

and ethionamide should be included in any list of drugs that may cause hypothyroidism.

Marie E. McDonnell, M.D.

Lewis E. Braverman, M.D.

John Bernardo, M.D.

Boston Medical Center
Boston, MA 02118
marie.mcdonnell@bmc.org

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Gestational Exposure to Lovastatin Followed by Cardiac Malformation Misclassified as Holoprosencephaly

TO THE EDITOR: In 2004, we reported central nervous system and limb anomalies that followed exposure to statin drugs in the first trimester of pregnancy (April 8, 2004, issue).¹ One case, in which there had been exposure to lovastatin, was described as involving holoprosencephaly on the basis of three separate reports of a "cerebral/brain ventricular septal defect," with accompanying cardiac malformations that had been submitted to the Food and Drug Administration adverse-event database. We recently learned that the manufacturer considered the structural anomalies to be solely cardiac, and therefore we requested source documentation to clarify the conflicting reports. A detailed clinical report that was located among archival documents clearly described an atrial septal defect, a ventricular septal defect, and aortic hypoplasia leading to cardiac failure, with secondary central nervous system dys-

function. It was apparent that a data-extraction error had occurred, incorrectly categorizing the ventricular septal defect as an intracranial anomaly. Correcting this misclassification reduces our reported number of lovastatin-exposed fetuses with midline central nervous system anomalies from three to two. We still believe that the preponderance of the evidence supports the hypothesis that early gestational exposure to statin drugs may be teratogenic and that prospective studies should be initiated.

Robin J. Edison, M.D., M.P.H.

Maximilian Muenke, M.D.

National Institutes of Health
Bethesda, MD 20892-3717
rmuenke@nih.gov

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