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NYSE: JNJ

MINNESOTA MAN FILES LAWSUIT IMPLICATING JOHNSON & JOHNSON'S CYPHER HEART STENT

MINNEAPOLIS: Zimmerman Reed law firm represents a local Minnesota man who suffered a heart attack as a result of a blood clot at the site of his Cypher stent implant. This is the first Minnesota resident to file such a lawsuit. The FDA has received numerous reports of thrombosis, or clots, in patients who received the Cypher heart stent; it is estimated that over 50,000 patients have been implanted with the Cypher stent.

According to Ronald Goldser, one of the attorneys representing the patient in the lawsuit, "We hope that a side benefit of bringing this case will be to determine why these stents failed so that doctors and patients can make more informed decisions."

The FDA approved the Cypher Sirolimus-eluting stent in April 2003 for patients undergoing procedures to open blocked coronary arteries. The stent is coated with a medication that is designed to keep the arteries from narrowing after the surgery. The Cypher stent is manufactured by Cordis Corporation, a subsidiary of Johnson & Johnson (NYSE: JNJ).

The problems are nothing new for the Cypher manufacturer. Problems surfaced in July 2003, just months after FDA approval, when Cordis Corporation issued a warning letter to health care professionals informing them of the potential risk of blood clots associated with the use of the Cypher stent. At the time the letter was sent, the FDA had received 47 reports of blood clotting occurring at the time of implantation or within a few days of implantation. Then in October 2003, the FDA issued an advisory to physicians that the Cypher stent has been associated with adverse events in patients who received the device. Recent studies have linked drug-coated stents with side effects such as thrombosis (blood clotting) after longer term use of these medical devices. It also requires patients to take costly blood thinning medication long-term in order to prevent thrombosis.

A recent FDA Advisory Panel determined that off-label use, or using a device for a purpose outside the scope of the device's approved label, of drug-eluting stents is associated with an increased risk of stent thrombosis, death or heart attack compared to approved, on-label uses. Some examples of off-label uses include use in previously stented patients, patients with diabetes, patients who have stents placed immediately after a heart attack or patients who have stents placed in two arteries which branch off from each other (bifurcation lesion).

To view a copy of the Complaint, please visit www.zimmreed.com.

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