FDA questions unreported robot surgery injuries

By Robert Langreth, Broomberg

When Sheena Wilson, 45, underwent robotic surgery for a hysterectomy in May, she didn't know the Intuitive Surgical Inc. system used by her doctor was previously tied to a variety of injuries for the same procedure.

Her rectum was badly burned in the operation, said Wilson, a mother of two from Parlin, N.J. Now she is on long-term disability, fearful of losing her job and facing a third corrective surgery, she said in a telephone interview.

"If I had known there were other people who had injuries, I would never have done this surgery," said Wilson, who has filed suit against Intuitive and her doctor. "Whatever they have in place is not working."

The use of complex medical devices is exploding. Last year, Intuitive's da Vinci robotic surgery system alone helped doctors perform more than 350,000 surgeries in U.S. hospitals.

Doctors at Barton Memorial Hospital in South Lake Tahoe use the da Vinci.

Patients like Wilson, whose lives depend on the proper use of increasingly complex high-tech medical equipment, often can't get a complete picture of potential problems.

While a U.S. database lists reports of deaths and injuries sent to the Food and Drug Administration, the agency has no authority to force doctors to contribute. And while hospitals are supposed to report, they often don't, critics say.

Indeed, a Bloomberg review of reports for operations with Intuitive's robotic system found dozens of injuries that went

unreported for years. Meanwhile, details of other patient problems involving use of the company’s product, cited in legal papers or in interviews with patients, were missing entirely.

Read the whole story