

James Baumberger, on behalf of the Friends of NICHD
Subcommittee on Labor, Health and Human Services, Education, and Related Agencies
National Institutes of Health, National Institute of Child Health and Human Development

My name is James Baumberger. I currently serve as Chair of the Friends of the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD). On behalf of the Friends, I urge the Labor, Health and Human Services, Education, and Related Agencies Appropriations Subcommittee to support at least \$34.5 billion for the National Institutes of Health (NIH), including \$1.441 billion for NICHD for fiscal year (FY) 2017. Our coalition includes over 100 organizations representing scientists, physicians, health care providers, patients, and parents concerned with the health and welfare of women, children, families, and people with disabilities. We are pleased to support the extraordinary work of NICHD.

Since its establishment in 1963, NICHD has achieved great success in meeting the objectives of its broad biomedical and behavioral research mission, which includes research on child development before and after birth; women's health throughout the life cycle; maternal, child, and family health; learning and language development; reproductive biology; population health; and medical rehabilitation. With sufficient resources, NICHD can build upon the promising initiatives it has undertaken over the last 50 years, produce new insights into human development, and develop solutions to health and developmental problems throughout the world, including individuals and families in your states. Scientific breakthroughs supported by NICHD serve to prevent and treat many of the nation's most devastating health problems including infant mortality and low birthweight, birth defects, intellectual and developmental disabilities, and the reproductive and gynecologic health of women throughout their lifespan. Some of NICHD's research activities are highlighted below.

Zika Virus: NICHD is also now playing a crucial role in research related to the Zika virus. Linked to the development of congenital microcephaly, Zika virus poses a clear threat to mothers and children in the United States and beyond. NICHD is uniquely positioned to investigate the mechanisms that lead to microcephaly during pregnancy and to help uncover medical breakthroughs to mitigate the harmful effects of Zika virus. In fact, NICHD recently funded U.S.-based researchers to conduct a large study of pregnant women in Brazil from the first trimester of pregnancy. The study will track Zika infection in these women and follow children suspected of being affected by the virus for two years.

Preterm Birth: NICHD supports a comprehensive research program to study the causes of preterm birth, prevention strategies, and treatment regimens. Preterm birth costs our nation \$26 billion annually and is a leading cause of infant mortality and intellectual and physical disabilities. Continued prioritization of extramural preterm birth prevention research, the Maternal-Fetal Medicine Units Network, the Neonatal Research Network, and the intramural research program related to prematurity are necessary to further this work. Resources should also be available to support transdisciplinary science as recommended in NICHD's Scientific Vision to study and identify the complex causes of preterm birth. NICHD supports research on the causes of preterm birth with the goal of discovering ways to prevent it. Although research has identified some factors that influence preterm birth (e.g., multiple gestation pregnancy, infections, diabetes, high blood pressure, closely spaced pregnancies), it cannot be fully explained by physical health. Robust funding is needed for research to determine the complex interaction of psychological, behavioral, social, and environmental factors, in addition to genetic and biological influences, that causes preterm birth with the ultimate goal of developing

interventions to decrease this epidemic. In addition, a baby is stillborn in the United States every 21 minutes, and NICHD should join with other researchers to establish a research agenda that will lead to better prevention strategies.

National Children's Study (NCS)-Alternative/Environmental Influences on Child Health Outcomes (ECHO) Program: The Children's Health Act of 2000 called for the NIH to evaluate a wide range of environmental influences on the health and development of children. While the National Children's Study was created to accomplish this goal, it was ultimately deemed unfeasible and was closed. However, the child health goals of the Children's Health Act remain as important today as 14 years ago. The President's FY2017 budget includes \$165 million within the NIH Office of the Director for a new program called the Environmental Influences on Child Health Outcomes (ECHO) to succeed the NCS. Initially, the ECHO program will fund expansions of existing cohorts to focus on four priority issues for child health: asthma, obesity, neurodevelopmental issues like autism, and prematurity. The Friends support this request and urge the NIH, with input and participation from NICHD, to undertake this important research project and include the prenatal period to determine the effects of physical and social environments on child health.

Intellectual and Developmental Disabilities Research Centers (IDDRC): Since their inception in the late 1960's, these Centers have been the national resource for basic research into the genetic and biological basis of human brain development, greatly improving our understanding of the causes of developmental disabilities and promoting the development of effective treatments consistent with their translational science mission. However, the Friends are concerned that the IDDRC network does not have sufficient resources to sustain the progress made in this critical area. We urge NICHD to provide additional resources to the IDDRCs for research infrastructure and expansion of cores so that they can conduct basic and translational research to develop effective prevention, treatment, and intervention strategies for children and adults with developmental disabilities.

Population Research: The NICHD Population Dynamics Branch supports a research portfolio investigating how population change affects the health, development, and wellbeing of children and their families. The branch is known for supporting large-scale longitudinal studies, such as the National Longitudinal Study of Adolescent to Adult Health (Add Health), a survey of over 20,000 adolescents who have been followed for 15 years into adulthood. Recent results from Add Health demonstrate how social relationships affect physical health, including chronic disease and longevity. The branch also leads the Fragile Families and Child Wellbeing Study, which follows nearly 5,000 children in large U.S. cities, most born to unmarried parents between 1998 and 2000. The Fragile Families study has demonstrated the role that family stability and parental involvement play in the long-term health and development of children. In 2014, researchers using both genetic and survey data from the study found that poverty and unstable family environments destabilize the DNA of young boys raised in such environments. This finding provides new insights into the insidious role chronic stress plays in child health. In 2015, findings derived from the Fragile Families and Child Wellbeing Study found that paternal engagement can reduce behavioral problems, independent of the mother's characteristics and her level of engagement.

Sex Differences in Research: The Friends encourages NICHD to look at ways to increase data reporting to address gaps in gender and sex differences in research. Sex differences need to be acknowledged as a critical biological variable. In addition to including more women in clinical research, we believe sex differences should be included as part of the design of all basic biological studies and clinical research. If researchers were to consider sex differences in the design of basic science studies, and incorporate data on sex as a biological variable in animal and human studies, more appropriate conclusions could be drawn from basic research and clinical research would provide more representative data on safety and efficacy of drugs.

Clinical Trials in Pregnant Women: Pregnant women have historically been excluded from most research trials due to concern that trial participation could harm the fetus. Although there has been substantial progress in the inclusion of women in federally funded research, pregnant women are still excluded, even from research that would advance our knowledge of medical conditions and treatments in pregnancy. Mindful of the important considerations of clinical trials on pregnant women, we support establishment of a federal work group to propose how clinical research might be done appropriately in this area.

PregSource: The PregSource crowd-sourcing project, to be unveiled in 2016, will allow pregnant women to track their health data from gestation to early infancy as well as access evidence-based information about healthy pregnancies. Unique to this project, however, will be the ability for researchers to connect with NICHD staff to access aggregate data and potentially recruit participants for clinical trials in order to eliminate knowledge gaps and improve care for pregnant and post-partum women.

Data on Pediatric Enrollment in NIH Trials: NIH policy mandates the inclusion of women, minorities, and children in clinical studies whenever appropriate. While NIH collects enrollment data on women and minorities, it does not collect enrollment data on children. We urge Congress to direct the NIH, with leadership from NICHD, to begin tracking the numbers of children, broken down by pediatric age group, enrolled in NIH-funded studies. Better tracking is needed to ensure adequate representation of children in relevant trials.

Best Pharmaceuticals for Children Act (BPCA): Through the BPCA program, NICHD funds the study of drug products that are important to children but have been inadequately studied in pediatric populations. We urge continued funding and support for this important research as well as support for training the next generation of pediatric clinical investigators.

Contraceptive Research and Development: NICHD's Contraceptive Discovery and Development Branch supports basic, applied and clinical research on contraceptive methods. Through its contraceptive evaluation research, NICHD plays a key role in addressing behavioral issues related to fertility and contraceptive use. Specific contraceptive evaluation opportunities and research priorities include evaluation of the safety and effectiveness of hormonal contraceptives for women who are overweight. NICHD's investment in contraceptive research and development is critical for producing new contraceptive modalities that are more effective, affordable, acceptable, and easier to deliver. Specific opportunities and research priorities in this area include the need for non-hormonal contraception, pericoital contraception, and multipurpose prevention technologies that would prevent both pregnancy and sexually transmitted infections.

Reproductive Sciences: Through its investment in reproductive science, NICHD conducts research to improve women's health by developing innovative medical therapies and technologies and improving existing treatment options for gynecological conditions affecting overall health and fertility. NICHD's reproductive science research makes a vital contribution to women's health by focusing on serious conditions that have been overlooked and underfunded, despite the fact that they impact many women. Future work could focus on infertility and the need for treatments for disorders such as endometriosis, polycystic ovarian syndrome (PCOS) and uterine fibroids which can prevent couples from achieving desired pregnancies.

Pelvic Floor Disorders Network (PFDN): Female pelvic floor disorders represent a major public health burden with high prevalence, impaired quality of life and substantial economic costs affecting approximately 25% of American women. The PFDN is conducting research to improve treatment of these painful conditions. Current research is aimed at improving female urinary incontinence outcome measures and ensuring high quality patient-centered outcomes.

Development of the Research Workforce: Adequate levels of research require a robust research workforce. The years of training combined with funding uncertainty are disincentives for students considering a career in biomedical research. For instance, there is a huge gap between the too-few women's reproductive health researchers being trained and the immense need for research. NICHD's Women's Reproductive Health Research (WRHR) Program and Reproductive Scientist Development Program (RSDP), both aimed at obstetrician-gynecologists to further their education and experience in basic, translational, and clinical research, provide training grants to hundreds of researchers and provide new insight into a host of diseases, such as ovarian cancer. Continued investment in these and other training programs is critical.

Mother-Infant Relationships: NICHD supports multidisciplinary, cutting edge research to advance our understanding of attachment in mother-infant relationships and its impact on development. Early life experiences can have profound impacts on behavioral and health outcomes later in life, but often require specific experimental controls to pinpoint the impacts of various factors. Thus, we urge NICHD to continue support of a robust intramural and extramural research portfolio identifying and describing the complex interaction of behavioral, social, environmental, and genetic factors on health outcomes leading to improved understanding of and interventions for mental illnesses such as depression, addiction, and autism.

Down Syndrome: NICHD-funded investigators have made unprecedented progress toward identifying treatments to reverse or ameliorate the cognitive impairment associated with Down syndrome, as well as understanding how a gene on the 21st chromosome might contribute to the development of Alzheimer's disease in people with Down syndrome. In addition, the NICHD-supported Down Syndrome Registry, DS Connect, has allowed the Down syndrome community to share information and health history in a safe, confidential, online database.

These research efforts have made significant contributions to the well-being of all Americans, but there is still much to discover. We urge you to support NICHD at funding levels that meet current needs for addressing health issues across the lifespan. Thank you for your consideration and we look forward to working with you on these critical issues.