Congress of the United States
Washington, DC 20515

August 25, 2015

Dr. Stephen Ostroff
Acting Commissioner of Food and Drugs
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Dear Dr. Ostroff:

We have been watching with great interest FDA's implementation of the Drug Quality and Security Act and are writing regarding concerns about patient access barriers for domperidone. As you may know, domperidone is a valuable therapeutic option for those who suffer from gastroparesis – a condition that causes delayed stomach emptying and can cause nausea, vomiting, abdominal pain, bloating, and malnutrition.

The health authorities of Canada, the United Kingdom, Germany and Australia have all approved a drug containing domperidone as the active ingredient for use in treating gastric disorders. Short of an invasive surgery, domperidone is often the last line of defense for gastroparesis.

Additionally, domperidone is prescribed "off-label" in many countries to breastfeeding mothers who are experiencing inadequate post-partum milk production. Breast milk is important in early child development and is recommended by the American Academy of Pediatrics as the primary form of nutrition for the first six months of life due to the improved health outcomes it provides. Domperidone has become the de facto "drug of choice" in these countries for the treatment of inadequate milk production because the only other drug shown to increase milk production, metoclopramide, presents many more risks to both mother and infant. Instead of putting mothers and infants at risk to the side effects of metoclopramide, domperidone is used with great success to help both mother and child.

FDA has not yet approved such a drug, and it is not available in the United States from manufacturers. Ensuring the continued availability of compounded domperidone is essential to patient health. Because domperidone is not a component of an FDA approved drug product and does not have a USP/NF monograph, currently, it must be on FDA's so-called "positive list" in order to be compounded. Our understanding is that the United States Pharmacopeia (USP) has elected not to move forward with a monograph for domperidone, at the request of FDA, because its consideration on the "positive list" is imminent.

Because the elongated timeframe for establishing this list is a threat to patient well-being, we respectfully request that FDA exercise enforcement discretion and allow the medication to be compounded. Further, given the patient need for this medication and to understand better FDA's thinking on the issue, please provide our offices with:

1. All records, regardless of format, and including electronic records and information, related to the risks associated with domperidone used in the treatment of gastroparesis and lactation;
2. All records, regardless of format, and including electronic records and information, related to the risks associated with domperidone passing through to breast milk and associated risks to infants who may ingest domperidone via this route; and
3. All records, regardless of format, and including electronic records and information, related to the Investigational New Drug (IND) program for domperidone including FDA's response time to each IND submission.

Please provide these records no later than September 15, 2015.

Thank you for your immediate consideration of this request. If you have questions about this and are unable to reach us, please have your staff contact Mary Dee Beal at mdb@mail.house.gov or 202-225-6531.

Sincerely,

Austin Scott

Member of Congress

Earl L. "Buddy" Carter

Member of Congress