

**2004N-0337 - (Subpart D IRB Referral) Solicitation of Public Review and Comments on
Research Protocol: Effects of a Single Dose of Dextroamphetamine in ADHD; A Functional
Magnetic Resonance Study**

FDA Comment Number : EC2

Submitter : Dr. Ellen Bernal

Date & Time: 09/01/2004 09:09:50

Organization : Dr. Ellen Bernal

Individual Consumer

Category :
Issue Areas/Comments

GENERAL

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I am the parent of a child with ADHD and have experience as Chair of an Institutional Review Board. My comments are made as an individual consumer. This study seems to have the possibility of great scientific benefit with respect to the causes, diagnosis, and treatment of ADHD. This disorder poses significant challenges to many children and their families. Studies such as this may also help distinguish between appropriate medical uses of dextroamphetamine and more questionable uses that fall under the category of 'enhancement.' A single dose of dextroamphetamine is unlikely to be harmful; further there are safeguards in place. The child and/or parent/guardian may discontinue participation at any time and the consent documents are clear.

The payment amounts are not too high, but you might wish to consider making sure that the payments are given in such a way to benefit the children directly, for example a savings bond or gift certificate to a bookstore, etc.

For children with ADHD, I would consider this study as a minor increase over minimal risk, within the range usually borne by children with the disease, with an offsetting societal benefit that could not otherwise be gained. For the normal controls, the risk is greater than minimal in that they would not receive the medication or fMRI in normal life.

However, it is unlikely that a single dose of dextroamphetamine would cause harm, and again, safeguards are in place. I would encourage approval of this study.