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Intuitive Surgical's Bad Day in Court: Trial Proceeds in Three Weeks

Citron breaks the latest news on Intuitive Surgical (NASDAQ:ISRG), and presents the documents the company **has been desperately maneuvering to prevent you from seeing**. Intuitive Surgical motion for summary judgment has been denied, and the documents in the case are now available. They make for very grim reading.



Latest Update: Yesterday Tuesday March 26: The judge in Taylor vs Intuitive Surgical ruled **against** Intuitive's motions to dismiss in summary judgment. The case is now set for trial to begin April 15th. The ruling held that negligence and defective product claims will be tried under Washington's Product Liability Act, while punitive damage claims can be tried under California law. The actions will be bifurcated to separate trials, without objection from either side. ([Click for the ruling](#))

What this is about:

Taylor vs Intuitive is the first of a series of recent liability cases against the company to come to trial. It sets a roadmap for all death and serious injury cases against Intuitive, by exposing for the first time, the company's failure in its commitments to the FDA and to the public, to properly train surgeons to use the da Vinci robotic surgery suite safely.

From today's New York Times ([here](#)) to last week Bloomberg story ([here](#)), Taylor vs Intuitive has begun to focus major press coverage on the real issues of robotic surgery since Citron alerted the Street to it just last month. Today's Boston Globe ([here](#)), focuses on the Massachusetts Board of Registration in Medicine's advisory letter ([here](#)) which cautions about inadequate credentialing of robotic surgeons.

The real questions being raised in Taylor vs Intuitive are **not** about the da Vinci device in the hands of an extremely skilled robotic surgeon. What **is** being exposed is the company's negligence in grossly undertraining doctors, directly leading to catastrophic outcomes for patients. As the documents linked in this piece make starkly clear, the company has been aggressively advising hospitals to **lower training standards** for robotic surgery certification, while **dumbing down its own training**, all to get more surgeons doing live cases with the da Vinci sooner and cheaper, at lower cost to the hospitals, regardless of the risks to the patients.

Case Background:

Fred Taylor was hospitalized for routine prostate surgery. Although his obese body build made him a poor candidate for robotic surgery, he was operated on using the da Vinci robotic device. Testimony states that Intuitive Surgical's Clinical Sales Representative (CSR), a company sales position compensated on the number of cases actually done using the system, apparently climbed under the operating table to try to adjust it to hold Mr. Taylor better. The surgery went very wrong and dragged on for many hours. At the end, Mr. Taylor was immediately transferred to ICU at another hospital with severe complications. Among other bad outcomes, his bowel had been punctured during surgery. A variety of

severe complications ensued; Mr. Taylor died four years later, never having recovered his health from the adverse events of his surgery. The surgeon performing the surgery had previously performed only one other robotic surgery, and subsequently decided not to perform further robotic surgeries; he felt misled by the company's estimate of training required to obtain proficiency using the da Vinci.

During discovery, counsel for Mr. Taylor's estate obtained numerous pieces of documentary evidence outlining Intuitive Surgical's culpability in establishing insufficient training for surgeons on the da Vinci. The cases tests whether the company is liable for Fred Taylor's injuries and/or subsequent death.



The Documents Intuitive doesn't want you to see:

1) Testimony of Gene Nagel: Vice President of Training and Development

Mr. Nagel was in charge of training customers – which included surgeons, and also Intuitive sales staff.

Education: Degree in operations management and marketing

Scientific or medical training: **None**

First employment: **Salesman in Wine Industry**

Next employment: Sales of medical technology (appx 9 years)

The Introductory Test for Intuitive was a 10-question multiple choice test given after a 45 minute video. **The surgeon could not fail – if any wrong answers were selected, the surgeon was just guided onscreen to try again.** It was impossible to get any questions wrong. The company sent a certificate of completion when the quiz was finished. Nagel testified that he was unaware if anyone had ever failed it. **Mr. Nagel also testified he was responsible for reducing Phase II (hands on) training at Intuitive's site from three days to one day.**

Most shockingly, Intuitive's **Training department** reported to its **Sales Department with** :

- **No medical or scientific oversight**
- **No minimum skills proficiency**
- **No demonstration of knowledge or competency required**

2) Sales Brochure for 2008 "Drive the Curves"

Internal sales department communication, emphasizing maximizing the number of cases "driven" onto the da Vinci platform. Not one word about doctor competency or patient care.

3) Dave Carson (area Sales Manager) memo : Sales goals = number of procedure targets

Urgent emphasis on meeting sales targets – more cases, no delays, shorter operating suite turnover. Not one word about patient outcomes.

4) Gilliam (CSM) email re importance of influencing hospital credentialing guidelines.

Reinforcement of the importance of being clinical consultants to client hospitals "especially with regard to "credentialing guidelines" – essentially influencing hospitals to lower their training requirements before allowing surgeons to begin to use the da Vinci on actual patients.

5) Michael Rose (Clinical Sales Representative for Montana Hospital) email

Specifically counseling a hospital client to **reduce** the number of proctored (supervised) surgeries using Da Vinci from 5 down to 3, and in another category from 3 to 2. In another email on the same topic,

pointing out that the cost to the hospital will be significantly reduced if this training component is reduced.

6) [Internal sales strategy document](#)

Admits the key sales strategy is to "Create a competitive landscape between hospitals & surgeons". (Citron wonders how client hospitals will feel about inking new systems purchase commitments now that the sales strategy is fully disclosed.) This strategy includes deeming certain hospitals "Centers of Excellence" again with no specific training requirements. It is purely a marketing credential. "Drive account procedure growth, leading to capacity and scheduling constraints".

- 7) [Intuitive's training brochure for surgeons](#) – four parts – basically two days prior to first da Vinci procedure on a patient
- 8) [Email from e-Marketing department re referrals](#): Clarifying policies for surgeons to be listed on Intuitive's patient referral website after 20 surgeries of any complexity.
- 9) [Market Protection Email](#): CSM to sales department internal email about granting a client hospital "market protection". What right does Intuitive Surgical have to extend such a right to a hospital? Was Fred Taylor's surgery, or dozens of others hurriedly scheduled under pressure from Intuitive to gain or keep "market protection" ?
- 10) [Email from VP of sales about pounding the bushes](#) for cases, going the extra mile, and "scrub all schedules" and "turn over every stone possible" to find one or two more cases to meet sales targets. How is this the practice of medicine?
- 11) [Taylor Post-operative notes](#) – stool coming out urinary catheter



Conclusion

Taylor v Intuitive will have tremendous impact on Intuitive Surgical's sales pipeline. Clearly Intuitive Surgical lost its moral and ethical compass somewhere a few years ago, and set forth on a "sales at all costs" strategy. This has led it to a variety of actions for which it will now be held accountable, including:

- Manipulating hospitals buying committees with promises of "exclusivity"
- Deeming certain hospitals "Centers of Excellence" designation for marketing benefit without establishing any professional criteria
- Producing a training program wholly inadequate to fully and properly train a surgeon to prevent serious injury or death to the early patients exposed to the surgeon after such training
- Flogging sales team members to pressure hospitals to convert as many procedures as possible to use the robotic surgery suite, regardless of the clinical appropriateness of the cases in question
- Compensating Sales team members directly for numbers of procedures done, without disclosing this to the client hospitals, where these personnel are often right in the surgical suite – during surgeries.

- But worst of all, pressuring hospitals to reduce credentialing standards for surgeons, while dumbing down its own training – all the while with the training department reporting to nobody except sales.

Again, Citron is **not** stating that in the context of an appropriate case, a da Vinci in the hands of a highly trained and experienced surgeon might deliver a great outcome. But it is clear that the solution has been heavily over-marketed, with training and its concomitant costs grossly short-changed, with huge costs in terms of adverse outcomes and deaths to patients. Further, these adverse outcomes have been chronically underreported. After hundreds of thousands of surgeries, the company has no data to support the correlation between adverse outcomes and surgeon experience, and no idea how many adverse outcomes of surgery with its product are out there.

Meanwhile, can you find the MAUDE record for Fred Taylor's disastrous surgery? It doesn't exist. So what are the true number of deaths and serious injuries resulting from inadequate training on da Vinci? Answer: After over 10 years in the field, nobody knows. Who is going to be held responsible for that?

It is Citron's opinion that the company is headed for a long period of painful reevaluation of its training and quality assurance policies, perhaps mandated by more intense FDA scrutiny. Its relationships with its client hospitals is going to be much more obstacle laden in future quarters, its reputation will suffer, and its sales growth will slow. Hospitals will be re-evaluating their aggressive marketing campaigns for robotic surgery, especially those without proper disclosures of risks.

As it takes its place among its peers in the medical device and technology industry, Intuitive's multiple will compress to comparable levels, and its share price will fall to appx. half its current levels.

This is not a "one day wonder" commentary piece. These consequences are inevitable. It is shameful that the company has been so quick to announce a stock buyback, but so reluctant to place its training operation in the hands of competent arms-length scientific and medical experts accountable to an independent oversight board.

Cautious investing to all.