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VA awards new contract for debunked PTSD drug

BY BOB BREWIN 08/25/2011

BROKEN WARRIORS
Examining the invisible wounds of war

This is the fourteenth story in an ongoing series.

The Veterans Affairs Department continues to issue contracts to purchase an anti-psychotic drug to treat post-traumatic stress disorder despite research showing the drug, risperidone, is no more effective than a placebo.

Nextgov reported Aug. 22 that VA spent $717 million over the past decade to purchase risperidone, the generic name for Risperdal, a second-generation anti-psychotic drug originally developed by the Janssen Pharmaceuticals division of Johnson & Johnson to treat severe mental conditions such as schizophrenia and bipolar disorder.

VA doctors prescribe the drug to treat PTSD, but a study by department researchers published Aug. 2 in the *Journal of the American Medical Association* concluded, "treatment with risperidone compared with placebo did not reduce PTSD symptoms."

Despite these findings, on Aug. 11, VA awarded a contract to Mylan Pharmaceuticals Inc. for more than 200,000 bottles of risperidone containing more than 20 million pills in multiple dosages. The announcement of the contract to the Morgantown, W.V., generic drug manufacturer did not provide a dollar value for the contract.

The Defense Department, Indian Health Service and Bureau of Prisons also can order off the Mylan contract, which has four option years.

The contract with Mylan is just one of more than 90 Federal Supply Schedule contracts for risperidone that VA has with other generic drug manufacturers and Janssen, according to the department's online pharmaceutical catalog.

The Food and Drug Administration has approved risperidone only for treatment of schizophrenia, bipolar disorder, and irritability associated with autistic disorder in children and adolescents, but clinicians can prescribe it for other conditions, a practice known as "off-label" use.

Janssen is under investigations by the Justice Department and several state attorneys general for its sales and marketing practices regarding Risperdal, according to Johnson & Johnson's quarterly report filed July 3 with the Securities and Exchange Commission.

A 2007 paper by two VA doctors who examined the marketing of second-generation anti-psychotic drugs provides insight into sales practices that contribute to such drugs' off-label use.

The paper, co-authored by Dr. Robert Rosenheck, a psychiatrist at the West Haven, Conn., VA medical center, reported that 639 department psychiatrists who responded to a Web survey said they were contacted an average of 14 times per year by pharmaceutical sales representatives, and were invited to attend continuing medical education seminars conducted by the companies.

Rosenheck, who also co-authored the Aug. 2 study on risperidone, reported that only half the assertions made by pharmaceutical sales representatives were consistent with FDA-approved labeling. "These findings suggest that there have been substantial discrepancies between information clinicians report having received in their contacts with industry representatives and FDA-approved information," he wrote.