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Drug-induced cardiac abnormalities in premature infants and neonates

The Cardiac Safety Research Consortium (CSRC) is a transparent, public-private partnership that was established in 2005 as a Critical Path Program and formalized in 2006 under a Memorandum of Understanding between the United States Food and Drug Administration and Duke University. Our continuing goal is to advance paradigms for more efficient regulatory science related to the cardiovascular safety of new therapeutics, both in the United States and globally, particularly where such safety questions add burden to innovative research and development. This presentation is a summary of a White Paper that provided a summary of discussions by a cardiovascular committee cosponsored by the CSRC and the US Food and Drug Administration (FDA) that initially met in December 2014 and periodically convened at FDA's White Oak headquarters from March 2015 to September 2016. The committee focused on the lack of information concerning the cardiac effects of medications in the premature infant and neonate population compared with that of the older pediatric and adult populations. Key objectives of this presentation are as follows: Provide an overview of human developmental cardiac electrophysiology, as well as the electrophysiology of premature infants and neonates; summarize all published juvenile animal models relevant to drug-induced cardiac toxicity; provide a consolidated source for all reported drug-induced cardiac toxicities by therapeutic area as a resource for neonatologists; present drugs that have a known cardiac effect in an adult population, but no reported toxicity in the premature infant and neonate populations and summarize what is not currently known about drug-induced cardiac toxicity in premature infants and neonates and what could be done to address this lack of knowledge. This presentation presents the views of the authors and should not be construed to represent the views or policies of the FDA or Health Canada.

Biography

Luana Pesco Koplowitz is a Chief Medical and Scientific Officer, received her MD from Rutgers Medical School and her PhD from Rutgers College of Pharmacy and Columbia Pacific University. She has completed her training in Clinical Pharmacology at the University of Miami, School of Medicine. She is an Adjunct Professor of Medicine, Department of Internal Medicine at the Medical Center of Delaware and is also Adjunct Faculty at the University of Miami, USA. She is a Fellow of the American College of Clinical Pharmacology and the Faculty of Pharmaceutical Medicine in UK. She is the President and Chief Medical and Scientific Officer of Duck Flats Pharma, LLC, USA. Previously, she was Chief Medical and Scientific Officer of Research Assist, Inc. She also held the position of Global Group Director of Clinical Pharmacology and US Nonclinical Development for the Janssen Research Foundation of Johnson & Johnson. She has been responsible for numerous successful INDs and NDAs during her 22-year career and holds several use patents in the treatment of various diseases. She has personal interests in the areas of overall drug development, PK/PD modeling and drug-drug interactions, receptor-binding modeling and special population clinical trials, especially pediatric, elderly and critical-care patients.

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