



Society for
Maternal – Fetal
Medicine



Coalition to Advance



Maternal Therapeutics

Kathryn G. Schubert, MPP | Chief Advocacy Officer

How Did We Get Here?



December 13, 2016: President Obama Signs 21st Century Cures Act into Law



Identify the Problems



- **More women with chronic conditions are becoming pregnant.**
- **90% of pregnant women take at least one medication, with 70% taking at least one prescription drug during pregnancy.¹**
- **There is a lack of robust information on the safety and efficacy of many drugs across the continuum from pregnancy through breastfeeding.²**
- **Without reliable data, women may decide to stop taking necessary medications, not to initiate breastfeeding or wean earlier than desired.**
- **We need better and more information.**
- **How can the community impact this issue?**



1 Mitchell et al. "Medication use during pregnancy, with particular focus on prescription drugs: 1976-2008." *Am J Obstet Gynecol* 2011 Jul 205(1): 51.e1-8. 2

2 U.S. Food and Drug Administration, "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling," 2014

Like-Minded Organizations Come Together



Steering Committee is Formed



Society for
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Medicine

High-risk pregnancy experts

ACOG

THE AMERICAN CONGRESS
OF OBSTETRICIANS
AND GYNECOLOGISTS



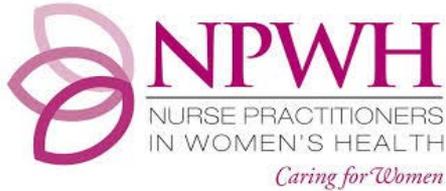
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A FIGHTING CHANCE FOR EVERY BABY™

American Academy of Pediatrics
DEDICATED TO THE HEALTH OF ALL CHILDREN™



Partners are Engaged



Society for Women's
Health Research



VACCINES AND MEDICATIONS IN PREGNANCY
SURVEILLANCE SYSTEM (VAMPSS)

Information Gathering



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



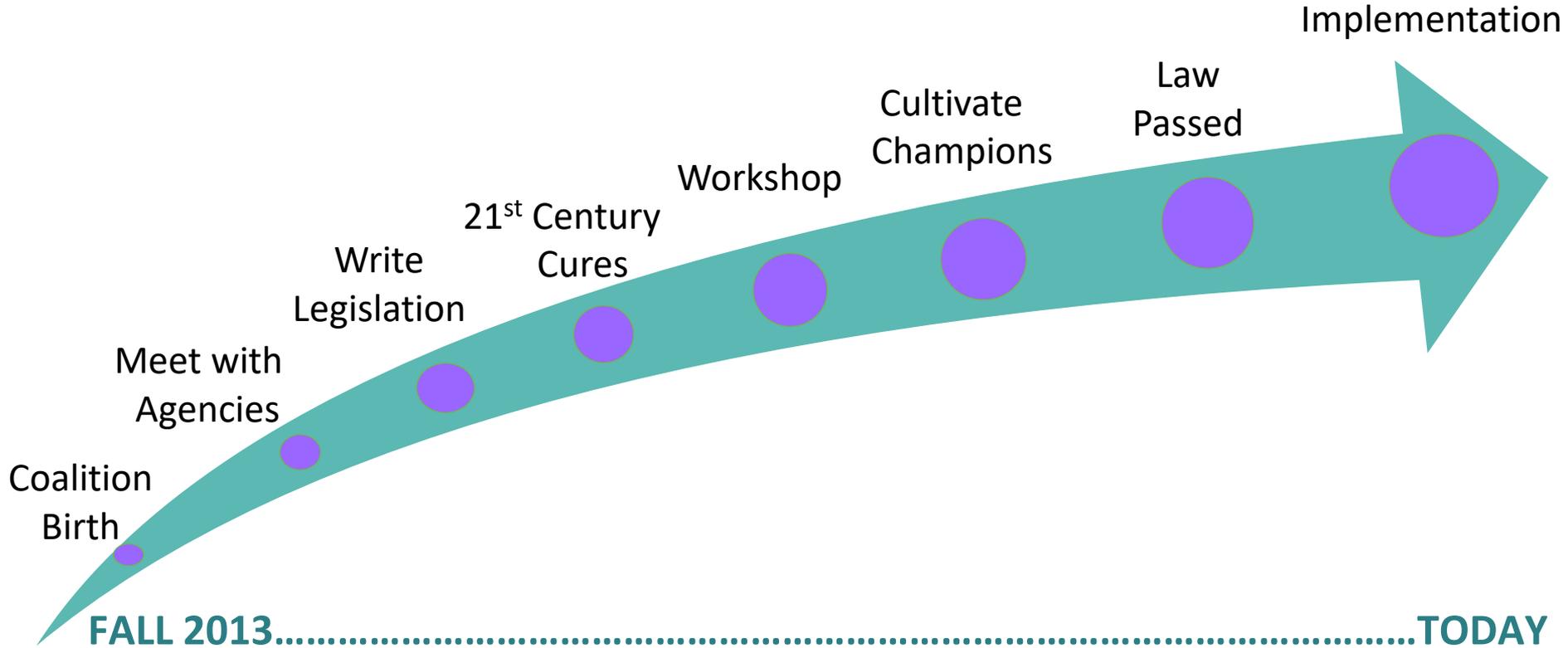
Coalition to Advance Maternal Therapeutics



- **Develop Guiding Principles**
- **Educate Legislators and Identify Champions**
- **Identify Legislative Vehicle**
- **Coalition Letters and Grassroots Advocacy**



Timeline



QUESTIONS?



Kathryn G. Schubert, MPP
Chief Advocacy Officer
Society for Maternal-Fetal Medicine
Phone: +1 (202) 517-6122
kschubert@smfm.org