The American College of
Obstetricians and Gynecologists
WOMEN'S HEALTH CARE PHYSICIANS

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Agency for Healthcare Research and Quality
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Dear Ms. Chowdhury:

Thank you for the opportunity to review the U.S. Preventive Services Task Force's draft recommendation statement, "Breastfeeding: Primary Care Interventions." The College's Breast Feeding Expert Work Group reviewed the draft materials and provided input for our response. Founded in 2014 to develop accurate content and education and to continue to demonstrate the College's commitment to helping women achieve their goals for the best care possible for their newborns, the Work Group is comprised of experts in breastfeeding medicine.

Like the American Academy of Pediatrics and the United States Breastfeeding Committee, the College does not support the draft recommendation statement as is. The College has concerns about the change in tone and language in the new draft recommendation compared with the 2008 recommendation statement. We are concerned that these changes may compromise delivery of evidence-based care for mothers and infants.

Recommendation Language

While the 2008 statement recommends providing interventions during pregnancy and after birth "to promote and support breastfeeding," the draft 2016 recommendation statement instead recommends interventions "to support breastfeeding." This shift in language implies that women who have already decided to breastfeeding should receive support, but that breastfeeding should not be discussed with women who are undecided or who plan to formula feed. All women should be educated regarding the benefits of breastfeeding by their providers, rather than seeking knowledge from less objective sources. The rationale for this change is not clear and has the potential to negatively affect practice.

Effectiveness

The draft evidence review did not find an effect of breastfeeding interventions on *initiation* of breastfeeding. The absence of an effect on initiation may have led the Task Force to conclude that promotion of breastfeeding was not effective. However, the authors of the systematic review note that a ceiling effect may have precluded a finding of benefit:

> *Although power could be an issue, the relatively high control group initiation rates and the small overall benefit suggested by the pooled results are consistent with ceiling effects for breastfeeding initiation in women similar to those selected for these interventions. In all but four of these trials,[81, 116, 118, 126] more than 80 percent of enrolled women intended to initiate breastfeeding (range: 51.6% to 100%).*[1]

Furthermore, many of the interventions that increased ongoing breastfeeding rates incorporated promotion of breastfeeding. For example, in the BINGO and PAIRINGS trials[2], the intervention protocol included discussion of the benefits and risks of breastfeeding and formula for all participants, regardless of feeding intention. These trials were among the most effective of those analyzed for any breastfeeding at <3 months and any breastfeeding at 3-6 months. The evidence supports promotion, as well as support, for breastfeeding in primary care. **We request that the Task Force maintain the language from the 2008 recommendation in its updated recommendation statement: *The USPSTF recommends interventions during pregnancy and after birth to promote and support breastfeeding.***

Burden of Disease

In comparison with the 2008 recommendation, language regarding the burden of disease has shifted from "not breastfeeding is associated with health risks" to "a history of being breastfed has been found to be associated with a reduced risk…." The described differences in health outcomes for mothers include ovarian cancer, breast cancer, and diabetes. **We request that the Task Force also include an association with reduced maternal hypertension and myocardial infarction**[3,4,5,6,7], two conditions that confer substantial morbidity among adult women in the U.S.

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[1] http://www.uspreventiveservicestaskforce.org/Page/Document/draft-evidence-review149/breastfeeding-primary-care-interventions

[2] Bonuck K, Stuebe A, Barnett J, Labbok MH, Fletcher J and Bernstein PS (2014). "Effect of primary care intervention on breastfeeding duration and intensity." Am J Public Health 104 Suppl 1: S119-27.

[3] Bartick MC, Stuebe AM, Schwarz EB, Luongo C, Reinhold AG and Foster EM (2013). "Cost Analysis of Maternal Disease Associated With Suboptimal Breastfeeding." Obstet Gynecol 122(1): 111-119.

[4] Schwarz EB, Ray RM, Stuebe AM, Allison MA, Ness RB, Freiberg MS and Cauley JA (2009). "Duration of lactation and risk factors for maternal cardiovascular disease." Obstet Gynecol 113(5): 974-82.

[5] Stuebe AM, Michels KB, Willett WC, Manson JE, Rexrode K and Rich-Edwards JW (2009). "Duration of lactation and incidence of myocardial infarction in middle to late adulthood." Am J Obstet Gynecol 200(2): 138.e1-138.e8.

[6] Stuebe AM and Schwarz EB (2010). "The risks and benefits of infant feeding practices for women and their children." J Perinatol 30(3): 155-62.

[7] Stuebe AM, Schwarz EB, Grewen K, Rich-Edwards JW, Michels KB, Foster EM, Curhan G and Forman J (2011). "Duration of lactation and incidence of maternal hypertension: a longitudinal cohort study." Am J Epidemiol 174(10): 1147-58.

Health Disparities

We request that **data regarding disparities in breastfeeding initiation and duration** be included in the paragraph beginning "estimates for any breastfeeding of infants born in 2012…." Reducing these disparities has the potential to improve health equity for women and children of color.

Potential Harms of Interventions to Support Breastfeeding

The draft recommendation statement notes that only two trials reported data on potential harms of interventions: one trial found no difference in anxiety symptoms; the other "reported that a few mothers expressed feelings of anxiety and decreased confidence in their breastfeeding ability despite breastfeeding going well and discontinued their participation in the peer counseling intervention." This statement implies that the breastfeeding support intervention induced anxiety in multiple women. We are concerned that this statement is misleading, and does not reflect the actual results reported in the source study:

> *Of the 130 mothers in the experimental group who completed the questionnaire, 9 indicated that they were not satisfied with their peer support experience; most of these mothers would have liked their peer volunteer to have telephoned more frequently. However, a few mothers responded that they did not like a specific aspect of their peer volunteer. For example,* ***only 1 mother requested to discontinue her participation in the intervention****, stating that the peer volunteer frightened her about the potential hazards of not breast-feeding. The peer volunteer's comments made her anxious and diminished her feelings of confidence, despite the fact that breast-feeding was going well. Another mother felt her right to confidentiality was violated when her peer volunteer contacted the public health department without her consent. Although this mother did require professional assistance, the peer volunteer should have discussed the referral with the new mother. These negative experiences necessitate attention in the development of future peer support interventions and can be easily addressed in the orientation session* [emphasis added].[8]

Although the draft recommendation statement language states that "a few mothers expressed feelings of anxiety," in fact, only 1 of 130 women reported feeling anxious due to her participation in the intervention. We request that the wording of "Potential Harms of Interventions to Support Breastfeeding" be revised to accurately reflect this evidence. For example: *There are very little data on the potential harms of interventions to support breastfeeding, which in theory could include guilt and anxiety. Only two trials reported on*

[8] Dennis CL, Hodnett E, Gallop R and Chalmers B (2002). "The effect of peer support on breast-feeding duration among primiparous women: a randomized controlled trial." Cmaj 166(1): 21-8.

potential adverse events related to a breastfeeding support intervention. One trial (N=514) found no significant differences in maternal anxiety between groups at 2 weeks. The other trial (N=258) reported that one mother among 130 randomized to a peer support intervention stated that the peer volunteer frightened her about the potential hazards of not breastfeeding, and these comments decreased her confidence in her breastfeeding ability despite breastfeeding going well. She therefore discontinued her participation in the peer counseling intervention.

We further encourage the Task Force to restore the language from the 2008 recommendation with respect to the importance of patient-centered health promotion:

> *Breastfeeding interventions, like all other health care interventions designed to encourage healthy behaviors, should aim to empower individuals to make informed choices supported by the best available evidence. As with interventions to achieve a healthy weight or to quit smoking, breastfeeding interventions should be designed and implemented in ways that do not make women feel guilty when they make an informed choice not to breastfeed.*[9]

The Influence of Formula Marketing

We were pleased to see that the College's recent Committee Opinion #658 was cited in this draft recommendation. However, we are concerned that the pervasive influence of infant formula marketing was not addressed. As noted in the Committee Opinion:

> *Families should receive noncommercial, accurate, and unbiased information so that they can make informed decisions about their health care. Obstetric care providers should be aware that personal experiences with infant feeding may affect their counseling. In addition, pervasive direct-to-consumer marketing of infant formula adversely affects patient and health care provider perception of the risks and benefits of breastfeeding.*[10]

In the 2005-2006 Infant Feeding Practices Survey II, 57.4% of participants reported having received a free formula sample in the mail by the time their baby was 1 month old.[11] Powdered infant formula sales in the U.S. total $3.2 billion per year[12], and formula companies spend 10-

[9] http://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/breastfeeding-counseling

[10] American College of Obstetricians and Gynecologists (2016). "Optimizing support for breastfeeding as part of obstetric practice. Commitee Opinion No. 658." Obstet Gynecol 127: e86-92. http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Obstetric-Practice/Optimizing-Support-for-Breastfeeding-as-Part-of-Obstetric-Practice

[11] Centers for Disease Control and Prevention. "2.19 Percent of mothers who received free samples of infant formula through the mail by selected demographics." http://www.cdc.gov/ifps/results/ch2/table2-19.htm.

[12] Grocery Headquarters. (2016). "Sales of the leading baby formula (powder) brands of the United States in 2016 (in million U.S. dollars)." http://www.statista.com/statistics/186157/top-powdered-baby-formula-brands-in-the-us/

15% of their net sales on advertising and promotion.[13] Conservatively, formula manufacturers spend $320 million (10% of net sales) each year marketing infant formula; this is more than 4 times the $68 million in total U.S. federal government expenditures for breastfeeding promotion and support. Rising breastfeeding rates are a well-recognized threat to formula manufacturers' financial bottom line. This sentiment was expressed by a recent CEO statement:

> *The start to the year in our U.S. business was affected by market share losses from the highs we saw in the middle of 2015.* ***On a positive note, we believe the strengthening labor market and workforce participation rates have caused a rise in breastfeeding rates to level off*** *over the last four months or so [emphasis added].*[14]

We request that the Task Force explicitly address the impact of formula marketing and the importance of non-commercial, unbiased information to enable each mother to make an informed decision regarding how to feed her infant.

The College thanks the Task Force for allowing us the opportunity to review and comment on the draft recommendation. Please don't hesitate to contact us with questions or for additional information.

Sincerely,

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Lauren E. Hanley, MD, IBCLC
Chair, ACOG Breast Feeding Expert Work Group

cc: Debra Hawks, Caitlin Phelps, Nancy O'Reilly, Rachel Gandell, Kathryn Moore, Elizabeth Wieand, Mary Schilling, Carla Wojnaroski, Kate Connors, Amanda Guiliano, Alison Stuebe, MD

[13] Piwoz EG and Huffman SL (2015). "The Impact of Marketing of Breast-Milk Substitutes on WHO-Recommended Breastfeeding Practices." Food Nutr Bull 36(4): 373-86.

[14] Seeking Alpha Transcripts. (2016). "Mead Johnson Nutrition (MJN) Peter Kasper Jakobsen on Q1 2016 Results - Earnings Call Transcript " http://seekingalpha.com/article/3969332-mead-johnson-nutrition-mjn-peter-kasper-jakobsen-q1-2016-results-earnings-call-transcript?app=1&auth_param=194o02:1bi5ips:94f548e697f06411e884bc95e22f5167&uprof=38&dr=1.