



February 18, 2015

Ms. Samantha McKinley
Dept for Medicaid Services
275 E. Main Street, 6 WA
Frankfort, KY 40621

Dear Ms. McKinley,

As a collective voice of multidisciplinary practitioners concerned about fail first and step therapy practices, we encourage you to improve access to the only FDA-approved therapy for nausea and vomiting of pregnancy (NVP).

We are concerned because requiring patients to try and fail on one or more medications not indicated for a particular medical condition could jeopardize patient health and prolong suffering when access to care is delayed. Further, it subjects patients to unintended consequences associated with exposure to medications that may not have been well studied for use in treating a particular medical condition.

We would like to point you to new data that has arisen since our first communication. There are several reputable sources that address the safety risks associated with products used off-label to treat NVP. These are professional governing societies providing recommendations for pregnant women to use FDA-approved medications for NVP.

- The **Association for Women’s Health Obstetric and Neonatal Nurses** (AWHONN) February/March 2014 edition of *Nursing for Women’s Health* article, *A New Pharmacologic Treatment for Nausea and Vomiting of Pregnancy*¹

¹ <http://onlinelibrary.wiley.com/enhanced/doi/10.1111/1751-486X.12096/>

- The **Association of Professors of Gynecology and Obstetrics (APGO)**, *Educational Series on Women's Health Issues*, focusing on Nausea and Vomiting of Pregnancy²
- The **New England Journal of Medicine** March 20, 2014 perspective, *FDA Approval of Doxylamine–Pyridoxine Therapy for Use in Pregnancy*³
- The **Journal of Family Practice** February 2014 article, *Pharmacologic Management of Nausea and Vomiting of Pregnancy*⁴

Since NVP is a short term condition, it is important that we continue to work together ensuring pregnant women have immediate and uninterrupted access to appropriate medication. Please improve access to the only FDA-approved therapy for nausea and vomiting of pregnancy.

Respectfully Submitted,

National Perinatal Association

Bernadette Hoppe, M.A., J.D., M.P.H., President

Alliance for Patient Access

Brian Kennedy, Executive Director

American Sexual Health Association

Deborah Arrindell, Vice President, Health Policy

Center for Medicine in the Public Interest

Peter Pitts, President

Faith Community Nurses International

Beverly Siegrist, EdD, MS, RN, CNE, Chair

Healthy Mothers, Healthy Babies Coalition

Janice Frey-Angel, CEO

HealthyWomen

Beth Bettaglino, RN, President and CEO

Men's Health Network

Ana Fadich, MPH, CHES, Vice President

National Association of Hispanic Nurses

Jose Alejandra, PhD, RN-BC, MBA, CCM, FACHE, President

National Association of Perinatal Social Workers

Lisa Baker, Ph.D., L.C.S.W., P.I.P., President

US Pain Foundation

Paul Gileno, President and Founder

² <https://www.apgo.org/education/women/nausea-and-vomiting-of-pregnancy.html>

³ <http://www.nejm.org/doi/full/10.1056/NEJMp1316042>

⁴ <http://www.ifponline.com/index.php?id=21913>