AACAP Member Email on Psychiatric Medication

Recently, the FDA has issued a statement on its Canadian counterpart's decision to suspend sales, but not revoke the approval in Canada, of the drug Adderall XR as a treatment for ADHD. The FDA is not changing the status of Adderall XR in the USA, but is continuing to monitor MEDWATCH surveillance data. This message is to share both the FDA statement and Health Canada's decision, and also to indicate that the AACAP agrees with the FDA's assessment that sufficient data are lacking at this time to infer causality between the medication and the sudden unexplained deaths (SUDs). The statements in the press and from the FDA are included below.

As with previous announcements regarding the use of medications in treating children and adolescents with mental illnesses, AACAP members are advised to:

- Include a thorough psychiatric and medical history in the context of a comprehensive evaluation when a child presents with symptoms for ADHD or any other disorder,
- Continue your practices as before without immediate changes based on the FDA's report stating that 12 youths experiencing sudden unexplained death (population rate for the SUDs is 1/100,000) is too low a rate to determine a causal link between the drug and the deaths,
- Describe and discuss with parents/guardians and with the child or adolescent patient the risks and benefits of any treatment, including treatment with medication, and
- Monitor the patient on a schedule that reflects his or her needs and medical history.

The AACAP will be providing additional information on this new FDA statement in the future. The FDA and Canadian statements can be accessed from the FDA website, www.fda.gov. Additional information on children's psychotropic medications is available on the AACAP website, www.aacap.org, and www.parentsmedguide.com.

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