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Lisa Cosgrove

University of Massachusetts Boston, lisa.cosgrove@umb.edu

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Psychiatric Taxonomy, Psychopharmacology and Big Pharma

Lisa Cosgrove, Ph.D.



Introduction

Clinicians practicing today need to be aware of the ways in which the current industry-dominated climate

may undermine the integrity of the scientific process and, thus, may compromise patient care. In the mental health field, corporate sponsorship bias can affect psychiatric taxonomy and clinical Practice Guidelines (CPG). Financial conflicts of interest (FCOI) can occur when there are financial associations between researchers, authors, or panel members developing psychiatric diagnostic and treatment guidelines, and the pharmaceutical industry, or when randomized clinical trials (RCTs) are industry funded. Therefore, clinicians need to be especially vigilant about the informed consent process when patients are prescribed psychotropic medications. As Past President, Elaine LeVine, Ph.D. noted in the December, 2007 issue of *The Tablet*, the issue of informed consent is a particularly salient one for Division 55 members:

Psychologists adopting a scientist-practitioner model are in an excellent position to carefully analyze the research regarding the efficacy and safety of various drugs. Because we view education as part of

our role as healers, we work with our patients to provide the extensive informed consent that allows them to make knowledgeable decisions about using medications, given a thorough understanding of the cost/benefit ratio. (p. 3)

In order to be fully educated about the risk/benefit ratio of psychotropic medications, we must critically evaluate the diagnostic and treatment information that is being produced and disseminated.

Psychiatric Taxonomy and the Pharmaceutical Industry

In 1952, the first official *Diagnostic and Statistical Manual of Mental Disorders* (DSM) was published by the American Psychiatric Association. Few outside the field had ever heard of what is now often referred to as the “bible” of psychiatric disorders. Fewer still would have predicted that 58 years later there would be a firestorm of controversy over the proposed revisions to the DSM.

In light of the DSM’s clinical importance, the appearance of industry bias, let alone the reality, can undermine its integrity and weaken public trust. The concern about undue industry influence was heightened when it was discovered that the organization that produces the DSM, the American Psychiatric Association, receives substantial drug industry

funding, and the majority of the individuals who serve as diagnostic panel members also have drug industry ties. My colleagues and I discovered that 100% of the individuals on two DSM panels, Schizophrenia and Psychotic Disorders, and Mood Disorders, had financial ties (e.g., served on speakers’ bureaus, corporate boards, received honoraria) with the pharmaceutical industry (Cosgrove, Krinsky, Vijayaraghavan, & Schneider, 2006). The fact that all of the members of these panels had industry ties is problematic because psychopharmacology is the standard treatment in these two categories of disorders.

To its credit, the American Psychiatric Association has required all DSM-V panel members to post financial disclosure statements (<http://www.dsm5.org>). Indeed, the American Psychiatric Association has made a commitment to better manage potential FCOI, and certainly this new disclosure requirement appears to be a step in the right direction. One would, therefore, expect to see a decrease in the number of individuals serving on the DSM-V panels who have corporate ties. However, as we reported in the *New England Journal of Medicine* last year, despite increased transparency, industry relationships with DSM panel members persist; approximately 68% of the DSM-V task-force members report having ties to the phar-



Cosgrove, *Psychiatric Taxonomy...*, continued

maceutical industry (Cosgrove, Bursztajn, & Krimsky, 2009). This represents a relative increase of 20% over the proportion of *DSM-IV* task-force members with such ties. But it is not only task force members who have financial relationships with Big Pharma; of the 137 *DSM-V* panel members who have posted disclosure statements, 77 (56%) reported industry ties, such as holding stock in pharmaceutical companies, serving as consultants to the drug industry, or serving on drug company boards, which is no improvement over the 56% of *DSM-IV* members who were found to have such industry relationships. Some *DSM-V* panels still have a majority of members with industry ties. If financial conflicts of interest are not reduced, private-sponsor bias in research will be exacerbated.

With concerns mounting about the American Psychiatric Association's financial ties with the pharmaceutical industry, questions have been raised by patient advocacy groups, investigative journalists, clinicians and researchers as to whether the proposed changes for the *DSM-V* are evidence-based. Because a *DSM* diagnosis influences treatment decisions, especially decisions about psychotropic medications, adding new disorders can have a significant impact on prescribing practices. Indeed, the lack of biological markers for psychiatric conditions renders the field vulnerable

to industry influence. Specifically, the lack of biological markers opens the door for what some have referred to as "disease mongering" or "widening the boundaries of treatable illness" (Moynihan, Heath, & Henry, 2002). In turn, this may allow pharmaceutical companies to apply for FDA approval of new medications that are actually "me too" drugs, drugs that are neither more efficacious nor safer than those already on the market. (See Egli and Egli's excellent essay in the July, 2007 *Tablet* on the FDA approval of Invega, then a new atypical antipsychotic that is essentially a patent extender). In fact, sometimes the iatrogenic harms of these medications may outweigh their benefits.

"... the lack of biological markers opens the door for what some have referred to as 'disease mongering' or 'widening the boundaries of treatable illness'"

My colleagues and I have been following the proposed revisions to the *DSM*. An example of a new disorder that expands diagnostic boundaries and would likely result in an increase in the number of individuals prescribed psychotropic medication, especially children and adolescents, is "Attenuated Psychotic Sym-

toms Syndrome" (<http://www.dsm5.org>). This syndrome, proposed for inclusion in the *DSM-V*, describes symptoms of psychosis that are theorized to appear in individuals at risk for developing schizophrenia, before they are actually diagnosed with the disease. The idea is that if prodromal psychotic symptoms are diagnosed and treated early enough, it will be possible to prevent at-risk individuals from developing schizophrenia (Gobal, Cosgrove, & Bursztajn, in press). However, the data do not support this reasoning. Various studies have demonstrated that only 16-30% of people with symptoms of psychosis end up developing schizophrenia later in life (McGorry et al., 2009; Yung et al., 2008). Moreover, it is not even clear that treatment with antipsychotic medications reduces their risk for developing schizophrenia any more than treatment with placebo (McGlashan et al., 2006). Based on these findings, and in light of the adverse side effects of antipsychotic medications, including movement disorders, weight gain, and diabetes, some researchers have concluded that the risk/benefit ratio does not justify treating those at risk for psychosis with these medications (De Koning et al., 2009; McGorry et al., 2009). We believe, therefore, that before the *DSM-V* adopts "Attenuated Psychotic Symptoms Syndrome," panel members need to provide further...

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... evidence regarding the validity and reliability of this newly proposed category (Gobal et al., in press).

Are clinical Practices Guidelines (CPG) and Randomized clinical Trials (RCTs) industry influenced?

As noted above, there are increasing concerns that the pharmaceutical industry may be able to influence the definition of a mental health problem. There also is the concern that drug industry involvement (e.g., funding of clinical trials, guideline authors serving on speakers' bureaus of pharmaceutical companies) could affect CPG development. In 2009, my colleagues and I published the results of a study that examined financial associations between the pharmaceutical industry and authors of three major CPG for Bipolar Disorder, Major Depressive Disorder and Schizophrenia. We found that 90% of the authors had financial ties to the pharmaceutical companies that manufactured the drugs that were identified in the guidelines as recommended therapies for the respective mental illnesses; None of these financial associations were disclosed in the CPG (Cosgrove, Bursztajn, Krinsky, Anaya, & Walker, 2009). The results of this and other studies highlight the need for greater transparency and management of FCOI in the development of CPG.

Because meaningful informed consent requires a full representation of adverse effects and accurate information on the efficacy of the recommended medications, clinicians rely upon results of RCTs as the "gold standard" for evidence-based medicine. Thus, it goes without saying that RCTs should be free of sponsor bias. However, in today's climate, should clinicians be wary about

"Results of these and other studies have led some to question whether financial conflicts of interest and marketing have triumphed over science."

the "evidence" being disseminated?

Let's look at the recent research that addresses this question. Pitrou, Boutron, Ahmad, and Ravaud (2009) examined reporting and presentation of harm-related results in RCTs published in general medical journals with high-impact factors. They concluded that reporting of harms continues to be inadequate. They found that information related to the severity of adverse events was not reported in 27.1% of RCTs, and withdrawal of patients because of adverse events was not reported in 47.4% of RCTs. Another study also raises questions as to whether clinicians should unquestioningly accept the re-

sults of RCTs. Researchers studying financial conflict of interest in clinical trials of psychiatric medications found that, "among the 162 randomized, double-blind, placebo-controlled studies examined, those that reported conflict of interest were 4.9 times more likely to report positive results" (Perlis et al., 2005). "[T]he randomized trials agenda may need to reprogram its whole mission, including its reporting, toward better understanding of harms" (Ioannidis, 2009, p. 1739).

Results of these and other studies have led some to question whether FCOI and marketing have triumphed over science. The under-reporting of negative results and publication bias, leading to unsubstantiated efficacy and safety data, may prevent clinicians from being able to fully inform their patients about the associated risks and benefits to taking a recommended medication.

This is not to suggest that pharmaceutically-funded researchers intentionally misrepresent their findings in a pro-industry way. Researchers are not always aware of the subtle ways in which their industry connections may influence their choice of language or influence their choice of which findings to highlight. It would also not be fair to say that we can never trust industry-sponsored research. In fact, some studies have found that, "the research methods of



Cosgrove, *Psychiatric Taxonomy...*, continued

trials sponsored by drug companies is at least as good as that of non-industry funded research, and in many cases better" (Lexchin, Bero, Djulbegovic, & Clark, 2003, p. 1168). However, as this brief review of the literature shows, current disclosure requirements and the peer-review process cannot ensure that treatment recommendations published in high-impact medical journals or produced by professional organizations will be accurate, balanced, and free of corporate sponsorship bias.

Conclusion

The field of psychiatry has been plagued by allegations that the pharmaceutical industry may be exerting an undue influence on the profession. For example, in 2008 Senator Charles Grassley widened his series of hearings and investigations into financial associations between medicine and the pharmaceutical industry by requiring the American Psychiatric Association to provide, "an accounting of industry funding that pharmaceutical companies and/or the foundations established by these companies have, including but not limited to grants, donations, and sponsorship for meetings or programs" (Moran, 2008).

The concerns about industry influence in organized psychiatry make Division 55's goal of granting prescriptive authority to all properly trained psychologists especially timely. As Dr. LeVine (2007)

astutely pointed out, psychologists' training in the scientist-practitioner model is essential in being able to carefully and thoroughly assess the scientific evidence regarding the efficacy and safety of psychotropic medications. However, this training needs to be augmented by incorporating a critical and reflective approach to psychiatric taxonomy, and to the treatment recommendations disseminated in clinical Practice Guidelines. Consideration of the role that the funding source may have played in the research design, data analysis, or reporting of results, is essential. For example, we must ask questions such as: Were adequate outcome measures used in this RCT? Was the effect size *clinically meaningful* as well as statistically significant? Was equipoise violated by comparing the new medication to a placebo rather than to a comparable drug already on the market? In terms of diagnosis, we must carefully examine the evidence when new *DSM* diagnoses are proposed or when changes in symptomatology are suggested, especially when these changes will have a direct and significant impact on prescribing practices.

Some psychiatrists have found it difficult to understand how financial conflicts of interest in the field may increase bias in the diagnosis and treatment of mental illness. As Upton Sinclair stated, "It is difficult to get a man to understand

something when his salary depends upon his not understanding it" (1935/1994, p. 109). Prescribing psychologists take heed.

Lisa Cosgrove, Ph.D. is a clinical psychologist and associate professor in the Counseling Psychology Department at the University of Massachusetts-Boston. She is a Residential Research Fellow at the Safra Center for Ethics, Harvard University (AY 2010-2011). She is co-editor of Bias in Psychiatric Diagnosis, and a contributing editor of Psychiatric Ethics and the Rights of Persons with Mental Disabilities in Institutions and the Community. Her work addresses the ethical dilemmas that arise in the biomedical field when there are financial ties between the pharmaceutical industry and academic institutions or professional organizations.

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DeLeon, *A Glimpse at...*, continued

and Nurses to Improve the Reach and Quality of Primary Care. As the landmark health reform law goes into effect, bringing millions of uninsured Americans onto insurance rolls over the next five years, demand for primary care services will increase; So, too, will demand for more accessible, effective, and efficient models of primary care. Rather than hiring more primary care physicians, many medical practices, health centers, and other primary care settings have been experimenting with innovative models of care that both extend the reach of primary care physicians and increase the quality of ambulatory services... [bringing] pharmacists, social workers, nurses, and nurse practitioners to

primary care practices. With them comes a new set of skills that can improve care and lower costs for patients with depression, physical disabilities, and other conditions that have proven difficult to treat in primary care settings....

The Commonwealth Care Alliance invested heavily in the model – spending approximately \$4 million on 25 practices, many of which are located in low-income, safety net clinics. The investment, which covers the cost of hiring the nurse practitioners by the primary care practices and investing in infrastructure such as electronic medical records, is more than offset in reductions in hospitalizations for preventable conditions as well as delays in nursing home place-

ments....

Dramatic Change Is Coming

Over the next five years, we will witness the systematic implementation of what is perhaps the most significant social legislation enacted by the Congress since the Great Society programs of President Lyndon Johnson. Change is definitely coming. This could well be an extremely exciting era for our profession's prescribing psychologists. Those with vision and perseverance will thrive and flourish.

Pat DeLeon, Ph.D., ABPP is affectionately known as the Father of RxP. He was President of the American Psychological Association (APA) in 2000. He won the Division 55 award for National Contributions to Psychopharmacology in 2001 and the Division 55 Meritorious Service Award in 2008.

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