

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

Fiscal Year 2015 Budget Request

Statement for the Record

Senate Subcommittee on Labor-HHS-Education Appropriations

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Mr. Chairman and Members of the Subcommittee:

I am pleased to present the President's budget request for the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH). The Fiscal Year (FY) 2015 NIEHS budget of \$665,080,000 includes an increase of \$556,000 from the comparable FY 2013 level of \$664,524,000. The NIEHS Strategic Plan, *Advancing Science, Improving Health* continues to guide efforts toward fulfilling our mission to discover how the environment affects people in order to prevent both acute and chronic illness.

#### BREAST CANCER

NIEHS continues its robust investment into environmental factors affecting breast cancer, with the goal of learning how we can prevent this widespread disease. NIEHS and the National Cancer Institute (NCI) collaborated to support the Interagency Breast Cancer and Environmental Research Coordinating Committee, whose report, *Prioritizing Prevention*, recommends strategies to mitigate the environmental causes of breast cancer. NIEHS supports several major epidemiological and translational breast cancer initiatives. The Breast Cancer and the Environment Research Program is a transdisciplinary initiative cosponsored by NCI and NIEHS, in which basic scientists, epidemiologists, clinicians, and community partners work together to examine the effects of environmental exposures that may predispose a woman to breast cancer throughout her life, including exposures during puberty, menopause, pregnancy, and other "windows of susceptibility." The NIEHS Sister Study has recruited a cohort of 50,884 U.S. and Puerto Rican women with a sister diagnosed with breast cancer, to prospectively study environmental and genetic factors that influence breast cancer risk

and survival. More than 1,500 incident breast cancers have been diagnosed to date. A May 2013 publication from these researchers showed that DNA methylation profiling in blood samples may hold promise for breast cancer detection and disease risk prediction. The Agricultural Health Study, a collaborative effort by NCI, NIEHS, the National Institute for Occupational safety and Health (NIOSH), and the Environmental Protection Agency (EPA), includes a comprehensive evaluation of many commonly used herbicides and pesticides and their potential impact on risk of breast cancer among 32,000 women who are married to pesticide applicators (primarily farmers).

#### ENVIRONMENT AND AUTOIMMUNITY

NIEHS supports scientists who are exploring how environmental exposures can cause immune system dysfunction. Grantees are conducting research on environmental influences on epigenetic immune programming, early arsenic exposure effects on the response to H1N1 influenza, and the immune system response to pesticide exposure. At the other end of the spectrum, there is evidence that autoimmune diseases likely involve an environmental component. Autoimmune diseases result from an immune response directed against the body's own tissues and they collectively afflict approximately 24.5 million Americans, with women disproportionately affected. The cause(s) of autoimmune disorders remain largely unknown and are likely multifactorial involving both genetic and environmental influences. In 2013, NIEHS released a Funding Opportunity Announcement (FOA) to enable a better understanding of the links between exposures and autoimmune disease.

NIEHS continues to support autoimmune disease research in the underserved community of Libby, Montana where the population has been exposed to asbestos

minerals as a byproduct of vermiculite ore mining. Of particular concern is early childhood exposure, since susceptibility may be increased during this life stage. Recent efforts to characterize children's exposure in Libby estimated up to 15 times higher levels of airborne asbestos concentrations during outdoor activities and 73% of the study participants indicated these activities occurred in the presence of children <sup>1</sup>. NIEHS grantees are investigating whether childhood asbestos exposures in Libby are associated with pulmonary disease later in life.

### ENVIRONMENT AND NEUROLOGICAL DISORDERS

Evidence indicates there is both an environmental and genetic component in neurological disorders. NIEHS funds research to advance the understanding of environmental factors and gene-environment interactions related to neurodegenerative diseases and to help create new prevention and treatment approaches. At the NIEHS Centers for Neurodegeneration Science (CNS), teams of top scientists from different disciplines collaborate to examine the root causes of neurodegenerative diseases. CNS researchers study how exposure to pesticides, metals, and other chemicals affect the development of neurodegenerative diseases such as Parkinson's and Alzheimer's disease. NIEHS recently published two Funding Opportunity Announcements to expand neurological research: one on environmental exposures and Alzheimer's disease, and the other on environmental exposures and neurodegenerative disease.

Autism is a highly variable neurodevelopmental disorder, which is likely influenced by environmental exposures. NIEHS-funded researchers have published work

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<sup>1</sup> Ryan PH et al. Childhood exposure to Libby amphibole during outdoor activities. May 22, 2013. J. Expo. Sci. Environ. Epidemiol. Published online at: <http://www.ncbi.nlm.nih.gov/pubmed/?term=PMID%3A+23695492>

indicating prenatal vitamins might reduce the risk of having children with autism<sup>2</sup>. Exposure to air pollution during pregnancy and during the first year of life was also associated with autism.<sup>3 4 5</sup> NIEHS funds three key autism studies: the Childhood Autism Risks from Genetics and the Environment (CHARGE) study, the Markers of Autism Risk in Babies-Learning Early Signs (MARBLES) study, and the Early Autism Risk Longitudinal Investigation (EARLI) study. On April 22, NIEHS is hosting a community virtual forum on autism and the environment that will be webcast live and will feature a panel of autism research experts.

#### RESEARCH UPDATE ON ENDOCRINE DISRUPTORS

NIEHS is the leading government agency funding research on the human health effects of exposure to endocrine disrupting chemicals (EDCs). EDCs have the potential to interfere with a host of physiological functions, contributing to the development of costly and devastating illnesses such as obesity, diabetes, attention deficit hyperactivity disorder (ADHD) and behavioral disorders, asthma, endometriosis and uterine fibroids, reproductive disorders and infertility, and breast, uterine, and prostate cancers. Exposures to EDCs have been documented across the population, with fetuses and

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<sup>2</sup> Int J Epidemiol. 2014 Feb 11. [Epub ahead of print] Maternal lifestyle and environmental risk factors for autism spectrum disorders. Lyall K1, Schmidt RJ, Hertz-Picciotto I.

<sup>3</sup> Epidemiology. 2014 Jan;25(1):44-7. Autism spectrum disorder: interaction of air pollution with the MET receptor tyrosine kinase gene. Volk HE1, Kerin T, Lurmann F, Hertz-Picciotto I, McConnell R, Campbell DB.

<sup>4</sup> JAMA Psychiatry. 2013 Jan;70(1):71-7. doi: 10.1001/jamapsychiatry.2013.266. Traffic-related air pollution, particulate matter, and autism. Volk HE1, Lurmann F, Penfold B, Hertz-Picciotto I, McConnell R.

<sup>5</sup> Autism Res. 2013 Aug;6(4):248-57. doi: 10.1002/aur.1287. Epub 2013 Mar 11. Prenatal and early-life exposure to high-level diesel exhaust particles leads to increased locomotor activity and repetitive behaviors in mice. Thirtamara Rajamani K1, Doherty-Lyons S, Bolden C, Willis D, Hoffman C, Zelikoff J, Chen LC, Gu H.

young children at greater risk due to their stages of rapid development. NIEHS is currently funding over 100 grants examining effects of EDCs including bisphenol A (BPA), arsenic, pesticides, flame retardants, and others.

NIEHS has focused particular efforts on BPA, in part due to its ubiquity, that results in daily exposures for most people, mainly through diet. The Consortium Linking Academic and Regulatory Insights on BPA Toxicity (CLARITY-BPA) research program is a collaborative effort of the NIEHS, the National Toxicology Program (NTP), the Food and Drug Administration's National Center for Toxicological Research, and academic researchers studying a range of health endpoints, while also establishing new testing standards and methodologies. A recent study of another EDC, phthalates, shows that levels of some plasticizers have fallen since a federal ban on their use in children's products and voluntary removal from many consumer goods.<sup>6</sup> However, research at Brown University suggests that replacement chemicals may be just as damaging to the reproductive development of boys.<sup>7</sup>

#### RESEARCH UPDATE ON GULF OIL SPILL

The release of millions of gallons of crude oil following the 2010 Deep Water Horizon (DWH) disaster posed unpredictable risk to over 130,000 workers trained and potentially involved in various remediation activities and to the people living along the Gulf Coast. To date, there have been limited studies on the human health effects of oil

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<sup>6</sup> Zota AR, Calafat AM, Woodruff TJ. 2014. Temporal trends in phthalate exposures: findings from the National Health and Nutrition Examination Survey, 2001-2010. *Environ Health Perspect*; <http://www.ncbi.nlm.nih.gov/pubmed/24425099>.

<sup>7</sup> Saffarini CM, Heger NE, Yamasaki H; Liu T, Hall SJ, Boekelheide K. 2012. Induction and persistence of abnormal testicular germ cells following gestational exposure to di-(n-butyl) phthalate in p53-null mice. *J Andrology*; 33(3):505-513. <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3607946>

spills, especially long-term effects. The NIEHS Gulf Long-term Follow-up Study (GuLF STUDY), funded in part by the NIH Common Fund, is investigating potential short- and long-term health effects associated with oil spill cleanup activities. The GuLF STUDY has enrolled 32,786 individuals and has completed home visits for 11,200 participants, during which clinical measurements were taken and biospecimens were collected for future research.

NIEHS leads the DWH Research Consortia that funds a network of academic and community partners to study health effects in people residing in regions affected by the disaster. These studies are examining resilience at the individual and community levels, perceptions of risk among women and children, and the potential contamination of seafood in the Gulf (Strategic Plan Goals 4-6). While NTP is conducting research to increase our understanding of the toxicology of crude oil, NIEHS grantees have preliminary results that suggest increased depression and anxiety among Gulf Coast residents, but also suggest strong community networks promote resilience.

**Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.**

**Director, National Institute of Environmental Health Sciences**

Linda S. Birnbaum, Ph.D., is director of the National Institute of Environmental Health Sciences (NIEHS) of the National Institutes of Health (NIH), and the National Toxicology Program. As NIEHS and NTP director, Dr. Birnbaum oversees the funding of biomedical research to discover how the environment influences human health and disease. The Institute also supports training, education, technology transfer, and community outreach.

A board-certified toxicologist, Dr. Birnbaum has served as a federal scientist for almost 35 years. Prior to her appointment as NIEHS and NTP Director in 2009, she spent 19 years at the Environmental Protection Agency (EPA) where she directed the largest division focusing on environmental health research. Dr. Birnbaum started her federal career with 10 years at NIEHS, first as a senior staff fellow at the National Toxicology Program, then as a principal investigator and research microbiologist, and finally as a group leader for the Institute's Chemical Disposition Group.

Dr. Birnbaum has received many awards and recognitions. In October 2010, she was elected to the Institute of Medicine (IOM) of the National Academies, one of the highest honors in the fields of medicine and health. She was elected to the Collegium Ramazzini, received an honorary Doctor of Science from the University of Rochester, and a Distinguished Alumna Award from the University of Illinois. Her awards include the Women in Toxicology Elsevier Mentoring Award, the Society of Toxicology Public Communications Award, EPA's Health Science Achievement Award and Diversity Leadership Award, the National Center for Women's 2012 Health

Policy Hero Award, Breast Cancer Fund Heroes Award, and 14 Science and Technology Achievement Awards, which reflect the recommendations of EPA's external Science Advisory Board, for specific publications. Dr. Birnbaum is also an active member of the scientific community. She was vice president 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.

Dr. Birnbaum is the author of more than 700 peer-reviewed publications, book chapters, and reports. Her own research focuses on the pharmacokinetic behavior of environmental chemicals; mechanisms of actions of toxicants, including endocrine disruption; and linking real-world exposures to health effects. She is also an adjunct professor in the Gillings School of Global Public Health, the Curriculum in Toxicology, and the Department of Environmental Sciences and Engineering at the University of North Carolina at Chapel Hill, and the Integrated Toxicology Program at Duke University. A native of New Jersey, Dr. Birnbaum received her M.S. and Ph.D. in microbiology from the University of Illinois at Urbana-Champaign.