

Frequently Asked Questions

Intuitive Surgical, Inc. Investigation and Lawsuit

Our firm is investigating possible violations of federal securities laws by officers and directors of Intuitive Surgical, Inc. (Intuitive Surgical) (Nasdaq: ISRG). A lawsuit has recently been filed against Intuitive Surgical and several officers and directors on account of such possible violations.

Persons with relevant information, and ISRG shareholders with questions about our investigation or the lawsuit, are invited to contact our Firm by calling 866.582.8140. Additional information, including relevant documents referenced below, are available on our website at:

<http://www.wohlfruchter.com/cases/isrg>.

Q1. What is the business of Intuitive Surgical?

A1. Intuitive Surgical manufactures and markets the da Vinci surgical system, which consists of robotic arms tipped with tiny surgical tools that allow surgeons to perform minimally invasive surgeries remotely from a computer terminal with joy-stick-like controls. The two most common surgeries performed with the da Vinci are prostate surgery and hysterectomies.

Intuitive Surgical sells its surgical systems to hospitals. Each da Vinci machine costs approximately \$1.5 million. Additionally, Intuitive Surgical earns money on contracts to service each machine sold over its useful life (approximately \$125,000/year), and replacement of consumable single-use instruments utilized in connection with surgeries performed using the machine (approximately \$2,000 per procedure).

The company's website, <http://www.davincisurgery.com/>, provides further information about the system to patients, doctors and hospitals.

Q2. What recent actions has the FDA taken with respect to the da Vinci surgical system?

A2. On February 28, 2013, the U.S. Food and Drug Administration (FDA) sent a letter to surgeons participating in MedSun, an FDA-sponsored medical product safety network, asking them to provide information about adverse events related to the da Vinci system. The FDA indicated that the survey was prompted by an "increase in [the] number of reports" of adverse events involving the da Vinci system.

Q3. What is the FDA’s MAUDE database, and what data does it contain regarding the da Vinci system?

A3. The FDA’s MAUDE database contains voluntary reports by manufacturers concerning adverse events involving medical devices, including reports of injuries and deaths associated with use of the da Vinci system.

The MAUDE database currently reports over 4,600 incidents involving the da Vinci system since 2000, including approximately 85 incidents reported involving the death of a patient, and approximately 235 incidents reported involving injury to a patient.

A complete download of all data in MAUDE related to the da Vinci system is available in Excel format via a link in a research report published by Citron Research at the following URL:

<http://www.citronresearch.com/intuitive-surgical-angel-with-broken-wings/>

Q4. What statements has the medical community issued concerning the da Vinci system?

A4. On March 14, 2013, the president of the American Congress of Obstetricians and Gynecologists (ACOG), Dr. James Breeden, issued a statement contending, among other things, that “[r]obotic surgery is not the only or the best minimally invasive approach for hysterectomy,” and “there is no good data proving that robotic hysterectomy is even as good as -- let alone better – than existing, and far less costly, minimally invasive alternatives.”

On March 20, 2013, Massachusetts’ Quality and Patient Safety Division of the Executive Office of Health and Human Services issued an advisory, which stated in part: “Over the last two years, the Quality and Patient Safety Division has received an increasing number of Safety and Quality Review reports of patient complications associated with robot-assisted surgery.”

Copies of the above statements are available on our website at:

<http://www.wohlfruchter.com/cases/isrg>

Q5. What reports have appeared in the media concerning the da Vinci system?

A5. The most comprehensive report by a media organization to date concerning the da Vinci system is an expose broadcast by CNBC’s Investigations, Inc. on April 18, 2013, consisting of interviews with, among others, doctors, lawyers, and patients who have filed lawsuits against Intuitive Surgical claiming they suffered injury while being operated on by surgeons using the da Vinci system.

A former ISRG employee, interviewed by CNBC during the show on condition of anonymity, stated that she recalls instances of da Vinci-related complications that were not reported in

MAUDE, and contended that the MAUDE database is "significantly understated in terms of [da Vinci-related] complications."

Concurring was Dr. Martin Makary, a prominent surgeon with the Johns Hopkins School of Medicine, and an international expert on patient safety, who shared with CNBC details of a study he co-authored entitled "Underreporting of Robotic Surgery Complications." The study contends there is "massive underreporting" of robotic surgery complications. In particular, the report states that "[i]n the case of Intuitive Surgical . . . some incidents [involving the da Vinci system] that have resulted in serious injury and death were never reported or were reported late."

The CNBC presentation can be accessed at the following link:

<http://video.cnbc.com/gallery/?play=1&video=3000162491>

Q6. How many lawsuits have been filed against Intuitive Surgical in connection with deaths or injuries associated with use of the da Vinci system?

A6. A sample list of lawsuits filed by patients against Intuitive Surgical in 2012, including links to copies of complaints, is available via a link in a research report published by Citron Research at the following URL:

<http://www.citronresearch.com/has-the-halo-been-broken-on-intuitive-surgical/>

The most recent development of interest was a ruling of a court in a case pending against Intuitive Surgical in Washington State, *Taylor v. Intuitive Surgical, Inc.*, No. 09-2-03136-5 (Superior Ct., Kitsap County), denying Intuitive Surgical's motion for summary judgment. The court held that the Washington Products Liability Act imposes a duty on product manufacturers to warn and instruct on the use of their products, and that there are material issues of fact concerning Intuitive Surgical's alleged failure to provide adequate warnings regarding the use of the da Vinci system, and to properly train and instruct plaintiff's physician on the safe use of the da Vinci system.

A copy of the Washington state court is available on our website at:

<http://www.wohlfruchter.com/cases/isrg>.

Q7. How has ISRG stock reacted to the above developments?

A7. Since February 27, 2013, the day before the FDA announced its MedSun survey, ISRG stock has fallen over 17% on account of the above news from \$573.52/share to a close of \$474.87 on April 22, 2013, resulting in a loss of nearly \$4 billion in shareholder value.

Conclusion

As noted, persons with relevant information, and ISRG investors with questions about this investigation, are invited to contact our Firm by calling 866.582.8140, or to contact the attorney below.

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Wohl & Fruchter LLP represents plaintiffs in litigation arising from fraud and other fiduciary breaches by corporate managers, as well as other complex litigation matters. Please visit our website, www.wohlfruchter.com, to learn more about our Firm, or contact one of our partners.

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