A New Federal Task Force on Research Specific to Pregnant Women and Lactating Women: From Idea to Implementation

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LAST DECEMBER, THE FIRST MAJOR PIECE of legislation reauthorizing and making changes at the National Institutes of Health (NIH) since 2006, called the 21st Century Cures Act, was signed into law. Final passage—by wide margins in both the House and Senate—was the culmination of at least 3 years of effort on the part of countless professional societies, organizations, and congressional staff. President Obama signed the bill on December 13.

I would like to give you a brief overview of some of the provisions in the Cures Act that affect *Eunice Kennedy Shriver* National Institute of Child Health and Human Development's (NICHD's) work, and then focus specifically on the implementation of a provision that is extremely important, especially to this audience—the mandate for a new task force on research specific to pregnant women and lactating women.

Public Law 114–255, which means that it was the 255th law passed by the 114th Congress, is to “accelerate the discovery, development, and delivery of 21st century cures.” After numerous hearings and briefings from NIH Director Francis Collins, other federal agencies, and patient organizations, many of the law's provisions are aimed at providing additional funding for the NIH and the Food and Drug Administration (FDA), and relieve certain administrative burdens for the agencies, to facilitate moving research results through the approval process toward cures for diseases.

Although the Cures Act is an “authorizing” bill (these are measures that make changes to federal programs but normally no funding is attached), the law does provide funding for several high-priority areas: at NIH, these include the Brain Research through Advancing Innovative Neurotechnologies (BRAIN), Precision Medicine Initiative (now renamed “All of Us”), the Cancer Moonshot that was headed by Vice President Biden, and Regenerative Medicine. Funding for these special projects comes from the United States' Strategic Petroleum Reserve, among others. Note that these are the only NIH projects that received funding through the Cures Act; any other required activities in the bill must come out of the agencies' regular budgets.

During the nearly 3-year course of hearings and debates on the Cures legislation, members of Congress made it very clear that a top priority is to maintain the pipeline of young researchers. That priority is reflected in several of the new law's provisions, such as the Next Generation Researchers

Initiative, EUREKA Prize Competitions that allows and encourages high-risk, high-reward research that might not otherwise make it through the rigorous peer review process, and increasing the cap on NIH's popular loan repayment program, which specifically includes young researchers who are engaging in clinical and pediatric work. In exchange for working in federal government for a period of time, a young scientist can now get her education loans repaid, tax free, up to \$50,000 a year.

With a lower public profile, but no less important for the scientists at NIH or receiving NIH grants, the Cures Act also increases the number of NIH scientists who may attend professional conferences (relieving a previously imposed limit), increases attention to financial conflicts of interest, aims to improve reporting of clinical trial results on clinicaltrials.gov, and authorizes the NIH Director to require grant recipients to share their data publicly.

Within this complex new law are five provisions that are highly pertinent to NICHD's research efforts. Three are already well underway. In brief, the requirement for a National Pediatric Research Network is being implemented by the NIH through the establishment of a new Pediatric Clinical Trials Network in 17 Institutional Development Award (IDeA) states around the country. A provision encouraging the NIH to establish a global pediatric network is being led by the FDA and a group from private industry. The revised authorization and new requirements for the National Center for Medical Rehabilitation Research within NICHD is being ably driven by Center Director Alison Cernich.

Implementation of two other provisions is at an earlier stage. Congress heard from numerous constituencies that women, children, racial, ethnic and sexual minorities, and older individuals should be appropriately included in clinical research. Although the NIH has policies in place to include individuals across the lifespan, clinical researchers have not always successfully included a wide range of people in their studies. The Cures Act requires the NIH to hold a workshop on inclusion of appropriate age groups (specific to pediatric and older populations): that workshop took place June 1–2, 2017. Informed by the findings from the workshop, the NIH Director is required to review current policies for any necessary changes to improve inclusion.

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Of most interest to the Academy is Section 2041 of the Cures Act, requiring the establishment of a new high-level task force on research specific to pregnant women and lactating women. This new body is charged with providing to the Secretary of Health and Human Services (HHS) guidance on gaps in knowledge and research regarding safe and effective therapies for use in these populations, and to make recommendations on actions that could be taken by HHS to address these gaps. The task force must report back to the Secretary and to Congress on its findings by September 2018; the Secretary must then decide whether changes need to be made to Federal regulations or other policies to address any identified issues. The task force sunsets (expires) within 2 years of establishment, but may be extended by the Secretary for another 2 years.

Credit for bringing the task force to fruition must be given to the non-Federal Coalition to Advance Maternal Therapeutics (CAMT). From conceptualization to implementation, the task force provides an excellent case study of how an idea becomes law, and then what happens afterward to turn the new mandate into substantive existence.

For many years, statistics had been reported that, on average, women take between three and five prescription medications during their pregnancies or while breastfeeding. Yet for liability and other reasons, very few pharmaceutical companies are willing to test new drug compounds in these populations. Although some research in this area is ongoing—some supported by NICHD—it does not cover the many medications used by pregnant or lactating women. Most medications are not labeled for use in pregnancy or lactation, and have not been thoroughly evaluated. Consequently, as a first step, the leadership of several relevant professional societies and research organizations decided to convene this coalition of groups interested in addressing this issue:

- Society for Maternal Fetal Medicine
- American Academy of Pediatrics
- American Congress of Obstetricians and Gynecologists
- March of Dimes
- Academy of Breastfeeding Medicine
- American College of Nurse-Midwives
- Association of Maternal & Child Health Programs
- Association of Women's Health, Obstetric, and Neonatal Nurses
- National Association of Nurse Practitioners in Women's Health
- Society for Women's Health Research

The next step, which can be a challenge given the varying agendas of member organizations, is to agree on a purpose for the coalition. CAMT developed and agreed upon guiding principles (www.smfm.org/advocacy/camt) that governed its subsequent activities, such as quality care and treatment for women and their infants, the need for evidence-based information about safety and efficacy of drugs used by pregnant and lactating women, and that government must conduct and prioritize clinical research on the effects of these drugs throughout pregnancy and lactation.

The task of any coalition seeking policy changes involves gathering the evidence and information to make recommendations for needed adjustments. In June 2014, CAMT held a meeting of stakeholders, including relevant Federal agencies,

including NICHD and other NIH Institutes and offices, the FDA, the Centers for Disease Control and Prevention, the Health Research and Services Administration, and other HHS offices. The meeting included an overview of the current state of research on therapeutics in pregnancy and breastfeeding, what roles agencies are playing, and a discussion of how awareness and education might be promoted.

Not every policy change involves the need for Congress to act. In many situations, ongoing efforts to work with decision-makers within Federal agencies or others can achieve the same goal. However, if congressional action is warranted, the next undertaking may be to find “champions,” that is, members of Congress who are willing to speak out and if necessary sponsor legislation. A bipartisan group of four members [Sen. Patty Murray (D-WA), Rep. Jaime Herrera Beutler (R-WA), Rep. Lucille Roybal-Allard (D-CA), and Rep. Kathy Castor (D-FL)] each played a role in the provision of the Cures Act that establishes the task force.

Introducing a piece of legislation is rarely sufficient to ensure passage. The CAMT continued to educate other members of Congress, their staff, and the public about the importance of medication use during pregnancy and breastfeeding. A briefing in mid-November 2016 highlighted personal experiences of several women, thus “putting a face on the issue,” focusing on the ongoing need for more complete information. Within a month, in December 2016, Congress passed the Cures Act with the task force provision included.

Implementing any new congressional directive that involves multiple agencies and offices can be challenging, particularly if legislatively set deadlines are involved. For example, NIH has a formal legislative implementation work group whose meetings are triggered by a new Federal law affecting the NIH. This group, comprising individuals from a variety of disciplines across the NIH, helps to decide which institute, center, or office should lead the implementation activities, including whether any changes to internal NIH policies or guidelines should be considered. Internal implementation plans are submitted by the lead IC to the NIH Director; the plan to implement the task force provision was submitted by NICHD in February 2017.

Since the Cures Act directed the Secretary of HHS to convene the task force, NIH requested a formal Delegation of Authority to establish and implement it. The statement transferring authority to the NIH for establishment of the task force was signed by the Secretary in January 2017; the authority to approve the non-Federal members was retained by the Secretary. Because of its research expertise in this area, NIH Director Francis Collins asked NICHD to spearhead the effort. NICHD's Deputy Director, Catherine Spong, an obstetrician-gynecologist and maternal-fetal medicine specialist, is leading the NICHD team to organize and run the task force. Meeting the congressional deadline, a formal charter establishing the task force was filed with HHS on March 13, 2017, and a slate of nominees has been prepared for the Secretary's approval that meets the requirements of the Cures Act legislation and the Federal Advisory Committee Act.

Initial plans include collecting and analyzing current data and enumerating Federal efforts on research related to medications used by pregnant women and lactating women. Each member agency will report on its relevant activities. At the NIH, new reporting categories are being developed for NIH's

public-facing Research Portfolio Online Reporting Tool: one on pregnancy and another covering breastfeeding, lactation, and breast milk. When they have been finalized, these new categories will be found at: (https://report.nih.gov/categorical_spending.aspx). This tool allows anyone to access the list of NIH-funded grants and contracts on any of about 250 research topics for the last complete fiscal year, including the lead investigator, institution, and funding level. The total dollars spent in each category are considered NIH's official budget numbers for these research areas, and the new categories will greatly enhance the task force's ability to determine whether there are gaps in NIH funding.

With the report and recommendations due to the Secretary by September 2018, the task force will be on a tight timeline. Four public 2-day meetings are being planned, all to be announced in the *Federal Register*. The first meeting will take place on the NIH campus in Bethesda, Maryland, in August 2017. Members of the public may attend, and with notice, may make brief remarks in addition to submitting written comments to the task force during its deliberations. To help publicize these meetings and other task force activities further, a web page has been created at: (www.nichd.nih.gov/about/advisory/PRGLAC/Pages/index.aspx).

Within a relatively short time, the task force on research specific to pregnant women and lactating women could make

a substantial contribution to the health of women and their infants.

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Disclosure Statement

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