Addressing Suicide and Its Risk

By Jack M. Gorman, MD

Last month, the media was awash with the story that a pharmaceutical company had announced that extensive review of data had revealed that its antidepressant medication had a greater risk for inducing suicidal behavior in adults compared with placebo. Following on the heels of the well-covered revelation that antidepressants also increase such risk among children, the case seems increasingly clear for a relationship between antidepressants and a small increase in suicidal behavior.

The announcement was front-page news and a highlighted story on television and radio. Always implied in these stories, sometimes explicitly and sometimes not, is the fear that the information regarding the link between antidepressants and suicidal behavior should have been known many years ago. Indeed, the "studies" that reveal this connection are actually mostly massive re-analyses of data accumulated during pre-registration studies for the serotonin reuptake inhibitors, most actually done over a decade ago. Some believe that drug companies deliberately suppressed the information, but I think a more useful approach going forward is to question how data from studies designed to obtain Food and Drug Administration approval for a psychiatric drug are analyzed in the first place. Drug companies and the FDA dance around complicated regulations and customs, some of which bear fresh looks. In essence, FDA regulations mandate that companies declare the principal outcome of interest and statistical analysis plan for each study prior to its initiation. While this obviously prevents post hoc data massage, it also locks in what a company feels compelled to review once the data are compiled.

Surprisingly, the FDA has few rules about how adverse event data are collected. Data and safety monitoring boards (DSMB) are increasingly used as an ongoing and independent way to watch for trends as studies are conducted, but they raise another important problem. Increasingly, leaders in the psychiatric research field are reluctant to accept compensation from the pharmaceutical industry due to conflict of interest regulations. Service on a DSMB is extremely time consuming and deserves compensation but that compensation presently comes directly from the company conducting the study. This means that many highly qualified experts will shun serving on them.

These considerations should make it clear that attempting to dismiss the link between suicidal behavior and medications as media hype is folly. There is something there and it is worth further investigation with studies attempting to elucidate the neurobiology of the link and by rethinking how clinical trials data are analyzed.

Nevertheless, something is still amiss with the way the media covers these stories and the fine articles in this month's *CNS Spectrums* assembled by Jan Fawcett, MD, give a clue about what is wrong. Almost none of the stories remind the reader that suicide is a real and frequent killer. Few point out that the risk of suicidal behavior is very small among those taking antidepressants. Rarely are recent studies suggesting that, overall, antidepressants may be decreasing the suicide rate cited. As in the treatment of pancreatic cancer, acute abdominal obstruction, and ruptured aortic aneurysm, there is a life and death struggle in trying to prevent death from suicide. It is always terrible news when an effective therapy for a life-threatening disease turns out to involve previously unrecognized adverse side effects. Protease inhibitors have dramatically improved outcomes for people with human immunodeficiency virus infection, but we are only now beginning to understand how some of them produce changes in fat metabolism than can lead to serious adverse events. We cannot, of course, give up on protease inhibitors, but at the same time we have to acknowledge, and be on alert for, a new class of adverse events that will make life more difficult for patients who take them.

Research will continue to tell us how best to assess suicidal risk and which interventions are most effective in reducing it. Those interventions may be psychotherapies, medications, or some combination of the two. There will be enormous bumps in the road along the way but we must not allow them to thwart our efforts. Dr. Fawcett's fine assembly of articles this month clearly tells us that we are making progress. ***CNS***

Dr. Gorman is the editor of this journal and adjunct professor of psychiatry at Mount Sinai School of Medicine in New York City.

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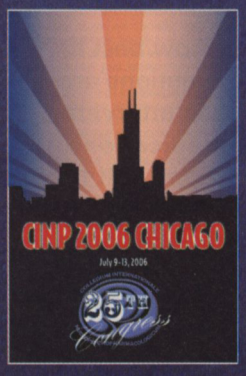

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