

A. WARREN



NEW JERSEY OFFICE

210 LAKE DRIVE EAST  
SUITE 101  
CHERRY HILL, NJ 08002  
(609) 941-2596  
FAX (215) 546-0942

1528 WALNUT STREET, 4th FLOOR  
PHILADELPHIA, PA 19102

(215) 790-7300 • (800) 883-2299  
FAX (215) 546-0942  
WEBSITE: [WWW.SHELLER.COM](http://WWW.SHELLER.COM)

OF COUNSEL

KENNETH W. SMITH, ESQUIRE  
ALEXANDRIA, VA 22306

Brian J. McCormick, Jr.  
[bjmccormick@sheller.com](mailto:bjmccormick@sheller.com)  
(215) 790-7325

**Control No. 12090793**

**Opposing Counsel**

**Drinker Biddle & Reath, LLP**

- **Kenneth A. Murphy, Esq.**
- **Melissa A. Graff, Esq.**

**Motion filed: September 9, 2012**

**Response date: September 19, 2012**

**VIA HAND DELIVERY AND ELECTRONIC MAIL**

The Honorable Sandra Mazer Moss  
Co-Coordinating Judge  
Complex Litigation Center  
392 City Hall  
Philadelphia, PA 19107

The Honorable Arnold L. New  
Co-Coordinating Judge  
Complex Litigation Center  
606 City Hall  
Philadelphia, PA 19107

***In re: Risperdal Litigation, March Term 2010, No. 296***

***AB, a minor, et al. v. Janssen Pharmaceuticals, et al., Jan. Term 2010, No. 00649***

---

**PLAINTIFFS' RESPONSE IN OPPOSITION TO THE JANSSEN DEFENDANTS'  
MOTION TO QUASH THE SUBPOENA DIRECTED AT JOHNSON & JOHNSON'S  
CHIEF EXECUTIVE OFFICER, ALEX GORSKY**

---

Dear Judge Moss and Judge New:

Plaintiffs AB, a minor, and Jennie Rolen, his mother, by and through their undersigned counsel, hereby oppose the Motion to Quash filed by the Janssen Defendants on September 6, 2012 (“Motion”). The Motion seeks to quash a subpoena issued by this Court, and served by Plaintiffs’ counsel on Alex Gorsky (Janssen’s former Vice President of Sales and Marketing), on August 29, 2012.

Plaintiffs simultaneously cross-file a Motion to Compel the Appearance of Mr. Gorsky before this Court to explain and clarify his travel plans for the upcoming weeks, since Janssen waited more than two weeks to bring such plans to Plaintiffs’ and the Court’s attention. While “trial by ambush” is not well-regarded in Pennsylvania, nor is ducking a Court-ordered subpoena.

### **EXECUTIVE SUMMARY**

In an effort to deprive Plaintiffs of an important fact witness at trial, the Janssen Defendants have asked this Court to quash a valid trial subpoena served on Alex Gorsky, the former Vice President of Sales and Marketing at Janssen, who had major responsibility for Risperdal during a crucial time period. Tellingly, Janssen’s motion is completely silent about the importance of Mr. Gorsky to Plaintiffs’ case, and for good reason.

There is no question that Mr. Gorsky had significant, direct and important involvement in the conduct that gave rise to this litigation. Indeed, in his *own résumé*, Mr. Gorsky actually brags that he “[e]xpanded RISPERDAL sales from \$500MM to \$800MM in US Sales.”<sup>1</sup> Further, based on documents and other information provided in discovery, it is clear that Mr. Gorsky was aware of, and actively involved in, a number of matters at issue in this case (*i.e.*,

---

<sup>1</sup> See Exhibit A.

elevated prolactin, off-label marketing, labeling issues, etc.). During the relevant time period, Mr. Gorsky oversaw the various divisions that managed Risperdal, including its promotional and marketing efforts.

Moreover, this Court's recent decision to deny Defendants' Motion for Summary Judgment and to apply Texas law,<sup>2</sup> makes the off-label promotion of Risperdal highly pertinent to this case, *see* TEX. CIV. PRAC & REM. CODE ANN. § 82.007(b)(3)(A) (evidence of off-label promotion is an exception to the Texas statutory FDA presumption against failure to warn claims) and Mr. Gorsky was, and remains, knowledgeable about that particular area of Risperdal's marketing. Indeed, an internal Janssen email from early 2003 confesses that the extraordinarily large number of children and adolescents ingesting Risperdal (compared to other atypical antipsychotics, presumably) keeps "Alex Gorsky awake at night."<sup>3</sup>

Plaintiffs should have the opportunity to demonstrate to a jury what Mr. Gorsky knew, and now knows, about Risperdal, particularly as it relates to the illegal marketing and promotion of Risperdal that occurred during his time as the Janssen employee in charge of Sales and Marketing for the division that supervised Risperdal. As will be shown by the documents below, Mr. Gorsky's involvement with Risperdal is undisputable and pronounced.

In addition, Plaintiffs cross-file a Motion to Compel Mr. Gorsky to appear before this Court on Friday, September 21, 2012, in order to offer an explanation regarding his newly-minted travel plans. The relevant timeline is important to recollect.

Defendants filed their Motion to Quash on September 6, 2012. They made no mention of any out-of-country travel plans for Mr. Gorsky in that Response. However, on Friday,

---

<sup>2</sup> At the time of filing, a listing of the Court's Order is viewable on the First Judicial District's electronic docket, but no "hard copy" of the Order is available to counsel yet.

<sup>3</sup> *See* Exhibit C.

September 14, 2012, more than a week later, and after business hours, at 5:43 p.m., Janssen served, and presumably filed, the Affidavit of one Kathleen Torok, who has been Mr. Gorsky's executive assistant since January 2011. According to Ms. Torok's Affidavit, which, is strangely undated, Mr. Gorsky currently has plans to be in Asia during the first week of Plaintiffs' trial (September 24-September 30). Ms. Torok claims that such plans have been scheduled since May 2012. However, Defendants chose to raise these plans only now, on the eve of trial.

The timing of Ms. Torok's Affidavit raises more questions than it answers. If Mr. Gorsky's schedule included these plans since May 2012, why wait to raise them only now?

Mr. Gorsky should be ordered to appear in Philadelphia, Pennsylvania during the first week of Plaintiffs' trial. In order to properly investigate and check Mr. Gorsky's newly-discovered travel plans, Mr. Gorsky should, at a minimum, be ordered to appear in Philadelphia on Friday, September 21, 2012 to explain his plans and availability to Plaintiffs' counsel and the Court in the face of a properly-served and executed trial subpoena issued in the Commonwealth of Pennsylvania.

## **I. FACTUAL BACKGROUND**

As this Court well knows, Plaintiff AB was prescribed and ingested the Risperdal and/or Invega that caused his gynecomastia when he was between the ages of 5 and 14 (2000-2007). However, until October 2006, the FDA had not approved Risperdal for any use in the child and adolescent population.

Prior to 2000, the year Plaintiff AB began his Risperdal prescription, Janssen began marketing the drug off-label for children. During that same time, Mr. Gorsky served as the Vice-President, Sales and Marketing, and as the Vice-President, Marketing, CNS [Central Nervous

System] Division.<sup>4</sup> In both of these positions, Mr. Gorsky had significant responsibility for Risperdal and its marketing and use.

Mr. Gorsky started with Janssen as a hospital sales representative in October 1988.<sup>5</sup> Although it appears that Mr. Gorsky had little or no sales or pharmaceutical experience, he quickly rose in the ranks at Janssen. He served as a Group Director in the Psychiatry, Neurology, Allergy, Analgesia and Oncology Franchises, and, by March 1997, he was promoted to Vice President of the CNS Division, which is the division that included Risperdal.<sup>6</sup>

Indeed, Mr. Gorsky's *own résumé* touts the fact that he "[e]xpanded RISPERDAL sales from \$500MM to \$800MM in US Sales."<sup>7</sup> In October 1998, he was made Vice-President of Marketing for a number of divisions, including the CNS Franchise where he "[e]xceeded forecasts for RISPERDAL."<sup>8</sup> In December 1999, he was promoted to Vice President of all sales and marketing at Janssen U.S.<sup>9</sup> Mr. Gorsky was eventually appointed President of Janssen in 2001.

Thus, from March 1995 until he left Janssen in February 2003, Mr. Gorsky had some, often considerable, responsibility for Risperdal, which was Janssen's largest selling drug during this time period.

The documents in this case show exactly how Mr. Gorsky expanded Risperdal sales by \$300 million. From 1998 through 2003, the off-label use of Risperdal in children grew from almost \$60 million per year to more than \$470 million per year. Another large portion of that increase came from illegally promoting the drug based on symptoms rather than diagnoses (*e.g.*,

---

<sup>4</sup> See Exhibit A.

<sup>5</sup> See *id.*

<sup>6</sup> See *id.*

<sup>7</sup> See *id.*

<sup>8</sup> See *id.*

<sup>9</sup> See *id.*

unlawfully selling based on a symptom of “aggression” rather than on a diagnosis of “schizophrenia”).<sup>10</sup> All of this occurred not only on Mr. Gorsky’s watch, but under his orders. No wonder he couldn’t sleep at night.

Moreover, appearing as a fact witness on behalf of Defendants to testify regarding Risperdal-related matters is not unusual for Mr. Gorsky. In fact, in the instant case, the Discovery Master, Thomas Rutter, ordered Mr. Gorsky to appear for a discovery deposition over Defendants’ objections. Similarly, Mr. Gorsky was deposed in a *qui tam* litigation in the state of Texas, *State of Texas ex rel. Allan Jones v. Janssen*, which involved claims that Janssen had marketed Risperdal for off-label uses in Texas.<sup>11</sup> This case eventually settled in January 2012 for \$158 million.

Finally, Mr. Gorsky has recently been subpoenaed for a deposition by the federal government in a *qui tam* case against Janssen and Omnicare, the nation's leading provider of long term care pharmacy, entitled *United States ex rel. Lisitza v. Johnson & Johnson, et al.*, Civil A. No. 07-10288-RGS. That case, which also involves claims relating to the off-label promotion of Risperdal, is currently stayed, as is discovery.

## **II. LEGAL ARGUMENT**

As will be shown below, Mr. Gorsky has important testimony to offer the jury in this case. Accordingly, Plaintiffs’ case will be severely prejudiced if they are not permitted to examine Mr. Gorsky live at trial, and have his responses, demeanor and credibility evaluated by the jury.

---

<sup>10</sup> See Exhibit D (relevant portions of CNS Training Manual), at JJRIS00431663. The remainder of that increase came from illegally promoting the drug for off-label use to sedate the elderly in nursing homes.

<sup>11</sup> Plaintiffs’ counsel in this case was not involved in the Texas case, nor notified of the deposition.

No reported Pennsylvania appellate court opinion has expressly adopted the “apex” doctrine, relied on by Janssen to prevent Mr. Gorsky’s deposition.<sup>12</sup> Moreover, Pennsylvania’s Rules of Civil Procedure do not contain a requirement that a party must show that a high level officer has unique or superior knowledge before the officer can be deposed or testify. *See, e.g.,* Pa.R.Civ.P. 4003.1(a) (allowing a party to discover any matter that is not privileged and is relevant to the subject matter of the pending action or whether it relates to any claim or defense in the case), 4007.1.

Some courts have, in very limited circumstances, protected the highest ranking individuals of companies from depositions (not testifying at trial pursuant to a valid subpoena) where those individuals had no connection to the case, and their knowledge was of no personal or relevant nature. Courts, however, do not see high executives as immune from being deposed. *See Bridgestone v. Products Liability Litigation*, 205 F.R.D. 535, 536 (S.D. Ind. 2002) (determining that even at Ford Motor Company, the knowledge of the highest ranking employees, including the Chairman of the Board, may be relevant to the issues presented in a litigation case); *Wauchop v. Domino Pizza*, 143 F.R.D. 199, 202 (N.D. Ind. 1992) (requiring CEO of Domino's to be deposed after evidence was presented of his direct involvement in implementing relevant corporate policies). Here, the Discovery Master has already ruled that Mr. Gorsky’s testimony was relevant for a discovery deposition; it is his appearance at trial that is at issue now.

The “apex doctrine” has very limited application, and does not bar litigants from obtaining the testimony of high-ranking corporate executives where they have personal knowledge of relevant events that is not obtainable elsewhere. *See, e.g., Six West Retail*

---

<sup>12</sup> In comparison, Texas has adopted such guidelines. *See Crown Central Petroleum Corp. v. Garcia*, 904 S.W.2d 125 (Tex. 1995). However, even under those guidelines, Mr. Gorsky would be ordered to testify.

*Acquisition, Inc. v. Sony Theatre Mgmt. Corp.*, 203 F.R.D. 98, 102 (S.D.N.Y. 2001); *Travelers Rental Co., Inc. v. Ford Motor Co.*, 116 F.R.D. 140, 142 (D. Mass. 1987) (rejecting claim that depositions of corporate executives were noticed solely to harass). Even where a high ranking executive denies having personal knowledge of relevant issues, a litigant is entitled to his sworn testimony to test the scope of his knowledge. *Six West*, 203 F.R.D. at 102 (citation omitted).

In comparison, the cases cited by Defendants present situations where the individual being deposed had zero knowledge regarding the case, and were essentially *being deposed* to determine whether the individual had any relevant information, creating a waste of all parties' time.<sup>13</sup> That is clearly not the case here. In contrast, Mr. Gorsky has personal knowledge to this case and was the final word in the relevant chain of command.

**A. Mr. Gorsky Was Extremely Involved In, And Admittedly Had Unique Knowledge Of, The Issues In This Lawsuit**

One of the crucial issues in this case is calculating when Janssen knew that elevated prolactin, which leads to the development of gynecomastia, was a risk and/or hazard for patients being prescribed Risperdal. In that vein, *since at least October 1998*, Mr. Gorsky has been aware that "prolactin levels" resulting from Risperdal use were a concern for Janssen, as well as "the effect of hyperprolactinemia [elevated prolactin] on sexual dysfunction, . . . and [its] long

---

<sup>13</sup> See *Reify v. CNA*, 248 F.R.D. 448, 454 (E.D. Pa. 2008) (deposition of CEO denied where CEO allegedly made one ageist comment at a quarterly corporate meeting four years prior to Plaintiffs termination); *Naylor Farms, Inc. v. Anadarko OCG Company*, Civil A. No. 11-cv-01528 (D. Colo. June 27, 2011) (CEO was not in office when contracts at issue were negotiated and he swore under oath that he was not involved in drafting the single PowerPoint presentation that the plaintiff wished to question him about); *Roman v. Cumberland Insurance Group, et al.*, No. 07-cv-1201, 2007 U.S. Dist. LEXIS 96775 (E.D. Pa. Oct. 26, 2007) (in a case involving a flood in a basement of a home, defendants provided sworn testimony that the board of directors and other executives had no direct knowledge of plaintiff's claim and claims adjuster who handled plaintiff's claim was available). Unlike the cases relied on by Janssen, Mr. Gorsky has never (because he cannot) denied, by way of Affidavit, that he has knowledge of the relevant facts.



term effects.”<sup>14</sup> Indeed, the minutes of a “Risperdal Brand Strategic Planning Meeting” on October 19, 1998 show that Mr. Gorsky was present when all of these issues were discussed.<sup>15</sup>

In a January 2001 email to other Janssen executives, *Mr. Gorsky himself identified prolactin as a “weak spot” that needed “defending”*.<sup>16</sup> This email also displays the depth of Mr. Gorsky’s knowledge of the antipsychotic market and his important participation in strategy decisions regarding the marketing of Risperdal.<sup>17</sup>

Similarly, Mr. Gorsky was also very knowledgeable about the extraordinary number of children and adolescents being prescribed and ingesting Risperdal. For example, when questioned about a 2001 business plan, Mr. Gorsky responded as follows:

Q. As of 2001 would it have been among the business goals of Janssen to grow awareness of Risperdal’s use in the child and adolescent market through medical education progress?

A. It would have been our – one – one of our business goals. . . .<sup>18</sup>

As of December 2000, Mr. Gorsky knew of, and helped develop, a “Risperdal Pediatric Market Overview.”<sup>19</sup> Some of the “key findings” sent to Mr. Gorsky and other Janssen management included:

- “Risperdal pediatric sales in 2000 is forecast at \$167MM [million] . . .”;
- “Risperdal pediatric TRXs [prescriptions] are growing at near 50% annually, . . .”;
- Risperdal has a 58% share of the pediatric APS [antipsychotic] Affective Disorder Market . . . .”<sup>20</sup>

---

<sup>14</sup> See Exhibit E (JJRE0246675), at -756.

<sup>15</sup> See *id.*

<sup>16</sup> See Exhibit F (JJRIS03135785), at -786.

<sup>17</sup> See *id.*

<sup>18</sup> Exhibit G, Texas Deposition Transcript, at page 368-69.

<sup>19</sup> Exhibit H (JJRE01513159), at -159, -160.

<sup>20</sup> See *id.* at -159.

The “Pediatric Market Overview” provided Mr. Gorsky with research about dosing, treatment of various disease states, adverse effects and sales figures for a population (children and adolescent) almost six years before the FDA approved the drug for that population.<sup>21</sup> Also, the business plan noted that one “Barrier to [Risperdal] Use” was “lactation,” which is an “acute side effect” of elevated prolactin.<sup>22</sup>

One day later, Mr. Gorsky was sent a document entitled “Financial Assessment of Risperdal Pediatric Indication.”<sup>23</sup> When asked if he thought that a meeting to discuss Risperdal in the use of children was necessary before a presentation to Janssen’s board, Mr. Gorsky responded “Absolutely.”<sup>24</sup> Despite Janssen’s protestations, *their own documents* show that Alex Gorsky is not an “apex” executive who has no knowledge of day-to-day operations. To the contrary, Mr. Gorsky often placed himself in the middle of these decisions and strategy;<sup>25</sup> Mr. Gorsky’s pronounced involvement with Risperdal would only be reasonable, considering that Risperdal was Janssen’s only true blockbuster drug, with sales reaching almost \$1 billion.

A 2001 “TACTICAL PLAN” developed under Mr. Gorsky’s stewardship states that one of the “2001 Base Business Goals” was to “grow awareness of RISPERDAL use in child/adolescent market via medical education.”<sup>26</sup> It also states the “RISPERDAL - Base Business Key Strategies” include “protect and expand partnerships with key customers” such as “child and adolescent.”<sup>27</sup> Finally, the presentation notes that “RISPERDAL - Base Business Key

---

<sup>21</sup> See, e.g., *id.* at -161, -163, -166, -177, -181, -183.

<sup>22</sup> See *id.* at -182.

<sup>23</sup> See Exhibit I (JJRE01547572), at -574.

<sup>24</sup> See *id.* at -573.

<sup>25</sup> Similarly, for example, in January 2002, Mr. Gorsky circulated an email to other Janssen executive asking for one of his co-workers to set up a “strategy” meeting related to RISP [Risperdal] and children.” Exhibit J (JJRE02265819).

<sup>26</sup> See Exhibit K (JJPHD00009380), -386.

<sup>27</sup> See *id.* at -387.

Strategy #2” is to “protect and expand reach/partnership with key customers”, *including pediatricians*.<sup>28</sup>

Another sales tactic to protect and expand reach/partnerships with key customers is identified as the “Child and Adolescent Plan”.<sup>29</sup> The “Child and Adolescent Plan” includes the objective of “reach[ing] psychiatrists who treat children and adolescent mental disorders”.<sup>30</sup> The methods to reach this objective include “DLN and Teletopics (Robert Findling)”, “Advisory Board” and “Key areas of focus for specific HOV’s [home office visits].”<sup>31</sup>

Janssen and J&J used “education” and contact with pediatric prescribing physicians to expand Risperdal’s market share in the child and adolescent market. Janssen had an affirmative and overt plan to promote and sell Risperdal off-label for children; Mr. Gorsky clearly was instrumental in implementing it. Janssen promoted Risperdal off-label by, among other things, offering free trips to hotels and vacation locations, free meals, free samples of Risperdal and other perks to further advance the “educational” information it was providing doctors, knowing Janssen’s sole motivation was to expand Risperdal prescription sales to children and protect its top-seller from competitor drugs. An internal Janssen email from February 2003 states that “these issues [off-label prescriptions to children] leave ‘Alex Gorsky awake at night.’”<sup>32</sup>

In addition, Mr. Gorsky was involved in Janssen’s inappropriate efforts to obtain a copy of an NIMH RUPP Study and “editorial comments” before it was even published in the NEW ENGLAND JOURNAL OF MEDICINE in 2002.<sup>33</sup> Somehow this article was leaked to J&J despite the

---

<sup>28</sup> See *id.* at -393.

<sup>29</sup> See *id.* at -394.

<sup>30</sup> See *id.*

<sup>31</sup> See *id.*

<sup>32</sup> Exhibit C.

<sup>33</sup> See Exhibit J, at -820.

fact it was supposed to be an independent study that Janssen did not sponsor.<sup>34</sup> In an email string between senior management, including Mr. Gorsky, J&J employees discussed the possibility of replicating a similar study in Europe which Janssen could use to obtain a pediatric approval. In an email addressed to Mr. Gorsky, Dr. Christine Cote, the VP of Medical Affairs for Janssen, wrote that “the replicate trial needs to be run very carefully so we really do end up with a second positive result, therefore I recommend that our team are involved in reviewing the design of the study and the data handling must be done to REG standards. . . . Either way we (JNJ) need to be sure it is fit for purpose.”<sup>35</sup> Mr. Gorsky replied – “I think it would be helpful to have a discussion at the BDUM on our strategy with RISP and children.” *Id.* When Mr. Gorsky sent this email, in January 2002, Janssen *was still more than four years from a pediatric indication.*

A month later, Mr. Gorsky was sent the results of an important clinical trial evaluating Risperdal’s use in patients with Bipolar I Disorder.<sup>36</sup> When asked why he sent the results of the trial to Mr. Gorsky, Carmen DeLoria, who was the Senior Product Director for Risperdal in the CNS division, testified that it was “customary” for him to send information related to “key clinical trials” to Mr. Gorsky.<sup>37</sup> Similarly, Kent Bockes, another marketing executive, testified that he recalled Mr. Gorsky being present when Mr. Bockes presented the “RISPERDAL Child and Adolescent Market” Business Plan to certain other Janssen employees in July 2001.<sup>38</sup> This Business Plan, which identified Risperdal as the “gold standard in the C&A market,” contained

---

<sup>34</sup> *See id.*

<sup>35</sup> *See id.*

<sup>36</sup> *See* Exhibit L (JJRE 06149148).

<sup>37</sup> *See* Exhibit M (deposition testimony of C. DeLoria), at 353, 358-59.

<sup>38</sup> *See* Exhibit N (deposition testimony of K. Bockes), at 174-75 and Exhibit O (RISPERDAL Child and Adolescent Market Business Plan).

numerous figures regarding the pediatric population's use of Risperdal, and also identified Prolactin as a "Weakness" for Risperdal.<sup>39</sup>

In addition, Mr. Gorsky approved and signed off on the 1999 Master Agency Agreement between Janssen and Excerpta Medica, the medical communications company hired to help Janssen develop and plan Risperdal's marketing strategy. That Agreement provided, in part:

The Client [Janssen Pharmaceutica, Inc.] desires for Agency [Excerpta Medica, Inc.] to perform certain work and services in the **general field relating to marketing and advertising**. Agency accepts such appointment and agrees to perform the services, which will be described in detail in addend to this agreement, according to the terms of this agreement.<sup>40</sup>

This marketing agreement was approved by Alex Gorsky.<sup>41</sup>

Finally, Mr. Gorsky was in the midst of the J&J-Massachusetts General Hospital-Dr. Biederman triumvirate that ended in a public apology from Dr. Biederman and an investigation by U.S. Senator Charles Grassley. Mr. Gorsky actually approved the \$500,000 grant to Massachusetts General Hospital in 2001.<sup>42</sup> Moreover, he gave the "Introduction and Welcome" at the "Formative Meeting" for the "Johnson & Johnson Center for Pediatric Psychopathology at Massachusetts General Hospital (MGH)" on March 14, 2002.<sup>43</sup> The goals of the J&J-MGH Center were many, including forming "a strategic collaboration between Johnson & Johnson and the Pediatric Psychopharmacology Research Program at the Massachusetts General Hospital" and "mov[ing] forward the commercial goals of J&J."<sup>44</sup>

Above are just a few examples of many which demonstrate that Mr. Gorsky was directly involved in J&J's off-label marketing of Risperdal and manipulation of the medical community.

---

<sup>39</sup> See Exhibit O at -182, -186, -191, -194.

<sup>40</sup> See Exhibit P (Master Agency Agreement).

<sup>41</sup> See *id.*

<sup>42</sup> See Exhibit Q (JJRIS 00302772).

<sup>43</sup> See Exhibit R (JJRE00052258), at -259.

<sup>44</sup> See Exhibit S (JJRE00053089), at -3091

Plaintiffs must be afforded an opportunity to ask Mr. Gorsky, for example, why he thought prolactin was a weak spot that needed defending, and what exactly it was that he described as Defendants' "strategy with [Risperdal] and children" in 2002. Plaintiffs cannot obtain the information known by Mr. Gorsky elsewhere. Without an ability to examine him at trial, Plaintiffs will be unfairly prejudiced in this litigation.

**B. The Court's Application Of Texas Law In This Case Makes Mr. Gorsky's Testimony Even More Pertinent And Necessary**

Based on the Court's recent ruling that Texas law applies to this case, substantive evidence of Janssen's off-label promotion of Risperdal is vitally relevant under the Texas Product Liability Act ("TPLA"), TEX. CIV. PRAC & REM. CODE ANN. §82.007.

Under the TPLA, there is a rebuttable presumption that Janssen is not liable on Plaintiff's claims based on the adequacy of its warnings because the Risperdal package insert was approved by the FDA. Specifically, the TPLA provides:

(a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider, manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:

(1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug, and Cosmetic Act [(the "FDCA")] (21 U.S.C. Section 301 et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended[.]

TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a)(1) (Vernon Supp. 2011-2012).

The TPLA provides plaintiffs with a limited number of ways to rebut the statutory presumption. Section 82.007(b)(3) (A) of the TPLA provides

The claimant may rebut the presumption in Subsection (a) as to each defendant by establishing that: . . .

the defendant recommended, promoted, or advertised the pharmaceutical product for an indication not approved by the United States Food and Drug Administration

TEX. CIV. PRAC & REM. CODE ANN. § 82.007(b)(3)(A). While the Risperdal package insert was approved at all times by the FDA, it was not approved for use in children at the time Plaintiff AB was prescribed and ingested the Risperdal.

This Court has already ruled that Plaintiffs have offered sufficient evidence of off-label promotion of Risperdal by Janssen to survive a motion for summary judgment. Substantive evidence supports this off-label exception to the Texas statutory FDA presumption against failure to warn claims. This exception requires inquiries into the off-label conduct of the manufacturer, including an examination on all of the promotional activities related to the drug. Therefore, such evidence is relevant and admissible. Mr. Gorsky, as the Janssen executive who headed Risperdal's sales and marketing department during the relevant time period, has a unique and useful history and perspective on these issues.

**C. Mr. Gorsky Should Be Compelled To Appear and Testify As to Travel Plans**

As described above, Mr. Gorsky has only recently made Plaintiffs aware of certain travel plans that have supposedly been in place since May of this year. Although he, his executive assistant, and presumably his counsel, have been aware of these plans for months, Mr. Gorsky's counsel did not make Plaintiffs' counsel or the Court aware of them until 5:43 on Friday afternoon, last week.

The importance of this trial and a subpoena issued from this Court cannot be minimized by this individual, no matter what his position. Mr. Gorsky should be made to appear in this Court and explain his reasoning for concealing his travel plans until more than a week after his initial Motion to Quash was filed and only one business day before Plaintiffs' Response was due.

### **III. CONCLUSION**

For all the foregoing reasons, Plaintiffs AB, a minor, and Jennie Rolen, his mother, respectfully request that the Gorsky Motion to Quash be DENIED.

Respectfully submitted,

**SHELLER, P.C.**

/s/ Brian J. McCormick, Jr.

Brian J. McCormick, Jr., Esquire

Stephen A. Sheller, Esquire

Attorney I.D. Nos. 81437, 03270

[bjmccormick@sheller.com](mailto:bjmccormick@sheller.com)

[sasheller@sheller.com](mailto:sasheller@sheller.com)

1528 Walnut St., 4<sup>th</sup> Floor

Philadelphia, PA 19102

(215) 790-7300

Robert C. Hilliard, Esquire (admitted *pro hac vice*)

HILLIARD MUNÕZ GONZALES LLP

719 S. Shoreline Blvd., Suite 500

Corpus Christi, Texas 78401

***Attorneys for Plaintiff***

BJM/lc

cc: The Honorable Mark I. Bernstein (w/encl.) (via hand delivery)  
Donna Candelora, Esquire (w/encl.) (via electronic mail)



## **CERTIFICATE OF SERVICE**

The undersigned certifies that a true and correct copy of the foregoing Plaintiffs' Response in Opposition to Defendants' Motion to Quash the Subpoena Directed at Johnson & Johnson's Chief Executive Officer, Alex Gorsky, was electronically filed with the Court this date and has been served via the court's Electronic Filing System on all Defendants' counsel, and a courtesy copy was forwarded by via electronic mail on the counsel listed below:

Kenneth A. Murphy, Esquire  
Drinker Biddle & Reath LLP  
One Logan Square, Ste. 2000  
Philadelphia, PA 19103-6996  
[kenneth.murphy@dbr.com](mailto:kenneth.murphy@dbr.com)

*Counsel for the Janssen Defendants*

Date: September 17, 2012

**SHELLER, P.C.**

/s/ Brian J. McCormick, Jr.  
Brian J. McCormick, Jr., Esquire