

To: CN=Kristine Healey/OU=AM/O=LLY@Lilly
Date: 09/16/2002 04:36:44 PM
From: CN=Robert W Baker/OU=AM/O=LLY
Subject: Re: Diabetes risk

thanks Kristine!

Robert

Kristine Healey

09/16/2002 03:36 PM

To: Robert W Baker/AM/LLY@Lilly
cc: Vicki Poole Hoffmann/AM/LLY@Lilly
Subject: Re: Diabetes risk

current diabetes letter states:

The reporting rate frequency of these events, potentially related to hyperglycemia in the Zyprexa spontaneous safety database, was found to be "very rare," defined as a frequency of <0.01%, according to guidelines published by the Council for International Organizations of Medical Sciences (CIOMS). Most reports of hyperglycemia during Zyprexa treatment were in patients with one or more risk factors for diabetes, such as family/personal history of diabetes, pancreatic disorders or alcoholism, obesity, ethnic origin, weight gain during treatment, or treatment with drugs that have been temporally associated with hyperglycemia. Reports that contained information on dechallenge and rechallenge were reviewed. In 28 of 34 reported cases, dechallenges were positive; two of these patients also had a positive rechallenge.

Robert W Baker

09/16/2002 03:32 PM

To: Kristine Healey/AM/LLY@Lilly

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cc: Vicki Poole Hoffmann/AM/LLY@Lilly
Subject: Re: Diabetes risk

thanks Kristine, is it mentioned in our current approved diabetes letter - ie, as these Doctors are quoting us as saying 1/1000?

R

Kristine Healey

09/16/2002 03:23 PM

To: Robert W Baker/AM/LLY@Lilly
cc: Vicki Poole Hoffmann/AM/LLY@Lilly
Subject: Re: Diabetes risk

Our DKA letter is not approved yet, however, the draft states

The reporting rate frequency of events potentially related to glucose dysregulation (including cases of diabetes mellitus, ketoacidosis, and hyperosmolar coma) in the Zyprexa spontaneous safety database was found to be “very rare”, defined as a frequency of <0.01% according to guidelines published by the Council for International Organizations of Medical Sciences (CIOMS). A direct causal relationship with Zyprexa treatment has not been established

Referenced as DAta on file

Robert W Baker

09/16/2002 03:19 PM

To: Kristine Healey/AM/LLY@Lilly, Vicki Poole Hoffmann/AM/LLY@Lilly
cc:
Subject: Diabetes risk

Kristine or Vicki, does our current medletter estimate DKA as <0.1% or <0.01%? would these be rare and very rare respectively?

R

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----- Forwarded by Robert W Baker/AM/LLY on 09/16/2002 03:16 PM -----

RPETTYUS (Redacted)

09/16/2002 02:21 PM

To:

BAKER_ROBERT_W@LILLY.COM

cc:

KINON_BRUCE@Lilly.com, Khlittrell (Redacted) PROUTY_ERIC_L@Lilly.com, RICHARDS_JOHN_R@Lilly.com

Subject:

Diabetes risk

Dear Robert,

I do hope that this finds you well.

I have just been involved in a lengthy conference call with two doctors in Norfolk, Nebraska. They recently had a 37 year old man on olanzapine die in ketoacidosis. The case has been reported to Lilly, but they wanted to talk to me as the only person they knew of, who might be able to give them some advice on how to proceed with caring for their other patients. They were obviously shocked and upset. I think that we clarified matters very considerably. I sent them a lot of my most recent materials on diabetes and insulin resistance, and I have invited them to contact me again. I shall probably also be seeing them face to face in the not too distant future.

The reason for this note is that they received a medical letter from Lilly, which - they tell me -- contains the assertion that ketoacidosis occurs in one in one thousand people treated with olanzapine. That would seem astonishingly high, and is not what we would calculate from the published data. So:

1. Is that figure actually in the medical letter?
2. Is it correct? (I think it may be two orders of magnitude off, though I know it is difficult to calculate these things).
3. Is that the figure for spontaneous appearance of DKA in mentally ill people regardless of medicine? (I remember showing you some calculations which I did on that a couple of years ago).
4. Is that figure being used in order to comply with the FDA's criteria of "Rare", "Uncommon", etc.?

Do let me know when you get a moment.

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With kindest regards,

R

Richard G. Petty, MD

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To: CN=Kristine Healey/OU=AM/O=LLY@Lilly
CC: CN=Vicki Poole Hoffmann/OU=AM/O=LLY@Lilly; CN=Donald P Hay/OU=AM/O=LLY@Lilly
Date: 09/24/2002 02:10:18 PM
From: CN=Robert W Baker/OU=AM/O=LLY
Subject: Re:
Attachments: Glucose GRD New.doc

Dear Kristine:

nice work, see suggestions, will need some reference help eg from Vicki



Glucose GRD New.doc

Kristine Healey

09/20/2002 10:13 AM

To: Robert W Baker/AM/LLY@Lilly
cc:
Subject:

Dr. Baker-

I know that you have been traveling a lot lately so I have attached an electronic copy of the diabetes letter for review.

Thanks!
Kristine

[attachment "Glucose GRD New.doc" has been removed by Robert W Baker/AM/LLY]

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