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Drugmakers criticized over release of trial data

Once again GSK... getting creative with clinical data.

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Drugmakers criticized over release of trial data
 Delayed or partial disclosure of clinicals worries experts
 Sunday, October 29, 2006
 BY ED SILVERMAN
 Star-Ledger Staff
 In 1998, a big pharmaceutical company completed a pair of clinical studies comparing rival drugs for treating genital herpes.

But the results weren't published until last month.

The unusual delay is being chalked up by one drugmaker to the complicated fallout from a merger, which caused one medicine to change hands and data to be misplaced.

But the lead researcher for the studies complained she was never given a satisfactory explanation, and noted the drugmaker responsible for the delay also owns the medicine that fared poorly.

"I was given all sorts of reasons," said Anna Wald, a professor of medicine at the University of Washington, whose work comparing the two drugs -- Valtrex and Famvir -- was recently published in Sexually Transmitted Diseases, a medical journal.

"It took years to receive any material," she said. "They should have moved faster."

The episode comes to light amid growing criticism of the pharmaceutical industry for failing to disclose results of clinical studies -- especially studies that provide information about the safety or effectiveness of medicines being taken by consumers. The charges became especially heated during the recent debate about the safety of antidepressants and the withdrawal of the once-popular painkiller Vioxx, which spurred accusations that, in some cases, side-effect data were suppressed.

The issue has prompted scrutiny from some members of Congress and calls by the editors of several leading medical journals to require greater -- and more timely -- disclosure of clinical trials. Put on the defensive, pharmaceutical companies are voluntarily registering more of their clinical trials on company and government Web sites.

The debate, however, is far from finished.

Last month, a report by the Institute of Medicine, which criticized industry oversight by the Food and Drug Administration, recommended results of nearly all clinical trials should be disclosed. The report also noted few meaningful studies are conducted after a drug goes on the market, and even then, the data are generally quite limited.

"The purpose in having greater disclosure is for doctors and patients to make informed choices about benefits and risks," said Bruce Psaty, a professor of medicine at the University of Washington and a member of the IOM drug safety panel that issued the report. "It's simply not appropriate to delay publication. It's not in the interest of public health."

The studies of Valtrex and Famvir, for treating genital herpes, originated in the mid-1990s with the former SmithKlineBeecham, which originally sold Famvir. A rival medicine, Valtrex, was sold by the former GlaxoWellcome. The drugs were already on the market and each company touted their treatment as superior, but there was no comparative data to bolster the claims.

To gain an edge, SmithKlineBeecham funded a pair of comparative studies. Such clinical trials are known as head-to-head studies, but are rarely undertaken voluntarily by drugmakers due to the expense and, in particular, the possibility that results will be unflattering. In effect, SmithKlineBeecham took a gamble in hopes of boosting sales.

There was good reason. In 1997, the drugs were in a dead heat. Valtrex sales totaled \$111million on 1.6million prescriptions, while Famvir rang up \$107million in revenue on 1.1million prescriptions, according to Verispan, a market-research firm.

A team of researchers led by Wald conducted the studies in 1997 and 1998, but SmithKlineBeecham never shared the results, even though Wald said she repeatedly asked for the data. As a result, Wald said she had no way of knowing SmithKlineBeecham's Famvir compared unfavorably with Valtrex.

In other words, SmithKlineBeecham lost its bet.

"They kept telling me they were analyzing the data and analyzing the data," she said. "I got nowhere."

In 2000, Glaxo and SmithKline merged, complicating the tale. The combined company promptly sold Famvir to Novartis to satisfy anti-trust concerns. A Glaxo spokeswoman said there was no information available about how the study data were handled at that time or why the data weren't given to Wald.

By then, Glaxo's Valtrex had taken the lead. In 2001, Valtrex generated \$413million in sales on 4.4million prescriptions; Famvir rang up \$191million in sales on 1.5million prescriptions, according to Verispan.

After the merger, Wald said she began asking Novartis for the study data, but didn't receive anything until early last year, when the drug maker sent what she described as an "enormous box of papers." She said Novartis personnel insisted the data couldn't be located.

"There are two possible interpretations," said Wald, who is also a consultant to Novartis. "Either the data got lost as part of the transfer from one company to another. The other is that Novartis didn't want to share the data because it wasn't favorable (to Famvir), which might hurt the sales. I don't know which it is."

In an e-mail, a Novartis spokeswoman, Lucia Aurello-Beauchamp, wrote that there was actually no statistical significance found between the two drugs in the studies.

However, Wald and her colleagues concluded in their recently published journal article that Valtrex appears to be "somewhat better" than Famvir.

The spokeswoman added Novartis supports timely disclosure of clinical trial results and last year agreed to support an industry initiative. But she acknowledged "it took longer to publish the results than we would have wished. This reflects the fact that we did not conduct the studies ourselves, but acquired the data from another company, which had not completely analyzed the results."

The Novartis spokeswoman also explained Famvir data were stored among 28,000 boxes sent by Glaxo, and that talks began with Wald in January 2003. But she couldn't explain the delay between 2003 and late 2005, when Wald finally received the data.

One physician said he might have given patients a different medicine if the studies had been published.

"We used to prescribe a lot of Famvir three to five years ago, although we've since come to believe Valtrex is a better drug," said Ronald Frank, a urologist in Livingston. "But maybe I would've prescribed more Valtrex back then if I'd known about the studies. It's something I would've like to have known."

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AKA Laurie

"Faith is taking the first step even when you don't see the whole staircase."
 MLK

BriOnH



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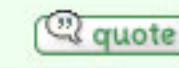
Re: Drugmakers criticized over release of trial data

Evil. Plain evil.

-Brian
1998 - put on paxil for panic disorder.
01/01/04 - Quit cold turkey 15mg - First Attempt.
05/18/04 - Went back on to 15 mg - I think I could have hung in there if I was aware of this forum.
07/28/2005 - Quit Paxil 15 mg - Second Attempt
11/06/2005 -- On 10 mg to stabilize and will try again
11/30/2005 -- Back to 15mg again.
12/18/05 -- 7.5 mg
12/31/05 -- 0
1/05/06 -- back on 15 mg

10/25/06 -- 1mg xanax down from 3 mg from 5 month taper.

www.diabuddies.com
Brian Hartigan



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