

Rachel Gandell, on behalf of the Friends of NICHD  
Prepared for the Subcommittee on Labor, Health and Human Services, Education, and Related  
Agencies  
National Institute of Child Health and Human Development

My name is Rachel Gandell. I currently serve as Chair of the Friends of the National Institute of Child Health and Human Development (NICHD). On behalf of the Friends, I urge the Labor, Health and Human Services, Education Appropriations Subcommittee to support at least \$32 billion for the NIH, including \$1.37 billion for NICHD for FY2016. 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 the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD).

Since its establishment in 1963, NICHD has achieved great success in meeting the objectives of its broad biomedical and behavioral research mission, including research on child development before and after birth; maternal, child, and family health; learning and language development; women's health and reproductive biology; population issues; and medical rehabilitation. With sufficient resources, NICHD could build upon the promising initiatives described in this testimony and produce new insights into human development and solutions to health and developmental problems throughout the world, including for women, children 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 these research areas are described below.

**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 effective ways to prevent it. In the U.S., the rate of preterm birth is approximately 11.4%, one of the highest rates in all industrialized countries. Although research has identified some factors that influence preterm birth (e.g., multiple gestation, infections, diabetes, high blood pressure, closely spaced pregnancies), it cannot be fully explained by physical health. Support is needed for research on the complex interaction of factors including psychological, behavioral, social, and environmental factors in addition to genetic and biological influences, with the ultimate goal of developing interventions to decrease this country's epidemic of preterm birth. In addition, a baby is stillborn in the U.S. 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)/Strategic Pediatrics Research:** The NCS was created as a result of the Children's Health Act of 2000 to evaluate a wide range of environmental influences on the health and development of children. After years of effort and public investment, the NCS was unfortunately 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 FY2016 budget includes \$158 million within the NIH Office of the Director for Strategic Pediatrics Research to succeed the NCS. The Friends support this request and urge the NIH, with meaningful input and participation from NICHD, to undertake innovative pediatric research beginning in the prenatal period to determine the effects of physical and social environments on child health. The Friends also support the President's budget request for \$7 million to continue to maintain and provide researcher access to the data and bio specimens collected during the NCS pilot phase.

**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 leadership role in addressing behavioral issues related to fertility and contraceptive use. Specific opportunities and research priorities in the area of contraceptive evaluation include evaluation of the safety and effectiveness of hormonal contraceptive options for women who are overweight or obese. 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 the area of contraceptive research and development 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 research into 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 (PFD) 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 gynecological 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 at NICHD is critical to helping ensure future scientific advances.

**Population Research:** The NICHD Population Dynamics Branch supports a research portfolio on 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, and the Fragile Families and Child Wellbeing Study, following nearly 5,000 children in large U.S. cities, most born to unmarried parents between 1998 and 2000. These datasets enable scientists to understand how genetic, biological and social factors, including family stability, parental involvement, social networks, and neighborhoods, interact to influence child health and development. In 2014, using Add Health data, scientists reported new findings on the long-term effects of birth weight and breastfeeding duration on inflammation (a contributing factor to disease and disability) in early adulthood.

**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 the 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.

**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 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.

**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.

**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.

**Rehabilitation Science:** The National Center for Medical Rehabilitation Research (NCMRR) currently resides within NICHD, yet there is a strong need for elevating the stature of NCMRR. We recommend moving the NCMRR to an independent Institute or Center reporting directly to the NIH Director, or to establish a new Office of Rehabilitation Research within the Office of the NIH Director. Implementation of this structural recommendation would require a statutory change. Elevation of NCMRR is a critical step in achieving enhanced coordination of rehabilitation science across all the Independent Centers at NIH that conduct and support research directly addressing or related to rehabilitation science.

**Human-Animal Interaction:** NICHD plays an essential role in human-animal interaction research. Sixty-five percent of American households include a pet, and there is growing evidence of the health benefits of pet ownership. The bond between humans and animals can impact the health and development of children, from strengthening early childhood immune systems to mitigating childhood obesity to improving mental health. Research on the benefits of animal-assisted therapy for children with autism spectrum disorder (ASD) and other neurological conditions relies on the NICHD human-animal interaction research program. We urge NICHD to continue to support a strong pipeline of peer-reviewed research in this area.

**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 21<sup>st</sup> 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 people with Down syndrome and their family members, researchers, and parent and support groups to share information and health history in a safe, confidential, online database.

**Intellectual and Developmental Disabilities Research Centers (IDDRC):** These Centers have greatly improved our understanding of the causes of developmental disabilities and have developed 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. FNICHD urges the committee to direct 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.

These research efforts have made significant contributions to the well-being of all Americans, but there is still much to discover. We support the NICHD's recently released Scientific Vision and 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.