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## Legal News

# Company Accused of Improprieties in Marketing Risperdal

Jim Rosack

**The Texas attorney general says TMAP was just one part of an elaborate marketing scheme to increase psychotropic drug sales.**

The Texas state attorney general joined a whistleblower lawsuit this past December accusing the pharmaceutical and consumer goods giant Johnson and Johnson inc. of exaggerating the benefits and minimizing the known adverse effects associated with its second-generation antipsychotic Risperdal (risperidone), marketed by subsidiary Janssen L.P.

The suit further alleges the company and its subsidiaries "improperly influenced" at least one Texas state mental health program official through the payment of "substantial financial contributions" aimed at ensuring a preferred position for Risperdal during the development and implementation of the Texas Medication Algorithm Project (TMAP).

The lawsuit was originally filed in 2004 by Allen Jones, a former employee in Pennsylvania's Office of the Inspector General (OIG). as an OIG investigator, Jones had investigated allegations of impropriety during Pennsylvania's efforts to implement PENNMAP, a slightly modified version of TMAP.

As a result of Johnson and Johnson's alleged improper influence of state officials through illegal payments of significant sums of money, the lawsuit claims that Risperdal became a widely prescribed "preferred" first-line medication in the TMAP and PENNMAP algorithms for the treatment of schizophrenia.

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To assure Risperdal a first-line spot in the algorithms, the suit alleges that Johnson and Johnson overstated Risperdal's effectiveness in treating patients with schizophrenia and downplayed the drug's side effects. The suit states that the company also manipulated data collected during development of TMAP, so that Risperdal would appear to be more effective and safer than it actually was.

As a result of Risperdal's preferred position in TMAP, the state mental health and Medicaid programs were said to have paid "dollars per pill" for Risperdal when it could have paid "pennies per pill" for generic first-generation antipsychotics that were equally effective.

Neither Johnson and Johnson nor Janssen responded to inquiries by *Psychiatric News* for this article.

Texas Attorney General Greg Abbott was quoted by the *Austin American-Statesman* newspaper as saying, "We believe Texas has been defrauded of some money, and we're going to be looking to get our money back."

Stephanie Goodman, a spokesperson for The Texas Health and Human Services Commission, defended TMAP's development and implementation. The TMAP algorithms, she said in a prepared statement, are "firmly grounded in the latest research and science."

The central issue in the lawsuit is the pharmaceutical company's alleged improper involvement in the development and implementation of TMAP.

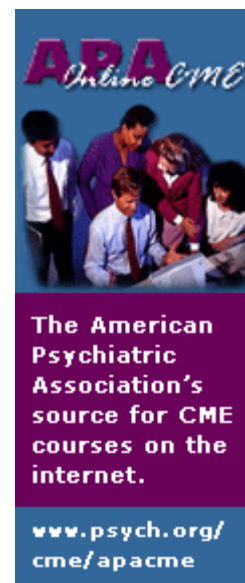
Developed in 1997, TMAP is composed of a series of flow charts that lead physicians through evidence-based decision trees to help them determine which psychotropic medication is most appropriate for patients with specific mental illnesses (*Psychiatric News*, August 6, 2004). As a result of a series of consensus conferences that included noted experts in each field, separate TMAP algorithms were developed for adult patients with schizophrenia, bipolar disorder, and depression.

After the adult algorithms were completed, Texas state employees began development of the Texas Children's Medication Algorithm Project, which the lawsuit alleges was also unduly influenced by Johnson and Johnson.

Development of TMAP cost the state of Texas a reported \$5.6 million; however, the Robert Wood Johnson Foundation (founded by a Johnson family member and a former company executive) gave the state \$1.8 million in the form of "unrestricted educational grants" toward the development of the algorithms.

In addition to those grants, the lawsuit alleges, Johnson and Johnson improperly influenced an unnamed "Texas mental health program decision maker" by paying that individual to promote the placement of Risperdal as a first-line medication in the TMAP schizophrenia algorithm.

Johnson and Johnson allegedly also paid the state official to further promote the TMAP program by funding trips to various states, including Pennsylvania, to promote the adoption of TMAP. As a result of those activities, the suit claims, 16 other states, in addition to Texas,



formally adopted TMAP or a closely related version of the algorithms.

The lawsuit asks for a jury trial. No trial date has been set.

*More information on TMAP is posted at*

[www.dshs.state.tx.us/mhprograms/TMAPtoc.shtm](http://www.dshs.state.tx.us/mhprograms/TMAPtoc.shtm). ■

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