

# Greenidge, Edmund

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**From:** Greenidge, Edmund  
**Sent:** 3/4/2001 11:30:17 AM  
**To:** Travers, John T /O=ZENECA/OU=PHWILM/CN=RECIPIENTS/CN=John .Travers;  
**Cc:**  
**Bcc:**  
**Subject:** RE: Brecher Reprint Holder

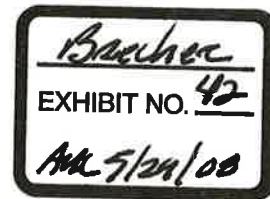
Hello John:

I had a discussion with Kendra Baker, our legal representative, regarding the Brecher reprint carrier. I told her about your objections and she indicated that she would like for us to meet to discuss the possible dissemination of this paper. Therefore, when you have completed your review of the piece, I will set up a meeting.

Thank you!

-----Original Message-----

**From:** Travers, John T  
**Sent:** Friday, March 02, 2001 3:01 PM  
**To:** Greenidge, Edmund  
**Subject:** Brecher Reprint Holder



Edmund,

Thanks for the loan of the IES Quality Standards Manual. Below I have summarized the significant representations from the reprint holder and the excerpts from the Quality Standards Manual (with Pg #s) which pertain.

I. Representations From Reprint Holder

- a. "Weight neutral over time"
- b. "Mean weight assessments demonstrated minimal weight change over time"
- c. "Potentially normalizing effect on weight"

II. (Pg 46) Clinical Studies: "...a drug is misbranded if its advertising represents that a drug is better, more effective, useful in a broader range of conditions, safer, has fewer or less incidence of or less serious side effects or contraindications than has been demonstrated by substantial evidence or substantial clinical experience. 'Substantial evidence' ordinarily means adequate and well controlled studies." [the representations above are based on the Brecher analysis which is not, I contend, an adequate or well-controlled study.]

III. (Pg 52) Adequate and Well-Controlled Studies

- a. A design which permits valid comparison with control [no such comparison is possible in the Brecher analysis]
- b. Measures to minimize bias (for example, blinding) [no blinding or other such method was employed in the Brecher analysis]

IV. (Pg 59) Pooled Studies: "It is ordinarily not permissible to pool the data from different studies. This is poor statistics, as well as a regulatory violation." [the data in the Brecher analysis is from pooled data from different studies]

I also sent a list of questions to the statistician as well as the other authors. I enclose this for your reference as well.

<< Message: Brecher, Rak, Melvin & Jones Long-Term Seroquel Weight Article >>

Unless the authors can convince me otherwise, I feel that a promotional piece around this publication is not-approvable.

Regards,  
John  
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