

Andres Martin on Study 329 (2001) 10.22.2014 [comments in red by ed]

Dr. Martin introduced the history of the article and distilled the allegations into the following: [Martin said he was aware some have raised the following questions:]

1. Was there failure to disclosure financial or other conflicts of interest?
2. Who exactly helped to design the study protocol—GSK or the authors? Were endpoints chosen and reported accurately? Was data concealed?
3. Were primary outcome measured falsified?
4. Was there misrepresentation of the primary outcome measures and adverse events?
5. Was there plagiarism?
6. ... an overall sense of the article was ‘false and misleading’

He reviewed the timeline of the lengthy process used to vet the allegations raised numerous times over many years and to decide whether or not to retract the article, which included consultation with the authors, experts in publications and publication ethics (the Committee on Publication Ethics (COPE)), experts in the field (psychology, child and adolescent psychiatry, clinical trialologists, etc), a whole range of attorneys, and more. By July 2010, Dr. Martin finished his independent assessment. He felt the process had been done correctly. [Letters to the editor to retract the article had no supporting information and the letters were rejected.](#) He wrote to the Executive Committee at the time summarizing the decision and the issue was laid to rest. [no details given to justify his opinion of the letters or of any other of his conclusions]

In 2012, a lawsuit between the Department of Justice and GSK for illegal marketing practices for which GSK was subsequently fined \$3B. [NY State sued 5 years earlier] In the lawsuit, the S329 article was mentioned. Reviewing these allegations again took a long period of time and much investigation with authors, attorneys, and experts, but again, there was no basis found for editorial action against the article. [how do we reconcile his saying “no basis” given the court findings?] The AACAP Executive Committee was notified of this decision. In an article in the Brown Daily Herald, reporters directly confronted the authors of the article and a Dean at Brown University, who supervised a major investigation. The article reported that Brown will not support an effort to retract. It quotes the dean’s response: “I would caution you not to confuse the University’s policy of confidentiality with inactivity.” This process has consumed an inordinate amount of time for JAACAP and countless other people. The related email correspondence has been voluminous. In 2013, the British Medical Journal published an article on the *RIAT* (restoring invisible and abandoned trials) *initiative*, which proposes the idea that any author can use publically available original data of any study to reanalyze the data and present the reanalysis. In that *RIAT* article, S329 article was a mentioned as a prime candidate and Dr. Martin shared with the audience that while he does not believe any reanalysis of S329 will be submitted to JAACAP, he would welcome it and send it out for peer review like any other submission.

NOTES FROM THE AFTERNOON DISCUSSION OF THE MOTION TO REFER THE QUESTION OF S329 TO THE ETHICS COMMITTEE:

CALIFORNIA

Lally Pia, MD

Dr. Pia revised the previously submitted request for action and resubmitted it to Dr. Ng who read it aloud,

Resolved: That the Assembly communicates and collaborates with the Ethics Committee to provide an independent assessment of issues and concerns raised by S329. We ask that the Ethics Committee provide to the membership of the Assembly their findings and opinion about the most appropriate and ethical path to take given these circumstances.

ACTION: DELEGATES MOTIONED, SECONDED, AND AGREED TO MOVE THE REQUEST TO DISCUSSION.

Ed Levin, MD/Northern California

Dr. Levin read a portion of the [Department of Justice's GSK Settlement Fact Sheet](#) and referenced that, as early as 2003, various articles stated that, on the surface, the study had to be false.

Sandra Sexson, MD/Georgia

Dr. Sexson commented that this may not fall under the purview of the Ethics Committee and may need Council's decision.

George Stewart, MD/Northern California

Dr. Stewart supports this issue, hopes it can be resolved, and is exhausted with this issue. The exhaustion comes from many sources but also a failure of leadership to address it openly. He stated, "The Ethics Committee was instructed not to investigate this." If the Ethics Committee cannot investigate it, he suggested we form an ethics committee that can look at it. Dr. Ng clarified that he spoke with the Ethics Committee co-chairs whose understanding was that all questions regarding S329 were to be directed to Dr. Martin.

Raymond Hearey, MD/ Northern California

Dr. Hearey stated that the S329 issue was his primary motivation for attending his first Assembly meeting. He believes Dr. Martin does not register his regional organization's concern in a way that is reconcilable. Further, fraud is not protected as academic speech. He believes this issue does harm and should have more light shone on it, which is why the Northern California Regional Council would like the Ethics Committee to take a look at it. Dr. Ng reminded Delegates that the opinions/comments of members and regional organizations should be respected.

Kory Stotesbery, MD/Northern California

Dr. Stotesbery, an ECP, commented that he does not know what to do or how to prescribe Paxil.

Dr. Ng clarified that the Assembly does not have governance over committees so the language in the action item regarding the Ethics Committee must state "request."

ACTION: DELEGATES MOTIONED AND VOTED NOT TO PASS THE RESOLUTION.