Black Box Warning Did Not Cause Increased Suicides

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In their article "Increases in suicide deaths among adolescents and young adults following US Food and Drug Administration antidepressant boxed warnings and declines in depression care" Lu et al. claimed that the suicidality Black Box Warning for antidepressants led to decreased treatment of depression, which caused a high number of excess suicides among adolescents and young adults in the United States (1).

Treatment of youth depression has actually not substantially decreased since the Black Box warning. Lu et al. found a decrease in antidepressant treatment of less than one percentage point among children and adolescents from 2000 to 2010 (2). Kafali et al. found that antidepressant prescription rates for youth returned to prewarning levels by 2009 (3). Among parents who indicated that their child had severe impairment on the Columbia Impairment Scale, there was no decrease in antidepressant prescriptions after the warning. Valluri et al. examined changes in antidepressant prescribing from 2004 to 2006 and found that adolescents with major depressive disorder did not experience a decrease in antidepressant treatment (4). Rather, decreases in antidepressant prescribing occurred among those with major depression not otherwise specified and dysthymia diagnoses.

Furthermore, Plöderl & Hengartner found a strong correlation between increased self-reported antidepressant use and more self-reported suicide attempts between 2004 and 2016 among adolescents (5). However, population-wide associations between antidepressant prescribing and suicides cannot establish causality, due to an inability to control for extraneous variables which may influence suicide rates (6). There are better ways to demonstrate whether a drug causes suicidality, such as the placebo-controlled trials that originally led to the FDA warning (7). In sum, the evidence does not support Lu et al.'s (1) contention that regulatory warnings led to decreased treatment, which then led to increased suicides.

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REFERENCES

- Lu CY, Penfold RB, Wallace J, et al. Increases in suicide deaths among adolescents and young adults following US Food and Drug Administration antidepressant boxed warnings and declines in depression care. Psychiatr Res Clin Pract 2020;2:43-52
- Lu CY, Zhang F, Lakoma MD, et al. Changes in antidepressant use by young people and suicidal behavior after FDA warnings and media coverage: quasi-experimental study. BMJ 2014;348: g3596
- Kafali N, Progovac A, Hou SS-Y, et al. Long-run trends in antidepressant use among youths after the FDA Black Box warning. Psychiatr Serv 2018;69:389–395
- Valluri S, Zito JM, Safer DJ, et al. Impact of the 2004 Food and Drug Administration pediatric suicidality warning on antidepressant and psychotherapy treatment for new-onset depression. Med Care 2010;48:947–954
- Plöderl M, Hengartner MP. Antidepressant prescription rates and suicide attempt rates from 2004 to 2016 in a nationally representative sample of adolescents in the USA. Epidemiol Psychiatr Sci 2019;28:589–591
- Spielmans GI, Spence-Sing T, Parry P. Duty to warn: antidepressant black box suicidality warning is empirically justified. Front Psychiatry 2020;11:18
- Hammad TA. Relationship between psychotropic drugs and pediatric suicidality. Food and Drug Administration. 2004. https:// www.dropbox.com/s/gto5w4qcumk9hic/2004%20FDA%20Hammad. pdf?dl=0