



Lack of Effectiveness and Harm of Psychiatric Medication
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General Lack of Effectiveness

2015 - After actual clinical trial data was altered by the pharmaceutical company Glaxo Smith Kline to show non-existent safety and effectiveness of paroxetine (Paxil) for adolescents with depression, and then an article was ghost written¹ by the company using a number of prominent child psychiatrists who allowed their names to be used as authors,² a group of top independent clinicians re-analyzed the original data and found the following, published in the British Medical Journal:³

Results: “The efficacy of paroxetine and imipramine was not statistically or clinically significantly different from placebo for any prespecified [sic] primary or secondary efficacy outcome. . . There were clinically significant increases in harms, including suicidal ideation and behaviour [sic] and other serious adverse events in the paroxetine group and cardiovascular problems in the imipramine group.”

Conclusions: “Access to primary data from trials has important implications for both clinical practice and research, including that published conclusions about efficacy and safety should not be read as authoritative. The reanalysis of Study 329 illustrates the necessity of making primary trial data and protocols available to increase the rigour [sic] of the evidence base.”

¹ Evidence of ghost writing documented in this letter from Vera Sharav, president of the Alliance for Human Research Protection to FDA Commissioner Andrew Eschenbach (4/25/08) available at <http://ahrp.org/wp->

² Keller MB, Ryan ND, Strober M, Klein RG, Kutcher SP, Birmaher B, Hagino OR, Koplewicz H, Carlson GA, Clarke GN, Emslie GJ, Feinberg D, Geller B, Kusumakar V, Papatheodorou G, Sack WH, Sweeney M, Wagner KD, Weller EB, Winters NC, Oakes R, McCafferty JP. "Efficacy of Paroxetine in the Treatment of Adolescent Major Depression: A Randomized, Controlled Trial" *J. Am. Academy Child Adolescent Psychiatry*, 2001; 40(7):762-72, abstract available at <https://www.ncbi.nlm.nih.gov/pubmed/11437014>

³ Le Noury, J; Nardo, J; Healy, D; Jureidini, J; Raven, M; Tufanaru, C; Abi-Jaoude, E. "Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence" *British Medical Journal* (9/16/2015), abstract available at <https://www.bmj.com/content/351/bmj.h4320> as discussed at Sharav, V. "May 2016: The State of Psychiatry — Child Psychiatrists at APA Meeting" Alliance for Human Research Protection (7/10/2016) available at <http://ahrp.org/june-2016-the-state-of-psychiatry-revealed-at-2-different-meetings-of-psychiatrists/>

2013 – “The study, in the journal JAMA Psychiatry, found that **55 percent of suicidal teenagers had received some therapy before they thought about suicide, planned it or tried to kill themselves, contradicting the widely held belief that suicide is due in part to a lack of access to treatment.**⁴” **This also shows that most psychiatric treatments are not helpful for depression**, especially antidepressants that can cause suicide separate from depression, as well as homicidal rages, and many other potentially life-threatening side effects.

2013 – Former director at the National Institutes of Mental Health and neuroscientist, Dr. Steve Hyman, said, “...**many patients with mental disorders remain symptomatic and often disabled despite existing treatments.** For some significantly disabling conditions, such as the core social deficits of autism and the cognitive impairments of schizophrenia, there simply are no effective treatments.”⁵

2010 – “**Conclusions: The magnitude of benefit of antidepressant medication compared with placebo increases with severity of depression symptoms and may be minimal or nonexistent, on average, in patients with mild or moderate symptoms.** For patients with very severe depression, the benefit of medications over placebo is substantial.”⁶

2010 – “The research had shown that antidepressants help about three quarters of people with depression who take them, a consistent finding that serves as the basis for the oft-repeated mantra "There is no question that the safety and efficacy of antidepressants rest on solid scientific evidence," as psychiatry professor Richard Friedman of Weill Cornell Medical College recently wrote in The New York Times. But ever since a seminal study in 1998, whose findings were reinforced by landmark research in The Journal of the American Medical Association last month, that evidence has come with a big asterisk. **Yes, the drugs are effective, in that they lift depression in most patients. But that benefit is hardly more than what patients get when they, unknowingly and as part of a study, take a dummy pill— a placebo. As more and more scientists who study depression and the drugs that treat it are concluding, that suggests that antidepressants are basically expensive Tic Tacs.**”⁷ [Time Magazine Review of study immediately above

⁴ Carey, B. “Study Questions Effectiveness of Therapy for Suicidal Teenagers” (1/8/13) *New York Times* at <https://www.nytimes.com/2013/01/09/health/gaps-seen-in-therapy-for-suicidal-teenagers.html> discussing Nock, M. et. al. “Prevalence, Correlates, and Treatment of Lifetime Suicidal Behavior Among Adolescents: Results From the National Comorbidity Survey Replication Adolescent Supplement” *JAMA Psychiatry* (3/2013) at <https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1555602?resultClick=1>

⁵ <http://dana.org/Cerebrum/Default.aspx?id=39489>

⁶ <http://jama.ama-assn.org/cgi/content/abstract/303/1/47>

⁷ Begley, Newsweek, 1/30/10, <http://www.newsweek.com/id/232781>

2005 – “Dr. Jeffrey Lieberman, the principal investigator of the NIMH schizophrenia study (known as CATIE), is quoted in the WS Journal stating: **‘Clinicians are just basically practicing seat-of-their-pants pharmacology based on their experience with patients.’** Clinicians are indeed skating on thin ice by prescribing drugs whose ill effects outweigh any perceived benefit—mostly attributable to the placebo effect. The prescribing of these drugs widely and in multiples—all at public expense—lacks clinical justification. According to the Wall Street Journal, even before the schizophrenia trial results have been fully analyzed for publication, **‘one striking fact has already emerged: nearly 70% of patients in the study didn’t do well on their first drug, and switched to another.’**”⁸

2005 - **“There is neither a systematic data base, clear criteria for [medication] treatment or dosage recommendations that have been identified or standardized for pediatric use”**⁹

A 2005 Oregon State University review of 2,287 studies involving ADHD drugs found no long- term safety or effectiveness of those drugs in children.¹⁰

2005 - **40% of patients diagnosed with schizophrenia who were NOT on antipsychotic drugs showed periods of recovery and better global functioning compared to only 5% of patients taking antipsychotics (p=.001).** These analyses indicated that in addition to the significant differences in global functioning between these groups, 19 of the 23 schizophrenia patients (83%) with uniformly poor outcome at the 15-year follow-ups were on antipsychotic medications.¹¹

2002 - Efficacy and safety of psychotropics have not been systematically evaluated in preschoolers. The major limitation to this research is the diagnostic uncertainty surrounding most manifestations of psychopathology in early childhood.¹²

⁸ Sharav, Vera “Largest Next Phase in Psychiatry? Or, NIMH Effort to Rescue Bad Drugs – WSJ” Alliance for Human Research Protection 7/29/05 <http://ahrp.org/next-phase-in-psychiatry-or-nimh-effort-to-rescue-bad-drugs-wsj/>

⁹ Greenhill et al. (2003), as quoted in National Center for Infant and Early Childhood Health Policy – Addressing Social-Emotional Development and Infant Mental Health in Early Childhood Systems – 2005 <http://files.eric.ed.gov/fulltext/ED496853.pdf>

¹⁰ <http://www.ahrp.org/infomail/05/09/13a.php>

¹¹ Harriow, et al Do Patients with Schizophrenia Ever Show Periods of Recovery? A 15-Year Multi-Follow-up Study, Schizophrenia Bulletin vol. 31 no. 3 pp. 723-734, 2005. <http://schizophreniabulletin.oxfordjournals.org/content/31/3/723.long>

¹² Vitiello, B. (chief of child and adolescent psychiatry, NIMH) “Psychopharmacology for Young Children: Clinical Needs and Research Opportunities” *Pediatrics* (October, 2002), abstract available at <http://pediatrics.aappublications.org/content/108/4/983>

Harm of Psychiatric Drugs

- **Death**

2011 – “Both drug companies and psychiatry’s leadership at prominent academic institutions who serve as industry’s paid consultant / promoters, have been shown to inflate minimal (clinically insignificant) benefits, while concealing severe, life-threatening risks posed by psychotropic drugs. **Neither industry nor the profession can be trusted**...Clinicians for the most part are ignorant about the hazards of psychotropic drugs they prescribe. Such prescribing has resulted in preventable, drug-related deaths—some of the casualties are as young as four year old, Rebecca Riley, who was healthy save for the toxic effects of the drugs she was prescribed by a child psychiatrist who followed the protocol recommended by prominent child psychiatrists on the faculty of Harvard Medical School...The latest publicized child casualty of psychiatry’s reckless prescribing practices is Gabriel Myers, a 7-year old boy who committed suicide by hanging himself from a shower rod. Gabriel had been prescribed four powerful psychotropic drugs by a ‘board certified child psychiatrist’ in Florida.”¹³

2006 - **In fact, people with serious mental illness (SMI) are dying 25 years earlier than the general population**... Beginning with the introduction of clozapine in 1991, and the subsequent introduction of five newer generation antipsychotics over the next decade or so, antipsychotic prescribing in the US has moved to the use of these second generation antipsychotics. This has occurred despite their significantly greater cost, largely due to a decrease in neurologic side effects and the perception that people using them may experience better outcomes, especially improvement in negative symptoms. **However, with time and experience the second generation antipsychotic medications have become more highly associated with weight gain, diabetes, dyslipidemia, insulin resistance and the metabolic syndrome and the superiority of clinical response (except for clozapine) has been questioned.** Other psychotropic medications that are associated with weight gain may also be of concern.¹⁴

- **Violent/Homicidal Rages**

2015 - The National Center for Health Research discussion of anti-depressants mentioned a **2015 Swedish study of their entire population ages 15 and older, which reported that those taking antidepressants had twice the percentage of conviction for violent crimes. The risk of being convicted of a violent crime was the highest among the youngest age group aged 15-24.**¹⁵

2015 - “After reviewing the research and thinking critically about the effects of psychiatric drugs and their minimal benefits, it is clear that the risks involved are significant. **Even though the drugs do not cause violence in all situations and for all people taking them, and the actual risk ratio may be relatively small, the practical meaning of subsequent violent behavior is too serious to ignore and of such a consequential level to question their continued use as the first line of treatment for emotional and behavioral problems.**”¹⁶

¹³ https://ahrp.org/rx-for-antipsychotic-drugs-for-children-begin-to-decelerate_wsj/

¹⁴ Parks, J. et al, (2006) Morbidity and Mortality in People with Serious Mental Illness, National Association of State Mental Health Program Directors

http://www.nasmhpd.org/general_files/publications/med_directors_pubs/Technical%20Report%20on%20Morbidity%20and%20Mortality%20-%20Final%2011-06.pdf, p. 5-6

¹⁵ Molero Y, Lichtenstein P, et al. Selective Serotonin Reuptake Inhibitors and Violent Crime: A Cohort Study. PLoS Med 12(9): e1001875. doi:10.1371/journal.pmed.1001875 as discussed in Diana Zuckerman, PhD, Sarah Miller, RN, Madeline Levin, MPH, Nicolas J. Jury, PhD “Do Antidepressants Increase Suicide Attempts? Do They Have Other Risks?” National Center for Health Research available at

<http://www.center4research.org/antidepressants-increase-suicide-attempts-risks/>

¹⁶ Ruby, C. “Psychiatric Drugs and Violence” International Society for Ethical Psychology and Psychiatry (Archived 8/8/15) available at <http://psychintegrity.org/wp-content/uploads/2015/08/White-Paper-Psychiatric-Drugs-and-Violence.pdf>

2011 - **Of the 129 persons who experienced drug-induced adverse effects, 8 had committed homicide, 3 had committed suicide, and one had sleepwalked to her death¹⁷...** “**In all of the cases presented here, the subjects were prescribed antidepressants that failed to mitigate distress emerging from their predicaments, which encompassed psychosocial stressors such as bereavement, marital and relationship difficulties, and work-related stress. Every subject’s emotional reaction worsened while their prescribing physicians continued the “trial and error” approach, increasing from standard to higher dose and/or switching to other antidepressants, with disastrous consequences. In some cases the violence ensued from changes occasioned by withdrawal and polypharmacy.**”¹⁸

2010 - **We identified 1527 cases of violence disproportionately reported for 31 drugs. Primary suspect drugs included varenicline (an aid to smoking cessation), 11 antidepressants, 6 sedative/hypnotics and 3 drugs for attention deficit hyperactivity disorder.** The evidence of an association was weaker and mixed for antipsychotic drugs and absent for all but 1 anticonvulsant/mood stabilizer. Two or fewer violence cases were reported for 435/484 (84.7%) of all evaluable drugs suggesting that an association with this adverse event is unlikely for these drugs.¹⁹

- **Brain Damage**

2011 – During longitudinal follow-up, antipsychotic treatment reflected national prescribing practices in 1991 through 2009. **Longer follow-up correlated with smaller brain tissue volumes and larger cerebrospinal fluid volumes. Greater intensity of antipsychotic treatment was associated with indicators of generalized and specific brain tissue reduction after controlling for effects of the other 3 predictors. More antipsychotic treatment was associated with smaller gray matter volumes.** Progressive decrement in white matter volume was most evident among patients who received more antipsychotic treatment. Illness severity had relatively modest correlations with tissue volume reduction, and alcohol/illicit drug misuse had no significant associations when effects of the other variables were adjusted.²⁰

- **Movement Disorders**

Some form of this language is found in the FDA medication guides for all antipsychotic drugs:

“A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.

¹⁷ Summary of results of the study by Lucire, Y and Crotty, C “Antidepressant-induced akathisia-related homicides associated with diminishing mutations in metabolizing genes of the CYP450 family” in *Pharmacogenomics and Personalized Medicine* (2011) available at <http://ahrp.org/the-truth-about-psychiatric-drugs/Pharmacogenomics%20and%20Personalized%20Medicine> as discussed in Sharav, V. “The Truth About Psychiatric Drugs” The Alliance for Human Research Protection (2011) available at <http://ahrp.org/the-truth-about-psychiatric-drugs/>

¹⁸ Quote from the research article linked in Ibid.

¹⁹ Moore T, Glenmullen J, & Furberg C “Prescription Drugs Associated with Reports of Violence Towards Others” Public Library of Science (12/15/10) available at <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0015337>

²⁰ Ho and Andreasen, Long-term Antipsychotic Treatment and Brain Volumes, *Archives of General Psychiatry*, VOL 68 (NO. 2), FEB 2011

The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses or may even arise after discontinuation of treatment.

There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.”²¹

- **Suicide**

2016 – Independent researcher and head of the Nordic Cochrane Center, Peter Gotszche, in introducing his new book, *Deadly Psychiatry and Organised Denial*, said, “...for instance, finding that **the number of suicides among adults and children taking antidepressant drugs is actually 15 times greater than the number calculated by the U.S. drugs watchdog, the Food and Drug Administration...** Yet psychiatrists and GPs generally ignore or deny the appalling scale of this damage from drugs that are all too often used without medical justification.”²²

2015 - **Results: “There were clinically significant increases in harms, including suicidal ideation and behaviour [sic] and other serious adverse events in the paroxetine group and cardiovascular problems in the imipramine group.”²³**

2006 - **Results: In adults (aged 19-64 years), antidepressant drug treatment was not significantly associated with suicide attempts (odds ratio [OR], 1.10; 95% confidence interval [CI], 0.86-1.39 [521 cases and 2394 controls]) or suicide deaths (OR, 0.90; 95% CI, 0.52-1.55 [86 cases and 396 controls]). However, in children and adolescents (aged 6-18 years), antidepressant drug treatment was significantly associated with suicide attempts (OR, 1.52; 95% CI, 1.12-2.07 [263 cases and 1241 controls]) and suicide deaths (OR, 15.62; 95% CI, 1.65-infinity [8 cases and 39 controls]).²⁴**

²¹ This was taken from the FDA Medication Guide for olanzapine (Zyprexa) available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020592s071,021086s046,021253s059lbl.pdf#page=36

²² Prescription pills are Britain's third biggest killer: Side-effects of drugs taken for insomnia and anxiety kill thousands (9/14/15) *The Daily Mail* at <http://www.dailymail.co.uk/health/article-3234334/Prescription-pills-Britain-s-biggest-killer-effects-drugs-taken-insomnia-anxiety-kill-thousands-doctors-hand-like-Smarties.html#ixzz4E7HWWWDv> discussing his book, *Deadly Psychiatry and Organised Denial*, (2015) The People's Press

²³ Le Noury, J; Nardo, J; Healy, D; Jureidini, J; Raven, M; Tufanaru, C; Abi-Jaoude, E. "Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence" *British Medical Journal* (9/16/2015), abstract available at <https://www.bmj.com/content/351/bmj.h4320>

²⁴ Olfson, et al, Antidepressant Drug Therapy and Suicide in Severely Depressed Children and Adults, *Arch Gen Psychiatry* 2006; 63:865-872