PUBLIC COMMENT
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My name is Nathan Nelson, I work for Balchem Corporation. I am here today on behalf of a Prescription Prenatal Vitamin Coalition. As many of you know, prenatal vitamins are widely used in the pregnant population and are perhaps the most commonly prescribed therapy for this segment. What you may not know is that there are still some major barriers for pregnant women to gain access to prenatal vitamins. I'd like to highlight just four of these barriers: clinical research gaps, economic gaps, regulatory gaps and logistical gaps.

Clinical Research Gaps. As with other drug and non-drug therapies for our pregnant and lactating population, there is little to no clinical research that supports the benefits of prescription prenatal vitamin therapies. We need to change that. The coalition I represent asks the PRGLAC committee to emphasize in its report to Congress that not only are there major gaps in clinical research to support prescription drugs addressing conditions that patients may suffer from during their pregnancy, there are also major gaps in clinical research related to the condition of pregnancy itself. We need to close these gaps.

Economic Gaps. Prescription prenatal supplements that are manufactured to drug standards and promoted with extensive detailing to prescribing physicians sometimes differ in quality and certainly in cost to their over-the-counter cousins. The higher costs may have to do with the research, development, and promotion of these higher quality supplements. Unless patients have some type of insurance coverage for such prenatal supplements, they may be forced to purchase lower quality over-the-counter vitamins that may be manufactured merely to food or dietary supplement standards.

Regulatory Gaps. Prenatal vitamins are not "approved drugs" in accordance with FDA regulation. However, the FDA has informally stated that due to the longstanding safe and effective use of prenatal vitamins, it chooses to take no enforcement action against these drugs as a class. Because they are not approved "drugs" but rather prescription dietary supplements properly bearing a prescriptive legend, we hope that the Task Force will include in the scope of its report to Congress a review of prescription dietary supplements in addition to its review of prescription drugs. But there is a more worrying gap related to economics and to regulation, which I refer to as a "logistical gap."

Logistical Gaps. We have heard that some major payers have pressured a prescription compendium company to reclassify prenatal vitamins from their current reimbursable status to a non-reimbursable status. These intermediaries act as blockades in the logistics of manufacturing high quality prescription prenatal vitamins and getting them to end-users. We believe that any effort to limit patient access to this prescriptive category is contrary to the Secretary's work

ensuring the health of this population. We believe these third-party payers attempt to increase their own profits at the expense of expecting mothers and their babies and are putting many women and their babies at risk. They argue that expecting mothers should simply pay for over-the-counter vitamins out of their own pocket. But what of Medicaid patients who can't afford to do that? Do they just go without a prenatal supplement? The risk of neural tube defects rises significantly when pregnant women are not adequately supplemented. Expecting mothers need to supplement iron, folate, choline, vitamin B12 and DHA. The cost of ensuring that pregnant women continue to have coverage is negligible, especially compared to the costs on our health care systems to care for children born with neural tube defects.

These gaps are real and the risks they bring are too great to overlook. Thank you for your time and attention. Please let our Coalition know if we can help the Task Force in any way to ensure that it meets its goal to guide and advise the Secretary in protecting the health and well-being of pregnant and lactating Americans.