

NOTICE OF CRIMINAL INFORMATION – JANSSEN

On November 4, 2013, the United States Attorney filed a criminal information charging Janssen Pharmaceuticals, Inc., with introducing a misbranded drug into interstate commerce between March 3, 2002 and December 31, 2003. The information alleges that Janssen (then known as Janssen Pharmaceutical, Inc.) promoted the atypical antipsychotic drug Risperdal for a new intended use not approved by the U.S. Food and Drug Administration. Its introduction of Risperdal for a new intended use was evidenced by its promotion of Risperdal during that period for treatment of psychotic symptoms and associated behavioral disturbances exhibited by elderly non-schizophrenic dementia patients. This off-label promotion evidenced misbranding because during most of that period Risperdal was only approved for treatment of schizophrenia, and Janssen distributed it without adequate directions for the new intended use.

Although the government does not believe that any specific victims can be identified with respect to this crime as charged, it is providing this notice to ensure that any interested person is advised of this prosecution and also is informed of the rights of victims.

Now that charges have been filed in federal court, victims of the charges filed are entitled to the following rights, according to the Crime Victims' Rights Act, Title 18 United States Code section 3771: (1) The right to be reasonably protected from the accused; (2) The right to reasonable, accurate, and timely notice of any public court proceeding, or any parole proceeding, involving the crime or of any release or escape of the accused; (3) The right not to be excluded from any such public court proceeding, unless the court, after receiving clear and convincing evidence, determines that testimony by the victim would be materially altered if the victim heard other testimony at that proceeding; (4) The right to be reasonably heard at any public proceeding in the district court involving release, plea, sentencing, or any parole proceeding; (5) The reasonable right to confer with the attorney for the Government in the case; (6) The right to full and timely restitution as provided in law; (7) The right to proceedings free from unreasonable delay; and (8) The right to be treated with fairness and with respect for the victim's dignity and privacy. The court hearing in this matter was held on November 7, 2013.

Any questions concerning victim rights should be directed to Marcia Bayne, Victim Witness Coordinator, in this United States Attorney's Office.