

(888) 899 2375

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Flewis, Nevada

ZY 9386 455

• Set up call MB/ ~~FL~~ FL or

① - 90 AP's in PCP

③ - we have data that  
we're safer/more  
effective than Haldol,  
Risperdal

④ - not trying to get away  
w/ anything

- woman is w/in range  
- has symptoms that  
could lead to  
diagnosis that's in

①

framing - we're really surprised  
if the PCP has objected



Valerie A Hobson  
08/30/01 10:50 AM

To: Michael E Bandick/AM/LLY@Lilly  
cc:  
Subject: DR LEMING LETTER

Per our conversation.

----- Forwarded by Valerie A Hobson/AM/LLY on 08/30/2001 10:44 AM -----



Steven B Cohen  
08/29/2001 10:10 PM

To: Valerie A Hobson

----- Forwarded by Steven B Cohen/AM/LLY on 08/29/2001 10:26 PM -----

**ANNE ELIZABETH TAYLOR**

08/22/2001 09:59 AM

To: Steven B Cohen

THOUGHT YOU OUGHT TO SEE THIS!

----- Forwarded by Anne Elizabeth Taylor/AM/LLY on 08/22/2001 09:58 AM -----



JALeming@aol.com on 08/21/2001 09:05:31 PM

To: medwatch cc: taylor\_anne\_elizabeth

Dear Medwatch:

I was detailed today by an Eli Lilly Senior Sales Representative (ELIZABETH TAYLOR - taylor\_anne\_elizabeth@lilly.com) on the product Zyprexa. During the detail presentation she presented me with a promotional brochure (which she said had been reviewed and approved by the FDA for use detailing physicians).

This brochure presented an elderly female patient who was presented to her physician by her family complaining of insomnia, agitation, slight confusion and had no physical finding to explain her state. She then proceeded to tell me what other physicians might prescribe for her (i.e., Zyprexa) and she attempted to engage me in the conversation by asking what I might prescribe for the sample patient. I indicated that I would try to arrive at a working diagnosis after history, physical examination and appropriate diagnostic testing and then prescribe for that tentative/working diagnosis.

I inquired what Zyprexa was indicated for she then indicated that many physicians might prescribe an antipsychotic for this patient. I then asked for the package insert and read to her that her product was indicated for schizophrenia and bipolar mania -- neither of which the presented patient had been diagnosed with. She then indicated that some physicians might have prescribed the patient Haldol (by name) or Resperdal (also by name) or other antipsychotic drugs that have been on the US market longer (she referred to these as "older" antipsychotics) and all she really wanted to do was to get physicians to prescribe the safest product for their patients. I am not aware of any head-to-head double-blind controlled studies comparing the

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safety of these three products no less the possible outcome(s) of these studies. I then challenged her again on what she could legitimately promote and wasn't she promoting her product (FAR) outside of its indications. She indicated that her promotional piece had been reviewed and approved by the FDA and that her presentation was legitimate. I have found Lilly to be a reputable firm in the past but this interaction causes me to question their promotion of this product to primary care physicians for use well outside of its approved indications. That caused me to question can a pharmaceutical representative (or their company) promote a product for "off-label" use? When can and or should they claim superiority? I was and am so disturbed that this drug is being (in my opinion) promoted inappropriately and its use therefore potentially pose a threat to public safety that I told her that I was going to write the FDA and see if her claims of approval and legitimacy were in fact true. I also told her I would copy her on the e-mail. Hence my e-mail. I have never contacted the FDA before and I do not believe that this E-mail has been generated out of a "personality conflict." Rather, I am genuinely concerned about the promotion of this powerful drug to my peer community of primary care physicians outside of its approved and intended purpose. I will let Lilly deal with the potential liability ramifications. I look forward to your response.

Truly,

Joseph A. Leming, MD, FAAFP  
President and Medical Director  
Prime Care Family Practice  
241 Charles Dimmock Parkway, Suite # 6  
Colonial Heights, Virginia 23843  
1.804.526.1111

PS this was a witnessed conversation by one of my partners, a pediatric nurse practitioner, one of our administrative managers etc.

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