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Prozac Is Unsafe and Ineffective for Young People, Analysis Finds

PREMIUM HEALTH VIEWPOINTS

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A [new analysis](#) finds that Prozac (generic name fluoxetine) is unsafe and ineffective for treating depression in children and adolescents.

Regulatory documents show that trial participants attempted suicide after taking fluoxetine, but these events were excluded from the final journal publication in the Archives of General Psychiatry.

I notified the journal of the new findings, but the editor refused to correct the record.

Prozac Approval

In 2002, Prozac (fluoxetine), manufactured by Eli Lilly, was FDA-approved for treating depression in children and adolescents based on data from two clinical trials.

The two trials were published in peer-reviewed journals in 1997 ([Study 1](#)) and 2002 ([Study 2](#)).

Both publications reported a small benefit of fluoxetine over placebo in young people with depression, and there appeared to be no significant safety concerns.

Subsequently, fluoxetine became one of the most prescribed antidepressants for children [aged 8 to 19](#) and under in the United States and is among the top five most prescribed [antidepressants in England](#).

Restoring Old Trials

An initiative called [Restoring Invisible and Abandoned Trials](#) (RIAT) has enabled researchers to “restore” old clinical trial publications by analyzing documents submitted to drug regulators by drug companies.

These analyses have revealed that serious drug harms are underreported or excluded entirely from medical journals.

Dr. Peter Gøtzsche and psychiatrist David Healy obtained regulatory documents (protocols and clinical study reports) from the UK’s drug regulator (MHRA) of the two fluoxetine trials that underpinned the drug’s approval in 2002.

 Epoch Times Photo

(Maryanne Demasi’s Substack)

The Discrepancies

Multiple problems were identified when Gøtzsche and Healy compared the clinical study reports of the two fluoxetine trials with those published in the medical journals.

Many suicidal events in people taking fluoxetine were either missing or mislabeled in the published reports.

For example, in Study 1, the clinical report described two patients who’d attempted suicide after 12 and 15 days of taking fluoxetine, but these events were excluded from the journal article.

Gøtzsche and Healy found problems with “blinding” in both trials, meaning the trial investigators were likely aware of which patients were on the drug or the placebo.

They also found that people recruited into the trial and who were already taking an antidepressant were only given one week to “wash out” the drug from their systems before commencing the randomization process.

This caused [severe withdrawal](#) symptoms in some participants who ended up in the placebo group, making it difficult to ascertain the true level of harm in the treatment group.

Finally, when Gøtzsche and Healy looked back and analyzed the data from the primary outcome—depression—there was no meaningful benefit from fluoxetine compared to placebo.

Journals Turn a Blind Eye?

[I wrote](#) to both journals asking if the editors would consider correcting the discrepancies and delineating the adverse events not reported in the published articles through an erratum.

Neither journal has done so.

The editor at the Archives of General Psychiatry (now called JAMA Psychiatry) rejected concerns about two suicide attempts omitted from its publication of Study 1 and has not made any corrections or clarifications.

In response, Gøtzsche said, “It’s totally unacceptable. When attempted suicides are left out of journal articles, which has happened in many such trials, it changes the safety profile of the drugs completely. This is important information that patients should know about before considering taking the pills.”

Gøtzsche drew similarities to another placebo-controlled trial in adolescents using Paxil (paroxetine).

GSK’s (formerly GlaxoSmithKline) [Study 329](#) famously claimed that “paroxetine is generally well tolerated and effective,” but when researchers [restored the trial data](#) using regulatory documents, the opposite became true.

“A restoration of the data from Study 329 showed that paroxetine was neither safe nor effective for treating depression in children and adolescents,” said Gøtzsche.

“Many suicidal events on paroxetine had been omitted or given an obscure name such as emotional lability. I consider this fraud,” he added.

The editor of the Journal of American Academy of Child and Adolescent Psychiatry (JAACAP), which published Study 2 on fluoxetine, said the journal would not respond to criticisms until the discrepancies documented by Gøtzsche and Healy were published in a peer-reviewed journal.

The process took over a year, but Gøtzsche and Healy’s paper has now been published in a peer-reviewed journal and sent to the JAACAP for review.

The JAACAP said in a statement:

“JAACAP takes seriously its responsibility to ensure scientific integrity. As stated in the guide for authors, review of post-publication critiques will be managed according to Committee on Publication Ethics (COPE) guidelines. We will let you know the outcome of the review process.”

Why Does It Matter?

The restoration of old trials has revealed to patients and physicians that much of the data in peer-reviewed journals is incomplete, biased, and often cherry-picked.

The exclusion of suicide attempts and suicides distorts the medical literature and prescribing guidelines to the extent that they cannot be trusted. It also may reduce options for safer, more effective interventions such as psychotherapy.

“I’ve heard from many families whose children committed suicide because of antidepressants. We should not be prescribing them to young people,” said Gøtzsche.

“Our [meta-analysis](#) of 10 trials showed that psychotherapy halved the occurrence of new suicide attempts in patients admitted after a suicide attempt. Psychotherapy is what they should be getting, not pills,” he added.

Ultimately, it’s the patients who pay the price, sometimes with their lives, from distorted clinical data and from journals that refuse to correct glaring errors.

Antidepressants like fluoxetine double the risk of [suicide and aggression](#) in children and adolescents, often lead to decreased quality of life, cause sexual dysfunction in [about 50 percent](#) of users, and these harms may continue long after patients try to quit.

In conclusion, there seems to be no rationale for using fluoxetine in young people to treat depression. This new analysis concludes the drug is unsafe and ineffective.

Disclosure: *I received funding from the RIAT Support Center for publishing two Expressions of Concern in 2021.*

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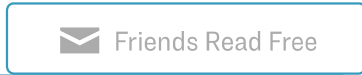
[Prozac](#)[antidepressants](#)[Adolescent psychology](#) Maryanne Demasi**Maryanne Demasi**

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Maryanne Demasi is an investigative medical reporter with a PhD in rheumatology, who writes for online media and top tiered medical journals. For over a decade, she produced TV documentaries for the Australian Broadcasting Corporation (ABC) and has worked as a speechwriter and political advisor for the South Australian Science Minister. Her work can be accessed on: MaryanneDemasi.Substack.com

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