

Point-Counterpoint

Have drug companies hyped social anxiety disorder to increase sales?

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Author declares that he has had consultancies with, been a principal investigator or clinical trialist for, and chaired or spoke at international symposia for or received support to attend foreign meetings from Astra, Astra-Zeneca, Boots/Knoll Pharmaceuticals, Eli Lilly, Janssen-Cilag, Lorex-Synthelabo, Lundbeck, Organon, Pharmacia & Upjohn, Pierre-Fabre, Pfizer, Rhone-Poulenc Rorer, Roche, SmithKline Beecham, Solvay, and Zeneca. He has been an expert witness for the plaintiff in 2 legal actions involving SSRIs and has been consulted on cases of attempted suicide, suicide, and suicide-homicide after antidepressant medication was used

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Yes: Marketing hinders discovery of long-term solutions

Social phobia, also called social anxiety disorder, can lead to alcoholism, drug abuse, job loss, and even suicide. It has been relatively unrecognized in the West compared with in the East, where it is seen as the most common neurotic condition.¹ GlaxoSmithKline's recent license to promote the use of paroxetine to treat social phobia looks certain to increase the recognition of this potentially serious condition. What could be wrong with this win-win situation?

The first problem lies in interpreting what a license means. A license is not a statement by the Food and Drug Administration that paroxetine will be effective for treating social phobia. Licenses legally cannot be denied if a treatment can be shown to do something for a condition, but they are no guarantee that this treatment is worthwhile. Although simply increasing the recognition of social phobia may reduce the isolation of sufferers, unless sufferers receive an effective treatment that makes a substantial difference in their lives, the treatment may not be worth the risks.

What are the risks? It is clear from studies undertaken by SmithKline in the 1980s that even a brief exposure to paroxetine can lead many takers to become physically dependent.² Trials have also shown that the use of selective serotonin reuptake inhibitors (SSRIs) can precipitate suicidality in patients and that these agents can cause sexual dysfunction and neurologic disorders.³ Although the SSRIs have been marketed as being free of side effects than older agents, results on the quality-of-life scales that should reflect this freedom, which have been used in up to 100 clinical trials, have been left unpublished.⁴ This strongly suggests that SSRIs may be the wrong drugs for

many people. All of these hazards could be minimized if SmithKline marketed the hazards of treatment as assiduously as they market the condition.

Unlike obsessive-compulsive disorder, which was recently marketed by companies, social phobia is more like depression—a syndrome that may result from a variety of conditions. In some instances, it may be a prodrome for a psychotic disorder. Whereas some patients may get better with the use of paroxetine, it is sobering to realize that the discovery of the first antidepressant agents came about because they made some patients psychotic. In trials of SSRIs to treat depression, a significant proportion of patients not already having psychosis became psychotic. The same can be expected for social phobia. What people with this potentially debilitating condition need is research to understand why this is the case, rather than the marketing of a drug that may be beneficial for a few sufferers but hazardous for an equally large group.

Undoubtedly some patients with social phobia will not become suicidal, dependent, or psychotic while taking paroxetine, and their quality of life will not be poor. Even these patients have something to worry about, however. When a condition like social phobia becomes a marketing "fig leaf" for a pharmaceutical company, we all lose because the results of clinical trials get sealed—left unpublished and inaccessible—the names of leading figures in the profession get put on ghost-written articles, and a dependence on pharmaceutical company funding develops.⁵ The renaming of social phobia as social anxiety disorder is symbolic of what can happen.

Finding genuinely breakthrough drugs is a case of finding the right key to unlock the dungeons of illness that imprison us. The marketing clout of modern pharmaceutical companies is such that they can mould and shape the lock in which keys must fit. Marketing paroxetine for social phobia is the kind of diversion likely to inhibit the discovery of long-term solutions.



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No: Efforts to relieve human suffering deserve rewards



The *US News and World Report* cover story, "How Shy Is Too Shy?" captured the debate about the pharmaceutical industry's role in bringing social anxiety disorder to the forefront of public awareness. Drug companies have been accused of fabricating this disorder to boost sales of selective serotonin reuptake inhibitors (SSRIs). This is untrue and does a great disservice to patients. In fact, the pharmaceutical industry was a reluctant participant in this area, funding studies in the mid-1990s only on the repeated urging of the academic research community.

Social anxiety disorder is a chronic, debilitating condition that has long been trivialized and even ignored. The high prevalence of social anxiety disorder became apparent after publication of the National Comorbidity Survey (NCS) data in 1994.¹ This congressionally mandated survey measured the presence of psychiatric diagnoses in more than 8,000 randomly selected American adults living in the community. As a result of this landmark study, social anxiety disorder was recognized as a condition to be taken seriously. The NCS study found that social anxiety disorder has a lifetime prevalence of 13.3%. It is the third most common disabling psychiatric disorder, after major depression (17.1%) and alcohol dependence (14.1%), and is the single most common disabling anxiety disorder in the United States.

Persons with social anxiety disorder dread scrutiny and embarrassment in social and performance situations. Symptoms are often so severe that they either avoid interpersonal interactions or endure them with dread. This leads to academic underachievement, poor performance at work, and isolated, lonely living. Social anxiety disorder is a persistent, lifelong condition with an insidious onset in childhood or adolescence. The development of social anxiety disorder in a child or teenager is a harbinger of a lifetime of suffering and comorbidity. Most persons with social anxiety disorder later develop major depression, and many will abuse or become dependent on alcohol. The combination of social anxiety disorder and depression is particularly deadly and is associated with a 6-fold greater risk of suicide attempts.² Dysfunction and missed opportunities are hallmark sequelae of social anxiety disorder. Compared with control subjects, individuals with

social anxiety disorder are 8.4% less likely to graduate from college, 14.5% less likely to secure a professional, technical, or managerial job, and will earn wages that are 14% lower.³

The good news is that social anxiety disorder is treatable. Monoamine oxidase inhibitors are effective,⁴ but concerns about adverse effects limit their use. It was not until late in the past decade that the SSRIs were shown to be a safe and effective treatment.⁵

The need for early recognition and intervention is clear and compelling. Yet, why is this condition so overlooked and undertreated?

There are numerous barriers to care. Social anxiety disorder, by definition, makes patients hesitant to seek treatment for this disability. Many have had symptoms for decades and believe that this is the way life is supposed to be. Physicians and other health care professionals do not actively look for social anxiety disorder and often do not take it seriously. Following the Food and Drug Administration's approval of the use of paroxetine for the treatment of social anxiety disorder, the pharmaceutical industry went to great lengths to educate the mental health community, primary care providers, and the public about this disorder. For this, they are to be applauded, not condemned. Medical luddites, in failing to embrace scientific advances, and even obstructing them, only perpetuate human suffering and contribute to scientific malfeasance. We should economically reward any successful effort to relieve human suffering, not disparage it. It will encourage others to invest more in finding effective treatments for medical illnesses. This is a more successful and a more compassionate strategy.

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