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Expression of Concern

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Abstract:	

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3 Expression of Concern regarding reporting of adverse events in the article “Bivalent Prefusion F
4 Vaccine in Pregnancy to Prevent RSV Illness in Infants” (1).

5 The article states “Among the infant participants, the incidences (sic) of adverse events of special
6 interest (Fig. 4B) and newly diagnosed chronic medical conditions (Fig. S1) were similar in the
7 two groups.
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9 One of the adverse events of special interest designated in the trial protocol was “preterm birth”.
10 The incidence of preterm birth was 19% greater in the babies of vaccinated mothers.

11 It is misleading to state that the incidence in the two groups was “similar”.

12 The Risk Summary contained in Pfizer’s drug label for this vaccine (2) contains the following
13 statement:

14 “In this study, there was a numerical imbalance in preterm births, with more preterm infants born
15 to individuals in the ABRYSSVO group compared to individuals in the placebo group”.
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18 The authors’ conclusion that “No safety concerns were identified” is unjustifiable and should be
19 corrected.
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