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Clinical Trials of Therapy versus Medication: Even in a Tie Medication Wins*

This article explores one example of conflict of interest within medical research and suggests that such interest has lead to a breakdown of science within scientific enquiry.

Central to the idea of evidence-based medicine is that the choices made by patients and doctors to use a certain treatment should at least in part be based on scientific studies published in peer reviewed academic journals. For a patient diagnosed with a mental illness the choice often comes down to whether to use behavioral therapy, psychotropic medications, or a combination of the two.

In the past decade, antidepressant medications known as selective serotonin reuptake inhibitors (SSRIs) have become the most prescribed medication in the United States. When they first appeared on the market in the late 1980s, they were marketed as medications that would correct a chemical imbalance associated with depression. During the past decade their scope has broadened widely and they are now prescribed for a wide variety of conditions. Concurrent with the rise of the SSRIs, many have observed fundamental changes in the culture of the medical community. For instance, it is now generally considered acceptable for medical school professors to receive one paycheck from the academic institution and another paycheck from the pharmaceutical company whose medications they both research and endorse– as long as the professor declares these conflicts. Yet lately, congressional investigators and the general public are starting to question whose motives are really best being served by such relationships. It is certainly true that having a conflict of interest does not automatically negate someone's view – even someone with a large conflict-of-interest can be correct. Yet, when facts emerge demonstrating that flawed information was disseminated by researchers with conflicts-of-interests, it is

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hard to not question whether the conflict was the root of the problem. We think the following story will shed some light on the problems with these conflicts.

Earlier this year, *The Journal of the American Medical Association* (JAMA) published a study examining the efficacy of both Lexapro, an SSRI, and problem-solving therapy in undepressed, recovering stroke patients. The study found that recovering stroke patients treated with either therapy or medication were less likely to be subsequently diagnosed with depression. After one year, 22% of the placebo group developed depression, while only 9% of the Lexapro group and 12% of the therapy group did. Following the study's publication there were numerous articles in the mainstream media extolling the benefits of the SSRIs. For instance, in *USA Today,* the lead author of the study stated: 'I hope I don't have a stroke, but if I do, I would certainly want to be on an antidepressant.' And as often happens after these types of studies, the media went to an outside expert to interpret the study. Fox News interviewed a psychiatrist from the University of Pittsburgh and reported that, 'he hopes doctors will start prescribing preventive antidepressants to stroke patients.' Neither article mentioned therapy. Yet, when we looked at the study, given that there was little difference between the therapy and drug groups, we were confused by a subtle but seemingly critical omission from the published paper.

While the authors compared both Lexapro and therapy to placebo, they did not report on the direct comparison of therapy to Lexapro – surely of interest to those making treatment decisions, especially since every medication has at least some adverse effects. In a letter to JAMA, we pointed out that the authors did not report this important statistical comparison between therapy and medication. Five months later, our letter was published along with an acknowledgement from the original authors that indeed there was no statistical difference between therapy and medication. Since newspapers rarely reflect on their original coverage, the benefits of therapy for stroke patients will continue to remain a mystery to most of the news reading public.

Journals such as JAMA require authors to publish their conflicts of interest at the end of their studies. The study in question did list several conflicts but the list did not include Forest pharmaceuticals, the manufacturer of Lexapro. During a subsequent internet search we were surprised to learn that the lead author was in fact listed on the speaker's bureau for Forest. The omission is disturbing; neither the JAMA article nor subsequent media accounts noted that the lead author had a past financial relationship with the makers of Lexapro. However, disclosure of the relationship would not have changed the troubling end result: a researcher with a history of being funded by SSRI makers completes a 'gold-standard' federally-funded study of post stroke SSRI use, which is published in one of the most prestigious medical journals in the world, and is given a forum in the national media to tell the general public that anyone who has had a stroke, whether or not they have been diagnosed with depression, should start a prophylactic regimen of Lexapro ... *even though non-medical approaches perform just as well.*

Besides the lead author having an undisclosed conflict with the company, a simple internet search also revealed that the expert who was subsequently asked to interpret the study for two different news outlets had been receiving money from Forest since 2004, yet neither outlet reported his conflict.

The medical community strives to make decisions based on evidence, but as this case illustrates we have arrived at a point where only a very naïve person would read a medication study in a medical journal and not be extremely sceptical. The problem is not limited to a couple of isolated cases of unreported conflicts but involves the entire culture of medicine that has developed over the past ten years. Put bluntly, the scientific machinery is broken. There is no easy fix, but surely patients deserve better.