

## ABSTRACT

Sarah D. Gordon

*Antidepressants and Teen Suicide: An Analysis of the FDA's Regulation of Pharmaceuticals for Use in Pediatric Patients*

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Abstract by Andrew Guhr

In this Comment, Gordon takes issue with the FDA's failure to act in a timely manner, when faced with a link between antidepressant prescription and suicide in teenagers. Despite well-documented evidence that antidepressants are ineffective in that population, the FDA failed to adequately distribute that information to doctors and patients. Moreover, the FDA failed to require "black box" warnings on packaging until teen-suicide rates hit crisis levels, despite early evidence of the possibility. Gordon suggests that the reactionary nature of FDA review in this area and the lack of pediatric drug testing are to blame.

Gordon finds particular fault with the FDA's scheme for pediatric testing of drugs already on the market. Congress recently mandated pediatric testing for most new drugs, but those currently available are generally excepted. Despite the lack of testing, doctors are permitted to prescribe these drugs on an "off-label" basis to untested populations. Since a lack of information does not bar doctors from prescribing these drugs, the manufacturers have little incentive to conduct costly research into the possible effects.

The author concludes that the FDA must take more proactive steps to protect children from these untested drugs. She suggests that the FDA must become more transparent in reviewing drug reports through a peer-review system. Moreover, she suggests that "off-label" prescribing should be suppressed as much as possible, so that drug manufacturers must conduct requisite testing before their drugs are introduced into pediatric populations.