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July 2, 2013

Janet Woodcock, M.D.
Food and Drug Administration
Director, Center for Drug Evaluation and Research
10903 New Hampshire Avenue
Building 51, Rm. 6133
Silver Spring, MD 20993

Re: Docket No. FDA-2012-P-0857; Petition to Revoke the Pediatric Indications for Risperdal®

Dear Dr. Woodcock:

We are writing in response to your letter dated June 11, 2013, in which you denied our request for a hearing regarding issues raised in our Citizen Petition, docket number FDA-2012-P-0857, which urges the Food and Drug Administration ("FDA") either to revoke the pediatric indications for Risperdal®, generic risperidone, and Invega® unless and until their long-term safety in this population can be established, or, in the alternative, require a Black Box Warning on the labels for these products.

You noted that our Citizen Petition also requested the FDA to "consent to release [us] from any and all standing Confidentiality/Protective Orders" in order for us to produce documents and testimony obtained during the discovery process that directly relate to the request in our Citizen Petition. In response, you recommend that, in place of a hearing, we submit the documentation we believe the FDA should have in order to evaluate the petition. It appears you misunderstand both our request and the legal status of those documents.

The full request set forth in the Citizen Petition is

> consent to release [us] from any and all standing Confidentiality/Protective Orders **so that** Petitioner can present **to the FDA** the internal documents and data, as well as an expert analysis thereof which we believe support the foregoing requested actions. [emphasis added].

We would like to submit to the FDA those documents we have uncovered during the discovery phase of various litigations against Janssen and Johnson & Johnson (collectively, "J&J") but we cannot. We are prevented, by court orders issued in the pending litigations,

from providing those documents and testimony to the FDA. They have been designated as "Confidential" under the purview of a Protective Order, so we cannot legally send them to the FDA to be placed on a publicly-viewed docket. We also suggested in our original petition that, in the alternative, **the FDA** could demand the relevant documents from J&J.

The purpose of these requests was not to have the FDA override a court order. It was to have the FDA direct J&J to allow us to turn over these documents to the FDA **or** to have the FDA acquire them directly from J&J. We believe that it is within the power and authority of the Commissioner of the FDA to order J&J to release us from the unjust strictures of a Protective Order in a civil lawsuit. Further, FDA has the authority to demand safety-related documents in order to review them. The J&J information is already available to FDA – all you have to do is ask them for the documents.

If the FDA chooses to request the document directly from J&J, we strongly recommend that oversight by someone in our firm should be permitted to help ensure that all relevant material is provided.

Yet another alternative is for the FDA to acquire a copy of J&J's proprietary safety/adverse event database and perform its own statistical analysis. While we suppose that this is not as cost-effective as acquiring the J&J documents we have examined, we mention it as another example of action that is within the authority of the FDA. We hope that there are no potential conflicts of interest to interfere with any of the FDA's safety-related activities.

Your letter notes that we have previously mentioned a report authored by David Kessler, M.D., former Commissioner of the Food and Drug Administration. Although Dr. Kessler's report is publicly available, the documents to which he refers are still subject to the Protective Order previously discussed so it makes little sense to submit this report to the docket without the substantiating materials.

We are agreeable, however, to submitting it to a designated person at the FDA if the FDA intends to demand the substantiating documents from J&J, as we strongly urge the FDA to do.

Dr. Kessler's report is especially insightful regarding a particular meta-analysis published in November, 2003 entitled, "Prolactin Levels During Long-Term Risperidone Treatment in Children and Adolescents" by Robert L. Findling, M.D., et al. One of the co-authors of this article, Denis Daneman, M.B.B.Ch., F.R.C.P.C., testified, during his publicly-available deposition earlier this year, that the article's abstract was inaccurate where it stated, "There was no direct correlation between prolactin elevation and SHAP" [Symptoms Hypothetically Attributable to Prolactin, i.e., gynecomastia in boys]. He also agreed that this article failed to report the statistically significant association between elevated prolactin levels and SHAP.

Despite Dr. Kessler's analysis of this article and Dr. Daneman's deposition testimony, J&J and major thought leaders are still citing this article as proof that there is no correlation

or association between elevated prolactin and the incidence of gynecomastia in boys. Dr. Kessler was recently deposed on the subjects of his expert report, including his criticism of the above cited meta-analysis. Although confidential, the FDA has no bar or impediment in its way and can simply ask J&J for a copy of the transcript to review. Regardless of the reason, ignoring the pediatric safety data and information available in these internal J&J documents, as well as the relevant, but confidential, testimony is tantamount to ignoring the safety and interests of the children the FDA is charged with protecting.

The FDA will find value in Dr. Kessler's analysis, **along with a review of the corroborating documents**. We find it difficult to understand, therefore, why the FDA has refused to avail itself of the tools and material it has to require that J&J produce these documents and review the pediatric safety data and information contained therein. It is even more difficult to understand, knowing that you are scheduled to be a keynote speaker at the upcoming Clinical Trials Disclosure and Transparency Summit, whose stated purpose is to examine the "tougher new FDA and EMA disclosure and transparency requirements for clinical trials."

It has been nearly one year since we submitted our Citizen Petition. The only action the FDA has taken in that time is to notify us, in an interim response, that our Petition "raises complex issues requiring extensive review and analysis by Agency officials" and then to deny a hearing request and advise us to submit documents we are legally barred from sharing.

In that time, thousands of children may have been harmed by using one of these drugs, when an alternative medication without these serious, prolactin-related adverse effects could have been administered instead.

If, indeed, the safety actions requested in our Citizen Petition are "complex issues" which require "extensive review and analysis," we urge the FDA to begin that process immediately and we reiterate our request for a hearing as the first step.

We ask that you contact us to arrange a meeting where we can discuss the issues raised in our Citizen Petition.

Sincerely,

Stephen A. Sheller, Esq.

Christopher A. Gomez, Esq.

SAS/