

April 6, 2000

Jamie Talan NEWSDAY

BY FAX: 516-843-2873

4 Pages

Dear Ms. Talan:

In the new book *Prozac Backlash*, Dr. Joseph Glenmullen discredits not only the work of the U.S. Food and Drug Administration he attacks the work of research scientists, academic medical institutions and doctors.

The book preys on the fear of people with clinical depression, and may prompt some people to abandon their medication and seek medically unproven alternatives for a debilitating disease with potentially life-threatening consequences.

Because you often cover mental health issues, we thought you might be interested to know about this book.

If we can offer you any information, or some balance to a story you may be planning, we would be more than happy to oblige. We can arrange for interviews with spokespeople from Eli Lilly and Company, as well as with independent researchers from the medical community.

We are attaching some commentary on the book for your review.

Thank you for your consideration. I will contact you tomorrow morning. Please feel free to call me in the interim. You may reach me at 212/732-6111, Ext. 213.

Sincerely,

Robert Schwadron

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Glenmullen is a master of textual exegesis, quoting fragments from other physicians that distort their larger meanings. Use of his and others' personal testimonials is a reminder of medicine's authoritarian past, where the long and dishonorable tradition of "In my experience" means one patient, "In my series" stands for 2 patients and "In patient after patient after patient" equals 3 patients. The alternative is the scientific method, where hypotheses tested in randomized controlled trials lead to incremental advances in knowledge.

SSRIs have beneficial effects on many well-defined psychiatric disorders other than depression (bulimia, OCD, panic disorder, social anxiety disorder, PTSD all have FDA approvals). Glenmullen diminishes these severe disorders and his hyperbole risks great harm to those who suffer their ravages, implying that other treatments are better and safer. His cant is at odds with present knowledge in many areas. Except for exposure therapy for anxiety disorders, alternative treatments he advocates have not been subjected to the same systematic scientific scrutiny that SSRIs have undergone and continue to experience.

While St John's Wort appears to be effective for some depressions, much more study is needed to define its strengths and limitations. NIMH is funding a large multicenter trial because past research failed to answer important questions. And the very after-marketing adverse effects reporting system that Glenmullen excoriates is identifying significant enzyme-inducing properties of St John's Wort that decrease the effectiveness of anticoagulants, protease inhibitors used to treat AIDS and the immune suppresant cyclosporine (Lancet. 355: 548-549, 2000).

As one who has done randomized controlled trials of exercise as a treatment for depression, I would be far more cautious in describing its benefits. As any effective treatment, exercise causes side effects, often musculoskeletal but sometimes compulsive exercise and even sudden death, in those with cardiovascular disease.

Glenmullen's emphasis on discontinuing antidepressant medications will encourage discontinuation by some who are best served by continuing their SSRI maintenance medication. Relapse will follow discontinuation, sometimes into severe depressions, some of which will likely lead to suicide. Glenmullen's misrepresentations and distortions are dangerous and violate one of medicine's oldest dictums: Primum nil nocere (First, do no harm).

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The title of this book appears appropriate as the term "backlash" has the connotation of over reaction to an event. This book presents a highly unbalanced view of a variety of areas of the treatment of depression and the use of SSRIs. Selected components of research studies, case vignettes, investigative reporting and personal opinion are used to present a slanted view of the status of antidepressant treatment. The boundaries between these sources of information are often unclear and much of the apparent "data" presented is in fact incorrect or quoted out of context.

While it is clear that more balanced point of view would probably not sell as well in book form it is a disservice to people with mental illness to present such unbalanced information. Many of the points presented are not new or even controversial. Patients should be adequately diagnosed, treated appropriately following accepted guidelines and adequately informed of the risks and benefits of treatment.

The comments with regards to children deserve some mention as they highlight some of the problems with the book. The author states (page 128) that "more than half a million children are on serotonin boosters" but provides no reference. There is a report that, the author does not quote, that about 500,000 prescriptions for SSRI's are being written annually, but that is not the same as the number of patients. Also what percentage of the child population in the US is half a million? In epidemiological studies approximately 10% of children with major depression actually get any treatment. This book was published this year and some of the references quoted were from 1999, yet controlled data that has been available on treatment of children and adolescents since 1997 is ignored in favor of inflated statements from earlier reviews.

SSRI's have been shown to be effective in children and adolescents for both depression and obsessive compulsive disorder (OCD) and side effects are generally comparable with placebo.

Finally, I would heartily agree with the author that "antidepressants can have an important place in balanced comprehensive psychiatric treatment" and that "judicious use of medication can be invaluable, even life-saving" (page 355). However this is not a new idea proposed by the author but a standard of psychiatric treatment aimed for by most competent psychiatrists.

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Dr. Glenmullen's book "Prozac Backlash" is introduced at a time when psychiatric research documents the devastating effects of mental depression. The large body of accumulated research on depression also notes the development of treatments that have been demonstrated to be effective and safe for the alleviation of depression. Continued use of treatments for depression reduces depression-related pain and suffering for those who experience depression. Even the Surgeon General of the United States has made adequate treatment of depression a priority.

Dr. Glenmullen is critical of this research, the diagnostic criteria developed by the American Psychiatric Association, the Food and Drug Administration, the pharmaceutical industry, and clinical investigators. He recommends treatments that for the most part are not adequately studied as alternatives to established methods of treating depression.

I am concerned that individuals who suffer from depression and who would likely benefit from established and well researched treatments might opt instead for the remedies suggested by Dr. Glenmullen. I acknowledge that we do not know the cause(s) of depression or how treatments work. Answers to these important questions, however, can only come from further research.

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My foremost concern with *Prozac Backlash* is that it is misleading in nature. As a result of reading the book, it is possible that people with depression may be steered away from safe and effective treatments like Prozac, Zoloft and Paxil, towards treatments whose safety and efficacy is still unclear (e.g. St. John's Wort).

Dr. Glenmullen is creating a great disservice by claiming that SSRIs are overused and often misused, when, in fact, millions of people have taken and derived benefit from these medications. Further, the very medications that Dr. Glenmullen claims are overused are well studied, scrutinized and closely regulated.

Conversely, the very medications he recommends using in lieu of the well-studied ones, like St. John's Wort are not well-regulated or well-studied. Patients should be warned when considering these medications that because they are not well regulated, the quality of the medication might not be verified.

I am also disheartened that Dr. Glenmullen bolsters many of his arguments and proves his hypotheses by borrowing liberally from others' work, including my own. In cases where Dr. Glenmullen quoted studies published by me, (pp. 124-125, 152-153) he tended to quote from the work out of context to fit his needs. At no point did Dr. Glenmullen consult me directly to question my studies, two of which he conveniently uses to prove his argument.

The book contains little, if any, truly helpful information for patients, and is a great disservice to people with depression. Patients should always discuss any medication questions with their physicians, particularly if they are considering switching from an SSRI to an over-the-counter herbal medication. It can be extremely dangerous to stop medication completely, or to mix a psychotropic with St. John's Wort.

Anthony J. Rothschild, M.D. Professor of Psychiatry University of Massachusetts Medical School Worcester, MA

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Throughout the book, Dr. Glenmullen presents his assertions as fact. And although many of Dr. Glenmullen's assertions are rooted in fact, he tends to overstate his case, going beyond the published research on side effects of SSRI medications, and into pure speculation.

Most of the SSRI-related side effects discussed in Dr. Glenmullen's book do exist. Additionally, it is true that some primary care physicians and internists may, at times, overprescribe or unnecessarily prescribe psychotropic medications to their patients. However, by depending on selective case studies to support his claims, Dr. Glenmullen causes great harm to both patients who need and do well on medications and to prospective patients.

Dr. Glenmullen's take-away message — that these agents are dangerous and cause serious problems, including death –goes well beyond what is appropriate. As such, it is an irresponsible detriment and deterrent to those seeking help for depression, and it borders on inflammatory journalism.

 Harvey L. Ruben, M.D., M.F.H. —
 Dr. Ruben is Clinical Professor and the Director of Continuing Education for the Department of Psychiatry at Yale University in New Haven, CT. He is also Vice President and President Elect of the National Association of Medical Communicators.