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In Reply

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Thank you for the opportunity to respond to this letter regarding our recent publication about the frequency of pregnancy testing when reproductive-aged women are administered or prescribed Category D or X medications in the emergency department. The authors' letter questions the accuracy of the FDA Pregnancy risk categorization system and cites the recent ruling passed on December 3, 2014 by the FDA to create a replacement of the current product letter categories (A, B, C, D, X) with three detailed subsections that describe risks "within the real-world context of caring for pregnant women who may need medication." It is important to note that the ABCDX *FDA classification system is currently the only source of medication classification in healthcare practice*. We did acknowledge in our manuscript that some population-based studies have failed to find associations of major congenital malformations with the use of Category D or X antibiotics and benzodiazepines. However, there are significant limitations to these studies. Congenital malformations are sufficiently rare that even population-based studies may fail to detect a harm signal. In addition, these studies provide insufficient data on pregnancy terminations. Furthermore, we also note that even when risk for congenital malformation risk may be low after drug exposure, knowledge of potential for teratogenic risk may cause undue stress and even termination of pregnancy with inadvertent exposure. Therefore, we stand by our contention that until the FDA changes are put into effect, healthcare professionals should exercise caution and should perform inexpensive and non-invasive pregnancy testing. From an ethical standpoint, we believe there is an obligation to discuss the potential for teratogenicity when administering or prescribing medications that have been labeled Category D or X by the FDA.