

**To:** Gibelin, Bruno  
**From:** Kaufman, Keith D.  
**Sent:** Wed 4/2/1997 9:16:25 AM  
**Importance:** Normal  
**Subject:** RE: Propecia press release

Bruno-

I do not think that the lack of statistical significance is the issue. This is almost certainly a real effect of the drug, and is supported both by the PROSCAR experience and by the statistically significant, though numerically small, changes seen in the sexual function questionnaire in the PROPECIA trials. Moreover, if the PROPECIA trials were larger (say 2000 patients/group), then we would have likely reached  $p < 0.05$ ; i.e., this is more of a sample size/statistical power issue than a physiological one. If asked, of course, you can respond that there is no statistically significant difference between treatment group for each of the 3 AE's.

Keith

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**From:** Gibelin, Bruno  
**To:** Kaufman, Keith D.  
**Cc:** Parent de Curzon, Agnès  
**Subject:** RE: Propecia press release  
**Date:** Wednesday, April 02, 1997 5:02AM

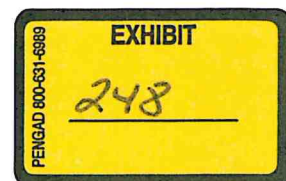
Thank you very much Keith for such a prompt answer.  
I understand perfectly what you say about labeling and the significance noticed when considering all the patients who had any of sexual AEs ...but when discussing with urologists in particular, I think it could help to know that in this population of younger men treated with 1mg the difference was not statistically different when it was different (at least for impotency and ejaculate volume decrease) with finasteride 5 mg in BPH.  
Even if it could not be used with the agency I'm sure sales forces would like to use it as an argument if the question was raised by the physician.  
Do you agree ?  
Thanks again.  
Bruno

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**From:** Kaufman, Keith D.  
**To:** Gibelin, Bruno  
**Cc:** Parent de Curzon, Agnès; Noon, David  
**Subject:** RE: Propecia press release  
**Date:** Tuesday 1 April 1997 19:14

Bruno-

The answer to your question is that, for each of the sexual AE's (decreased libido, erectile dysfunction, decreased ejaculate volume), the differences between treatment groups were NOT statistically significant. However, this is irrelevant for labeling purposes since, in general, all drug-related clinical AE's that occur at an incidence of at least 1% and are greater in active vs placebo wind up in the label under potential side effects reported in the studies, regardless of statistical significance. If one summarizes the data differently such that we look at ALL patients who had ANY of sexual AE, then the differences between groups (3.8% for finasteride vs 2.1% for placebo) become statistically significant.

Keith



From: Gibelin, Bruno  
To: Kaufman, Keith D.  
Cc: Parent de Curzon, Agnès; Noon, David  
Subject: FW: Propecia press release  
Date: Tuesday, April 01, 1997 4:42AM

Hi Keith,

Just a question concerning the sexual AEs with Propecia .  
Even if there is a small number of each of these side effects their number in the finasteride group is always higher than in the placebo group . Could you please provide the p values since I don't remember you have pointed on during your presentation ? In other words is the higher number of these side effects in the finasteride group statistically significant vs placebo ?

Thank you very much for answering.

Best Regards.

Bruno

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From: Noon, David  
To: Gibelin, Bruno  
Subject: FW: Propecia press release  
Date: Wednesday 26 March 1997 09:15

Bruno,

It was great seeing you again in San Francisco. I spoke with Dr. Regayne (I think that that is how you spell his name) after Keith's talk on Tuesday and he had interest in obtaining the efficacy numbers from the study for use in an article that he is writing. I told him that I would get the press release that Merck issued from the meeting, forward it to you, and you would get the information to him.

Please find it attached to give to Dr. Regayne. I hope it helps.

Dave

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From: Sinnott, Janet  
Sent: Monday, March 24, 1997 2:29 PM  
To: Bergh, Geoffrey K.; Casola, Thomas M.; Woodward, Jim; Gormley, Glenn J.; Silverstein, Leonard; Noon, David; Kaufman, Keith D.; Stoner, Elizabeth; Olson, R. Brent; Chusid, Paul  
Cc: Allman, Christopher D.; Munsell, Sherry; Weiner, Jan D.  
Subject: Propecia press release

Attached is the news release on the presentation of data on Propecia at the American Academy of Dermatology meeting in San Francisco.

<<File Attachment: PROPECIA.DOC>>