Justice Department Settles $2.2B J&J Off-Label Marketing Cases

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Johnson & Johnson (J&J) will pay more than $2.2 billion to resolve criminal and civil liabilities over marketing prescription medications for uses not approved by the U.S. Food and Drug Administration (FDA), according to a U.S. Department of Justice (DOJ) statement.

Criminal fines and forfeiture total $485 million, and civil settlements with federal and state governments total $1.72 billion. Prosecutors claim J&J subsidiary Janssen Pharmaceuticals promoted the schizophrenia drug Risperdal for use by elderly dementia patients, which increases their risk of strokes, and promoted off-label uses for Invega, which is approved only for schizophrenia and schizoaffective disorder. They also claim J&J subsidiary Scios promoted Natrecor, which is approved for severe heart failure, to patients with less severe heart failure. Substantial kickbacks to physicians and nursing home pharmacies to promote improper use also are alleged. This resolution, which is one of the largest health care fraud settlements in U.S. history, also will subject J&J to new requirements with the U.S. Department of Health and Human Services (HHS) to increase transparency and accountability.

To read the statement, click here.

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