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**CN :** SQ1ED00446381  
**Date :** Tuesday, October 30, 2001 8:00:00 AM GMT  
**From :** Tugend, Georgia L  
**To :** Allsop, Jeffery; Beamish, Don G; Lloyd (Washington) Lisa M; Maseth, Sarah; Mullen, Jamie A; Palczuk, Linda S  
**Subject :** Reinstein Letter and my comments (same as paper distribution)  
**Attachments :**  ReinsteinLetter.pdf  
 Reinstein CommentsGeorgia.doc  
**Custodians :** Beamish, Don

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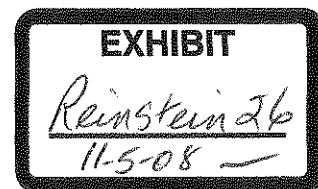
**From:**  
Tugend, Georgia L

**Sent:**  
Tuesday, October 30, 2001 7:59 PM

**To:**  
Allsop, Jeffery; Maseth, Sarah; Palczuk, Linda S; Beamish, Don G; Mullen, Jamie A; Lloyd (Washington) Lisa M

**Subject:**  
Reinstein Letter and my comments (same as paper distribution)

**Attachments:**  
ReinsteinLetter.pdf; Reinstein CommentsGeorgia.doc





Tuesday, October 30, 2001

To: L. Palczuk  
D. Beamish  
L. Lloyd-Washington  
J. Mullen  
J. Allsop (via E Mail)  
S. Maseth (via E Mail)

From: G. Tugend

Re: Letter to D. Brennan from Dr. Reinstein and colleagues, dated 10/23/01

I have attached the subject letter, a copy of which I received today. The following represents my comments but I would appreciate the opinions of Jamie, Lisa, Jeff and Sarah as well in the areas that they are familiar with.

Point 1. No doubt Janssen does significantly more research than AZ which is not surprising given the resources that Janssen provides to the #1 drug in their overall business. The fact that they were launched nearly 4 years before SEROQUEL also results in a research portfolio that is significantly more robust than ours. However, the remark about the quality of our studies is both untrue and unfair. This group is constantly demanding research grants from us but the quality of their research and poor reputation in the psychiatry community has limited our work with them to retrospective chart reviews or small pilot trials. In fact they have blatantly threatened to switch their SEROQUEL patients to Geodon (or back to Risperdol <sic> Risperdal) if they do not get research funding from AZ.

Point 2. There is really no dispute in my opinion on the comments made here. But regarding the actual dosing, we are restricted to the Prescribing Information which was based upon the registration trials which gave us the "initial target dose of 300-450 mg" and dose range of 750 mg in Study 13 and 800 mg for safety. We do have high dose and rapid titration trials planned although they will not result in a label change. Again, this group is practically demanding funding to do a SEROQUEL high dose study.

Regarding the points about claims being denied beyond 800 mg/day I would be interested in our Field Sales and Account Directors asking around to see if Zyprexa claims are denied over 20 mg/day, which is their label maximum.

Point 3. Customer has very good point, in particular regarding reimbursements and honoraria resulting from field-sponsored programs. The Marketing team has heard this on more than one occasion from customers and in fact pursued with Field PREP the possibility of out-sourcing and/or providing a person/group to handle such payments from field programs. Field PREP, who felt that the current system was adequate, did not entertain this recommendation. (Note: Payments to faculty participating in central Marketing programs such as National/Regional Ad Boards, National Speakers Updates, Satellite Symposia, etc are reimbursed by the vendor on our behalf and are not the programs referred to in this letter).

My only comment on the "time for some new leadership" is that I was personally very surprised by this letter, given that I have had several conversations with both Drs. Reinstein and Sonneberg over the past few months and without exception that have been collegial, cordial and positive in the outcome. I know that this is also the case with Jamie, Jeff and his group, and Sarah.

Please let me know if you want me to compile comments from Jamie and Lisa and respond to David and James, as well as to the customer. This customer does generate a tremendous amount of business for us and Sales, Marketing and Medical have all had significant open and honest dialog with them over the past weeks. Therefore, I am puzzled by their on-going lack of understanding, particularly as pertains to Points 1 and 2.

Thanks, Georgia

ADT.  
24/01

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October 23,2001

David Brennan, C.E.O.  
AstraZeneca Pharmaceutical, U.S.A.  
1800 Concord Pike  
P.O. Box 15437  
Wilmington, Delaware 19850

Dear Mr. Brennan;

RE:Seroquel(Quetiapine)

We have been informed by several of AstraZeneca's Pharmaceutical Sales Specialist that the physicians in our practice are the largest prescribers of Seroquel in the world and we have consistently taken an active role in promoting Seroquel. We want to express our long term frustration with certain practices of your company which, we feel have limited the overall use of Seroquel. Although the use of this drug is slowly increasing we feel that this drug should have a much higher market share. It seems almost laughable that Risperdol has approximately double the market share of Seroquel since, Seroquel has now been available for over four years has better efficacy and fewer side effects than Risperdol.

The reasons for Risperdol having a higher market share than Seroquel are obvious:

1. The promotion of Seroquel lacks medical direction. Janssen does far more research than AstraZeneca. Risperdol studies are of better quality and Janssen has published far more studies on their product than AstraZeneca has.
2. AstraZeneca still has not promoted an appropriate dosing strategy. When Seroquel was initially launched in 1997, the dosing strategy was, 300mg/day. Our dosing practices and research indicate that for a large number of patients a therapeutic dose of 1200mg/day is needed. The perception of most psychiatrist is that Seroquel lacks efficacy. This false perception prevents them from using it and/or using it effectively.

Daily we have encountered third party payers that refuse to pay for Seroquel prescriptions over 800mg/day due to the dose range listed in the P.D.R. This has made it difficult for us to appropriately treat our patients. When our physicians lecture across the country, we encounter complains from other psychiatrist who have been unable to get third party payers to pay for prescriptions over 800mg/day. More research needs to be done and submitted to the F.D.A. to increase the dose range.

3. Functioning as a speaker for Seroquel in the United States is problematic to say the least. Unlike AstraZeneca Canada and other pharmaceutical companies the speaker must pay his airfare, hotel and other expenses. Despite numerous promises collecting our out of pocket expense and honorarium continues to be very difficult. Complicating this further is the large number of speaking engagements that are canceled due to the Sales Representatives who scheduled the engagement being, "over budget". The speaker doesn't get reimbursed for his/her time scheduling the speaking engagement, long distance calls and faxes to the sales representative or lose revenue due to inability to replace the time slot with another revenue source at such a late date. Another major inconvenience is the lack of a coordinator for AstraZeneca in the United States. The Canadian division and other pharmaceutical companies have such a person. We must mail or fax our vitae and program description to each sales representative.

We feel it is time for some new leadership with this exciting product which could help so many patients. We would like to share our thoughts further with anyone in your organization that is willing to work with us to make the needed changes.

Sincerely,

Michael J. Reinstein M.D.,P.C.

S.C. Mohan M.D., S.C.

Maxim Chasanov M.D.,P.C.

S.A. Patel M.D.,S.C.

Rad Gharavi M.D.,S.C.

Lynne E. Jones R.N.

John Sonneberg Ph.D.