



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Assistant Secretary for Health
Office of Research Integrity
1101 Wootton Parkway, Suite 750
Rockville, MD 20852

Ph. 240-453-8800
FAX 301-594-0043
e-mail: john.dahlberg@hhs.gov
Web: <http://ori.dhhs.gov/>

CONFIDENTIAL

November 15, 2011

Jon Jureidini, PhD, MBBS FRANZCP
Head, Department of Psychological Medicine
Womens's and Children's Health Network, Adelaide
Professor, Disciplines of Psychiatry and Pediatrics
University of Adelaide
jon.jureidini@health.sa.gov.au

RE: DIO 4566

Dear Dr. Jureidini:

The Division of Investigative Oversight (DIO), Office of Research Integrity (ORI) has received your email of November 6, 2011, transmitting a copy of your October 4, 2011, letter to President Simmons of Brown University. In your letter, you describe long-standing issues resulting from a paper published in 2001 in the *Journal of the American Academy of Child and Adolescent Psychiatry* entitled "Efficacy of paroxetine in the treatment of adolescent major depression: a randomized, controlled trial," by Martin Keller and 21 co-authors. You pointed out to President Simmons that "the paper has been thoroughly exposed in legal actions, the bioethical and medical literature, a book, and a BBC Panorama documentary. Despite these negative commentaries regarding the paper, neither the journal nor Dr. Keller have agreed to retract the paper.

Your e-mail to ORI is informational, without making any specific request for action. I have spent some time reviewing your letter, the original paper, and additional literature and comments on the study available on-line. My understanding is that, indeed, paroxetine's efficacy was apparently exaggerated by reporting only a subset of outcome measures, among other matters. However, as you have acknowledged, a significant body of scientific and legal information exists to help put the 2001 study in perspective.

Regardless of whether or not the authors of the 2001 study intentionally, knowingly, or recklessly¹ reported false data, ORI is unable to assist in this matter for several reasons.

¹ ORI must prove each allegation of misconduct by meeting all three elements of 42 C.F.R. Part 93.104. Generally, establishing the level of knowledge (subpart (b)0 is the most challenging burden for institutions and ORI.

Foremost is the six year statute of limitations, meaning that allegations of falsification, fabrication, or plagiarism must be made within six years of the act of alleged misconduct. In addition, although your principal objective seems to be ensuring that the questioned paper is retracted, ORI lacks any authority to require retractions, although we do communicate our findings of misconduct to journal editors where appropriate. Further, given the significant lapse of time between the time the study was conducted and concerns raised, the likelihood of being able to conduct a fair and objective review, given the inevitable difficulties in locating records and relying on memories of events well over 10 years ago, seems remote.

I regret that ORI can not be of greater assistance.

Sincerely,



John E. Dahlberg, Ph.D.
Director
Division of Investigation Oversight
Office of Research Integrity

Sec. 93.104 Requirements for findings of research misconduct.

A finding of research misconduct made under this part requires that--

- (a) There be a significant departure from accepted practices of the relevant research community; and
- (b) The misconduct be committed intentionally, knowingly, or recklessly; and
- (c) The allegation be proven by a preponderance of the evidence.