

**UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF LOUISIANA**

In re Actos (Pioglitazone) Product Liability Litigation	*	6:11-md-2299
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This Document Relates to:	*	JUDGE DOHERTY
<i>All Cases</i>	*	MAGISTRATE JUDGE HANNA
	*	

**TAKEDA’S RESPONSE TO THE MOTION TO PERMIT PUBLICATION  
OF STATISTICAL ANALYSIS OF KPNC DATA  
PURSUANT TO STIPULATED PROTECTIVE ORDER OF MARCH 3, 2015**

Defendants Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International, Inc., Takeda Pharmaceuticals LLC, Takeda Development Center Americas, Inc., Takeda California, Inc. (collectively, “Takeda”) respectfully respond as follows to the Motion to Permit Publication of Statistical Analysis of KPNC Data Pursuant to Stipulated Protective Order of March 3, 2015 (the “Motion”) that Plaintiffs’ Steering Committee (the “PSC”) sent Takeda on the evening of Thursday, August 13, 2015:

1. The PSC’s Motion requests an order lifting the confidentiality of statistical data analyses from the KPNC study of Actos and bladder cancer, and this response addresses the *JAMA* issue and several inaccuracies in the Motion.
2. The PSC states that the “origin” (*see* Motion at 5) of the KPNC Study demonstrates that Takeda has used the study data for litigation purposes all along. However, Takeda first discussed a possible epidemiologic study to assess the relative risk of developing bladder cancer among users of Actos during a February 2003 meeting with the FDA, and provided a proposed protocol in September 2003 for what would later become the KPNC Study.

The protocol was approved by the FDA in 2004 and the investigators began working on the study that year. The first bladder cancer case regarding Actos, on the other hand, was not filed until 2011, eight years after Takeda submitted the protocol to the FDA and seven years after the FDA approved the protocol (as amended) and the 10-year study began. The notion that the KPNC Study was hatched for litigation purposes is nonsense and contrary to the common sense chronology of these events.

3. The PSC's argument that Takeda's sponsorship of the KPNC Study is somehow improper ignores the fact that the FDA wanted this study and approved the protocol. In addition, Drs. Strom and Lewis from the University of Pennsylvania are prominent and well respected epidemiologists, and communications between them and a sponsor of their study are customary and ordinary. Indeed, the 2004 contract between Takeda and the University of Pennsylvania gave Takeda the right to preview any of the researchers' draft reports and publications. In short, the communications between Takeda and the researchers did not transform the KPNC Study into a "litigation study" simply because litigation was filed seven years after the study began.

4. The PSC's argument that Takeda is using the KPNC study as a "litigation study" is odd considering the fact that only the PSC's litigation experts have had access to the raw data files and have been paid by the PSC to review the data. The Protective Order that governs the restrictions governing use of the data files gave the PSC access to the raw data files. It did not give such access to Takeda unless and until a separate Protective Order was issued by this Court. Takeda has not sought permission to have its litigation experts be given access to the raw data

files. Thus a litigation advantage, if one exists with respect to access to and use of the raw data, is currently solely with the PSC.<sup>1</sup>

5. This past Friday afternoon (August 13, 2015), the Court asked Takeda to attest by Monday morning (August 16, 2015) as to whether Takeda has had access to the KPNC raw data files. Since Friday afternoon, Takeda's counsel have done their best to contact the current and former Takeda employees involved with KPNC in order to respond to the Court's question. Takeda's counsel have discussed the issue with Drs. Yates, Spanheimer, Perez, and Dolin, and all four have assured that they are unaware of any Takeda employee, past or current, having access to the data. The same answer is true with respect to outside consultants (aside from the PSC's argument about Drs. Lewis and Strom being Takeda's consultants). Takeda's inquiry continues with other scientists who may have information responsive to the Court's question.

6. The PSC also contends that Takeda has gone on a "public relations rampage" to deny a risk of bladder cancer with Actos and embarked on a "litigation-inspired PR campaign." (See Motion at 6.) Plaintiffs' evidence of this supposed campaign consists of fourteen news articles, editorials and commentaries that various medical writers have published since *JAMA*'s KPNC article. (See *id.* at 6 – 7.) However, those editorials and commentaries are typical responses within the medical field to an article in a widely circulated and prominent journal like *JAMA* which reveals the final results of a well-known and long-term study like the KPNC Study. What is noticeably absent from the PSC's allegations of a public relations rampage and the editorials on which they rely is a single press release from or editorial by anyone from Takeda. That is because there are none, and there has been no public relations campaign of any kind. Plaintiffs imply that there has been a media campaign by Takeda because two commentators

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<sup>1</sup> In September 2013, KPNC briefly created a "portal" to the data for "attorney eyes only" (and their consultants) that would have allowed Takeda's litigation experts access to the data. Undersigned counsel can attest to the fact that no counsel or expert on behalf of Takeda accessed the portal.

(Drs. DeFronzo and Ryder), who have in the past consulted with Takeda, published an editorial about Actos. (*See id.* at 7.) This editorial was not paid for by Takeda, and counsel are unaware of any information which would suggest that Takeda requested publication of the editorial. The PSC's assertion that Takeda has orchestrated a media campaign around the published KPNC study is a product of their fertile imaginations, not facts.

7. If the PSC and its paid experts want to criticize the KPNC Study, Takeda's sponsorship of it, and the *JAMA* article, they can do so by writing a letter to *JAMA* with the same critiques they have used repeatedly in this Court. The PSC's experts did not need the raw KPNC data to testify to the jury in *Allen* that KPNC was a "bad" study. Similarly, they don't need to use the raw data to criticize the KPNC methodology in editorials or letters to medical journals, as the PSC appears to be asking them to do.

8. The PSC argues that there is "no reason" for their Motion "other than its necessity for litigation" (*see* Motion at 5), just as it similarly argued when it wanted to obtain access to the KPNC data in the first place. However, if the PSC's goal is to advance plaintiffs' litigation interests through expert analysis of the raw data, the PSC can pursue that goal by having its experts present the analysis to juries in the court room. There is no need to present the analysis of the raw data in a letter to the *JAMA* editor.

9. The PSC's attacks on *JAMA*'s publication of the KPNC article suggest that *JAMA* is some kind of fly-by-night shill medical publication that is under the thumb of pharmaceutical companies like Takeda. Nothing could be further from the truth. *JAMA*, the Journal of the American Medical Association, is one of the most well respected medical journals in the world and *the* most widely circulated medical journal in the world. *JAMA* is an internationally peer-reviewed journal and has been in existence since 1883. It only accepts approximately 9% of the

nearly 7,000 manuscripts it receives annually.<sup>2</sup> Thus, all of the PSC's innuendos about the shortcomings that it and its consultants have supposedly uncovered about the KPNC Study must be considered while keeping in mind that the publication of the final results were vetted by one of the pre-eminent journals in the world.

### **CONCLUSION**

The PSC has shown no compelling reason to alter the terms of the Protective Order that gave the PSC access to the raw data for litigation purposes.

DATED: August 17, 2015

Respectfully Submitted,

*/s/ Sara J. Gourley* \_\_\_\_\_

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<sup>2</sup> (See <http://store.jamanetwork.com/productDetails.aspx?productcodeID=64>).

**CERTIFICATE OF SERVICE**

I hereby certify that on August 17, 2015 I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send a notice of electronic filing to Plaintiffs' Steering Committee, Lead Defense Counsel and Defendants' and Plaintiffs' designees. The designees will forward the NEFs to the appropriate attorneys as outlined by the Court's Case Management Order: Notice of Procedure [D.E. 3398].

*/s/ Sara J. Gourley* \_\_\_\_\_

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