and the environment at the University of California, San Francisco, and a former Environmental Protection Agency scientist: "Unless the evidence is very compelling, you don't get such a strong statement from a group of scientists."

It's now up to Von Eschenbach to decide how to proceed. He may start from scratch and commission another report that includes the most recent findings on BPA; he may reject the panel's review and adhere to the FDA's original conclusion that BPA is harmless at current exposure levels; or he may ban the chemical from baby products, as the Canadian government did in April. Or he may draw no further conclusions about BPA until additional studies can be commissioned and completed to answer some unresolved questions.

"While we have some idea of how much BPA might leach from a baby bottle, there are intermediate steps between that and how much gets into an infant that we still need to model and establish mathematically," says **John Bucher, associate director of the National Toxicology Program**, which collaborates with the FDA, NIH and CDC. "And we don't have that yet." The FDA report maintains, for example, that a BPA exposure level of 5 mg/kg per day is acceptable. Health officials have determined that baby bottles can produce anywhere from 7 micrograms/g to 57.7 micrograms/g of BPA. The questions are: How much of the compound is absorbed into an infant's body? How much remains, and how much is excreted? And does that exposure come close to the FDA threshold?

The FDA can't answer those questions yet, but some experts argue that the agency doesn't need to wait to take action. "The Federal Government entered into a voluntary recall of the Teflon chemicals [in pots and pans] on less evidence than we have for BPA," says Woodruff, "because there was concern that people were chronically exposed to a chemical linked to some evidence of potential human harm." Woodruff says the estimated range of exposure to BPA for formula-fed infants is within the range of doses that have led to adverse effects in animal studies.

Until the government settles on a new assessment or action, experts say parents have the option of using BPA-free products — including glass, stainless steel and some innovative next-generation plastics that do not contain the chemical.

<http://www.time.com/time/health/article/0,8599,1855853,00.html>

November 1, 2008  
EDITORIAL

### ***A Flawed Assessment of BPA***

After reports of a possible conflict of interest, we worried that a scientific advisory panel might pull its punches in evaluating the Food and Drug Administration's judgments on the safety of bisphenol-A, known as BPA. It didn't.

In a devastating new report, the panel charged that a draft safety assessment prepared by the F.D.A. ignored relevant studies, used flawed methodology and created "a false sense of security" about the safety of BPA, which is found in baby bottles, plastic water bottles and the liners of cans, among other products.

The draft assessment had concluded that the small amounts of BPA that leach into milk or food are not dangerous. The advisory panel did not directly dispute this. But it left little doubt that the weight of the evidence, in its view, suggests the need for a much greater safety margin than the F.D.A. draft deemed adequate.

The United States **National Toxicology Program** — which considered many of the studies the F.D.A. had discounted — has expressed some concern about BPA's safety, and Canada has moved toward banning the sale of baby bottles made with BPA. Some research suggests that BPA might cause neurological damage, accelerate puberty, interfere with chemotherapy and increase the risk for heart disease, diabetes and cancer.

The F.D.A.'s Science Board, an advisory group, endorsed the panel's critique on Friday. Now it is imperative that the F.D.A. complete a more rigorous assessment. It must also consider whether to restrict some uses of BPA without waiting for further research.

<http://www.nytimes.com/2008/11/01/opinion/01sat3.html>



December 30, 2008

## Top health stories of '08: Stress, drugs and chemical lows

The following is one of the stories listed in this article ...

### Public, Congress examine chemicals in kids' products

People took a closer look at the plastic in their children's toys and baby bottles this year, as scientists, lawmakers and regulators debated the safety of hormone-like chemicals that were unknown to most Americans a year or two ago.

- In August, Congress passed a sweeping product-safety law to dramatically lower the amount of lead in products for children under 12 and virtually ban six types of phthalates, hormone-like chemicals that are used to soften plastic and have been linked to reproductive changes in boys. The law takes effect Feb. 10 ([full story](#)).

- In September, the **National Toxicology Program** expressed "some concern" about the effects of another plastic ingredient, bisphenol A, or BPA, on the development of the brain and prostate in children and fetuses. The ingredient has also been linked to behavioral issues in young children.

- In October, Canada declared BPA to be toxic and announced plans to ban its use in baby bottles.

Also in October, an advisory panel to the Food and Drug Administration harshly criticized the agency, which says that BPA is safe at the level to which people are commonly exposed ([full story](#)). The outside panel says the FDA ignored important evidence, including studies that suggest babies are at risk. Although the FDA says it's committed to additional research, the agency hasn't changed its opinion on BPA's safety.

The marketplace, however, responded quickly to these concerns.

In anticipation of Canada's decision, most baby-bottle makers now sell BPA-free alternatives. Makers of liquid infant formula say they're looking for alternatives to BPA, which they now use to line their metal cans. Retailers such as Wal-Mart, CVS and Babies R Us also are phasing out BPA.

— **By Liz Szabo**

[http://www.usatoday.com/news/health/2008-12-28-year-medical\\_N.htm](http://www.usatoday.com/news/health/2008-12-28-year-medical_N.htm)

## The Scariest Health Threat You've Never Heard Of

September 2008 Issue

by Donna Jackson Nakazawa

Early in 2004 Erin Farley, 26, began to suffer from fatigue, fevers, dizziness and joint pain. "It was so bad that shaking hands was excruciating," she says. "I couldn't open a jar or a car door; I couldn't even button my pants. I just didn't have the strength." Eventually the pain became so intense that she couldn't get out of bed. Newly married, she and her husband spent the better part of their honeymoon year dealing with her illness: "He'd brush my hair, dress me, cook what food I could swallow." Farley went from doctor to doctor in search of answers, and finally, a year and a half after she first noticed her symptoms, was diagnosed with rheumatoid arthritis, an autoimmune disease. A family of nearly 100 conditions, autoimmune diseases strike when the body's immune system, which is meant to protect you from foreign invaders such as bacteria and viruses, mistakenly turns on your own organs and systems; in rheumatoid arthritis sufferers like Farley, the joints and tissues are under attack.

It took three years, and Farley now has some control over her health. Still, she remembers the baffling period before her diagnosis as one of the worst times in her life. "No one, not even your friends, really understands what you're going through," she says. "People aren't *trying* to be mean, but if your doctors don't understand what's happening to you, it's no surprise that other people may think you're making it up."

Stories like Farley's are strikingly common among young women with autoimmune disease. For seven months Kathy Curran, 28, experienced severe tingling in her arms, recurrent migraines, blurred vision and even one scary episode of momentary blindness—but doctors "said my symptoms were just pinched nerves," she says. An MRI and a spinal tap finally gave a name to her ailment: multiple sclerosis (MS), which causes the immune system to attack the central nervous system and can lead to paralysis. Since then, she says, "it seems as soon as I tell someone I have MS, they always say, 'Oh! I just found out that my friend's sister has that too!'"

Melissa Weissman, 24, had similar terrifying vision problems along with a sensation of pins and needles down her back. When tests delivered a verdict of MS, it felt surreal: Three of her friends, all women between the ages of 25 and 35, had recently been diagnosed with autoimmune diseases, including type 1 diabetes, in which the immune system attacks insulin-producing cells in the pancreas. "It already seemed odd to me that so many young women I knew were being diagnosed with diseases in which the body basically turns against itself," Weissman says. "I just never thought that I could be one of them."

Katie Hall was 19 when her excruciating stomach pains led to the diagnosis of ulcerative colitis, in which the immune system attacks the lining of the intestines. Her best friend suffers from rheumatoid arthritis. "We always talk about how bizarre it is that two young, confident college girls like us could be hit by autoimmune diseases out of the blue," says Hall, now 21. They weren't an atypical pair; when she went to the hospital for treatment, she was shocked to see that "so many patients sitting in the IV infusion chairs were women my age. I just don't get it. Why?"

These young women are the living faces of what many scientists call an alarming trend. Rates of autoimmune diseases have been climbing rapidly over the past four decades. These illnesses now afflict an estimated 23.5 million Americans—78 percent of whom are female. That means that more than 18 million women in this country are living with an autoimmune disease, compared with 2.4 million with breast cancer. Why are women more at risk than men? "We suspect that estrogen may cause our immune systems to produce more antibodies, which are meant to protect us, but may make it more likely for the body to turn on itself," says DeLisa Fairweather, Ph.D., assistant professor in the division of toxicology at the Johns Hopkins Bloomberg School of Public Health's department of environmental health sciences.

Experts say that some of the increase in these diseases is really an increase in diagnoses—but that the climb is too dramatic to attribute to that alone. “Although the research in this area is limited, many autoimmune diseases appear to be steadily on the rise,” says Fred Miller, M.D., Ph.D., chief of the environmental autoimmunity group at the National Institute of Environmental Health Sciences. “That’s in contrast to rates of many other illnesses that have remained flat or even decreased.”

Doctors are seeing the trend play out in exam rooms every day. “Autoimmune diseases such as MS and transverse myelitis [a similar disease] used to be rare disorders. Now estimates show there may be 400,000 people with MS in the United States alone,” says Douglas Kerr, M.D., director of the Transverse Myelitis Center at Johns Hopkins. “Most of the patients we’re now seeing are young, previously healthy women. We’re facing an epidemic of autoimmune disease—one that we need to recognize now.”

Despite the mounting evidence, talking about the autoimmune epidemic today is a bit like talking about global warming before *An Inconvenient Truth* was released. Ninety-four percent of people can’t name a single autoimmune disease, according to one study, and many doctors haven’t fully educated themselves on how to diagnose these conditions. As a result, most autoimmune patients see four doctors over four years before they receive a diagnosis. Kathleen Arntsen, president of the Lupus Foundation of Mid and Northern New York, was in her early thirties when she began suffering from severe muscle fatigue and disabling weakness. She was told dismissively by a doctor, “We’ve given you every test known to man except for an autopsy. Would you like one of those, too?” It was five years before Arntsen received the diagnosis of myasthenia gravis, an autoimmune disease that destroys the nerves’ ability to stimulate and control muscle action. “Young women are so often treated like fruitcakes when they fall ill with these diseases,” Arntsen says. “Meanwhile, their entire lives are turned upside down.”

Thankfully, researchers have begun to slowly unlock key findings about autoimmune disease. “These diseases all begin the same way—something triggers the immune system to attack your own body,” says Fairweather. What flips the switch? Signs increasingly point to environmental factors such as the food we eat, the levels of stress we live with and the pollutants our immune systems are exposed to. No one factor is deadly; in most cases it’s likely that the cumulative buildup of many environmental problems poses health risks. “Even though you may have the same genetic tendencies as your mother or grandmother, today’s environment is more likely to pull the trigger that makes you get sick,” explains Pamela Peeke, M.D., author of *Body for Life for Women* and a former senior research fellow specializing in integrative medicine at the National Institutes of Health.

The best analogy is the age-old idea of the straw that broke the camel’s back: Your immune system can function under even a heavy load of environmental stressors. But one too many and it completely breaks down. What are the most common straws for young women? And how can *you* stay safe? Experts are beginning to understand exactly that.

## **Our Junk Food Ways**

“Today’s highly processed food diet is a contributor to the autoimmune epidemic,” says Gerard Mullin, M.D., director of integrative gastroenterology nutrition services at the Johns Hopkins Medical Institutions. He cites the refined carbs and dangerous fats found in many processed foods, as well as the lack of fiber, antioxidants and phytonutrients. How does what’s in your stomach affect your immune system? “The lining of the gut is on alert for any strange stuff we’re eating,” says Dr. Peeke. “The body has to decide at that moment, ‘Do I digest that, absorb that or get rid of it right away?’ If the food is, say, a whole food like broccoli, the gut doesn’t give a damn, and it’s quickly digested. But spray that broccoli with pesticides, and the gut says, ‘Now you’ve got my attention.’ And the immune system has to go to work.” Recent studies show that when immigrants from South Asian countries move to Western countries and likely begin to eat processed food diets, they have an increased incidence of autoimmune diseases such as Crohn’s and ulcerative colitis. Studies like this haven’t been the only thing to sway Dr. Mullin, whose own autoimmune disease, a rare condition called arachnoiditis, once nearly paralyzed him. “I’ve been extra vigilant about eating a whole foods diet,” he says—and his health has improved as a result. On his and most experts’ good-to-eat list: skinless chicken; low-mercury wild fish such as flounder and tilapia; vegetables; fresh fruits; whole grains from gluten-free sources; nuts; and olive and flaxseed oils. On the

not-good list: highly processed foods, including preserved bread products and cereals, preserved meats and other foods that are often full of chemicals, preservatives and additives. Sufferers should eat them rarely, if at all.

Dietary changes helped Angela Doss. Last December Doss, 28, was suffering from severe thirst, dizziness and fatigue—and had lost almost 20 pounds in three weeks. She says a doctor told her, “You just need to gain some weight. Go have a banana split and you’ll be just fine.” She was later rushed to the emergency room, where physicians diagnosed Doss—who was in a near-diabetic coma—with type 1 diabetes. In addition to daily insulin shots, “now I eat as many organic vegetables and fruits as I can,” Doss says. “I grew up on a fast-food diet of fried foods—Oklahoma meat and potatoes. It took me a while to learn to eat whole foods. But I’ve noticed a big difference in how I feel.”

Should we all cut back on junk? Yes, say experts like Dr. Peeke, who argue that doing so may help the average American woman cut her risk of contracting autoimmune disease. “People say we don’t have perfectly wonderful data yet, but come on,” says Dr. Peeke. “The best thing to do is to eat whole foods.”

### **Our 24/7 Stress Habit**

If you’re skeptical that emotional issues can have real physical consequences, consider this: Parents who have suffered the loss of a child are 50 percent more likely to develop MS than those who’ve never gone through that trauma, according to one 2004 study. “Chronic stress has a toxic effect on almost every single tissue in the human body,” explains Dr. Peeke. “The immune system puts up the best front it can, but after being beaten up enough, it can no longer optimally protect you.” MS and rheumatoid arthritis are both associated with stressful life events, but it doesn’t take personal tragedy to raise your risk of autoimmune disease—being chronically stressed can also alter the immune response. And perhaps not surprisingly, women today seem to be more stressed than in generations past, says Robin Goland, M.D., an endocrinologist and codirector of the Naomi Berrie Diabetes Center at Columbia University Medical Center. “Today, we’re trying to do everything,” she says. “You have to be a little selfish to be healthy, and that’s hard for women.” If you’re chronically stressed, or, as Dr. Peeke says, “feeling helpless, hopeless or defeated,” finding an outlet is critical. “You can’t avoid stress; we need some in order to grow and evolve,” she says. “But you have to eliminate the stuff that wears you down, the stuff you ruminate about, as best you can.” Exercise, yoga or meditation are prime choices, since they can help steady stress hormones, but anything that breaks up your daily grind is beneficial.

### **Our Chemical World**

Environmentalists talk about the carbon footprint we’re leaving on our planet; some health experts say we should also look at the chemical imprint we’re leaving within our own bodies. And many agree that our day-to-day exposure to pollutants, pesticides, heavy metals and chemicals is, in Dr. Kerr’s words, “a significant contributor to today’s rising rates of autoimmune disease.”

How can those pollutants have such an impact? It takes the human body thousands of years to adapt to new environmental stresses, explains Ahmet Hoeke, M.D., Ph.D., associate professor of neurology and neuroscience and director of the neuromuscular division at Johns Hopkins. “We’ve outpaced our evolutionary ability to keep up with the number of chemicals we come into contact with every day,” he says. And those numbers are huge: In 2005 the Centers for Disease Control and Prevention reported that when they sampled 2,500 people across the country to look for the “body burden,” or amount of chemicals each individual was carrying, they found traces of all 148 chemicals and pollutants they tested for, including PCBs, insecticides, dioxins, mercury and cadmium, which are toxic in higher doses.

Not all experts believe our polluted world makes us sick—some proponents of the “hygiene hypothesis” argue it’s too *clean*, believing that our germ-free homes and childhood vaccinations have eliminated the natural challenges to our immune systems that once taught our bodies how to defend us properly. But many specialists and some research dispute this idea; studies have found no link between infections, vaccinations and the diagnosis of type 1 diabetes, for example.

Still other critics refute the idea that chemicals might make us sick at all. “Just because we can measure a chemical in the blood doesn’t therefore mean it’s harmful,” says Jeff Stier, spokesman for the American Council on Science and Health (ACSH), a group that gets about 40 percent of its financial support from industry sources. (The ACSH says these are no-strings-attached donations.) “People want to be able to blame chemicals where they don’t have another explanation for the cause of a disease. I think we need more psychologists rather than more toxicologists.” The ACSH argues that we should focus on the things we know will improve health. “There are so many things we can do to protect ourselves—get good nutrition, quit smoking, buckle up,” says Stier.

Doubtless those universal guidelines are important, but an increasing number of researchers say possible chemical risks shouldn’t be ignored. “The people who first studied the connection between cigarette smoking and lung cancer faced the same criticism,” says Kathleen Gilbert, Ph.D., an associate professor in the department of microbiology and immunology at the Arkansas Children’s Hospital Research Institute in Little Rock, who has studied autoimmune diseases. “The only reason these things are ‘obvious’ now is because scientists decided to study them. Surely we owe it to the folks with autoimmune diseases to investigate.” Some research, Gilbert points out, shows a link between autoimmune disease and chemical exposures *below* levels of supposed toxicity.

To live as healthy a life as she can with lupus, Marisa Zeppleri-Caruana, 30, never takes her clothes to a dry cleaner and doesn’t use any products with pesticides. “After so many years of being sick, you learn that you *have* to be vigilant,” she says. Katie Hall looks for natural or organic beauty products. “I check everything that I put on my body because it’s just one more way chemicals can get absorbed,” she says. Erin Farley has switched from traditional cleansers to natural alternatives. “My mother taught me how to make an all- natural cleaner she calls ‘witches’ brew’: one part water, one part white vinegar and a splash of lemon,” says Farley. “I use it to wipe down everything.”

What do experts think of these steps? “I know we don’t have all the science to back it up, but I see how patients who do this are healthier and feel better, and I can only tell them that what they are doing makes sense and is a good prescription for better health,” says Dr. Mullin.

It’s a prescription Dr. Peeke follows herself. “The most important thing you can do is avoid toxic stress. Whenever you can, eat whole foods, whole foods, whole foods. And in the best of all worlds, go green,” she says. “There’s no question that if we made these kinds of changes, we would not only slow the sharp increase in autoimmune disease, we would impact heart disease, cancer and *all* health.”

*Donna Jackson Nakazawa is the author of The Autoimmune Epidemic and the website [autoimmuneepidemic.com](http://www.autoimmuneepidemic.com).*

<http://www.glamour.com/health-fitness/2008/10/the-scariest-health-threat-youve-never-heard-of>

## **ABC's Robin Roberts' Sisters Participate In Breast Cancer Study**

Sep 10, 2008 05:25 PM EDT

By Danielle Thomas



LONG BEACH, MS (WLOX) - Two sisters of Good Morning America anchor Robin Roberts are doing their part to fight breast cancer. You may remember how Roberts went through a very public battle with breast cancer. Now Sally Ann Roberts and Dorothy Roberts-McEwen are both taking part in the **Sister Study**, a research project that looks for genetic and environmental links to the disease.

Dorothy Roberts-McEwen had to be measured, poked, weighed and more to take part in the **Sister Study**.

"They're going to be taking information from you and asking you all kinds of questions," said McEwen. "Sometimes it can make you a little hesitant to be involved in something like that. But to me, the factors of being afraid of all that were outweighed by, 'What if something I share with this study helps other people?' So that part of it is what really inspired me to be a part of it."

McEwen is a healthcare administrator. Her sister Sally Ann Roberts is a television broadcaster in New Orleans. McEwen says their main inspiration for joining the **Sister Study** was their sister Robin Roberts who recently underwent treatment for breast cancer.

"Right now, the **Sister Study** has a really excellent representation of white American women involved in it, but it's very under-represented with women of color," said McEwen. "So there's a really big push to include our study, our information, so this study is very well balanced."

Home health practitioner Mary Jane Greenwood took McEwen's vitals for the research project. Greenwood is breast cancer survivor.

"It would be nice to be able to eradicate the disease all together," said Greenwood. "It would be nice to be able to give women hope rather than fear."

McEwen said, "You can donate money and that's great. A lot of research projects need money. But to actually be a part of a research study, you don't actually get a chance to do that all the time. But if you're a sister, who has a sister who has developed breast cancer, we really encourage you to be a part of it."

McEwen says she and her sisters have become spokespeople for the **Sister Study**. The trio's participation in the study will be featured in the October Issue of Essence Magazine.

If you'd like to learn more about taking part in the study, call 1-877-4-SISTER.

## Sisters Of Good Morning America's Robin Roberts Join Sister Study For Breast Cancer Research

19 Sep 2008

Sally-Ann Roberts and Dorothy Roberts McEwen LCSW, sisters of ABC's Good Morning America co-anchor Robin Roberts recently became participants and volunteer spokespersons for the Sister Study. Conducted by the National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health, the Sister

Study is a prospective observational study that will help researchers learn how environment and genes affect the chances of getting breast cancer. The study which is in its final phase of recruitment is committed to enrolling 50,000 diverse women who have never had breast cancer but whose sisters had the disease.

Like their sister, Sally-Ann and Dorothy are no strangers to working hard everyday to change the lives of others. Sally-Ann is co-anchor on New Orleans' CBS Eyewitness Morning News and leads a non-profit organization, Each One Save One; and Dorothy is a healthcare administrator as assistant director at South MS Regional Center. As Sister Study spokespersons, the duo will encourage more women to enroll in this important effort, which researchers hope will identify causes of breast cancer and yield information that will help prevent breast cancer for generations to come.

Breast cancer hit close to home when their younger sister, Robin was diagnosed in 2007. It was natural for them to be strong for one another through Robin's recovery but they were less accustomed to sometimes feeling helpless as they watched their sister battle the disease. Sally-Ann, 54, and Dorothy, 51, both decided that enrolling in the Sister Study would be a way to honor Robin, contribute to a good cause and hopefully help scientists learn about the causes of the disease.

"I learned about the Sister Study while interviewing another study spokesperson on the show," said Sally-Ann. "I immediately felt that this was an opportunity for me to help answer questions about why Robin may have gotten breast cancer while I had not." She added, "Future generations will truly benefit from the collective efforts of sisters participating in this study." While on air, Sally-Ann promised to join the Sister Study and did in fact honor that promise.

The news segment not only encouraged women of New Orleans to enroll, increasing local enrollment by 29%, but Sally-Ann's commitment motivated her younger sister Dorothy to enroll and also become a spokesperson. As a social worker Dorothy understands the need for research, but wasn't sure about participating herself. But, like other women who hear about the Sister Study, she overcame her initial reluctance to participate.

"When I compared the amount of time it takes to participate in the Sister Study to the countless hours my sister Robin spent fighting breast cancer, I got past my hesitation and signed up," said Dorothy. "It's so important to develop solutions that will answer questions about the environment, genes and breast cancer." She added, "Unless a wide range of women take their place in research helping to answer these questions, being able to prevent this disease in the future becomes nearly impossible. Sally-Ann and I are encouraging more women to participate, and make a difference in the fight against breast cancer."

Sally-Ann and Dorothy will tell their stories and reach out to women in their communities and beyond. The three sisters will also be featured in the October issue of *Essence Magazine*.

Fewer than 20% of women with breast cancer have any family history of the disease, and less than half of all women diagnosed with breast cancer have any of the known risk factors. Sister Study researchers believe there is much more to be learned about how environment and genes are related to breast cancer

risk. Sisters of women with breast cancer have about twice the risk of developing breast cancer themselves, as compared to most women so studying these sisters may provide important clues to breast cancer causes. Important clues will also come from studies that include a wide range of women from different backgrounds which is why the researchers are so committed to enrolling a diverse cohort.

Women ages 35 to 74 may be eligible to join the study if they have never had breast cancer themselves; their sister (living or deceased) related to them by blood, had breast cancer; and they live in the United States or Puerto Rico. The study is quickly approaching the goal of enrolling 50,000 diverse women, but to ensure the results benefit all women, researchers are asking African Americans, Latinas, Asians, Pacific Islanders and Native Americans to enroll immediately. Caucasian women with a high school degree or less, or who are between the ages of 65-74 are also still needed.

The study is no longer enrolling new volunteers who are Caucasians 35-64 years old with more than a high school degree - these women are already well represented in the study group. During the remaining months of enrollment, the Sister Study is making special outreach to women who have ever held blue collar or non-traditional jobs, because of the wide-range of environmental and chemical exposures that might be found at work.

Dale Sandler, Ph.D., Chief of the Epidemiology Branch at NIEHS and Principal Investigator of the Sister Study said, "After four years, we are almost at our goal of 50,000 participants and the team is working extremely hard to wrap up recruitment during these last few months of 2008." She added, "Over time, we look forward to continuing to follow the participants and having results that could benefit our daughters and granddaughters."

Sister Study partners include NIH's National Center on Minority Health and Health Disparities, the American Cancer Society, Sisters Network Inc., Susan G. Komen for the Cure, Breast Cancer Network of Strength, and the Intercultural Cancer Council. In addition to working with its national partners, the Sister Study works with local, regional, and national organizations to inform diverse women about the study.

To volunteer or learn more about the Sister Study, visit <http://www.sisterstudy.org>, (for Spanish <http://www.estudiodehermanas.org>), or call toll free 1-877-4SISTER (877-474-7837). Deaf/Hard of Hearing call 1-866-TTY-4SIS (866-889-4747). All activities are available in English and Spanish.

<http://www.medicalnewstoday.com/articles/122060.php>

## ***NTP Hosts RFI Meeting to Develop 'Rigorous, Comprehensive' HTS Toxicity-Screen Battery***

By Charlotte LoBuono

**Research Triangle Park, NC** — The **National Toxicology Program**, seeking information on how to identify and select critical cellular toxicity pathways to be interrogated by cell-based high-throughput screens, this week held a Request for Information meeting at its facility here, and said it will use the responses to develop what it terms a "rigorous and comprehensive" battery of high-throughput assays, an **NTP** official told *CBA News*.

The **NTP** also solicited recommendations on particular molecular targets within these cell-tox pathways that are most informative for profiling the pathways in both cell-based and biochemical assays, and on technologies and assay systems that may enable a comprehensive approach to high-throughput toxicological screening.

"The simplest reason for [the meeting] is that we are interested in identifying both critical pathways and assays that inform on those pathways, that provide information relevant to those pathways," **Raymond Tice, acting chief of the National Toxicology Program biomolecular screening branch**, told *CBA News* in an interview following the first day of the meeting.

Researchers are evaluating chemicals and their relationship to toxicity through their own experiences and their methodologies, **Tice** said. He explained that companies employ people with experience in a particular arena, who then start thinking about how to apply their experience and expertise from drug-discovery and toxicology perspectives.

"So, by having a meeting, we start bringing together a critical mass of people," and all of those people who are in the **NTP Toxicology in the 21st Century** focus group on pathways and assays get all this information, see the presentations, think about it, and then go back to those companies that they feel have the most interesting approaches and do a follow-up, **Tice** explained.

"I think that not only was this meeting of benefit to those of us in the government as we develop these screening approaches as alternatives to investigating toxicology, but I think it also was of benefit to the participants" because it brought people together from all over the country who may have similar interests but who may not have communicated with each other before, said **Kristine Witt, a toxicologist at the NTP biomolecular screening branch**.

**Witt** told *CBA News* that "one of the things that I was pleased to see was how much discussion occurred among the attendees during the breaks and during lunch." Because many pharmaceutical companies are currently reorganizing their businesses and laying off research staffers, this is a good time for cell-based assay tool and technology companies to consider diversifying beyond drug discovery into areas such as toxicology, said John Westwick, president and CEO of Odyssey Thera and a presenter at the meeting. Westwick told *CBA News* that the meeting could be a prelude to something bigger, such as an RFA.

"It is also nice to have some external validation for what you are doing," he said. Toxicology strategies are likely to be similar to drug discovery, which Westwick said seems to spark the question, "Is the line being blurred between environmental and pharmacological toxicology, allowing companies to expand into both spheres?"

### **Interagency Collaboration**

In February, the National Human Genome Research Institute and the **National Institute of Environmental Sciences** signed an agreement with the US Environmental Protection Agency to use the NHGRI'S National Chemical Genomics Center high-speed automated screening robots to test suspected toxic compounds using cells and isolated molecular targets (see *CBA News*, 2/15/08).

**Witt** said this week that the **NTP** is looking for assays that are ready to be installed as soon as possible, or could be installed shortly following modification, at the NCGC screening program.

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*"[H]earing about the options at this meeting will allow us to think about how we might develop that full, comprehensive screening program."*

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In addition, "As our program grows, it is going to expand, and we have to look at other options that go beyond the capabilities of NCGC, because they are exploiting a particular technology, and there are limits to that technology," Witt said.

As the NTP examines the significance of the biological responses that it comes across in the NCGC's high-throughput screens, "we will have to move into different kinds of systems, so hearing about

the options at this meeting will allow us to think about how we might develop that full, comprehensive screening program," Witt said.

The NCGC will ultimately have a library of about 8,000 to 10,000 compounds, comprising "every single chemical that we can find that is of environmental concern or in commerce, or is of interest to organizations such as the EPA, NIEHS, or the US Centers for Disease Control," said Tice.

These compounds generally have to be those about whose structure something is known. They should also be purchasable and should be soluble in DMSO because that is the vehicle in which the center tests its compounds. "There are certain limits to the kinds of compounds in the library, but there will be a library that gets tested," said Tice.

The NCGC also has limits in terms of the assays it runs in that they have to be compatible with a 1,536-well format and be add-on assays. Within that context, however, the NCGC has the ability to test large numbers of compounds.

The EPA's ToxCast program, another part of the memorandum of understanding signed between the EPA, NHGRI, and the NIEHS, focuses on contracts with small companies, each of which has a spectrum of assays.

"What we are trying to do is take the data from the NCGC, which involves screening lots of compounds, but fewer assays, with that from ToxCast, which involves many assays but fewer compounds, and integrate it with the data that we already have from animals, and human data that we are trying to get from the FDA — whatever we can find," said Tice.

There is probably built-in redundancy in those assays. For example, different companies measure estrogen receptor activation in different ways. "By looking at the redundancy, we will be able to look at the total package and determine if the data is consistent for a particular compound and across different assays measuring different or related endpoints," Tice said.

Companies, organizations, or individuals in the scientific community are joining ToxCast who are not being paid by contract, but who are testing ToxCast's 320 phase 1 compounds anyway in their own assay systems, to leverage what they are trying to do.

"We are trying to ... bring these companies and individuals in who may test the same compounds on their own dime to further their own efforts," Tice said.

In terms of follow-ups to the RFI meeting, "one of the questions that we are still trying to resolve is, "How do you prioritize pathways?" said Tice. That may be a practical issue, in terms of there may be an assay for that pathway that already can be put into high throughput.

However, another pathway may exist that is more valuable from the standpoint of disease, but for which an assay has not been developed. "What we will do is put out RFPs that say we are interested in having someone develop assays using an SBIR grant in that particular pathway or arena," said Tice.

In addition to Odyssey Thera, shops that play in the cell-based assay market that participated in the RFI meeting included Invitrogen, PerkinElmer, Promega, BioSeek, DiscoverX, and Cellumen.

"We did not have any criteria" for inviting companies to participate," Tice said. "These are companies that actually submitted something to us and said that they were interested in attending. To the best of my knowledge, we did not turn anyone down."

[http://www.cba-news.com/issues/5\\_36/features/149368-1.html](http://www.cba-news.com/issues/5_36/features/149368-1.html)

## ***Deep Pockets Being Opened for Parkinson's Research***

By: Lara Endreszl  
Monday, 22 September 2008

Parkinson's disease (PD) has affected the global awareness by striking people within the public eye that we look up to and can empathize with. In 2003 I saw Pope John Paul II in an audience at the Vatican and under the weight of Parkinson's, the leader of the Catholic Church had no power against the will of his own body; his hands shook instead of waved, his body was hunched over in pain, and his voice trembled with instability. Stung like a bee with the diagnosis in 1984, Mohammed Ali, an honored man and boxing legend, is now confined to a wheelchair and while he still attends functions as a living sports legacy, he nods and twitches his head and hands not to the words being spoken or the songs being sung but to the beat of the Parkinson's resounding in his head; he hasn't won this fight yet. Michael J. Fox, a beloved character for years from television to the future on the big screen and back again, is most often recognized now as the brave young actor who was diagnosed at age 30 and is still fighting against the disease's crippling effects. With the exposure of Parkinson's disease reaching high-calibers, it's no wonder that [The National Institute of Environmental Health Sciences \(NIEHS\)](#)—a division of The National Institutes of Health (NIH)—is reaching deep into their pockets. It looks like the global awareness of the PD has sparked an interest in the reasons behind the diagnoses and what we can do to find a cure.

Over the next five years, [NIEHS](#) will grant \$21.25 million to three research schools in the United States to fund studies relating to how environmental factors contribute to the cause, prevention, and treatment of Parkinson's disease. A central nervous system disorder, Parkinson's disease affects over one million Americans each year and the disease progresses with age. In most cases, scientists don't know specifically what brings on the disease, but some cases are known to be caused by severe head trauma (such is the speculation in Mohammed Ali's case) or patterns of genetic abnormalities. Parkinson's is thought to be a derivative of genetic mutations and outside environmental causes. For example, prolonged exposure to pesticides is thought to [double a person's risk for the disease](#).

The three grantees are from respected research schools around the country and are using their grants to cover a specific area of researching the disease. Gary Miller, Ph.D., at Emory University, Atlanta, Georgia, receives a grant for prolonged research of how environmental and genetic factors change dopamine cells within the brain that lead to Parkinson's disease. The second grant goes to Marie-Françoise Chesselet, M.D., Ph.D., at the University of California, Los Angeles, who plans to specifically research pesticides that may be the main cause of sporadic Parkinson's diagnoses and possibly come up with a prevention plan by cautioning the use of certain pesticides. Lastly, Stuart Lipton, M.D., Ph.D., Burnham Institute for Medical Research in La Jolla, California, will investigate free radical stress caused by environmental toxins that cause genetic mutations responsible for helping to progress the disease and hopefully be able to isolate the body's proteins damaged in the process.

[Acting director of the Division of Extramural Research and Training at NIEHS, Dennis Lang, Ph.D.](#), said of the grantees, "The UCLA and Emory CNS grants will extend the exciting lines of research previously supported by [NIEHS](#), while the Burnham Institute grant will bring an important new perspective to research on gene-environment interplay in Parkinson's disease."

Perhaps the most influential person in my life who lived with Parkinson's disease wasn't a public figure and wasn't world-renown for anything special; she was my grandmother. She raised seven children in a modest home, she was a do-gooder and revered by the community for her cooking talent and quilting techniques. As the years rolled by and she wasn't able to stand up much less get out of the house, my dad's mother spent her remaining years cooped up in a nursing home shaking and drooling, but always believed that she would walk again. That faith was finally lost in April 2005 when—the same day as Pope John Paul II—my grandmother passed on. With the generous research grants from [NIEHS](#) dedicated to finding a cure, I hope continuing investigations will be able to finally give those living with Parkinson's the second chance at life they deserve.

<http://www.healthnews.com/medical-updates/deep-pockets-being-opened-parkinsons-research-1818.html>

*The Chronicle of Higher Education*

## **Hidden Hazards: Could pollutants trigger Alzheimer's and Parkinson's diseases?**

By Lila Guterman

Dec. 9, 2008

The symptoms of Alzheimer's or Parkinson's diseases are frightening: They include memory loss, change of personality, gait disturbance, and speech problems.

Worse is the caprice with which the diseases appear to choose their sufferers. Seemingly healthy people gradually become completely unlike themselves. Although scientists have discovered genes that increase the risks of both diseases, the genes account for just a small percentage of the millions of cases.

And so researchers are searching the environment for a cause, or causes, of neurodegenerative disease. They have theorized that exposure to pesticides or metals may trigger neuron loss or damage, perhaps decades before symptoms begin. These diseases that primarily affect the aged may even begin in the womb.

But figuring out which exposures matter is extraordinarily difficult. Such sleuthing can be tricky for any human disease — in looking backward at a person's life history, the best scientists can do is to identify likely causes.

When it comes to neurodegenerative disease, the link to toxins is even harder to establish. A person's exposure to a pollutant is usually not measured or recorded. Remembering an episode some 60 years earlier is difficult under the best of circumstances, and even harder when memory is affected by Alzheimer's disease.

But thanks in part to some lucky breaks, researchers have been making progress in studies of large human populations and in experiments on animals. They have shown that early exposure to low levels of pollutants can end up killing neurons in the same areas of the brain that are damaged in people with neurodegenerative disease. In some cases, people known to have inhaled or ingested the same pollutants have proved more likely to experience dementia or motion disorders.

The payoff of such research could be more than just a stronger grasp of which chemicals to avoid. The diseases have proved difficult to understand, and no drugs exist that stop their progression. Working out how various compounds induce the diseases in animals could help scientists better understand their mechanism in people.

To aid such research, the **National Institutes of Health** announced in September that it had **awarded \$21-million in grants to scientists who study environmental causes of Parkinson's disease**. "It's very important to have a lifetime perspective," says Giancarlo Logroscino, a professor of neurology at the University of Bari, in Italy. "Even if these are diseases of aging, what happens in early life can be important."

Although something besides genetics must explain all or even most cases of Parkinson's and Alzheimer's diseases, the evidence of environmental risk factors is much stronger for Parkinson's.

Scientists have long looked for similarities among sufferers of Parkinson's. Epidemiologists typically study people who have the disease and compare their life histories with those of healthy counterparts. Such studies have turned up risk factors like living on a farm or drinking well water, and being exposed to certain metals.

But other studies have looked at the same characteristics and found no link to disease. That's a difficulty with epidemiology: Unless the exposure causes huge changes in health, connections can be hard to

ferret out. Perhaps the studies that find no link just involve too few people. Or perhaps the studies that do find connections are statistical flukes.

The key is to keep looking in different populations. "The evidence as it accumulates is getting stronger," says Freya Kamel, a research scientist at the National Institute of Environmental Health Sciences, in North Carolina.

Researchers agree that smoking, surprisingly, offers some protection against Parkinson's disease. And, says Kamel, the weight of the evidence shows that pesticides increase the risk of the disease.

A question that remains, though, is which pesticides? Most studies track exposure to pesticides only as a group instead of looking at specific herbicides, insecticides, or fungicides. Many of these pesticides can no longer be detected in the body years after exposure; some are gone after only weeks or months.

But research in this area got an unexpected boost in 1982 after seven drug users in Northern California showed up at emergency rooms displaying symptoms of Parkinson's disease. A neurologist from Stanford University, J. William Langston, discovered that they all had used a batch of heroin contaminated with a compound called MPTP.

Fingering MPTP as the responsible agent took a lot of medical detective work. "I remember thinking that if the medical director of the hospital knew how much time I was spending on a single case, he would probably fire me," Langston says.

Langston, who is now scientific director and chief executive of a nonprofit organization he founded, the Parkinson's Institute and Clinical Center, recalls the moment when he realized MPTP was the culprit. "Just like an explorer who hits a new land and knows there will be a rush of people behind him," he says, "I stood there for a moment and enjoyed the view."

The day that his results appeared in Science, his phone rang off the hook. Every researcher calling asked the same question: Where can I get MPTP? The company that made it had sold out immediately.

Quickly, scientists discovered that MPTP could cause Parkinsonian symptoms in monkeys. (The compound thus provided scientists with their first experimental version of the disease.) In the body, MPTP converts to a molecule called MPP+ and systematically assaults neurons in the same area of the brain that is damaged in Parkinson's patients.

The benefits to science of the chance discovery were tremendous. Researchers now possessed strong evidence that a chemical in the environment could cause Parkinson's disease.

The MPTP case is science's only "clear-cut demonstration," Logroscino says, that a specific toxin can induce a chronic disease of any type. (Even though lung cancer, for example, has been clearly linked to cigarette smoking, scientists do not know what elements of the smoke are to blame.) The molecule itself, MPP+, pointed directly at a pesticide as a potential bad actor. The chemical structure of MPP+ is remarkably similar to that of paraquat, a widely used herbicide, suggesting that the product might wreak havoc in the same way in the brain.

Studies in animals have since shown that paraquat kills neurons, but its effects on mouse brains do not perfectly mirror the attack by Parkinson's disease on human brains. A spokesman for the company that sells paraquat, Syngenta, calls the relevance of mouse data for human health "dubious." A controversy among scientists continues about the relevance of paraquat experiments to Parkinson's disease — it was debated this year in the pages of Toxicological Studies and discussed in October at the annual International Neurotoxicology Conference.

Acting alone, paraquat may not cause changes resembling Parkinson's disease. But Deborah A. Cory-Slechta, a professor of environmental medicine at the University of Rochester, discovered in the late 1990s that when mice received shots of both paraquat and a fungicide called maneb, their brains started

to look much more like those of Parkinson's patients. Neurons died only in the area of the brain that was damaged in Parkinson's disease.

"Never when we started this did I think we would see the kinds of things we actually saw," Cory-Slechta says. The two pesticides acted in synergy on the brain.

Cory-Slechta's team later discovered that if they gave mice shots of the pesticides very early in life, the neurons that produced dopamine gradually died off throughout the rodents' lifetimes. (Dopamine is the neurotransmitter that runs low in the brains of Parkinson's patients.) If they then exposed those mice again as adults, the effects were stronger than after the first exposure even though no traces remained of pesticide from that first dose. That showed that the toxicity to the brain was cumulative.

Cory-Slechta does not yet understand the synergy or the delayed effects, and guesses that there may be many other pairs of chemicals that could also act together. "It's frightening when you think about it," she says. "How many of these things are going on that we don't know about?"

Philip J. Landrigan, a professor of pediatrics and of community and preventive medicine at Mount Sinai School of Medicine, calls Cory-Slechta's results "tantalizing."

A group of researchers including **Kamel** and Langston is also making use of human data to try to blame or exonerate individual pesticides. In the mid-1990s, the National Institutes of Health began a study of workers in North Carolina and Iowa who apply pesticides, including checkups and surveys every two years about the workers' pesticide use. Nearly 80,000 people participate.

"It's a huge gold mine," Langston says. The researchers are writing manuscripts now and expect to publish results soon. Langston says their results should be "somewhat definitive."

But Landrigan argues that, to really connect cause with effect, studies need to measure peoples' exposure to chemicals from birth — or even from the womb — till death. The National Children's Study, an enormous endeavor to study the health of 100,000 children, is scheduled to begin in the coming months. It plans to follow the children until they are 21, but, says Landrigan, "I'm sure 21 years from now people aren't going to just walk away."

Science will not wait decades for such studies to take place. And so it continues with animal research, which has recently produced intriguing links between Alzheimer's disease and chemicals in the environment.

Richard M. LoPachin, a professor of anesthesiology at Albert Einstein College of Medicine, has found that a class of chemicals called type-2 alkenes can damage neurons in rats in a way similar to harm seen in the brains of patients with Alzheimer's disease. The chemicals are common environmental pollutants that are heavily used in manufacturing, agriculture, and other industries.

What's more, other researchers have found that the brains of patients actually produce the same types of chemicals. He proposes in an article published this fall in *NeuroToxicology* that external exposure to the pollutants may work together with the internally produced compounds to speed Alzheimer's disease toward its sad conclusion.

No one has looked in human studies for links between those alkenes and neurodegenerative diseases. "It's a brand new idea," says LoPachin. "We're waiting for epidemiology to catch up to it."

Meanwhile, another contaminant may also set people up for the dread disease. Nasser H. Zawia, a professor of toxicology at the University of Rhode Island, published research in 2005 that found that baby mice fed small quantities of lead — that already-worrisome pollutant — produced, as adults, the proteins that are one of the signatures of Alzheimer's disease.

Mice do not develop plaques in their brains, as people do, so it was not clear how well their brains resembled the brains of people with Alzheimer's disease. But Zawia got lucky: He found a group of monkeys that had been born in 1980 and fed, by a scientist, with infant formula containing lead. The elderly monkeys lived at the National Institutes of Health until 2003, when scientists euthanized them and stored tissues from various organs, including their brains.

"It was a miracle to find them," Zawia says.

In January, Zawia wrote in the *Journal of Neuroscience* that, remarkably, no traces of lead appeared, but the monkeys' brains were full of plaques.

"Everybody thought lead was just a problem for children," Zawia says. So researchers had not done experiments with older animals that had been exposed to lead early in life, as his mice and monkeys had. Scientists usually have neither the patience nor the money to do those longer experiments, he says. He hopes to study whether people who were exposed as small children to lead are more likely to get Alzheimer's disease.

He and other scientists emphasize that although the environmental hazards' links to brain disease are unexpected and frightening, they are not reason to panic. Most peoples' exposure to the pollutants is very low, and the diseases are complex and most likely require more than one instance of bad genetic or environmental luck.

"I don't talk about [pesticides] as causing Parkinson's disease," says Cory-Slechta. "I think of these as risk factors."

Zawia agrees. If you were exposed to lead as an infant, he says, you may have "the deck stacked against you. But that does not mean you will get Alzheimer's disease."

<http://chronicle.com/weekly/v55/i16/16b01001.htm>

## ***Binational Environmental Outreach and Education Efforts Honored***

### ***UA researchers are invited to speak at National Institute of Environmental Health Sciences Hispanic Heritage event.***

By Rebecca Ruiz-McGill, University Communications  
September 23, 2008

The **National Institute of Environmental Health Sciences** has invited University of Arizona researchers Denise Moreno and Monica Ramirez to speak about their educational outreach to the Hispanic community.

The **National Institute of Environmental Health Services**, also known as NIEHS, provides federal research funding to universities for environmental health and science research projects.

Moreno and Ramirez are program coordinators for both the **NIEHS Hazardous Waste Program** and the U.S.-Mexico Binational Center for Environmental Sciences and Toxicology housed within the UA's College of Pharmacy. The Hazardous Waste Program conducts studies concerning hazardous environmental contaminants along the border region.

The Binational Center supports environmental science and toxicology training, research and policy development. In association with these two projects, Moreno and Ramirez conduct community outreach with a special focus on Spanish-speaking communities.

"The funding from **NIEHS** involves faculty members, staff and students from 5 UA colleges and 10 departments who are applying their expertise to hazardous waste issues," Ramirez said. "It is an interdisciplinary approach to environmental research and education with a central theme in detecting, assessing and ameliorating environmental pollution and determining the impact of environmental pollution on human health."

Their presentation will include discussion of their outreach efforts, including the training of community health advocates or promotoras, who advise businesses on how to minimize pollution, as well as conserve energy and water. They also will share their work on making hazardous mine tailings safer and will also discuss the development of a youth science program, which was offered in the summer of 2008 to students living along the Arizona-Mexico border.

"The program works to translate years of study into real world solutions and moves science projects and research from the laboratory to the field," Moreno added.

The **NIEHS Diversity Council** selected to feature Moreno and Ramirez's work as part of its 2008 Hispanic Heritage Celebration.

<http://uanews.org/node/21627>



## ***Founding Dean Named for CUNY School of Public Health***

By E.B. Solomont, Staff Reporter of the Sun  
September 29, 2008

A former top official at the National Institutes of Health, **Dr. Kenneth Olden**, has been appointed founding and acting dean of the proposed CUNY School of Public Health at Hunter College.

Previously, **Dr. Olden** headed the **National Institute of Environmental Health Sciences** and the **National Toxicology Program**, both parts of the NIH. He recently served as Yerby Visiting Professor at the Harvard School of Public Health.

"**Dr. Olden** is a distinguished scientific leader and cancer researcher," CUNY's chancellor, Matthew Goldstein, said in a statement announcing the appointment. "He brings an impressive combination of national and indeed international experience and service to the country to this vitally important and new initiative."

Plans for a school of public health were announced in October 2006. Billed as the city's first public school of public health, it plans to offer master's and doctoral degrees. It is expected to open by 2010.

<http://www.nysun.com/health-fitness/founding-dean-named-for-cuny-school-of-public/86780/>

## Chemical Reactions

By Laura Beil

December 24, 2008

We live our lives in the company of chemicals, from the pollution that makes its way into our air and food, to the synthetic material in the products we use every day. These compounds are considered safe, based on tests that look for the degree of exposure necessary to trigger DNA damage. But just as epigenetics is changing the way people think about cancer, it's starting to change the way people think about cancer causes.

"I think the field of epigenetics is going to turn the field of toxicology on its head," says Randy Jirtle, PhD, of Duke University Medical Center. Why? Because it raises the possibility that low levels of chemicals—chemicals now considered safe—are in fact silently marking our DNA in ways that can lead to cancer.

And these pollutants might not only affect our lives, but our children and grandchildren. In 2006, scientists from Washington State University reported that mice exposed to a certain fungicide experienced epigenetic changes that were passed to future generations. Preliminary data have suggested similar connections with smoking.

At this point, little is certain, says Jirtle, who has conducted experiments with bisphenol A, a controversial chemical found in plastic bottles and canned-food liners. Experiments on bisphenol A have suggested that the compound, which is so ubiquitous it can be measured in the bodies of 93 percent of Americans, can cause epigenetic changes. But the research has been conducted in laboratory rodents, and animal epigenomes differ from humans. This is the case for most chemicals: Data on the epigenetic impact is either non-existent or limited to laboratory experiments.

The federal government is now trying to change that, with the National Institute of Environmental Health Sciences (part of the National Institutes of Health) investing almost \$30 million in epigenetic studies of environmental exposures over five years. Some of the first human data from those studies may be released soon, says Fred Tyson, PhD, a scientific program director at NIEHS. The pollutants under examination include arsenic, air particulates, bio-active dietary zeranol (from injected cattle), dietary biotin, polychlorinated biphenyls (PCBs), and polycyclic aromatic hydrocarbons (byproducts of burning fossil fuels).

"It's possible it (epigenetics) could have some policy implications for what acceptable levels of exposure are," Tyson says, though no one can yet say what the outcome of the research will be.

Jirtle believes that, at the very least, the most common environmental pollutants need to be reexamined for safety. "It's been assumed that since they don't cause mutations that they aren't problematic," he says. "I don't think that's good enough."

[http://www.curetoday.com/index.cfm/fuseaction/article.showArticleByTumorType/id/98/tumorCategory/Myelodysplastic%20syndrome/article\\_id/951](http://www.curetoday.com/index.cfm/fuseaction/article.showArticleByTumorType/id/98/tumorCategory/Myelodysplastic%20syndrome/article_id/951)



## Cancer in a can?

There's mounting concern that a chemical in the lining of food cans and in some plastic containers may cause health problems. Here's how to protect yourself.

By Bijal Trivedi  
From the October 2008 Issue

When she first hung up with her doctor one December day in 2004, Rachael Rawlins could only cry. "I was shocked, surprised, incredulous," she says. The doctor, who had biopsied two lumps in her breast, informed her that she had aggressive cancer and needed a mastectomy. Later during her chemotherapy, Rawlins, an environmental lawyer in Austin, Texas, did what she does best: She searched for answers. "I was only 40. It wasn't in my family. I was very fit. I didn't drink much alcohol. I didn't think I had any risk factors." Rawlins wondered if she'd been exposed to a toxin that could have had anything to do with the cancer. She and her husband began trawling the Internet for leads.

What she found was compelling: bisphenol A (BPA), a harmless-seeming material that is an ingredient in certain plastics. It is used to line billions of cans and in other forms of packaging, including polycarbonate water bottles, those hard, shatterproof containers often used for sports. Rawlins learned that in ultra-low doses—the amount that can leach from packaging and bottles into food and drink—BPA has been shown in lab animals to cause immune disorders and early onset of puberty, and to fuel various cancers.

Most every drop of Rawlins's drinking water had contact with BPA, she says. The cooler at her office, where she drank the most, was likely made of BPA. At home, she stored filtered water in a polycarbonate container from Whole Foods and was especially careful when she was pregnant. "While I was trying to protect myself and my babies from pollutants, the entire time the water was being contaminated by its container," she says.

### CHEMICAL INACTION

In the past year, the dangers of polycarbonate baby and water bottles have gotten a lot of press. Not so BPA levels in food, which is how most Americans are exposed to the substance, according to the Centers for Disease Control and Prevention in Atlanta. If BPA affected Rawlins's cancer, some of her exposure may also have come from her food.

Food cans are lined with epoxy resins made up of approximately 60 percent BPA, which prevents the cans from rusting and the contents from picking up a metallic taste. But minute amounts of BPA, which are not chemically bound in the resin, seep into food and beverages. What's more, BPA is also sometimes present in pizza boxes made from recycled materials, as some of the paper they're made from contains BPA. The American Chemistry Council in Arlington, Virginia, which represents BPA manufacturers, and the Food and Drug Administration insist that the amounts from packaging that wind up in food are harmless. Last year, the Environmental Working Group (EWG) in Washington, D.C., tested 97 canned items from three states for BPA. They looked at beans, fruit, liquid meal replacements, infant formula, pasta and soup and found that 57 percent of the foods were contaminated—although with amounts well below what the Environmental Protection Agency says is safe.

## DOSE AND DANGER

The EWG finding sounds like good news, but many experts say it's not—what are thought to be safe levels may still pose a threat to a fetus or child, and to adults as well. Some say there's no such thing as a safe dose. In fact, most people are already exposed to amounts that cause alarming effects in animals, says Retha Newbold, Ph.D., head of developmental endocrinology at the National Institute of Environmental Health Sciences in Research Triangle Park, North Carolina. Nearly 93 percent of Americans have BPA in their urine, according to the CDC study. Although Newbold says the amounts in our blood are some 250-fold lower than the dose the EPA considers safe, she is not reassured: "We do not have definitive proof that these low doses cause adverse effects in humans—but I don't know if we want to wait for definitive proof."

Most people agree that BPA is harmful in large quantities. As it has done with many high-volume industrial chemicals, the EPA has conducted standard risk-assessment studies. In 1982, toxicologists exposed adult rats to high doses of BPA in order to identify the largest dose that proved harmless and extrapolated what they thought would then be a safe dose for humans. The EPA then divided this dose by 1,000 to protect more vulnerable citizens and account for any undiscovered risks. The final "safe" dose is 50 micrograms per kilogram of body weight per day. This standard was confirmed in 1993 and holds today. When rats are exposed to more, their body weight begins to drop. In mice, very high levels will kill the mother and her fetus.

But what is dividing scientists, industry types and regulators is whether trace amounts of BPA—parts per billion, 0.000000705 ounces—that leach from packaging might, in fact, pose a different kind of danger than a high dose. In traditional toxicology, the basic scientific principle is the higher the dose of a poison, the greater the effect. But if the substance is a hormone—and BPA is structurally similar to estrogen—things work differently: Low doses may also produce a great effect, although of a different kind. "That's not intuitively obvious," says Newbold, who studies how estrogen and estrogenlike chemicals affect the genes. So similar to estrogen is BPA, that, like an evil twin, it mimics the hormone by fulfilling some of its duties—interacting with proteins and DNA in a way that only estrogen should. Recent studies on animals have shown that BPA can switch on and off genes that would normally be under the hormone's control.

## CANCER CONNECTION

Ordinarily, estrogen is present in small quantities for brief periods while a fetus (human or animal) is developing, and that is enough to lay the foundation for the reproductive system and the architecture of milk ducts and lobe tissue in the breasts. After this, estrogen is mostly absent until puberty onward, when cyclical secretion of estrogen stimulates the turnover of healthy cells to keep them in working order. One of estrogen's main functions is to make breast cells multiply. Every time this happens, a cell is vulnerable to carcinogens and DNA mutations. That's why over a lifetime, the risk of breast cancer increases naturally: The more estrogen a woman is exposed to, the greater the risk.

But getting too much estrogen during fetal development—whether naturally or in the form of a man-made endocrine disrupter such as BPA—creates abnormally developed breast tissue in the fetus that grows into adult tissue that is unusually sensitive to estrogen.

Animal studies clearly show these effects. Maricel V. Maffini, Ph.D., research endocrinologist at Tufts University School of Medicine in Boston, exposed pregnant mice to extremely low doses of BPA. Then she studied the development of the offspring's mammary glands. Those whose mothers took in even minuscule amounts had accelerated breast development. "Everything is hyperactive," Maffini says. In a similar study, rats exposed in utero were examined at four months—the equivalent of a woman in her early 20s—and their breasts showed precancerous cells and tumors. "The mammary gland is like a network of pipes all going to the nipple," Maffini

explains. "When cells lining the pipe grow inward, the pipe gets blocked." That cluster of abnormal cells is the first stage of tumor formation, and a third of the BPA-treated animals had blockages. None of the untreated ones did. In short, BPA seemed to prime the fetal rats for cancer, so when they were exposed to natural estrogen as adults, the abnormally developed tissue overreacted and proliferated into cancerous tumors.

**Newbold**'s experiments bring home the idea that even fleeting exposure to BPA can trigger cancer later in life. She exposed mice to minute doses for the first five days of their life. At 18 months, she found that the mice suffered from a significantly greater number of uterine tumors and fibroids, and ovarian cysts than the unexposed animals. Some increase in the incidence of tumors is normal with aging, but these tumors arose earlier, at about 12 months (equivalent of age 40), in mice exposed to BPA, and there were more of them. "That seems to match what we are seeing in the general population," of humans, **Newbold** says: More women being diagnosed younger and with more aggressive tumors.

As scientists learn more about the effects of low doses of BPA, a series of disturbing health trends begins to make sense. BPA has been used in cans and plastics since the 1950s, and there has been a rise in prostate and breast cancers in Europe and the United States since that time. Initial studies with human cells do little to calm fears. Shanaz H. Dairkee, Ph.D., senior scientist for cancer research at the California Pacific Medical Center Research Institute in San Francisco, exposed noncancerous breast cells in women with breast cancer to a "safe" dose of BPA. She then compared the gene activity in these cells with typical gene activity in breast cancer cells. Although BPA did not transform normal cells into cancer cells per se, it did have a Jekyll and Hyde effect: BPA caused groups of genes in healthy cells to behave abnormally, as they might in the aggressive cancer cells. "This shows cause and effect," Dairkee says.

That's not to say that BPA is the sole or primary trigger of breast cancer. "I think that BPA, along with a number of environmental estrogens, is playing a role in the increase in incidence in a number of cancers. I don't believe it's BPA alone," **Newbold** says. Dairkee says a woman's genetic makeup plays a larger role. "For some people, BPA may have no effect." But if a woman is prone to cancer or has an early stage of it, "then exposure to BPA may lead to a more aggressive form that is almost impossible to cure," she says.

## **WHAT'S BEING DONE**

A draft of a government report, which was expected to be finalized in late summer, does not capture the urgency that **Newbold** and others think it should. The **National Toxicology Program** of the **National Institute of Environmental Health Sciences** has "some concern" that low doses of BPA could alter mammary and prostate development in fetuses, and that females could experience early puberty. But it has "negligible" concern that these levels pose a danger to pregnant women.

Although Canada has proposed banning the sale of baby bottles containing BPA and many retailers and manufacturers such as Toys "R" Us, Wal-Mart and Nalgene are phasing it out, little is being done about food packaging. The Environmental Working Group study of canned goods found that, depending on the type of food, a mere one to three servings could expose a woman or child to the doses of BPA that caused serious adverse effects in animals. "We have all the pieces of the puzzle," says Anila Jacob, M.D., who worked on the EWG study. "A good start would be to ban its use in all food packaging." In June, Massachusetts congressman Edward J. Markey proposed exactly that. "For the sake of the health of every man, woman and child in America, the best course of action we can take right now is to completely ban BPA in food and beverage containers, especially because there are alternatives already available."

For now, a ban seems unlikely. BPA is heavily produced—between 6 and 7 billion pounds each year, says John Peterson Myers, Ph.D., chief scientist of Environmental Health Sciences, a not-for-profit science education organization in Charlottesville, Virginia. "So there's a lot of money at stake," Myers says.

Banning the chemical, even in children's products, as has been proposed in California, is unnecessary, industry representatives say. "There is only limited and inconclusive evidence from laboratory animals. Additional research is needed to see whether these findings are relevant for human health," says Steven G. Hentges, executive director of the Polycarbonate/BPA Global Group at the American Chemistry Council. "Science supports the safety of BPA." The FDA concurs that BPA is safe for use in baby and children's products and in food packaging. "Dietary exposure to BPA from these uses...is well below the levels that would cause adverse health effects," Norris Alderson, Ph.D., associate commissioner for science at the FDA, testified before Congress in May.

"It is mind-boggling that regulators and industry can still ignore the low-dose studies," Myers contends. He says that if the government acknowledged that testing high doses of chemicals may not predict the effects of low doses, it would be forced to look more closely at hundreds of other endocrine-disrupting contaminants. "The system doesn't protect public health," Myers says. "It protects products."

Proving that Rachael Rawlins's cancer was connected to BPA is impossible. Because everyone in the United States is continually exposed to BPA, there is no control group with which to compare the rates of cancer. Still, for Rawlins, the BPA ban was immediate. She and her husband "tossed all plastic, because we weren't sure which things contained BPA," she says. They now use glass and stainless steel. She also eschews canned foods and eats mostly organic products.

Rawlins, who is now healthy, has become a grassroots advocate, talking to friends, neighborhood associations and retailers about BPA. When she comes across people using polycarbonate bottles, she'll "give them my five-minute speech" on the chemical and the controversy. She's also writing law and policy articles and trying to get the government to regulate BPA and other toxins more tightly. "I am not a scientist," she says. "But I don't need proof that BPA harmed me. It is enough that the studies indicate there is a serious risk of harm. If I had been informed, I would not have taken that risk."

<http://www.self.com/health/2008/09/cancer-from-food-packaging?currentPage=2>



## Steering clear of BPA

If you'd like to avoid bisphenol A, as **environmental biologist Retha Newbold** advises women with a family history of cancer or those of childbearing age to do, try these tips.

**By Bijal Trivedi**  
**From the October 2008 Issue**

**Sip from stainless steel or glass**, which do not contain BPA. Some plastics do and it's not easy to tell which ones. If you use plastic, avoid any with 7 in the recycling triangle on the bottom. These codes were never meant to indicate the presence of BPA and so are not foolproof guides, but numbers 1 through 6 are less likely to contain the chemical.

**Nuke food in ceramic or glass.** High temperatures make BPA in plastic containers more likely to leach. Avoid putting plastics (polycarbonate especially) in the dishwasher.

**Stick to fresh or frozen foods.** Most cans are lined with BPA-epoxy liner. Of foods tested, the highest levels of BPA were in pasta, vegetables and soups. But many haven't been tested.

**Demand BPA-free cans**, as advocate John Peterson Myers advises. Eden Foods in Michigan uses BPA-free cans for all low-acid foods. They cannot be used for acidic items such as tomatoes, however, so stick to glass jars for foods like that.

*<http://www.self.com/health/2008/09/how-to-avoid-bisphenol-a?>*

**Wide range of opponents lining up to contest route of 500,000-volt PPL line**

*First in a two-part series*

**By David Singleton, Staff Writer**

Monday, October 6, 2008 10:27 AM EDT

When a pair of administrative law judges recommended in August that the state Public Utility Commission reject a proposed high-voltage transmission line in southwestern Pennsylvania, Peter Derrenbacher found the news encouraging.

But he finally allowed himself to hope two weeks ago after prospective builder Allegheny Energy Inc. bowed to public opposition and announced it will seriously scale down the proposed \$1.1 billion project in Greene and Washington counties.

Mr. Derrenbacher, president of the Saw Creek Estates Community Association in Pike County, knows the proposed Susquehanna-Roseland Power Line is a different project by a different utility in a different part of the state.

But in what he characterizes as a David-versus-Goliath struggle to keep PPL Electric Utilities from putting its 500,000-volt transmission line through the heart of their 3,000-home development, residents will take inspiration wherever they find it.

"It shows that when these proposals are made by these utilities, they are not irreversible," Mr. Derrenbacher said. "What is implied is going to happen may not necessarily happen."

The swift unraveling of the Allegheny Energy project, known as the Trans-Allegheny Interstate Line, or TrAIL, provides an intriguing backdrop against which PPL will make the case for its line.

PPL expects to ask the PUC by year's end for authorization to construct the 99-mile line from the Susquehanna nuclear plant in Luzerne County's Salem Twp. to the Delaware River near Bushkill. That's where it will meet a similar line Public Service Electric and Gas Co. wants to build between the river and its Roseland substation in New Jersey.

PPL spokesman Paul Wirth insists the TrAIL case will not change how the Allentown utility approaches the Susquehanna-Roseland project.

Jeff Schmidt, state director of the Sierra Club, thinks the western Pennsylvania case is going to be almost impossible for the utility to ignore.

"We see that decision as an important foundation upon which the PPL power line proposal will have to be debated," he said.

State Consumer Advocate Irwin A. "Sonny" Popowsky, whose office intends to intervene in the PPL case, just as it did on the TrAIL application to the PUC, cautioned against reading too much into the outcome in western Pennsylvania.

"One thing I can say is, each line has to be judged on its own merits," Mr. Popowsky said.

Battle brewing

PPL's application to state regulators will set in motion a review process in which the company and other

formal parties, such as the PUC's Office of Trial Staff, the Office of Consumer Advocate, environmental groups and individuals, will present evidence to an administrative law judge.

Consumers who don't wish to file a formal protest can still make informal complaints to the PUC. In addition, the administrative law judge will conduct public input hearings separate from the formal evidentiary hearings.

After reviewing the evidence and arguments, the administrative law judge will recommend a decision to the PUC. The commission may accept, reject or modify the decision.

Transmission line siting reviews typically involve two questions: Is the project needed? Is the proposed route the best of the alternatives, given factors such as safety and environmental impacts?

PPL will argue the Susquehanna-Roseland line is necessary to prevent overloads on 23 transmission lines in Pennsylvania and New Jersey as early as 2013.

The recommended route, one of three alternatives considered, follows the path of an existing 230,000-volt transmission line — acknowledged by the utility as the primary reason for its selection.

In the TrAIL case, Allegheny Energy proposed construction of a 37-mile, 500,000-volt line from Washington County through Greene County to address local reliability issues. It would have been part of a larger, 240-mile high-voltage line extending through West Virginia and Virginia to the Washington, D.C., area.

But the two administrative law judges who handled the case concluded the local line wasn't needed, branding it "a grandiose answer to a minor or nonexistent problem." They also found the utility failed to make a case for the interstate line, saying the "true impetus" was to transport cheaper, coal-generated electricity to mid-Atlantic markets.

In addition, the judges hit the utility on route selection, saying its siting decisions were mandated by pre-existing right-of-way agreements, and said its proposal failed to adequately address the potential impacts on public health and safety.

On Sept. 22, faced with the unfavorable recommendation and continuing public outcry, Allegheny Energy scrapped plans for 36 miles of the proposed power line. Instead, under a proposed settlement with Greene County officials, it would build a 1.2-mile, 500-kilovolt line to link a new substation in southern Greene County to the remainder of the line at the West Virginia border.

EMFs sure to be debated

One of the health issues in the western Pennsylvania case is almost certain to be an issue when PPL takes its project before the PUC — exposure to electromagnetic fields.

Electromagnetic fields, or EMFs, are unseen lines of force associated with the transmission and use of electricity. Because of the ubiquitous nature of electric power, people are constantly being exposed to electric and magnetic fields of varying strength, produced by everything from power lines to auto ignitions to electric razors.

But since the late 1970s, when studies first suggested an association between long-term exposure to magnetic fields and the incidence of childhood leukemia, EMFs have become an elusive bogeyman in the debate over where to site — and not to site — high-voltage lines.

As the judges in the TrAIL case noted in their decision, "No issue in a proceeding to locate and construct high-voltage transmission lines is more controversial or fraught with more conflicting information than the alleged effect of exposure to electromagnetic fields."

The PUC has no formal position on EMFs, spokeswoman Jennifer Kocher said. Mr. Popowsky said to the extent a utility can take steps to minimize public exposure to EMFs at a “modest and reasonable” cost, his office will push those.

Linda Erdreich, Ph.D., a New York epidemiologist and health risk assessment specialist who has been working with PPL as a consultant, acknowledged associations between EMFs and childhood cancer have been observed.

But there is inadequate evidence to show a cause-and-effect relationship between long-term EMF exposure and any disease, despite repeated attempts to find it, she said.

Still, she understands why EMFs are such a hot-button issue in power line discussions.

“There is nothing — nothing — more important to people than their children,” Dr. Erdreich said. “Childhood leukemia is scary ... no matter how weak the evidence is.”

Christopher Portier, Ph.D., associate director of the National Institute of Environmental Health Sciences, said while there is no definitive evidence magnetic fields cause childhood leukemia, the association between the two is clear.

What is still unclear is the mechanism behind the association, whether it is the field or something else, Dr. Portier said.

The link is strong enough that both his agency and the World Health Organization classify EMFs as a possible human carcinogen.

“There is an association,” he said. “You can’t minimize the association by wishing it away.”

Louis Slesin, editor of Microwave News, a respected online journal that has covered EMF-related issues for more than 25 years, said a favored argument of utilities is magnetic fields from appliances such as hair dryers and can openers are often stronger than those directly beneath power lines.

The logic, Mr. Slesin said, is spurious. While fields from appliances are high, they drop off “really, really quickly” at distance, much more quickly than the field from a 500,000-volt transmission line, he said. And while you can choose not to use a hair dryer, there is often no option if a utility decides to put a line near your house.

“Your exposure is 24/7,” Mr. Slesin. “That’s the issue. It is the chronic exposure.”

PPL looks to mitigate EMFs

PPL is planning to take steps to minimize exposure to EMFs generated by the new transmission line in accordance with a magnetic field management program it put in place in 1991 for new or rebuilt lines, Mr. Wirth, the utility’s spokesman, said.

The benefit of a couple of those is self-evident; as Mr. Slesin says when it comes to EMFs, “Distance is your friend.”

Instead of the 85-foot towers that now carry a 230,000-volt line along most of the route, the towers PPL will construct for the new line will be 175 to 185 feet tall. And although the utility already has the easements in place in most cases, the right of way beneath the line will expand from 150 feet to 200 feet.

But Mr. Slesin said the easiest way to get rid of a magnetic field is through phasing, or arranging the lines in such a way to cancel out or reduce the field. According to PPL, phasing can reduce the strength of a magnetic field by up to 69 percent.

Mr. Wirth said PPL plans to use a technique known as reverse phasing, employed in the configuration of the double-circuit transmission lines, along the entire 49-mile length of the line from the Peckville area to the Delaware River.

That is the span that runs past the homes in Saw Creek Estates. Mr. Wirth said PPL models show EMF levels in the development will be lower after the 500-kilovolt line is in place than they are now with the existing 230-kilovolt line.

There may be portions of the line where a different phasing arrangement produces lower EMF readings, such as the 13-mile stretch in the Scranton area where the new line will parallel the existing 230-kilovolt line, Mr. Wirth said.

“The bottom line is that we will use the phasing arrangement that produces the lowest EMF readings,” he said.

‘100 percent adverse impact’

Rocco Pannoza, vice president of the Saw Creek Estates Community Association, said whether it is the EMFs, the unsightly transmission towers, the impact of construction on the environment, or any combination of those, the PPL project has no positives for people who live along the route.

“There is going to be a 100 percent adverse impact — period,” he said.

Like many of his neighbors, Mr. Pannoza believes the utility is motivated by greed, viewing the line as a conduit to sell more power to Northeast markets.

“The question that comes up is, where is the real need for this?” he said. “Is there really a justifiable need for this line to begin with?”

Mr. Popowsky, the consumer advocate, expects that question to be the central issue when PPL takes the Susquehanna-Roseland proposal to the Public Utility Commission. If nothing else, the TrAIL case in western Pennsylvania demonstrated the project will not be rubber-stamped, he said.

“What people can take from that,” Mr. Popowsky said, “is the Pennsylvania Public Utility Commission will give careful consideration to not just what the company has to say but what the residents and customers in Northeastern Pennsylvania have to say.”

[http://www.thetimes-tribune.com/articles/2008/10/06/news/sc\\_times\\_trib.20081006.a.pg1.tt06powerline\\_s1.1982018\\_top2.txt](http://www.thetimes-tribune.com/articles/2008/10/06/news/sc_times_trib.20081006.a.pg1.tt06powerline_s1.1982018_top2.txt)

October 6, 2008

## Sister study focuses on genetic link to cancer Research to include varying backgrounds

By Julie M. McKinnon  
Blade Staff Writer



Moore



Ruge



Gerber

Marilyn Moore was more worried about her twin sister going through treatment for breast cancer than her own ordeal with cervical cancer about a year earlier.

So when Ms. Moore heard about the **Sister Study Breast Cancer Research** project - which is focused on looking at environmental and genetic causes of the disease - she knew without asking that two of the twins' sisters would join her in volunteering for the 10-year effort.

The natives of rural Attica, Ohio, hope to help researchers looking for causes of breast cancer in women like Carolyn Ruge of Toledo, their 53-year-old sister who was successfully treated two years ago.

Yet Ms. Moore, Ms. Ruge's twin, said she has tried with no avail to recruit others to the study conducted by the **National Institute of Environmental Sciences**, one of the National Institutes of Health.

"I don't know why they would be hesitant," Ms. Moore of Shelby, Ohio, said. "To me, it is a no-brainer. Why wouldn't they want to do it?"

Scientists are in their final push to get the last of 50,000 participants for the study, which three of Ms. Ruge's sisters joined two years ago. Minority women aged 35 to 74, including those of African, Latina, and Asian descent, are especially in demand to make the study representative of American women.

So far, 2,023 women from Ohio and 2,179 from Michigan have volunteered for the study, and all participants are eager to help, **Lisa DeRoo, the study's lead investigator**, said.

"They're very much invested in the study," she said. "A lot of them are doing it in memory of their sisters or in honor, if they're a survivor."

Ms. Moore and another sister participating in the study, Denise Gerber, 48, of Bellevue, Ohio, said they worry about whether they or other relatives could get breast cancer. The family's four brothers and five sisters, including study participant Darlene Hart, 54, of Richmond, Ind., collectively have 12 daughters and 11 granddaughters so far.

"You are concerned about them, because no one wants to put their children at risk," said Ms. Ruge, mother of Jessica Lashley of Toledo, 30, and grandmother of Olivia Lashley, 6.

Added the breast cancer survivor: "There has to be some link."

Having a sister with breast cancer doubles a woman's risk to have breast cancer, which could be because of genetics or shared environmental exposures, said **Ms. DeRoo, the scientist from the National Institute of Environmental Sciences**. Some special analysis likely will be done on twins such as Ms. Moore and Ms. Ruge, she said.

Participants start with telephone interviews and questionnaires, and they provide samples of their blood, urine, nails, and household dust so scientists can assess various factors and exposures believed to cause cancer, including arsenic and other chemicals, Ms. DeRoo said. Most of the study's work is done up front, she said.

Ms. Gerber, Ms. Ruge's sister in Bellevue, said they were all weighed and measured, and they were asked to recall living conditions from childhood.

"You had to really go back," she said.

Participants answer a questionnaire annually for 10 years to update their medical conditions, but they do not take medication or otherwise alter their lifestyle, Ms. DeRoo said.

"They're just supposed to do what they normally do," she said.

<http://www.toledoblade.com/apps/pbcs.dll/article?Date=20081006&Category=NEWS32&ArtNo=810060318&SectionCat=&Template=printart>

Oct 07, 2008

## ***Telecommuters look smart as gas prices go up***

Bruce Sicheloff, Staff Writer

**Gloria Jahnke** wants to have it both ways. And who doesn't?

Most days, she wants to rub elbows with her stimulating colleagues at the **National Institute for Environmental Health Sciences**.

"I like that interaction," said **Jahnke**, 60, a health scientist in toxicology. "You run into people during the day. You learn things you wouldn't pick up otherwise."

But sometimes -- no disrespect to those brainy **NIEHS** types -- **Jahnke** just wants to shut out all distractions. She needs to sit at her computer and stay focused on her deadline.

On those days, she can get more work done at her house in Orange County. After all, she has a phone at home, a laptop and an Internet connection.

So why waste time and gas on a 45-minute drive to Research Triangle Park? This summer, **Jahnke** joined the ranks of a modest movement to let workers stay home a few days a month -- and phone it in.

Telecommuting isn't new, but it seems to be growing. As \$4 gas makes driving more expensive, some bosses are getting up the courage to let workers out of their sight every now and then.

Cisco Systems, with 4,500 full-timers in RTP, ranked sixth this year in Fortune magazine's survey of the 100 best places to work -- partly on the strength of its No.1 rank in telecommuting. About 70 percent of Cisco employees work from home at least one day a week.

When 12,210 Triangle-area commuters pledged in the SmartCommute Challenge this summer to try a different way of traveling to work, 5,806 of them said they would telecommute.

A national nonprofit group that promotes commuter benefits cited **NIEHS** recently for a 33 percent increase this year in what the federal agency calls teleworking.

**Jahnke** is among 113 of the 950 employees at **NIEHS** who occasionally work from home. She started work there in May and got approval this summer to try telecommuting one day every other week. So far, she likes it.

"I like having that option when you have to focus," said **Jahnke** (pronounced Yon-kee). "You don't want an interruption. Nobody can actually pop in to see you unless they drive out there to your house. That can help, if you really have to get things done."

Márcia Clover of Apex says her 2-year-old at home is less a distraction than co-workers at her office. She works for Clean Design, an RTP advertising agency.

When she was preparing for her daughter's birth two years ago, she agreed to take a reduced pay raise if her bosses would let her work at home two days a week.

### **Good gas savings**

"Then when gas prices started going up, I was like, man, that was a good choice," said Clover, 34. "The two days I save on gas and day-care costs make a difference at the end of the month."

Clover's work on advertising projects includes interactive programming, video editing and writing. She can do all that, and even log her daily work hours, on her home computer.

Each Wednesday and Friday, she skips the 30-minute drive to RTP and starts work early.

"I feel like I'm more productive the days I work from home -- even with a 2-year-old -- than when I'm at the office," Clover said. "She's really good. I take a five-minute break every now and then to read a book to her."

Because she keeps her files at home, bad weather doesn't keep her from doing her job.

"My productivity, rain or shine, it's still the same," Clover said.

**NIEHS** began moving a few years ago to protect itself against natural and manmade disasters that might interrupt work at its RTP campus. Suddenly, working at home was government policy.

"So when management bought into it, that really changed things," said **Dick Sloane**, who promotes commuter alternatives as part of his job at **NIEHS**. "We have a number of managers who telework, and they're strongly enthusiastic."

Some government agencies are still catching up.

The state Department of Transportation is leading a quiet effort to help state workers cut back on their driving. DOT and other agency workers are eligible for vanpool subsidies, free bus rides and flexible work hours.

But in 2003, DOT managers canceled a program in which more than 100 employees were allowed to work from home a few days a month. Five years later, DOT still does not allow telecommuting.

<http://www.newsobserver.com/news/story/1245631.html>

PLUS A DESPERATE DAD GIVES UP HIS NINE KIDS

OCTOBER 20, 2008

# People

NICOLE  
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## MY LIFE AS A MOM

Nine months after baby Harlow's arrival, Nicole and Joel talk about loving parenthood. 'I can't imagine life without her,' says Joel

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## BREAST CANCER SURVIVOR ROBIN ROBERTS AND HER SISTERS



"They've carried a load for me," says Roberts (at home in New York City with Sally-Ann, left, and Dorothy).

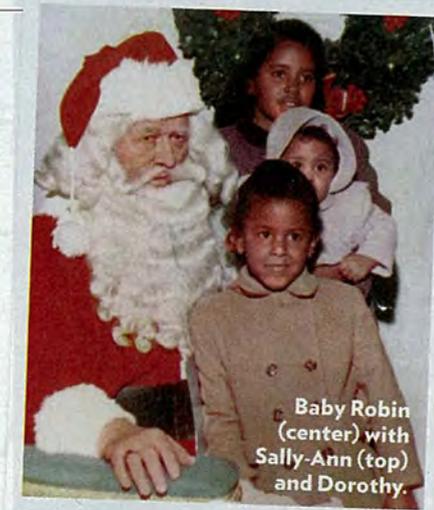
# The Power of Three

Her cancer was aggressive and could recur at any time. But with sisters Sally-Ann and Dorothy on her team, the *Good Morning America* coanchor says nothing can stop her

**T**he night before her breast cancer surgery last August, Robin Roberts roamed around her New York City apartment, too scared to feel anything. "I was in a fog," she recalls. But the *Good Morning America* coanchor wasn't alone. Her 84-year-old mother, Lucimarian, was there and so were her big sisters: Sally-Ann, who'd flown from Louisiana, air mattress in tow, and Dorothy Roberts McEwen, up from Mississippi. At one point, Robin placed Dorothy's hand

on her own right breast so Dorothy could feel the malignant mass. Dorothy's eyes widened in shock. "It was like marble, like a rock," she recalls. "I thought, 'Oh, my God.'"

It was a momentary lapse. For the most part Dorothy, 52, a healthcare administrator, and Sally-Ann, 55, a New Orleans news anchor, have been towers of strength for their baby sister, visiting and phoning through the entire roiling journey, from the discovery of Roberts's cancer in the summer of 2007 to



Baby Robin (center) with Sally-Ann (top) and Dorothy.

“Yes, I am living with cancer. But don't go ‘woe is me.’ I don't want it. Don't need it” —ROBIN ROBERTS

her emotional on-air announcement, partial mastectomy, chemotherapy and radiation. The siblings have also helped by enrolling in the Sister Study, a National Institutes of Environmental Health Sciences survey of women whose sisters have suffered from breast cancer [see box]. “I have good days and bad days,” says Roberts, 47, amply energetic as she bantered with her sisters at home Sept. 27. “I'm dealing with the side effects [from chemo].

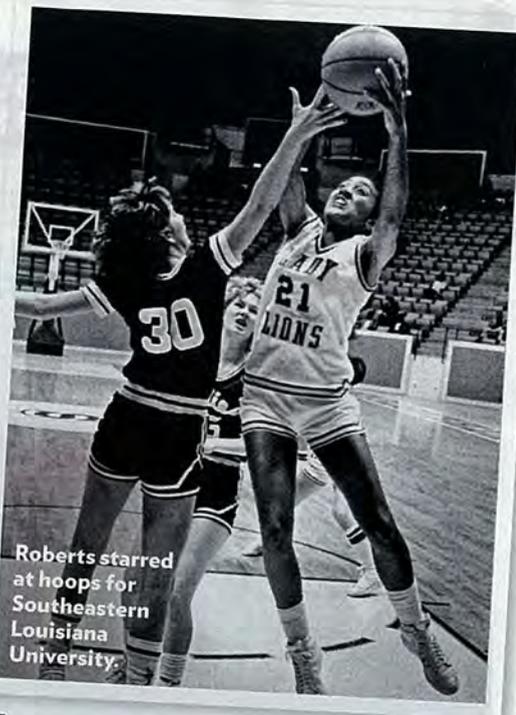
I get sinus infections and colds. I walk like an old lady in the morning and evening.”

Growing up in the small town of Pass Christian, Miss., the Roberts girls (who have a brother Lawrence, 60) were always close. Sally-Ann recalls Robin as a good-natured pleaser. “I'd say ‘Go into the house and bring the Oreos’ and she would.” The dynamic would change. As Roberts grew up into a success as a local sports reporter, making the leap to ESPN and GMA, she “became the leader, the organizer, the benefactor,” Dorothy says. But after her diagnosis, Roberts admits, “I felt like the baby again.”

Tears stream down her face as she recalls an especially grueling round of chemotherapy. “I was in bed, and had this terrible sore on my leg,” she says. “Sally-Ann said, ‘What's that?’ I said that's the chemo trying to get out of my body. She just put her hand on my leg and started praying.” Then there was the time Dorothy made her a butterfly bracelet that said, “You're my breast friend.” Says Robin: “It's those sweet, unspoken things.”

The sisters flew north again last December after Roberts, depressed near the end of her chemo, asked for them. “I knew she really needed us,” Dorothy says. “She'd be on TV smiling, but when I saw her in her apartment, she was like, ‘I had a good life. If I don't wake up tomorrow, I'm okay.’”

After three weeks off and some long walks with KJ, her Jack Russell, Roberts rebounded. She remains resolutely positive, though acutely aware that a recurrence could lurk in the shadows. “I'm not telling you I'm cancer-free,” she says. “I have a very aggressive type called triple-negative that happens in a lot of African-American women. I had a screening last week, and nothing



Roberts starred at hoops for Southeastern Louisiana University.

showed up. The trick is to find it early.” Aside from doctor's visits every couple of months, she undergoes acupuncture, sees a nutritionist and hits the gym. “Yes, I am living with cancer,” she says. “But don't go ‘woe is me.’ I don't want it. Don't need it. I'm still in the game. I don't want to say ‘survivor.’ I want to thrive.”

By Sharon Cotliar and Richard Jerome

## THE SISTER STUDY

African-American women are less likely than white women to develop breast cancer but slightly more likely to die from it. One reason, experts say, is they are prone to the aggressive “triple-negative” variety (in which tumors resist some targeted treatments). The NIEHS is recruiting more women of color to the Sister Study ([sisterstudy.org](http://sisterstudy.org)), designed to analyze genetic and environmental risk factors over a life span among some 50,000 women. To begin with, those enrolled offer samples of blood, urine and toenails as well as household dust. They also answer yearly medical questionnaires. Says study director Dr. Dale Sandler: “We hope to get some answers.”



“People I don't know write to say, ‘I'm getting my mammogram,’” says Roberts (modeling at a Fashion Week show in February).

## ***Dentists Back Sealants, Despite Concerns***

By Tara Parker-Pope

October 21, 2008

Cavities or chemicals? That's the dilemma for parents worried about a controversial substance found in the popular sealants that are painted on children's molars to prevent decay.

The chemical is bisphenol-A, or BPA, which is widely used in the making of the hard, clear plastic called polycarbonate, and is also found in the linings of food and soft-drink cans. Most human exposure to the chemical clearly comes from the food supply. But traces have also been found in dental sealants.

Although the Food and Drug Administration has reassured consumers that the chemical appears to be safe, it has received increasing scrutiny in recent months from health officials in the United States and Canada.

The National Toxicology Program, part of the Department of Health and Human Services, has raised concerns about BPA, particularly over childhood exposure to the traces that leach from polycarbonate baby bottles and the linings of infant formula cans. The 2003-4 National Health and Nutrition Examination Survey by the Centers for Disease Control and Prevention found detectable levels of BPA in 93 percent of urine samples collected from more than 2,500 adults and children over 6.

BPA has estrogenlike effects, and animal studies have suggested that exposure may accelerate puberty and raise a potential risk of cancer. This month, the journal Environmental Health Perspectives reported that the chemical might interfere with chemotherapy treatment. And last month The Journal of the American Medical Association reported that adults with higher levels of BPA in their urine were more likely to have heart disease or diabetes.

Despite these concerns, the American Dental Association remains strongly in favor of sealants. Dentists note that numerous studies show that any exposure they cause is negligible and temporary, lasting no more than three hours after the initial application. And other studies have found no detectable levels of BPA in most American-made sealants. Meanwhile, sealants have been shown to offer years of protection against cavities.

"This is such an enormously valuable tool to prevent tooth decay," said Dr. Leslie Seldin, a New York City dentist and consumer adviser for the American Dental Association. "The BPA issue, I think, is so minuscule in impact that it doesn't really warrant the attention it's been getting."

Dental sealants have the consistency of syrup so that they can seep into the crevices of molars. A light is used to harden the sealants, which are then buffed smooth. The coatings prevent the growth of bacteria that promote decay in the grooves of molars.

Just this month, a review of 16 studies by the Cochrane Collaboration, a nonprofit group that evaluates medical research, showed sealants offered significant protection from cavities. In the seven studies that compared sealants and regular brushing alone, the 5- to 10-year-olds who used sealants had less than half as much decay on biting surfaces four and a half years after the treatment. One study with a nine-year followup found that only 27 percent of sealed tooth surfaces had developed cavities, compared with 77 percent of unsealed surfaces.

The Cochrane review did not address BPA, but it did cite a March review article in The Journal of the Canadian Dental Association, looking at 11 major studies of BPA exposure from dental sealants. That review, financed by the nation's health system and conducted by researchers with no industry ties,

concluded that patients were not at risk for exposure to the chemical. And it noted that dentists and patients could further limit any exposure with simple steps like buffing tooth surfaces and gargling and rinsing after sealants are applied, all of which are standard practices in most dental offices.

The review also found that three products did not release detectable amounts of BPA: Helioseal from Ivoclar Vivadent; Seal-Rite from the Pulpdent Corporation; and Con Seal f from SDI (North America). All carried the 2007 American Dental Association seal.

The amount of BPA exposure can vary depending on the sealant. In a 2006 article in The Journal of the American Dental Association, researchers from the United States Public Health Service and the Centers for Disease Control and Prevention studied the effects of two dental sealants on 14 men, based on saliva and urine samples. They found that patients treated with an Ivoclar Vivadent product called Helioseal F showed no change in urinary or salivary levels of BPA, while patients treated with Delton Light Cure sealant, from Dentsply Ash, were exposed to about 20 times higher doses of BPA.

Linda C. Niessen of Dentsply International said in a statement that the A.D.A. says sealants are safe, and she notes that any exposure from a sealant is "significantly lower and occurs infrequently" compared with other sources of BPA.

Parents concerned about BPA exposure should ask their dentists what type of sealants they use and whether it has been tested for BPA. But researchers from the Centers for Disease Control and Prevention offered this bottom line: "Sealants should remain a useful part of routine preventive dental practice."

<http://www.nytimes.com/2008/10/21/health/21well.html>

### Two Speakers Launch Wyatt Lecture Series

**Media Contact:** Dan Adkins

**LEXINGTON, Ky. (Oct. 29, 2008)** – Two national leaders in environmental health and disease will present the University of Kentucky's inaugural John P. Wyatt Lecture at 9 a.m. Wednesday, Nov. 5, in the William T. Young Library auditorium.

William A. Suk, acting deputy director of the National Institute of Environmental Health Sciences (NIEHS) and National Toxicology Program, and Philip H. Landrigan, director of the Mount Sinai School of Medicine Children's Environmental Health Center, will be joined by three invited doctoral students.

At NIEHS, Suk assists the director in formulating and implementing plans and policies necessary to carry out the missions of NIEHS/NIH and the National Toxicology Program. He previously has served as director of the NIEHS Superfund Hazardous Substances Basic Research and Training Program and currently is director of the Center for Risk and Integrated Sciences. He has published extensively on issues linking exposures with disease and on research and prevention strategies to reduce risks of environmentally induced diseases and disorders. His presentation is titled "Environmental Exposure and Disease Links in Global Health: Addressing Health Needs and Disease Outcomes."

Landrigan, a pediatrician, epidemiologist, and internationally recognized leader in public health and preventive medicine, is a member of the Institute of Medicine of the National Academy of Sciences. He is known for his many decades of work in protecting children against environmental threats to health, most notably lead and pesticides. Landrigan served for 15 years as an epidemic intelligence service officer and medical epidemiologist at the Centers for Disease Control and Prevention and the National Institute for Occupational Safety and Health. In addition, Landrigan has been centrally involved in the medical and epidemiologic studies that followed the destruction of the World Trade Center on Sept. 11, 2001. Landrigan will speak about "Children's Health and the Environment: The Problem and the Solution."

In addition to Suk and Landrigan, UK doctoral student Zuzana Majkova and postdoctoral scholar Jignesh Pandya will speak about their own environmental health research. Also speaking about related research will be invited Michigan State University doctoral student Haitian Lu.

The event will kick off at 8:30 a.m. with a poster exhibition in the William T. Young Library Gallery.

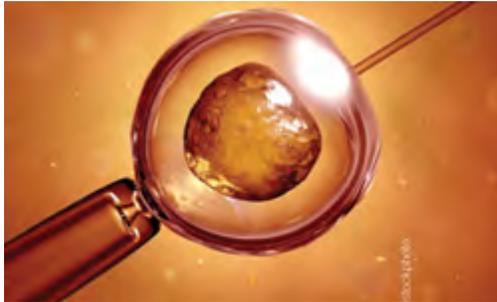
The inaugural John P. Wyatt Lecture is made possible through the Dr. John P. Wyatt Endowment at UK, as well as by the UK Office of the Vice President for Research, the UK College of Agriculture, and the UK Superfund Basic Research Program.

[http://news.uky.edu/news/display\\_article.php?category=2&artid=4096](http://news.uky.edu/news/display_article.php?category=2&artid=4096)

## As IVF becomes more common, some concerns remain

Prashant Nair, Chapel Hill, North Carolina

### Introduction



Istockphoto

**The magic moment:** Fertilization of the egg

An increasing number of infertile couples have turned to assisted reproduction technology, which facilitates the union of the sperm and the egg. But, in recent years, controversial reports of birth defects in babies conceived through assisted reproduction have led a few researchers to raise concerns about the technology's safety.

Assisted reproduction includes a handful of procedures, many of which are based on *in vitro* fertilization (IVF) of the egg. In the US alone, assisted reproduction accounted for slightly more than 1% of all births in 2005, according to the country's Centers for Disease Control and Prevention. The IVF process poses some minor risks to women, including ovarian cysts, mood changes and hot flashes. But a few rare risks to the fetus have given some fertility researchers pause.

Tinkering with sex cells and embryos outside the body, scientists worry, might spur genetic changes that manifest as congenital birth defects. No direct evidence supports that notion, but epidemiological studies have shored up possible links between assisted reproduction and rare genetic syndromes in newborns, such as Beckwith-Wiedemann syndrome, a condition marked by premature birth, an enlarged tongue and heightened susceptibility to tumors, respiratory and speech defects (*Hum. Reprod. Update* **10**, 3–18; 2004).

Fortunately, the syndrome is rare: it normally affects about 1 out of every 12,000 newborns worldwide. But a study found that 3 out of 65 US children afflicted with the syndrome had been conceived through IVF (*Am. J. Hum. Genet.* **72**, 156–160; 2003). In other studies, 6 out of 149 children in British and French medical registries of the syndrome were found to have been conceived through IVF or through a specialized technique called intracytoplasmic sperm injection, or ICSI (*J. Med. Genet.* **40**, 62–64; 2003; *Am. J. Hum. Genet.* **72**, 1338–1341; 2003).

"There appeared to be more children with the syndrome conceived through ART [assisted reproductive technology] than we might have expected by chance alone," says Eamonn Maher, a geneticist at the University of Birmingham, UK. Many cases of Beckwith-Wiedemann syndrome, Maher says, stem from abnormalities in DNA methylation—addition of a chemical tag called a methyl group—occurring in specific genes on chromosome 11.

Methylation is one of an array of DNA markers, called imprints, that guide normal development of the embryo. For example, imprinting seems crucial to proper brain growth, says **Carmen Williams, a clinical**

investigator at the US National Institute of Environmental Health Sciences in North Carolina. "The concern is that while the embryo is being cultured in the [IVF] lab, maybe the imprint marks are being changed. We know for sure that happens in mice," she adds (*Biol. Reprod.* **62**, 1526–1535; 2000).

Some studies have suggested a causal relationship between ICSI and abnormal methylation patterns (*Am. J. Hum. Genet.* **71**, 162–164; 2002; *Am. J. Hum. Genet.* **72**, 218–219; 2003). And Maher says the findings hint that imprinting defects might trigger Beckwith-Wiedemann syndrome.

But he also cautions that the absolute risk of giving birth to a child with Beckwith-Wiedemann syndrome is low.

"The disease is so rare that it's difficult to counsel an infertile couple not to go forth with ART," Williams says.

Conclusive evidence for the possible adverse effects of IVF is unavailable, owing to the dearth of long-term follow up of babies conceived through the technology. One Canadian study reported at the Society for Maternal-Fetal Medicine's conference in 2007 found that babies conceived through IVF were nearly 60% more likely to develop birth defects than naturally conceived ones. Most of the defects were gastrointestinal, although some were bone, muscle or heart related. Another study, from the University of Iowa, found birth defects in about 6.2% of about 1,500 IVF-conceived children, in contrast to 4.4% among naturally conceived ones (*Fertil. Steril.* **84**, 1308–1315; 2005).

If future studies bear out these links, Williams suggests that one can perhaps decrease the risk to the child by avoiding certain invasive procedures that might not be necessary depending on individual circumstances, such as biopsies of implanted embryos, culturing embryos in the lab longer than the minimal time period and using ICSI in the absence of male fertility problems.

<http://www.nature.com/nm/journal/v14/n11/full/nm1108-1171.html>

## **Enviro health scientists, chemists join forces to promote safe chemicals**

*Scientists convene in Southern California to draft a consensus statement designed to overcome obstacles to creating new, environmentally benign industrial compounds.*

By Marla Cone, Editor in Chief  
Environmental Health News  
published 12 November 2008

In an effort to match problems with solutions, environmental health scientists and chemists convened this week to chart a path to promoting development of safe, sustainable chemicals.

Leaders in environmental health and green chemistry met at University of California, Irvine to draft a consensus statement designed to offer advice and overcome obstacles to creating new industrial compounds that won't endanger public health or the environment.

"Our understanding of toxicity has gone through a transformational evolution in the last decades. Everyday chemicals that once looked benign no longer do," said Lynn Goldman, a professor of environmental health sciences at Johns Hopkins University's Bloomberg School of Public Health.

The goal of the collaboration is to merge the knowledge and ideas of toxicologists and others who specialize in the dangers posed by chemicals with experts in green chemistry, who design nontoxic, environmentally benign materials.

Monday's session at the National Academies' Beckman Conference Center was open to the public, drawing an audience of about 200. But the scientists on Tuesday and Wednesday met behind closed doors to craft a consensus statement they plan to deliver in a few weeks to the public, particularly policymakers.

Facing scientific uncertainty, controversy generated by industry and ever-increasing complexity of issues, many environmental scientists in recent years have turned to consensus statements, which summarize the state of the science and recommend steps to address problems.

Pete Myers, chief executive officer of Environmental Health Sciences, which organized the conference with the nonprofit group Advancing Green Chemistry, said the group's mission is to avoid "yet another generation of problematic chemicals." The central theme, he said, is that new chemical compounds can be both profitable and safe.

The scientists involved in this week's meetings expressed a sense of urgency, a desire to ensure that green chemistry becomes a priority. They are particularly concerned about hundreds of industrial compounds that can disrupt hormones at low levels. Animal studies, as well as some human data, suggest that exposure to many chemicals, particularly in the womb, can alter reproduction, immune systems, brain development and other vital functions.

Endocrine disruptors are to the chemical industry what sub-prime mortgages are to the banking industry, said Terry Collins, Thomas Lord Professor of Chemistry at Carnegie Mellon University and director of its Institute for Green Science.

As with the mortgage crisis, he said, "it's important not to drag our feet."

However, many obstacles remain to promoting development of safer chemicals.

Lack of regulation, insufficient investment and inadequate training keep many chemists from embracing green chemistry. Of the estimated 83,000 chemicals in commerce, only a few hundred are "green." For the vast majority of the others, the risks are unknown.

“The current regulatory strategy of testing chemicals one by one cannot possibly identify all of the substances that threaten health,” said Joe Thornton, an associate professor in the Center for Ecology and Evolutionary Biology at the University of Oregon.

Thornton recommended three changes:

- Reform the nation’s chemical-by-chemical regulatory process.
- Put precautionary policies in place when the science about a compound is uncertain.
- End the use of chemicals with properties that are likely to disrupt hormones.

Goldman said one major barrier is that chemicals are regulated one at a time, while in human bodies, they always occur in mixtures. She said the current U.S. law, the Toxic Substances Control Act, “will never be effective unless the burden can be shifted to industry to prove a product is safe.”

Under the law, enacted in 1976, the Environmental Protection Agency can only ban or restrict an industrial chemical if it poses an “unreasonable” risk to humans or the environment. In addition, the EPA is required to choose the “least burdensome” approach to regulate the chemicals.

As a result, the environmental agency has not banned any existing industrial chemical since 1989, when it tried to phase out asbestos. The asbestos ban was overturned in 1991 when a federal appeals court ruled that the EPA had not proven it was necessary. Since then, the agency has relied mostly on voluntary efforts by chemical companies.

The European Union already reformed its policies. Two years ago, the EU enacted the world’s most stringent law aimed at toxic chemicals, and it already is having global effects on the chemical industry, which must test and register thousands of compounds.

In September, California launched its own program, the nation’s most comprehensive reform of chemicals policy. The new law requires the state to evaluate, identify and perhaps ban industrial chemicals that are linked to health effects.

The group’s consensus statement is likely to tackle one of the newest environmental health issues-- epigenetics. Some scientists believe that exposure to many chemicals can trigger heritable changes in how genes express themselves, making a person more susceptible to disease. Those changes might remain in place not just for the exposed fetus, but for all future generations.



Dr. Jerrold Heindel, NIEHS

Jerrold Heindel, scientific program administrator at the National Institute of Environmental Health Sciences, said many diseases and disorders, including asthma, obesity, attention deficit disorder and heart disease, may be triggered when fetuses, babies or young children are exposed to chemicals in plastics, cosmetics, pesticides and other consumer products.

By changing chemical policy, we can “shift the focus from curing disease to prevention and intervention,” Heindel said.

When pregnant rats are exposed for a few days to a mix of two pesticides, 90% of their offspring have reduced sperm counts and 10% are infertile. And those effects lasted for at least four generations of the rats.

"If it's true" for humans, Heindel said, "imagine the implications." What that means, he said, is that your great-grandmother's chemical exposure could be harming your own health and fertility.

Nevertheless, the number of students studying to become chemists is declining right at the time that innovation is desperately needed, said John Warner, president of the Warner Babcock Institute for Green Chemistry.

"The large army of practicing scientists worldwide investigating the next generation of materials has no training or skills necessary to meet these challenges," Warner said.

Some industries are slow in following the tenets of green chemistry.

EPA officials say many high-tech industries, including the pharmaceuticals industry, are among the most wasteful in terms of the chemicals they use and the hazardous waste they create. For every kilogram of a drug they make, pharmaceutical companies use more than 100 kilograms of chlorinated compounds and other solvents that are thrown away. In comparison, the oil industry wastes a much smaller amount of solvents: 0.1 kilogram for every kilogram of product.

Many pharmaceuticals wind up in surface waters and drinking water after they are excreted. Berkeley Cue, formerly an executive at Pfizer Global Research and Development, said the biggest challenge is that a drug needs to be stable in manufacturing and in shelf life, so it is difficult to make ones that degrade to something benign in the environment.

Making environmentally benign active ingredients for drugs "is beyond our scientific understanding today," Cue said.

Currently, drugs are screened for environmental toxicity late in the development process. Cue recommends that such screening come early in the drug discovery stage.

Chemists attending the conference said industries need incentives, sometimes regulations, to switch to environmentally benign chemicals.

Donald Blake, chair of UCI's chemistry department who works with Nobel Laureate F. Sherwood Rowland, said the aerospace industry was resistant to eliminate metal-cleaning solvents that deplete the ozone layer. But when the Montreal Protocol phased out such substances in the 1990s, the industry discovered that a citrus-based cleaner worked just as well.

Sometimes the pursuit of profits isn't enough to persuade companies to replace risky compounds, Warner said. For many chemicals, substitutes already have been invented, but they are not manufactured because they are big, risky investments.

Collins recommended multiple changes in policies to transform industrial chemicals, including a way to prioritize chemicals that should be replaced and elimination of all compounds that are persistent in the environment or are transported globally via the air or oceans.

"We have no choice but to embark on a course to adapt the economy to these realities," he said.

Otherwise, chemicals invented today could harm people's descendants hundreds of years from now.

"Trans-generational justice is really the critical thing for our civilization in the next century," Collins said.

Link to [meeting program](#).

<http://www.environmentalhealthnews.org/ehs/news/enviro-scientists-chemists-join-forces-to-promote-safe-chemicals>

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Modified: Nov 12, 2008 09:21 AM

## Looking at drugs in water

Experts gather in the Triangle to assess a public health question

Sabine Vollmer, Staff Writer

RESEARCH TRIANGLE PARK - Despite rising fear -- and rhetoric -- about the presence of pharmaceuticals in drinking water, there is actually very little evidence of whether there are health risks related to the issue.

That was one main message from 150 researchers and public health experts who huddled at the N.C. Biotechnology Center this week. The two-day conference, the first by a collaborative group of Triangle environmental health experts, was an attempt to answer some of the questions being raised by regulators, scientists and lawmakers.

Drawing on data collected by water treatment plants and federal agencies such as the U.S. Geological Survey, The Associated Press in March reported that treated drinking water in Philadelphia, northern New Jersey, San Francisco and Washington, D.C., tested positive for traces of prescription drugs, including antibiotics, mood stabilizers and sex hormones.

But more and better data is needed to figure out which pharmaceutical chemicals are likely to cause the most harm to the environment and people and how contaminants get into the water.

"We cannot afford to have the whole industry destroyed by a couple of bad actors," said **Kenneth Olden**, chairman of the newly formed Research Triangle Environmental Health Collaborative. The group counts the **National Institute of Environmental Health Sciences**, the University of North Carolina, Duke University, the U.S. Environmental Protection Agency and research institutes in the Triangle among its supporters.

"We want to provide leadership," said **Olden**, the **former director of the NIEHS' toxicology program**. "The expertise is here in North Carolina."

"There's been a lot of frustration that we've been talking about this for as long as we have and nothing is done," said Doug Finan of GlaxoSmithKline's environmental health and safety regulatory affairs.

On Tuesday, conference participants came up with several recommendations, which they plan to present to state and federal lawmakers and publish in a peer-reviewed journal:

\* The EPA monitors pesticides, herbicides and other chemicals for possible harm. Researchers have long known that pharmaceutical chemicals also show up in the water, but none is on the EPA monitoring list. Lawmakers need to determine which regulatory agency should be in charge of testing water for pharmaceutical chemicals and their byproducts.

"We can't measure everything all the time," said Damian Shea of the N.C. State Department of Biology.

\* Consumers need to know what to do with unused medicine. Physicians and pharmacists should be tapped as advocates to prescribe and fill only as much medicine as needed and tell consumers how to dispose properly of leftovers.

<http://www.newsobserver.com/business/story/1291129.html>

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Modified: Nov 16, 2008 05:06 AM

## Some moms ditch plastic cups Safety of additive is topic of debate

Wade Rawlins, Staff Writer [Comment on this story](#)

Conflicting reports over the safety of the plastic additive bisphenol A have forced parents to decide for themselves whether to keep using plastic baby bottles and cups made with the widely used compound.

Some, like Keira McNeill, a Knightdale mother of two, decided to stop waiting for the government to settle the safety issues. McNeill opted to replace her children's baby bottles and cups to protect them from any potential harm. Others, like Grace Danuck of Apex, still take comfort in the U.S. Food and Drug Administration's safety assessment and are taking a wait-and-see approach.

Bisphenol A, also called BPA, is used in the plastic linings of food and soda cans to prevent corrosion. It is also used in hard clear polycarbonate plastics, such as for baby bottles and water bottles.

More than 90 percent of Americans have bisphenol A in their bodies, from consuming food and beverages stored in containers made with BPA.

The FDA insists that the chemical compound is safe at low doses. But an independent science panel, convened by the FDA and including researchers from the Triangle, found in October that the FDA's safety assessment was flawed.

The advisory panel concluded the FDA should have considered a wider range of studies beyond the two industry-funded ones that found the product safe. The FDA is expected to respond to the recommendation by February.

Based on animal research, some researchers have raised questions about the chemical's effect on reproductive systems in newborns and fetuses.

In October, Canada became the first country to add bisphenol A to its list of toxic substances, because of concern that infants might be ingesting too much of the chemical, which mimics the hormone estrogen. Canada's health agency has said it would end the sale of baby bottles containing BPA and support infant formula makers in switching to different packaging. BPA leaches from plastics.

McNeill said questions raised by researchers about BPA's potential harm convinced her that her family should avoid it.

"When Canada banned it, that spoke volumes to me," said McNeill, a hospital surgical technician. "That same weekend, I went through and threw out a lot of things, all my kids' sippy cups and all the plastic dishes. To me, it should not be in things we are consuming."

But not everyone agrees. Grace Danuck said the FDA's assessment gives her a level of comfort.

"With medical science, we know so much now that we almost know too much," Danuck said. "Coffee is bad for you, then it's good for you. We can nit-pick just about anything that has less than healthy ingredients in it."

Danuck, who sells Tupperware products, said that at every housewares party, someone asks, "Is this a safe plastic?" So she did some reading to satisfy herself.

"The main thing I say to people is not everything goes in the microwave," Danuck said. "We have microwave-safe products, and within that group, some of them are polycarbonate and some are not. I feel safe with it."

The FDA has acknowledged that more research is needed on bisphenol A in light of uncertainties underscored by the advisory panel's review. The panel's report was endorsed by the FDA's science advisory board Oct. 31.

John Vandenberg, associate director for health at the U.S. Environmental Protection Agency's National Center for Environmental Assessment in Research Triangle Park, served on the review panel because of his expertise in risk assessment of chemicals found in the environment.

Vandenberg said there are a lot of uncertainties about the chemical and some hints of potential concerns. He said the FDA had not considered more narrowly focused studies that also had merit.

Vandenberg said the concern is with infants, because their bodies don't flush chemicals.

"As you age, you develop ability to metabolize or excrete chemicals differently than as newborns," he said. "Newborns don't have the same ability to metabolize."

### **Animal effects studied**

Panel member Philip J. Bushnell, a neurotoxicologist in the EPA's National Health and Environmental Effects Research Laboratory in RTP, said some studies of bisphenol A involving animals had shown behavioral changes, suggesting gender-bending effects.

"When you have a chemical with estrogenic potency, you can change the way the fetus develops," Bushnell said. "How this translates into humans is a very big question. There is a lot more work that needs to be done to sort that out."

Michael Herndon, a spokesman for the FDA, said the panel's report raises important questions regarding the FDA's draft safety assessment and that the agency would respond by February.

The "FDA is already moving forward with planned research to address the potential low-dose effects of bisphenol A, and we will carefully evaluate the findings of these studies," Herndon said.

Kimberly Ballard of Raleigh, who has two young sons, decided to get rid of most of the plastic cups her children used.

"I would like to think our government would have our best interest at heart and our children's best interest," Ballard said. "If something comes up that could be harmful, I'd like to hear the alarms go off and someone say this is something possibly dangerous for your child."

### **STUDIES DIFFER ON BPA**

Bisphenol A is a chemical produced in large quantities and used to produce hard clear plastics and epoxy resins. Epoxy resin is used to line metal food cans and bottle tops. The plastics are used to make products such as baby bottles and water bottles. Bisphenol A can leach out of the plastic or epoxy resin into the food or beverage.

Scientific studies offer conflicting results about the safety of bisphenol A at low doses.

After reviewing a vast number of studies, the **National Toxicology Program**, an interagency program that does research across the federal government, expressed "some concern" for effects on the brain, behavior, and prostate gland in fetuses, infants, and children at current human exposures to bisphenol A.

There is limited evidence of developmental changes occurring in some animal studies at doses that are experienced by humans. But it's unclear whether similar changes would occur in humans.

The FDA is not recommending that anyone discontinue using products that contain BPA. Concerned consumers should know that several alternatives to polycarbonate baby bottles exist, including glass baby bottles.

<http://www.newsobserver.com/news/story/1296742.html>

## ADHD Medications Don't Pose Cancer Risk

Friday, November 21, 2008

(HealthDay News) -- Two popular medications for treating attention-deficit hyperactivity disorder (ADHD) do not cause genetic damage linked to an increased risk for developing cancer, a new study says.

The study, done by researchers at Duke University Medical Center and the [National Institutes of Health](#), counters a previous one that reported biomarkers associated with an increased cancer risk were present in the blood of children taking the ADHD drug methylphenidate.

"The new findings should help alleviate some of the concerns that were raised by the previous study," study co-author Scott Kollins, director of Duke's ADHD program, said in a university news release. "However, we need to continue to study the long-term effects of these medications and expand our analyses to include older patient populations."

The new study, which looked at methylphenidate (Ritalin LA and Concerta) and amphetamine (Adderall and Adderall XR), used a larger study sample and conditions that apply to a wider cross-section of children with ADHD than the initial study did, he said.

"We looked at three common markers associated with damaged chromosomes and did not find increased genetic abnormalities in children taking either medication, regardless of a variety of factors, such as age, sex, body weight, height, race or ADHD subtype," Kollins said.

About 2 million children have ADHD, a condition commonly characterized by inattention, hyperactivity and impulsivity. Methylphenidates and amphetamines have been used to treat the condition for decades, with millions of prescriptions written for them in the United States every year.

The study was published in the November online issue of the *Journal of the American Academy of Child & Adolescent Psychiatry*.

### More information

The U.S. National Institute of Mental Health has more about [ADHD](#).  
SOURCE: Duke University Medical Center, news release, Nov. 19, 2008

([Kristine Witt](#) study)

<http://www.washingtonpost.com/wp-dyn/content/article/2008/11/21/AR2008112102135.html>

## ADHD meds do not induce cell damage

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Wed Nov 26, 2008 11:48am EST

NEW YORK (Reuters Health) - Countering the findings from a 2005 study, new research supported by the United States National Institutes of Health indicates that stimulants used in the treatment of attention deficit/hyperactivity disorder (ADHD) do not cause chromosomal changes in children.

The earlier work identified an increased frequency of DNA damage and structural aberrations in chromosomes, which are associated with an increased risk of cancer. The abnormalities were observed in the white blood cells (lymphocytes) of 12 children after 3 months of methylphenidate, a drug commonly used to treat ADHD, **Kristine L. Witt** and associates explain in the *Journal of the American Academy of Child and Adolescent Psychiatry*.

Although research since then failed to replicate the earlier findings, "the enormous public health significance of this issue requires additional investigation," note **Witt**, at the **National Institute of Environmental Health Sciences** in Research Triangle Park, North Carolina, and co-investigators.

To this end, they recruited 63 previously untreated patients ages 6 to 12 diagnosed with ADHD. The children were randomly assigned to treatment with methylphenidate (Ritalin LA or Concerta) or to mixed amphetamine salts (Adderall or Adderall XR). The 3-month trial was completed by 25 and 22 subjects, respectively.

No significant treatment-related increases in cell damage were detected in the lymphocytes of the group as a whole or in the 47 subjects who were treated for the full 90 days.

According to **Witt's** team, these results add to the growing body of evidence that therapeutic levels of methylphenidate or mixed amphetamine salts do not induce chromosomal damage in humans.

Still, the investigators recommend that studies "continue to monitor these and related genetic damage endpoints in larger study groups...after longer exposure periods."

SOURCE: *Journal of the American Academy of Child and Adolescent Psychiatry*, December 2008.

<http://www.reuters.com/article/healthNews/idUSTRE4AP5UL20081126>

## **ADHD Drugs Don't Cause Genetic Damage Study of Ritalin, Adderall, and Concerta Shows No Chromosomal Damage**

By Salynn Boyles  
WebMD Health News  
Reviewed by Louise Chang, MD

Nov. 19, 2008 -- Ritalin, Adderall, and Concerta do not appear to cause genetic damage in children who take them for attention deficit hyperactivity disorder (ADHD), a new government-funded study concludes.

The findings should reassure parents concerned that the stimulant drugs used to treat ADHD may be linked to an increased risk of cancer.

Those concerns were raised by a 2005 study showing evidence of drug-related chromosomal damage in 12 out of 12 children with ADHD taking Ritalin.

The new study, conducted by researchers from the National Institutes of Health and Duke University Medical Center, shared a similar design with the earlier trial.

But it was larger and also included children taking Adderall and Concerta.

"We saw no [chromosomal] effect associated with medication in any of our treatment groups," genetic toxicologist and researcher **Kristine L. Witt**, MS, tells WebMD. "These findings were extremely reassuring."

### ADHD Drugs and Cancer

Millions of children take either methylphenidate-based stimulants, like Ritalin and Concerta, or the mixed amphetamine stimulant Adderall for the treatment of ADHD symptoms.

Approved in 1955, Ritalin is the oldest and most widely studied ADHD drug. Adderall and Concerta have been sold in the U.S. for about a decade.

While a few animal studies have linked Ritalin use to tumor growth, the 2005 pilot study was the first human study to link Ritalin use to chromosomal damage that could promote cancer.

Subsequent studies examining the proposed link have not supported these findings.

In the current study, 47 children with ADHD between the ages of 6 and 12 took either Ritalin LA, Adderall, Adderall XR, or Concerta for three months.

Blood samples taken prior to starting the drugs and at the end of three months of treatment were assessed for chromosomal breaks, chromosome fragments suggestive of breaks, and exchanges of genetic material between pairs of identical chromosomes.

These three standard measures of chromosomal damage were the endpoints examined in the 2005 study.

But the outcomes in the two trials were very different.

"We did not see any significant treatment-related increases in any of these endpoints," Donald R. Mattison, MD, of the National Institute of Child Health and Human Development, says in a news release. "These results add to a growing body of evidence that therapeutic levels of these medications do not damage chromosomes."

#### Long-Term Safety of ADHD Drugs

ADHD expert Regina Bussing, MD, says the fact that the new study was publicly financed is a major strength. Bussing is a professor of psychiatry at the University of Florida, Gainesville.

"This was a high-quality study that was funded by the government, not the drug industry," she says.

Duke University ADHD program director Scott H. Kollins, PhD, who also participated in the study, says it is now clear that ADHD drugs do not cause chromosomal damage. But he adds that important questions remain about their long-term safety.

"We don't have a lot of information about long-term effects," he tells WebMD. "We need to follow patients on these drugs to address other concerns."

Concerns about the impact of long-term stimulant use on growth and later-life substance abuse have yet to be addressed, he says.

There are also suggestions that years of stimulant use during childhood might increase the risk for heart attacks and strokes during adulthood.

"We still don't know if treating a child for 15 years with these drugs will have a long-term impact on hypertension or other cardiovascular risk factors," he says. "We have no evidence that it will, but these studies have not been done."

#### SOURCES:

Witt, K.L. Journal of the American Academy of Child & Adolescent Psychiatry, December 2008; vol 47: pp 1375-1383.

Kristine L. Witt, MS, genetic toxicologist, National Institute of Environmental Health Sciences, Research Triangle Park, N.C.

El-Zein, R.A. Cancer Letters, 2005; vol 230.

Donald Mattison, MD, senior advisor to the director, National Institute of Child Health and Human Development.

Regina Bussing, MD, professor of psychiatry, University of Florida, Gainesville.

<http://www.webmd.com/add-adhd/news/20081119/adhd-drugs-dont-cause-genetic-damage>

## **ADHD drugs don't cause genetic damage**

Published: Nov. 20, 2008 at 8:33 PM

BETHESDA, Md., Nov. 20 (UPI) -- Two common medications used to treat attention-deficit hyperactivity disorder do not appear to cause genetic damage in children, U.S. researchers said.

Research at the National Institutes of Health and Duke University Medical Center in Durham, N.C., provides new evidence that therapeutic doses of stimulant medications, such as methylphenidate and amphetamine, do not cause cytogenetic, or chromosomal, damage in humans.

The study, published in the Journal of the American Academy of Child and Adolescent Psychiatry, looked at three measures of cytogenetic damage in white blood cells of each child participating in the study, and found no evidence of any changes after three months of continuous treatment.

"This is good news for parents," said study co-author **Kristine L. Witt, a genetic toxicologist at the National Institute of Environmental Health Sciences.** "Our results indicate that methylphenidate- and amphetamine-based products do not induce cytogenetic damage in children."

However, the researchers emphasize that the findings should not be interpreted as final proof of the long-term safety of stimulant drugs for the treatment of ADHD.

"More research and close monitoring of children taking these medications for extended periods of time is needed to fully evaluate the physical and behavioral effects of prolonged treatment with stimulants," study co-author Scott H. Kollins of Duke University said.

[http://www.upi.com/Health\\_News/2008/11/20/ADHD\\_drugs\\_dont\\_cause\\_genetic\\_damage/UPI-29911227231234/](http://www.upi.com/Health_News/2008/11/20/ADHD_drugs_dont_cause_genetic_damage/UPI-29911227231234/)

## ADHD Meds Seen as Safe for Kids

### New research refutes fears that medicines cause genetic damage

November 21, 2008

In contrast to recent findings, two of the most common **medications** used to treat attention deficit **hyperactivity disorder** do not appear to cause genetic damage in children who take them as prescribed, according to a new **study** by researchers at the National Institutes of **Health** and Duke University Medical Center.

The study published online this month in the Journal of the American Academy of Child and **Adolescent Psychiatry** (JAACAP) provides new evidence that therapeutic doses of stimulant medications, such as methylphenidate and amphetamine, do not cause chromosomal damage in humans.

The researchers looked at three measures of cytogenetic damage in white blood cells of each child participating in the study and found no evidence of any changes after three months of continuous treatment.

"This is good news for parents," said **Kristine L. Witt, M.Sc., a genetic toxicologist at the National Institute of Environmental Health Sciences and co-author on the study.** "Our results indicate that methylphenidate- and amphetamine-based products do not induce cytogenetic damage in children."

The researchers involved emphasize that the findings should not be interpreted as final proof of the long-term safety of stimulant **drugs** for the treatment of ADHD.

"More research and close monitoring of children taking these medications for extended periods of time is needed to fully evaluate the physical and behavioral effects of prolonged treatment with stimulants," noted Scott H. Kollins, Ph.D., director of the Duke ADHD Program and a co-author of the paper.

ADHD is a disorder characterized by attention problems, impulsivity, and hyperactivity. About 3 to 5 percent of children in the United States have been diagnosed with the disorder, although several studies suggest 7 to 12 percent of children may be affected.

[http://www.consumeraffairs.com/news04/2008/11/adhd\\_kids.html](http://www.consumeraffairs.com/news04/2008/11/adhd_kids.html)

## Fibroid growth differs in black and white women

*Last Updated: 2008-12-01 17:00:53 -0400 (Reuters Health)*

NEW YORK (Reuters Health) - Differences in the growth of fibroid tumors may explain why black women typically have more symptoms than white women, according to a study in the Proceedings of the National Academy of Sciences.

Fibroids, also known as leiomyomata, are growths within the walls of the uterus. Although almost always benign, these tumors can become quite large and produce heavy menstrual periods, pelvic pain, and other symptoms. They occur in about 25 percent of all women and are the leading cause of hysterectomy, or removal of the uterus, in the United States.

Dr. Donna Day Baird, at the National Institute of Environmental Health Sciences in Research Triangle Park, North Carolina, and her associates conducted the Fibroid Growth Study, designed to measure fibroids in women with symptoms.

Included were 262 tumors in 72 women, ages 24 to 54 years. Thirty-eight subjects were African American and 34 were Caucasian. Fibroid volume was documented by MRI performed four times over a 1-year period.

Typically, the fibroids grew by about 9 percent every 6 months. However, 7 percent of tumors regressed by more than 20 percent.

Growth rates varied even within the same woman and "were not influenced by tumor size, location, body (weight or number of prior pregnancies)," Baird's team reports.

Before age 35, rates of fibroid growth were not associated with subject's race. However, growth rates declined with age only among white women who were older than 35 years of age.

Aside from age and race, the only other factor affecting the growth rate was the number of tumors, with single tumors growing much faster than multiple fibroids.

Based on their findings, the researchers suggest that "it may be possible to extend the follow-up time for assessment of fibroid growth" beyond the current clinical practice of evaluation at 6-month intervals.

"In addition," they write, "if further research supports our findings that tumor growth rates decline in white women as they age, those approaching perimenopause might choose to delay treatment and wait for menopause when tumors are likely to shrink."

SOURCE: Proceedings of the National Academy of Sciences, online December 1, 2008.

<http://www.reuters.com/article/healthNews/idUSTRE4B08SY20081201?feedType=RSS&feedName=healthNews>

Q & A

## What's the Frequency?

December 16, 2008  
By C. Claiborne Ray

Q. Is it dangerous for children to go through metal detectors?

A. "I would be surprised to see health effects that could be discernible," said Christopher **J. Portier**, **associate director of the National Institute of Environmental Health Sciences**, "but it has not been studied as well as it could be."

With a school metal scanner, he said, "even if you go through it every day, it is just a few seconds," minimizing risk.

Metal detectors generally fall into the midrange of frequency for electromagnetic devices. Research on power lines, which are extremely low frequency, and on cell phones, at the high end, is not relevant, he said.

"This falls into a middle area, the frequencies of FM, AM and CB radios, where there is much less research and much grayer findings," he said.

At the low end of the midrange, **Dr. Portier** said, as magnetic fields penetrate the body, extremely small electrical impulses are generated.

"We have never been able to conclusively show any effects from those small pulses," he said.

"Toward the high end of the middle range of frequencies, if the field is really, really strong," he said, "you could get slight microwave heating effects, which would dissipate very rapidly, but that would only occur at thousands to tens of thousands of times stronger fields than in a metal detector."

**Dr. Portier** said his real concern was with the people who operate and maintain the equipment, especially the **X-ray** backpack scanners, who are continually exposed. He suggested that they should probably be studied as the canaries in the mine for a clue to anything that might suggest the potential to injure children.

*Readers are invited to submit questions by mail to Question, Science Times, The New York Times, 620 Eighth Avenue, New York, N.Y. 10018-1405, or by e-mail to [question@nytimes.com](mailto:question@nytimes.com).*

[http://www.nytimes.com/2008/12/16/science/16qna.html?\\_r=2&ref=science](http://www.nytimes.com/2008/12/16/science/16qna.html?_r=2&ref=science)

## **EPA should test demasculinizing pollutants collectively, NRC says**

*Cumulative effects of phthalates and related compounds will be larger than effects measured one chemical at a time, reports a National Research Council panel*

By [Janet Raloff](#)

Web edition: Thursday, December 18th, 2008

On December 18, a National Research Council panel told the Environmental Protection Agency that sufficient data exist to begin assessing the potential health risks posed by phthalates, among the most ubiquitous pollutants on the planet. At the same time, the NRC panel strongly recommended that the agency adopt a “paradigm shift” in the way it assesses the chemicals’ toxicity to humans.

Instead of evaluating each phthalate compound individually, EPA should begin assessing risks from likely combos of these and related chemicals — even if each chemical works differently, according to the panel’s new report.

Phthalates are a widely used family of plasticizers and solvents. Owing to the chemicals’ presence in plastics, cosmetics, personal care products and even medicines, residues of these chemicals show up in everyone throughout the developed world.

For more than a decade, studies in rodents have been demonstrating that exposures to phthalates early in life can perturb — in some cases derail — development of an animal’s reproductive organs (*SN*: 9/2/00, p. 152). Males are most sensitive, largely because these chemicals act as anti-androgens. That is, the chemicals lower concentrations of testosterone, the primary male sex hormone. Especially concerning: In females, phthalates can cross the placenta and pollute the womb.

The NRC panel advocated that EPA assess cumulative risks from all phthalates and other anti-androgenic compounds together — even if the way each pollutant depresses testosterone action or availability results from differing modes of action.

Whether these pollutants pose serious risks to people remains an open question, acknowledged several authors of the NRC report, who took part in a teleconference for the report’s release.

EPA didn’t ask NRC to assess phthalates’ toxicity to humans, notes Deborah Cory-Slechta of the University of Rochester School of Medicine and Dentistry in New York. Instead, EPA asked her panel to evaluate whether sufficient data exist to conduct a human risk assessment. And if so, how should the risks be evaluated: on the basis of single compounds considered separately, as a group evaluated together, or as a group assessed along with additional anti-androgenic agents.

Cory-Slechta says her panel found that there are plenty of data for EPA “to go ahead and do it [a human risk assessment].” But the panel also recommended that when EPA does such an assessment, it should take a sharply different tack from its normal approach.

To Shanna Swan, a phthalate researcher at the University of Rochester, the recommended change in how to calculate the risk of these chemicals “is a big deal. Cumulative risk assessment is the way it *must* be done,” she says, “given the dose additivity of these chemicals and the multiplicity of our exposures.”

Most people regularly encounter many phthalates, and as a class these compounds tend to have similar impacts. So, even if each of five phthalates had no apparent effects at a particular dose when delivered

individually, coincident exposure to the mix might easily prove to compound the toxicity, the new report explained.

Indeed, published data show that “phthalates can work together at quite low doses,” noted NRC panel member Andreas Kortenkamp of the University of London School of Pharmacy in England. “So if combination effects were not taken into consideration at this level, we would underestimate possible risks.” In fact, he said, his committee’s new paradigm for considering phthalate toxicity cumulatively must inevitably result in findings of higher risks than would have been calculated by assessing each chemical in isolation.

In the new report, NRC concluded that a lifelong testosterone shortfall triggered by phthalate exposures can cause “the variety of effects observed” in animals — including infertility, reduced sperm production, undescended testes, penile birth defects and other reproductive-tract malformations — “if it occurs at times that are critical for male reproductive development.” The most sensitive exposure period: time in the womb.

Indeed, concentrations of phthalates measured in amniotic fluid in the human womb can be “in the range of levels in rat amniotic fluid that gives rise to adverse effects in the offspring,” Kortenkamp said.

However, links to human effects have been quite limited, observes panel member **Paul Foster** of the **National Institute of Environmental Health Sciences** in Research Triangle Park, N.C. One exception: a study of infant boys linking phthalate exposure in the womb to a feminization of the anogenital distance — the span separating the gonads and anus (*SN*: 6/4/05, p. 355).

In rodents, this distance is demonstrably longer in males. In fact, researchers depend on this sex-linked distance to visually determine the gender of young rodents.

Follow-up studies are needed with more subjects to test the validity of those preliminary data, Foster says. That said, this phthalates toxicologist points out that the general processes by which these chemicals interfere with sexual differentiation “are common to all mammals. And so, having seen them in rats, one would not expect them not to occur in humans — providing, of course, the exposure was high enough.”

[http://www.sciencenews.org/view/generic/id/39447/title/EPA\\_should\\_test\\_demasculinizing\\_pollutants\\_collectively,\\_NRC\\_says\\_](http://www.sciencenews.org/view/generic/id/39447/title/EPA_should_test_demasculinizing_pollutants_collectively,_NRC_says_)



## Panel: EPA must consider effects of chemical barrage

December 18, 2008

By Liz Szabo, USA TODAY

Chemicals that interfere with the male hormone system are so common — and so potentially damaging — that the government should stop studying them one by one and consider their combined effect, an expert panel said Thursday.

Phthalates and other hormone-disrupting chemicals pollute the air, water and dust and are found in hundreds of consumer products — including bug spray, perfume, pesticides, shower curtains, food containers, and plastic toys, according to a report released today from the National Research Council, which advises the government on science policy.

**BETTER LIFE:** [Finding toys free of phthalates and BPA](#)

**IN-DEPTH:** [What you need to know about 'everywhere chemical' bisphenol A](#)

Studies from the Centers for Disease Control and Prevention and independent scientists have found phthalates in virtually everyone, including pregnant women and babies.

The Environmental Protection Agency typically studies the impact of these and other chemicals individually. But that approach may underestimate the effect of being exposed to many different chemicals with similar effects, says the University of Rochester School of Medicine and Dentistry's Deborah Cory-Slechta, chairwoman of the committee that wrote the report.

The best way to protect people — especially infants and fetuses, whose reproductive systems are still developing — is to measure the cumulative impact of this hormonal barrage, Cory-Slechta says. In fact, she says that the EPA should always consider cumulative effects — not just for hormone disruptors, but for all potential toxins.

That will allow the EPA to figure out the maximum level to which humans can safely be exposed and create regulations to protect Americans from exposures that could be harmful, says Sarah Janssen of the National Resources Defense Council, an environmental group. Janssen says she hopes that other government agencies — such as the Food and Drug Administration and the Consumer Product Safety Commission — will also consider the cumulative effect of hormone disruptors in food additives, medical equipment, toys and other products.

"We're exposed to a complex soup of chemicals," Janssen says. "It's a warning we can't ignore."

There's enough evidence to start that assessment right away, instead of waiting until additional studies are finished, Cory-Slechta says.

Although the report focused primarily on phthalates, Cory-Slechta note that other products, such as pesticides used in food, also lower testosterone levels.

Animal and human studies link all of these chemicals to a wide spectrum of problems, from reduced sperm counts to genital malformations. Scientists are also studying the chemicals' link to testicular cancer and other problems, the report says.

Although most of the research has been done in animals, there's no reason to think that the substances wouldn't affect humans the same way, says report co-author **Paul Foster**, of the **National Institute of Environmental Health Sciences**.

But the American Chemistry Council, an industry group, says that considering the risks of so many chemicals that affect male hormones would be "remarkably ambitious" — and maybe impossible.

"This essentially could result in a study without limits, financially or otherwise," says the council's Chris Bryant in a statement.

Lawmakers and business around the world already have taken steps to limit phthalate exposure.

The European Union has restricted phthalates in cosmetics and children's toys. A growing number of hospitals are phasing out phthalates in neonatal intensive care units, hoping to protect premature and sickly newborn boys.

Congress last summer passed a ban banning several phthalates in children's products. The Consumer Product Safety Commission has said that it will allow stores to continue selling toys made with phthalates, as long as they were manufactured before the law takes effect Feb. 10th.

*[http://www.usatoday.com/news/health/2008-12-18-phthalates-chemicalsoup\\_N.htm](http://www.usatoday.com/news/health/2008-12-18-phthalates-chemicalsoup_N.htm)*

## **Pain pills may cut risk of bowel cancer: study**

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Fri Dec 26, 2008 9:33am EST

By Joene Hendry

NEW YORK (Reuters Health) - Use of a non-steroidal anti-inflammatory drug (NSAID) for over 5 years may lessen a person's risk of developing cancer of the lower portion of the large bowel, study findings suggest.

This risk reduction appears more robust among whites than among African Americans, **Dr. Sangmi Kim, of the National Institute of Environmental Health Sciences** in Research Triangle Park, North Carolina, and colleagues found.

The investigators evaluated use of NSAIDs (i.e., aspirin, ibuprofen, and selective COX-2 inhibitors, taken to ease pain and inflammation) among 1,057 white and African American men and women with cancer of the lower bowel and rectum and 1,019 individuals who were cancer-free.

The participants with cancer included 790 whites and 267 African Americans, of whom 76 percent reported ever using NSAIDs during the 5 years prior to diagnosis. Of the cancer-free group, 83 percent reported NSAID use during the 5 years prior to study participation.

Compared with those never using NSAIDs, NSAID use was associated with about 40 percent reduced risk for cancer in the lower portion of the large bowel overall, after allowing for age, gender, race, body mass, physical activity, and other factors potentially associated with distal large bowel cancers.

In analyses that factored for race, the investigators found a "strongly protective" association between NSAIDs and large bowel cancer in whites, according to a report in the American Journal of Epidemiology.

"However," **Kim** told Reuters Health, "the risk reduction associated with NSAID use was less evident among African Americans."

Risk reduction was slightly stronger with prescription, rather than non-prescription NSAID use, but again this association was stronger among whites than among African Americans.

The apparent protective effect between NSAID use and cancer of the lower portion of the large bowel noted in this study is similar to that previously reported between NSAIDs and colon cancer.

Nonetheless, **Kim** and colleagues say more study is needed before recommending NSAIDs for the prevention of colorectal cancer in the general public.

SOURCE: American Journal of Epidemiology, December 1, 2008

<http://www.reuters.com/article/healthNews/idUSTRE4BP20820081226>

Online publication October 21, 2008, actual publication December 1, 2008:  
<http://aje.oxfordjournals.org/cgi/reprint/168/11/1292>

## Climate Change May Boost Contact With Pollutants

Friday, December 26, 2008; 12:00 AM

FRIDAY, Dec. 26 (HealthDay News) -- Global climate change may lead to a rise in health problems due to increased exposure to harmful air pollutants, suggest researchers who reviewed studies projecting the impact of climate change on air quality.

The review authors also concluded that reducing greenhouse gas emissions could help reduce the harmful effects of climate change.

The review looked at how climate change will affect ground-level ozone, a known pulmonary irritant that affects the respiratory mucous membranes, other lung tissues, and respiratory function. Exposure to elevated levels of ozone is associated with increased hospital admissions for asthma, allergic rhinitis, pneumonia, chronic obstructive pulmonary disease (COPD), and other respiratory diseases.

"Projections suggest that climate change will increase concentrations of tropospheric ozone, at least in high-income countries, when precursor emissions are held constant, which would increase morbidity and mortality," wrote review authors Kristie L. Ebi and Glenn McGregor. "The potential impact of climate change on ozone concentrations have not been projected for low-income countries, many of which currently have significantly higher ozone exposures."

The authors said further research is needed to better project the health impacts caused by changing concentrations of ozone caused by climate change. They said areas of uncertainty include the projected degree of future climate change, the impact of future emissions and their pathways, potential changing weather patterns, severity of episodes of poor air quality, and changes in population vulnerability.

The review findings were published in the journal *Environmental Health Perspectives*. According to journal editor-in-chief Hugh A. Tilson: "As we reduce vehicle-based emissions of pollutants, urban concentrations of ozone will also be reduced, thereby positively protecting the health of humans for generations to come."

In 2000, urban air pollution caused 800,000 deaths and resulted in 7.9 million disability-adjusted life-years lost due to respiratory problems, lung disease and cancer, according to the World Health Organization.

### More information

The World Health Organization has more about [climate change and health](#).

SOURCE: *Environmental Health Perspectives*, news release, December 2008

<http://www.washingtonpost.com/wp-dyn/content/article/2008/12/26/AR2008122601247.html>

Article: <http://www.ehponline.org/docs/2008/11463/abstract.html>

## The Huffington Post

David Kirby

Posted January 8, 2009 | 02:35 AM (EST)

### UC Davis Study: Autism is Environmental (Can We Move On Now?)

I have always said there may be a small percentage of people with autism spectrum disorder (perhaps those with Asperger Syndrome) whose symptoms are a result only of their genetic makeup, with no environmental factors involved at all.

But a new study out of [UC Davis' MIND Institute](#) says that it's time to abandon science's long, expensive, and not very fruitful quest to find the gene or genes that cause autism alone, without any environmental triggers.

"We need to keep (environmental) studies going," Irva Hertz-Picciotto, the co-author of the study and professor of environmental and occupational health and epidemiology at UC Davis, said in a statement.

"We're looking at the possible effects of metals, pesticides and infectious agents on neurodevelopment," Hertz-Picciotto said. "If we're going to stop the rise in autism in California, we need to keep these studies going and expand them to the extent possible."

Autism is predominantly an environmentally acquired disease, the study seems to conclude. Its meteoric rise, at least in California, cannot possibly be attributed to that shopworn mantra we still hear everyday, incredibly, from far too many public health officials: It's due to better diagnosing and counting.

The autism epidemic is real, and it is not caused by genes alone: You cannot have a genetic epidemic. It really is time that we, as a society, accept that cold, hard truth.

"It's time to start looking for the environmental culprits responsible for the remarkable increase in the rate of autism in California," Dr. Hertz-Picciotto said.

The study results suggest that "research should shift from genetics, to the host of chemicals and infectious microbes in the environment that are likely at the root of changes in the neurodevelopment of California's children," the statement added.

The UC Davis Study, funded in part by the National Institute of Environmental Health Sciences (NIEHS) found that the rate of autism among six-year-olds in California mushroomed from less than 9 per 10,000 among the 1990 birth cohort, to more than 44 per 10,000 for kids born in 2000.

This increase, "cannot be explained by either changes in how the condition is diagnosed or counted," the statement said, "and the trend shows no sign of abating."

(It is important to keep in mind that almost every child born in 2000 would have received many vaccines that contained the mercury preservative thimerosal, which was not completely phased out of most - but not all - childhood vaccines until at least 2003.)

Of the 600-to-700 percent increase in autism reported in California between 1990 and 2000, fewer than 10 percent were due to the inclusion of milder cases, the study found, while only 24 percent could be attributed to earlier age at diagnosis.

There was only one logical conclusion: some thing or things in the environment had to be at play here.

I have always said that all environmental factors should be considered in at least some subgroups of autism. This position has been met with considerable ridicule. I believe that opponents are afraid that, if we start looking at toxins like heavy metals, it might one day lead back to thimerosal. Likewise, if we consider live virus triggers, we may have to take another look at the measles-mumps-rubella vaccine (which thousands of parents swear was the trigger that sent their children tumbling into autism).

Now, it's always been easier and more reassuring to tell ourselves that autism was almost purely genetic, that it was always with us at the rate of 1 in 90 men (1 in 60 in New Jersey) and that, gee, weren't doctors doing a great job these days of recognizing and diagnosis this disorder.

This pathetic groupthink has helped create hugely lopsided funding priorities in autism, where genetic studies get lavishly funded, while environmental ones are lucky to even pick up the dollar scraps left behind

"Right now, about 10 to 20 times more research dollars are spent on studies of the genetic causes of autism than on environmental ones," Hertz-Picciotto said. "We need to even out the funding."

I agree.

Yes, we must continue to look for the susceptibility genes that make some kids more vulnerable to environmental triggers - possibly through a diminished capacity to detoxify themselves.

But the sooner our best minds in science and medicine come to grips with the fact that these poor, hapless kids have been exposed to the wrong environmental toxins and/or infectious agents at the wrong time, the sooner we can find out how to best treat what really ails them.

It is illogical for us to oppose the study of, say, mercury exposures and autism, because it might somehow implicate thimerosal, and by extension, vaccines.

After all, heavy metal studies into autism could very well incriminate background environmental sources, but exonerate metal sources found in vaccines, such as mercury and aluminum.

And that would be a good thing for everyone.

- [http://www.huffingtonpost.com/david-kirby/uc-davis-study-autism-is\\_b\\_156153.html](http://www.huffingtonpost.com/david-kirby/uc-davis-study-autism-is_b_156153.html)

tably lead to unapproved pharmaceuticals adulterating the food supply.”

In November, a coalition of 26 environmental advocacy groups, including the Center for Food Safety and the Natural Resources Defense Council, urged the incoming administration to ban the use of food crops to produce medical drugs because they pose “a long list of risks to health.”

But BIO’s Bomer Lauritsen said pharma-crops provide “very important medical benefits” and are “very strictly regulated.”

“We’re very supportive of [research and development] for plant-made pharmaceuticals,” she said.

Schechtman, the USDA biotechnology coordinator, said his agency is “committed to ensuring field trials [are] done safely.”

He noted that its *Guidance for Industry: Drugs, Biologics, and Medical Devices Derived from Bioengineered Plants for Use in Humans and Animals* provides the biotechnology industry with direction on developing such plants.

APHIS plans to work on establishing a new regulatory category for importing plants awaiting risk assessments in 2009. It plans to issue a notice of proposed rulemaking on this issue in February.

**Rulemaking on PIPs Scheduled for 2009.** The Environmental Protection Agency will continue working on new data requirements for producers of plant-incorporated protectants (PIPs).

Those potential new requirements include defining the nature of regulated production of PIPs and associated issues such as reporting, product labeling, and recordkeeping, according to EPA’s fall 2008 regulatory agenda. The rule is expected to clarify the legal requirements of these products at various phases of production, it said.

EPA said it also plans to address activities that it does not believe warrant regulation and will consider exempting those activities from Federal Insecticide, Fungicide, and Rodenticide Act regulation.

According to the regulatory agenda, the agency plans to issue a notice of proposed rulemaking in September.

**Biotechnology Developments in Works.** Bomer Lauritsen said the biotechnology industry is expanding development of stacked traits—combinations of built-in features such as insect and herbicide resistance, drought tolerance, and crops that use nitrogen more efficiently to reduce the amount of fertilizer needed to grow them.

Researchers are also working on ways to fortify some food plants with higher nutritional content, she said.

But Greg Jaffe, director of the biotechnology project at the Center for Science in the Public Interest, told BNA that agricultural biotechnology developments will probably be “variations on a theme” in the near future—focusing on herbicide tolerance and pest protectants.

There is likely to be greater stacking of genetically engineered traits because that seems to be a big money-maker, Jaffe noted.

By BILL PRITCHARD

## Science Policy

### Nanotechnology Funding, Toxicology Changes, Air Pollutant Assessments to Be Priorities

**P**assage of legislation to reauthorize funding for the National Nanotechnology Initiative, research to transform toxicology, required evaluations of the hazards of air pollutants, studies of nanomaterials, and priority-setting for research in general will be among the priorities for federal agencies dealing with chemicals in 2009.

E. Clayton Teague, director of the National Nanotechnology Coordinating Office, said he expects legislation to reauthorize the 21st Century Nanotechnology Research and Development Act (Pub. L. No. 108-153) to be approved by Congress in 2009.

Reauthorization of the legislation will continue to provide funding for nanoscience research, which is expected to transform many industries and to create many jobs.

**Modernizing Toxicology.** Senior officials at the Environmental Protection Agency and the **National Toxicology Program (NTP)** expect to continue to take steps toward developing quick, cost-effective tests to identify chemical and pollutant hazards.

Early in 2009, EPA will publish an analysis of how well its ToxCast<sup>®</sup> robotic system has worked for testing more than 400 ways a chemical affects the body, said Robert Kavlock, director of EPA’s National Center for Computational Toxicology. The agency will compare the results of the ToxCast screenings with information from traditional toxicity tests.

The agency has used ToxCast to test more than 300 chemicals, primarily pesticides with rich data sets from traditional toxicology tests, Kavlock said. The goal is to see whether ToxCast identifies “signatures” or patterns of biological response that will predict toxicity.

Kavlock expects the results to be published in a peer-reviewed journal in March or April. EPA will hold a workshop in May to examine various ways to analyze the ToxCast data.

The National Center for Computational Toxicology will launch the second phase of its ToxCast analysis in 2009 by testing a larger and more diverse set of chemicals, Kavlock said. For example, the agency will work with a pharmaceutical company to obtain 100 medicines that have failed in clinical trials, Kavlock said. The medicines will be put through the ToxCast screening process to determine how they caused harm.

**Testing 10,000 Chemicals a Week.** In addition to the second phase of ToxCast, Kavlock said the National Center for Computational Toxicology will work with NTP and the National Institutes of Health’s Chemical Genomics Center, which uses robotic technologies to study protein and cell function along with genetic responses to chemicals. The NIH Chemical Genomics Center uses equipment that can perform two tests on more than 10,000 chemicals in a week, he said.

The agencies anticipate studying thousands of chemicals by the summer of 2009, Kavlock said.

**John Bucher, NTP’s associate director,** said the tests will evaluate a range of biological effects and different concentrations of the chemicals.

### Top Science Policy Issues in 2009

The issues that will dominate the science policy agenda in 2009 include:

- reauthorization of the National Nanotechnology Initiative,
- transformation of toxicology research at EPA, and
- evaluation of the hazards of air pollutants.

In addition, the computational toxicology center is working with nearly two dozen laboratories to develop additional high-throughput screening tests, Kavlock said.

The laboratories test chemicals ToxCast already has evaluated in order to determine how well their tests work, Kavlock said.

"This will be an amazing data set," Kavlock predicted.

Peter Preuss, director of EPA's National Center for Environmental Assessment, said his office will seek to determine how the data generated by ToxCast and other high throughput screening tests can be used in risk assessments.

He said the NIH Chemical Genomics Center will be evaluating phthalates with ToxCast, and the National Center for Environmental Assessment expects to compare that data to information it has from traditional tests.

"I think 2009 will be a very important year in terms of taking some of those [alternative] studies and thinking through how we use them in risk assessment," Preuss said.

**Nanomaterial Toxicity Tests.** In 2009, the ToxCast system also will be used to test nanomaterials.

EPA will test 14 nanomaterials that the Organization for Economic Cooperation and Development (OECD) is evaluating through a comprehensive, traditional toxicity testing program, said Jim Willis, director of EPA's Chemical Control Division and chairman of OECD's Working Party on Manufactured Nanomaterials.

The OECD, comprising 30 of the world's industrialized nations, launched a multilateral program in 2007 to test the safety of 14 manufactured nanomaterials, including nanoengineered buckyballs, carbon nanotubes, and nanoscale silver and iron.

The results of the traditional tests on the nanomaterials will help EPA to learn how well ToxCast predicts any harmful effects, Willis said.

Charles Auer, who recently retired as the head of EPA's Office of Pollution Prevention and Toxics, said it is vital to have the robotic assessments the National Center for Computational Toxicology is developing used for nanomaterials because the materials are so expensive that it is cost-prohibitive to secure the quantities needed for animal tests.

Regarding animal testing, Troy Seidle, senior adviser for science policy for three Humane Society organizations, said he anticipates a number of developments in cellular studies in 2009.

European regulators are expected to adopt three in vitro methods that will fully replace animals used for skin irritation tests, Seidle said.

"This will represent the first case in which an animal test is fully replaced by non-animal test methods," he said.

Seidle said the next step will be to work toward having OECD accept the non-animal tests. Once accepted by OECD, the non-animal tests effectively will be globally accepted, he noted.

**Studying Genetic Susceptibility.** In addition to working with EPA to further define chemical toxicity, Bucher said, NTP will continue its Host Susceptibility Program, which seeks to understand the genetic basis for why some individuals are more susceptible than others to some substances in the environment.

Asthma, heart disease, cancer, and diabetes are examples of diseases thought to be affected by genetic susceptibility and environmental exposures, according to NTP. It is working with universities to examine strains of mice to see how small genetic differences change their response to environmental agents, Bucher said.

NTP hopes the information from the high throughput screening and host susceptibility programs will be able to identify genetic factors that govern susceptibility to environmental exposures, he said.

**Air Pollutant Studies Required.** Preuss of NCEA said his office's top priority in 2009 will be meeting court-ordered deadlines to evaluate the health hazards of criteria air pollutants.

The Clean Air Act requires EPA to reassess every five years the health risks of six common air pollutants—particulates, ground-level ozone, carbon monoxide, sulfur oxides, nitrogen oxides, and lead.

The agency has been sued for missing deadlines for all of the criteria pollutants except particulates, Preuss said.

"As a result we have a court-ordered deadline for nearly every criteria air pollutant," he said. Many of those deadlines are in 2009 and 2010, Preuss said.

In the past, the National Center for Environmental Assessment has focused on one criteria air pollutant at a time, but this year, the agency will work on all six simultaneously, Preuss said. "That will be the top priority for NCEA in 2009."

In addition to working on the criteria air pollutants, the National Center for Environmental Assessment expects to release in 2009 draft toxicological reviews of several high-profile chemicals including trichloroethylene and formaldehyde, Preuss said.

Preuss also said the agency will determine how it will respond to a National Academies report issued in December, *Science and Decisions: Advancing Risk Assessment*, criticizing the EPA risk assessment process as bogged down by funding and staff shortages and saying its current approach to scientific uncertainty contributes to decisionmaking gridlock.

In the past, it sometimes has taken EPA more than a year to respond to National Academy recommendations.

**Global Assessment of Nanotechnology.** EPA's Willis, who also chairs OECD's nanomaterials working party, said a number of countries, including China, Russia, and Thailand, already have volunteered to test 10 of the 14 nanomaterials OECD is targeting.

Neither of the three countries is a member of OECD.

"It's great to see this kind of international cooperation on issues of mutual importance," Willis said.

The countries will test the selected nanomaterials for 59 different types of environmental, health, and safety effects they might have, Willis said.

By March, the working party hopes to release a database of nanomaterials research being conducted by both countries, and hopefully some companies, around the world, Willis said.

That database will help OECD, individual countries, and companies to shape a strategic plan to research the environmental, health, and safety questions surrounding engineered nanomaterials, he said.

The OECD working party will develop test guidelines and other documents through a "wiki" format so that the guidance can be updated as new information becomes available, Willis said.

In conjunction with the OECD efforts, Teague of the National Nanotechnology Coordinating Office said he expects academic, corporate, professional, and nongovernmental organizations to agree in 2009 on a base set of physical and chemical characterizations to describe nanomaterials, which will be particularly useful for toxicological studies.

Willis added that the OECD working party will host a conference on the environmental benefits of nanotechnology to take place in Prague in June. Some of the benefits include improving the collection of solar energy, improving battery technology, cleaning groundwater, and improving the energy efficiency of building materials.

**Setting Agency Research Priorities.** EPA's Chief Scientist Pai-Yei Whung said she will work with the Science Policy Council, which consists of the agency's top sci-

entists, to set priorities for the research EPA will conduct in 2009 and beyond.

Issues the council is considering include climate change, energy, future contaminants, homeland security, and pollution prevention, Whung said.

EPA's Risk Assessment Forum, a committee of senior EPA scientists established to promote consensus on risk assessment issues, will be working to integrate its environmental and human health risk assessments, Whung said.

Currently, the agency's ecological risk assessments and human health risk assessments are separate documents, she said. It will take time to combine them, but it will be important to do so, Whung added.

Whung said EPA will be developing a Climate Change Technology Activity Database to collect and analyze the work under way in various agency offices. The database is intended initially for internal use to determine where there may be gaps in EPA's research, she said. But, after appropriate review, Whung said, it could be used for a cross-federal needs assessment.

David Rejeski, director of the Synthetic Biology Project and Project on Emerging Nanotechnologies, took an overarching view of how the incoming administration should address technology generally.

Rejeski noted that the National Academies' report, *Review of Federal Strategy for Nanotechnology-Related Environmental, Health, and Safety Research*, found in December that the federal government lacked a national strategy to address environmental, health, and safety questions arising from nanotechnology.

"The next administration needs to put in place the people and institutions to finally, and effectively, make public policy on the technological frontier," Rejeski said.

BY PAT RIZZUTO

# DISCOVER

## Is One Very Tough Rat a Very Big Risk to Human Health?

The rodents charged with testing environmental chemicals may be too tough for their jobs.

January 21, 2009  
by Marilyn Berlin Snell

The success of one of the most ambitious and contested federal science programs in years may rest on the delicate shoulders of a one-pound albino breed of rat known as Sprague Dawley. In a hotly debated move, the U.S. Environmental Protection Agency (EPA) has selected this unassuming rodent as the primary test animal for a vastly complex and comprehensive new chemical-evaluation program. The effort is designed to investigate many of the most vexing public-health questions of the day: Are you putting yourself, your children, or even your children's children at risk when you microwave food in plastic containers? What is contributing to hormone-related killers like breast, uterine, and testicular cancer? And are common garden sprays—like the one you use to keep the aphids off your hybrid tea rose—affecting your unborn baby's developing brain?

The EPA initiative, called the [Endocrine Disruptor Screening Program](#), is set to begin testing some of the 87,000 chemicals identified by a federal advisory panel for their potential to interfere with the body's endocrine, or hormone, system. As the body's chemical messengers, hormones play a critical role in regulating biological processes including metabolism, reproduction, and brain development. The female ovaries, male testes, and pituitary, thyroid, and adrenal glands are all part of this complex system. Endocrine disruptors may mimic natural hormones or block their normal action, cause the body to produce too much or too little of a hormone, or scramble a hormone's message so that the body thinks it should abort a fetus, for example, or produce extra insulin. If any of the thousands of chemicals in common use today adversely affect the human hormone system, the EPA's testing program should catch them—but only if Sprague Dawley catches them first. And therein lies the controversy.

Since World War II, this white-furred rodent with beady red eyes has been among industry's most often used lab rats for testing drugs and chemicals before they hit the market. The animal's utility is undisputed; it has helped researchers study not just pharmacology and toxicology but everything from cancer and AIDS to obesity and aging. In this case, though, it may be the wrong rat for the job. Critics say that Sprague Dawley is a kind of superrodent whose hearty constitution may not react in ways an average human's would. If so, the animal could give a clean bill of health to chemicals that actually pose a real threat to human well-being.

Last spring the EPA convened a scientific advisory panel to make final adjustments to the proposed testing program. One panelist was David Furlow, a University of California at Davis endocrinologist with extensive experience in rat-strain variations and how they can affect outcomes in the lab. He tried repeatedly to raise a red flag about Sprague Dawley. "I've known about these differences since I was an undergraduate in the 1980s," Furlow says, citing scientific literature that suggests it is more resistant to endocrine-disrupting chemicals than other rat strains. His concerns, he says, were downplayed.

Sprague Dawley's unique characteristics have been evident for decades. In 1946 physical chemist Robert Dawley's company sent a letter to the National Institutes of Health (NIH) detailing how, through selective breeding, Dawley had developed a rat (Sprague was his first wife's maiden name) with good temperament, vigor, and high rates of lactation. But Sprague Dawley's good genes—not to mention its fecundity—could have bad consequences for humans: A prolific breeder may not be the best test subject for chemicals that may cause infertility and other reproductive problems. The letter to the NIH also stated that the rat strain had been bred for "high resistance to arsenic trioxide," a toxic substance used in insecticides and herbicides and known today to be an endocrine disruptor.

"It's a significant problem," says [Jef French](#), acting chief of the Host Susceptibility Branch of the [National Toxicology Program](#) at the National Institute of Environmental Health Sciences. (French emphasized that he was speaking for himself and not the government.) "Because of Sprague Dawley's [genetic] selection, chemicals that might be harmful to humans might be judged to be nonharmful to the rat," he says.

The results of the EPA's tests could guide federal regulation of numerous chemicals for many years to come, so the stakes for both the public and the chemical industry are enormous.

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The far-reaching Endocrine Disruptor Screening Program dates to 1996, when Congress ordered the EPA to begin testing chemicals for their potential to interfere with the human endocrine system. By some accounts the legislation was prompted by the publication earlier that year of a book titled [Our Stolen Future](#). Called “an environmental thriller” by [The Washington Post](#), the book, by two zoologists and an environmental journalist, called attention to a longtime concern of environmentalists: failing wildlife populations and strange deformities in the offspring of those that survived. For instance, there was a massive die-off of alligators after a 1980 pesticide spill in Florida’s Lake Apopka. Studies later found deformed sex organs in the offspring of the remaining gator population, even after tests showed the water in the lake to be apparently clean. Mink ranchers in the Great Lakes region who fed their animals local fish began noticing that the females weren’t producing pups, a problem later linked to PCB contamination. In California researchers found what came to be known in the press as “gay gulls”: same-sex seagull couples shacking up together in the nest, protecting eggs with abnormally thin shells that often harbored dead chicks. DDT was the suspected culprit.

Because of genetic selection, chemicals that might be harmful to humans might be judged nonharmful to the rat.

Confronted with these findings, scientists began to wonder whether small quantities of synthetic chemical compounds found in our food and water—and in everyday products like makeup, plastics, and bug spray—could be sabotaging human fertility, undermining our immune systems, or affecting prenatal development. When the public got wind of the possible threat and started demanding answers, the EPA’s Endocrine Disruptor Screening Program was born.

Twelve years and \$76 million later, not a single chemical has been screened by the EPA for its potential to scramble male, female, and thyroid hormones. Before screening could begin in earnest, the agency had to make sure that the protocols used in the screens would be reliable and reproducible. In this validation phase, studies were conducted at several labs using the same protocol, with the results then compared to ensure that the screens are replicable across labs. In this preliminary phase, several rat strains were used, including ones known as Long-Evans Hooded and Wistar, but Sprague Dawley was always the top pick.

During the validation studies, Sprague Dawley and other strains were housed in polycarbonate cages with wire lids. In some tests their life spans were brief—around six to eight weeks. Juvenile males were dosed with chemicals, then decapitated and examined. Pubescent males and females were injected with atrazine and myriad other chemicals, then had ovaries removed and studied, tiny testicles weighed, and kidney and thyroid glands checked for toxic effects.

A [2003 white paper commissioned by the EPA](#) notes that because companies have for decades conducted these kinds of tests on Sprague Dawley, there is a large database of information on them that is lacking for other strains. But a “reviewer’s appendix” to the white paper—in which an independent scientist is asked to critique the report—argues that Sprague Dawley may be a poor choice for endocrine disruptor screening because the animal was bred to be resistant to known environmental toxicants. Written by research geneticist Jimmy Spearow, then at U.C. Davis, the appendix presented evidence that other rat strains, including Fischer 344, were more sensitive to more chemicals than was Sprague Dawley. “Compared with several other strains that have been studied, the strain that is least sensitive to the most endocrine-disrupting chemicals has been identified, and the EPA is planning to use it in the screening assays,” says Spearow, now a staff toxicologist for the California EPA; he emphasizes that this is his personal opinion, based on previous work conducted at Davis. In 2007 the EPA finally acknowledged there was reason to believe that Sprague Dawley might be less sensitive to certain endocrine tests, which made critics like Spearow wonder what other toxic effects the rat had failed to catch all those years.

Which rat to use in the EPA study isn’t the only thing being fought over. There has been a pitched battle between the chemical industry and its many critics regarding the Endocrine Disruptor Screening Program itself, with some industry representatives questioning the very premise that endocrine disruption is a human health risk. At a recent industry-sponsored workshop on the endocrine disruptor program that included representatives from Procter & Gamble, Monsanto, the American Chemistry Council, and Dow, one speaker repeatedly prefaced the phrase “endocrine disruptor” with “quote unquote.”

“There will always be different interpretations of science,” says Angelina Duggan, an original member of the EPA advisory panel and today a managing scientist at Exponent, a chemical industry consulting firm. “Whether this issue is more emotion or science remains to be seen.”

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To Marion Moses, a physician who runs the [Pesticide Education Center](#) in San Francisco, there is no need for such equivocation. “It’s become a fight over process and whether one can extrapolate animal studies to humans,” she says. “It’s a charade, and it has been going on for 12 years.” Trying to nail down unassailable proof of endocrine disruption

in humans is essentially a fool's errand, in her view. Moses, who has treated farmworkers for acute poisoning, rashes, and asthma that seem to be related to the spraying season, feels that the wildlife data alone should be enough to outlaw certain pesticides. "I spent a lot of time trying to get these awful chemicals off the market," she says while walking in a San Francisco garden-supply store. The snail bait, lawn weed-and-feed products, fungicides, and insect repellents she pulls off the shelf all contain chemicals slated for testing.

The 2003 white paper that drew such strong criticism from Spearow, who called it "disturbing" and "misleading," was coauthored by Rochelle Tyl, another member of the EPA advisory panel. Tyl, who runs a lab in North Carolina's Research Triangle Park where many of the screens and tests will eventually be done, acknowledges that Sprague Dawley isn't the perfect choice. Still, she defends the report, calling Fischer 344, for instance, a "lousy" test animal because the males have reproductive problems. Asked about rats bred to be super reproducers, she waves her arm impatiently. "I know that's the criticism, that Sprague Dawleys are good breeders. But if you don't have an animal that gives decent litters, how do you run a study?"

Gary Timm, a senior environmental scientist with the EPA, has been working on the endocrine disruptor program since its very first days and likewise recognizes the complexity of the process. "I've been totally surprised at how long it's taken," he says. The agency felt a constant tug between "keep it simple" and "be comprehensive."

"Compromises have been struck," Timm continues. He, too, cites the problem of Sprague Dawley's virility. "People say, 'Look, these rats suffer a 50 percent decrease in sperm and they still reproduce.' They say, 'If you had a guy who had a 50 percent decrease in sperm, he'd be infertile!'" Asked how he responds to such criticism, he answers, "Those are just some of the things we have to allow for."

Representative Henry Waxman and others on the House Committee on Oversight and Government Reform are not so sure. In 2007 the committee sent a letter to the administrator of the EPA voicing concern that public health was being put at risk by the selection of Sprague Dawley. The agency responded, "While the EPA recognizes there are reasons to believe that this strain might be less sensitive, the data currently available appear to show that it is no worse (or better) than other strains for screening for endocrine activity."

In some ways the EPA is correct, Spearow says. No one rat strain is most sensitive to all endocrine-disrupting chemicals. "However, available data show that the Sprague Dawley rat strain is least sensitive to the most endocrine-disrupting chemicals relative to other strains that have been studied," he says. "I'm not saying it is inappropriate for all testing, but to use it as the only test animal in this program means that we could really underestimate the effects of certain kinds of chemicals. Do we make sure they're safe for King Kong? Or do we make sure they're safe for you and me and Bambi?"

Congress, fed up with the EPA's delay of more than a decade, wrote into the 2008 appropriations bill that the screening of possible endocrine-disrupting compounds was to begin last summer. Testing of the first chemicals, including the herbicides 2,4-D and atrazine and the insecticide malathion, was scheduled to follow, but the EPA pushed back its deadlines yet again, to early 2009.

Endocrine disruption, with its diffuse causes and effects that may not show up for a generation, is a hydra-headed 21st-century health challenge. Thousands of chemicals will be tested and many millions of dollars will be spent. Still, opponents of using Sprague Dawley say one nagging question remains: If the whiskered workhorse in the laboratory isn't up to the task, who will be the real lab rats?

## Database Helps Assess Your Breast Cancer Risk

By Serena Gordon  
HealthDay Reporter

Sunday, January 25, 2009; 12:00 AM

(HealthDay News) -- If you want to learn more about the key risk factors for breast cancer, such as obesity, pollutants or smoking, a database can guide you to the available evidence that confirms or quells an association.

"Breast cancer is multifactorial. It would be rare for there to be a single environmental chemical that alone would be sufficient to cause an increase in breast cancer," said Dr. Robert Schneider, co-director of breast cancer research at New York University School of Medicine in New York City.

"In many cases, an increased risk of breast cancer is quite small, and we don't yet know how each factor affects the risk of breast cancer," he said, explaining that it's similar to a puzzle. "We need to know how all of the pieces fit together, and this database begins to help us start assessing some of that."

The database, a joint project of Susan G. Komen for the Cure and the Environmental Factors and Breast Cancer Science Review project led by the Silent Spring Institute, includes information on 216 chemicals, diet, smoking, physical activity and weight that may play a role in the development of breast cancer.

Fewer than 100 chemical compounds have been identified as human carcinogens by the International Agency of Research on *Cancer*. However, that doesn't mean that all other chemicals are safe, just that they haven't been tested. And, an estimated 80,000 chemicals have been registered for commercial use in the United States, according to the database study, which was published in a recent issue of the journal *Cancer*.

Although many factors have been associated with breast cancer, Schneider said his top three would include the chemical bisphenol A, radiation exposure from CT scans and delayed first pregnancy.

Bisphenol A (BPA) is an estrogenic chemical found in many products made of polycarbonate plastic (clear, hard plastic), such as baby bottles, reusable water bottles, food storage containers, food cans and water supply pipes, according to the [National Institute of Environmental Health Sciences](#). Although no human studies have confirmed an association with breast cancer, a study done in mice suggests there may be a link. However, the U.S Food and Drug Administration recently said the agency felt there were "adequate margins of safety" for the chemical in the amounts commonly consumed.

"We don't know what constitutes an unacceptable level," said Schneider who would prefer to err on the side of caution and limit BPA exposure, especially in infants and young girls.

Schneider said another concerning risk factor is the amount of radiation people are exposed to for routine health problems, particularly from CT scans.

Although the last risk factor from Schneider's top three -- delayed first pregnancy -- isn't one people are likely to change, he said it's important to be aware of it. "In a modern society, it's exceedingly difficult to have a pregnancy before 20 when it would be quite protective," said Schneider.

Dr. Jay Brooks is chair of hematology/oncology at Ochsner Health System in Baton Rouge, La. He said, "When you look at environmental and chemical risk factors, you have to remember that we live in a sea of chemicals, and those chemicals have made our lives so much nicer, and it's hard to know exactly what each one does to an individual's risk.

"I advise my patients to try to control the things you have good control over. Weight is a huge issue in breast cancer, as is the use of combined estrogen/progesterone after menopause," he added.

Brooks said extra weight is a risk factor that many women underestimate, but being overweight clearly increases risk. And, he said, estrogen therapy alone used to ease menopausal symptoms doesn't seem to increase risk the way the estrogen/progesterone combination does.

### **More information**

To learn more about breast cancer risk factors, check the searchable database from the [Silent Spring Institute](#).

SOURCES: Robert Schneider, Ph.D., co-director, cancer research, New York University School of Medicine, New York City; Jay Brooks, M.D., chair, hematology/oncology, Ochsner Health System, Baton Rouge, La.

[http://www.washingtonpost.com/wp-dyn/content/article/2009/01/25/AR2009012500665\\_pf.html](http://www.washingtonpost.com/wp-dyn/content/article/2009/01/25/AR2009012500665_pf.html)

February 1, 2009  
by Katie Burns

## Training program brings veterinary pathologists to NIH

Participants complete residencies at veterinary colleges, dissertation work at National Institutes of Health

Genetic causes of breast cancer and leukemia were the topics of dissertations by the first two veterinary pathologists to complete a joint training program between the National Institutes of Health and five veterinary colleges.

The NIH recently held a symposium to highlight the program's early progress and participants' contributions to biomedical research. The Comparative Biomedical Scientist Training Program Symposium took place Oct. 2-3, 2008, on the NIH campus in Bethesda, Md.

The National Cancer Institute launched the veterinary training program in 2003, and four other NIH institutes have joined. The NCI has partnered with the veterinary schools/colleges in Illinois, Indiana, Maryland, Michigan, and North Carolina. Ten veterinarians are training in the program, which starts with a pathology residency at one of the veterinary colleges and ends with dissertation work at an NIH institute.

"It provides us the opportunity to train additional pathologists for a global need," said Dr. John Cullen, who directs the program at the North Carolina State University College of Veterinary Medicine.

Dr. Cullen noted that the program combines anatomic and investigative pathology. Also, the program allows veterinarians to develop relationships with other scientists—working together to improve animal and human health so that the idea of "one medicine" is more than an idle concept.

Dr. Willie Reed, dean of the Purdue University School of Veterinary Medicine, said the program specifically helps meet needs for veterinarians in biomedical research and pathologists at veterinary colleges.

"It allows our faculty and students access to cutting-edge research conducted by world-class NIH scientists," Dr. Reed added.

Last year, Drs. Mark Hoenerhoff and David Caudell were the first veterinarians who completed their PhDs through the program.

"As veterinarians and as pathologists, we have a great opportunity to really make a difference in biomedical research through using our knowledge of biological systems to solve problems relating to human health," said Dr. Hoenerhoff, who completed his training at NCI and now conducts research at the NIH National Institute of Environmental Health Sciences.

Dr. Hoenerhoff studied the BMI1 gene in vitro and in mice. The gene can contribute to the development of breast cancer. Dr. Hoenerhoff's team found that overexpression of BMI1 in conjunction with overexpression of Hras, an oncogene commonly overexpressed in a number of cancers in humans, augments tumorigenesis.

Dr. David Caudell focused his work at the NCI on leukemia research in rabbits and mice. Studying the role of chromosomal translocations, Dr. Caudell generated transgenic mice that expressed a CALM-AF10 fusion gene. Almost half the mice developed acute leukemia—providing experimental confirmation that this fusion, isolated from patients with some forms of leukemia, is leukemogenic.

Dr. Caudell said he enjoyed the chance to pioneer the veterinary training program at the NIH. "It's been really great watching the program evolve, watching it grow exponentially."

Dr. R. Mark Simpson, director of the Molecular Pathology Unit within the NCI Laboratory of Cancer Biology and Genetics, was the founder of the training partnerships with the veterinary colleges. He said the NIH institutes benefit from veterinarians' comparative perspectives in problem solving, hypothesis testing, and critical thinking.

Dr. Simpson also received the 2008 Leading Diversity Award from the NCI for recruiting and mentoring African-American veterinarians and veterinary students.

"We have been successful in our ability to include underrepresented minority veterinarians, in large part, due to combined efforts in building a network of supportive programs and people at both the NIH and our veterinary college partners," he said.

Dr. Simpson said the joint training program's ultimate goal is to prepare interdisciplinary, comparative biomedical scientists who will help lead the research teams of the future—opening new synergies to address public health challenges impacting humans, animals, and the environment.

Information is available at [http://ccr.ncifcrf.gov/resources/molecular\\_pathology](http://ccr.ncifcrf.gov/resources/molecular_pathology).

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## Researchers find way to cut ozone's effects on asthma

by Ginger Rough

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Researchers say they may have found a key to treating the ozone-triggered asthma attacks and respiratory problems that plague residents in hot-weather states like Arizona.

A study released Tuesday by the National Institutes of Health shows for the first time how ozone irritates the lungs, findings that could ultimately lead to better treatment options for asthma sufferers.

The report has particularly wide-reaching implications in this state, which not only has one of the nation's highest rates of asthma but struggles to control [ozone pollution](#) during the summer months.

"I can't say we found the cause of asthma, but in this instance, we were able to completely get rid of the symptoms," said [Stavros Garantziotis, principal investigator with the National Institute of Environmental Health Sciences](#), part of the NIH. "We were able to stop the irritation (in the lungs)."

Any new drugs or therapies that arise from the research are still years away, he cautioned.

The study, done in conjunction with Duke [University](#), found that mice exposed to so-called bad ozone, a key component of urban smog, produced high amounts of a sugar called hyaluronan.

The sugar was directly responsible for the narrowing or constriction of the animals' airways, a primary cause of asthma symptoms and attacks in humans.

### Discovering a clue

"We found that it is not the ozone itself that causes the body to wheeze but the way the lungs respond to (it)," [Garantziotis](#) said.

Hyaluronan is found naturally in many tissues of the body, including skin and cartilage, and has been used to treat such conditions as osteoarthritis of the knee.

But researchers found that the mice produced it in a different, more harmful form after being exposed to ozone.

They also discovered they were able to neutralize this "bad" hyaluronan and stop the lungs' airways from narrowing by using several proteins and an altered form of the sugar.

As many as 548,000 state residents suffer from asthma, according to the American Lung Association of Arizona, and studies suggest that Valley's year-round pollution problems exacerbate those symptoms.

Much of the local attention has focused on links between respiratory problems and particulate pollution, the tiny bits of dust and soot in the air.

But ozone is a growing concern for state and local health officials.

In 2008, metro Phoenix exceeded the [federal health standard](#) for ozone on 28 days, compared with none in 2007 and nine in 2006.

Part of the jump was due to a tightening of federal standards.

Nationally, the [Environmental Protection Agency](#) estimates that ozone-related health problems cost the United States \$5 billion a year in premature deaths, hospitalizations and school absences.

"This finding has real-life therapeutic implications," [Garantziotis](#) said of the study, which was published in the *Journal of Biological Chemistry*.