Citron RESEARCH

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AMA Editorial and New Lawsuit a Must Read for Investors…and Patients.

Citron reaffirms its $300 price target on Intuitive Surgical

Journal of the AMA study **plus** a **devastating new lawsuit** expose the dark secrets behind the dramatic rise in robotic surgeries….and foretell its end.

This is not a story of shorts vs Intuitive Surgical , this is a story of the American Medical Association, the Affordable Health Care Act, and tort law vs Intuitive Surgical.

The headline news surrounding Intuitive Surgical yesterday was the publication of a study by the Journal of the American Medical Association funded by the National Cancer Institute, proving surgeries summarizing data that gynecological surgeries with the Intuitive Surgical robot cost thousands of dollars more, without reducing complications compared to standard less-invasive (laparoscopic) surgery.

http://www.bloomberg.com/news/2013-02-19/robot-surgery-for-hysterectomy-doesn-t-give-more-benefit.html

Click here for a copy of the actual study

Citron calls to readers' attention not only the study, but the significance of the **editorial** written about the study that was also published in Journal of the AMA. It is the editorial that explains the future contraction of earnings for Intuitive.

Click here for a copy of the Journal of the AMA Editorial.
Here are some pivotal excerpts of the editorial:

> Such consumer-directed advertising is not without merit if it uses consumer awareness to advance underused medical discoveries that benefit the popula tion. However, when the innovation being advertised is of questionable advantage, direct-to-consumer promotion may only fuel unnecessary utilization. Consumer adver-tising of expensive devices should be subjected to the same scrutiny as that of new and expensive medications.

In the absence of additional research or decreases in price, the path taken by the medical and payer community should be one of caution. At a minimum, manufacturers might begin by voluntarily restricting their promotional activities. Public health entities could consider exercising greater oversight over claims that appear on websites.

The results of this study could inform the development of medical payment policy, that is, the set of decisions made by public and private payers about whether to cover a procedure or service or, if covered, how to manage its utilization.

Inefficiency in health care delivery can trace some of its roots to the use of new and expensive interventions for conditions where other effective treatment options already exist. Evidence-based medicine and comparative effectiveness research (CER) can help ensure the optimal treatment for a given class of patients by reducing the influence of non- clinical factors

The United States is embarking on an unprecedented era in support of evidence- based medicine. The Patient-Centered Outcomes Research Institute was created under health care reform to move the field forward and will have significant resources.

Jason Wright, a gynecologic oncologist at Columbia University College of Physicians and Surgeons, conducted the study that was published. Dr. Wright stated in the above article:

"The major concern is that the robotic procedure really didn't show a lower complication rate yet it was substantially more expensive," Wright said. Why the robot took off so fast "is the million dollar question."

This million-dollar question is answered in pleadings filed just two weeks ago in the state of Washington that completely blows the cover off of Intuitive Surgical.

YOU MUST READ THIS CASE:
Intuitive Surgical: COMPLETELY EXPOSED

While there are many injury lawsuits currently in the courts against the company, attorney Richard Friedman from Seattle Washington has meticulously documented the history of marketing tactics used by Intuitive, which provide the most complete answer to date to Dr. Wrights $20 billion question. Atty. Friedman represents the estate of Joelle Taylor, the widow of Fred Taylor, who went to Harrison Hospital to get a routine prostatectomy, which caused his death.

This comprehensive body of information has just appeared in the public domain because attorney Friedman did not want the court to absorb the information in "piecemeal fashion". So for the first time, the investing public as well as the medical community, can see, with the benefit of discovery and depositions, how Intuitive positions its robotic surgery to hospitals and doctors, and how it trains surgeons to use its products. It is Citron's opinion that the company's overly aggressive sales strategy is going to lead to devastating backlash.

Citron believes that every investor, patient, and most importantly hospital must read this case, which lays bare exactly how Intuitive Surgical has manipulated the healthcare system in the United States to generate profits for a procedure that has been deemed to have "no medical benefit to alternatives".

As expressed in our earlier reports, one of Citron's main contentions about Intuitive Surgical was the inadequate training of physicians: how in the hands of the wrong surgeon the da Vinci machine transforms from a surgical tool to a dangerous weapon. Intuitive has always tried to distance itself from training; we now read how it committed to the FDA that it would be responsible for training doctors, but that Intuitive has systematically acted to circumvent that requirement. All of this will quickly become a major barrier to finding new adopters/customers for its robotic surgery machines.

What we now read is that Intuitive has known all along of the dangers of the da Vinci. Nonetheless, it and has financially incentivized its sales force to ignore those dangers at the cost of patients to "shove" the procedures down the throats of its customer base. While Citron recommends that every Intuitive investor read this entire case (a carefully footnoted 95 pages) , here are just a few important excerpts:

[Link to Entire Court Filing]

Damon Daniels, the lSI sales rep who gave Dr. Bildsten the "Clinical Pathway", admitted that he would tell the surgeons, and wanted those surgeons to believe, that the Clinical Pathway would ensure the surgeon's success in becoming a proficient robotic surgeon.

lSI assumed a duty beyond those imposed by statute upon manufacturers: ***it assumed a duty to train with reasonable care***. lSI's disclaimers to the contrary do nothing more than create a genuine factual dispute as to the assumption of the duty and its scope.

The declaration of William Scott Helton, M.D. states that the lSI training program applied to Dr. Bildsten "incomplete and potentially unsafe ... Further, to suggest that any surgeon could be adequately trained to perform any type of major surgery using the da Vinci surgical system after only the level of training proposed is unfounded and unsupported by any data, a leap of faith, potentially unsafe, and irresponsible.'"

A jury could reasonably conclude that the mistakes he made in this robotic procedure were a result of the poor training and lack of warnings he received from lSI. Indeed, that is the conclusion Dr. Bildsten has reached:

I was not told by lSI that, especially for surgeons with no prior laparoscopic experience doing prostatectomies, this was very unlikely until I accomplished 100 or more robotic surgeries. Had I been informed of that fact, I would not have performed da Vinci surgery on Fred Taylor.

lSI'si founder, Dr. Fred Moll, personally presented information to the Panel, which asked numerous questions about the learning curve and training plan for surgeons who would use the robot. Dr. Moll assured the Panel that lSI had specific, concrete plans for training on the device:

"I am probably not the right person to do that, but it is at the top of our mind and we will have very clear plans for introducing a training protocol together with the sale of this device.[48]

Dr. Moll later added that lSI took training "very seriously," and even regarded training as "one of the keys to both clinical and commercial success.'49 ' The Panel advised that the robot was "approvable with conditions. [50] One of the conditions was training: "The sponsor needs to provide a comprehensive training program for the users .of this device."[51]

As explained by Suzanne Parisian, M.D. - a former FDA Medical Officer and instructor at the FDA's "staff college" - lSI was ***required*** to provide no less than the rigorous training program described in its submissions.

In fact, Parisian explained, the only way a product like da Vinci *could* have been cleared via Premarket Notification was with a commitment for "adequate physician training". [177]

In November 2000, only four months after receiving its first surgical clearance, lSI hired Gene Nagel to take over (among other things) its surgeon training program. Nagel was not a physician or an educator. His college degree was in marketing and operations management. [195] After college, he had spent thirteen years as a salesman, first on behalf of two wineries, and then at a medical device company.[196] He then spent two years as a manager at the device company, "teaching the salespeople how to sell. [197]

When he joined lSI in 2000, he had never had any higher education in the fields of education [198] or "medical related subjects. [199]

With respect to Phase One, lSI did not, under Nagel, provide a 70-question exam followed by specific "feedback" and remediation from an "instructor." Rather, the entirety of Phase One [training] … was simply a video that was less than one hour long and a ten question quiz.[208] Moreover, this quiz was impossible to fail because, when a trainee selected an incorrect answer, the online program would simply prompt the trainee to choose a different answer.[209] When the trainee finally selected the correct answer, only that correct answer would be recorded in the test taker's final score.[210] For this reason, *every test-taker receives a perfect score at the end of the exam.*[211]

Notably, no urologist has ever failed lSI's "certification" course.[236] Nor is there any indication that any other surgeon has failed any of the other phases of lSI's training program. [237]

[Editor's note CSR/ CSM are ISI sales staff: Clinical Sales Representatives / Managers]

These CSMs even required the CSRs to read new sales books each quarter.[286] The book for the fiscal quarter in which Fred Taylor's surgery occurred was called "Hardball Selling" [287]

Importantly, other than the training they received at lSI, these CSRs had no medical or educational training. Damon Daniels, the CSR who worked with Dr. Bildsten, for example, had a 1995 business degree.[294] Nor has any other member of lSI's sales force yet deposed in this case had any prior medical or educational training.[295] Nonetheless, lSI expected these CSRs to be able to successfully challenge reluctant surgeons to convert previously scheduled open surgeries into robotic surgeries.[296] As one lSI Clinical Sales Director put it to a group of CSRs over whom he had direct authority:

We've all invested a lot of energy into developing our Equal Clinical Stature skill sets. It is now a matter of putting all of that practice to action. Be proactive in finding cases to convert. Be prepared to challenge each trained surgeon every time you see a lap or open case. Be unsatisfied with the thought of ending a day without a converted case.[297]

"Converting," in this context, means finding a scheduled operation that a surgeon has decided to do without a robot, and convincing him against his initial judgment, to operate with the da Vinci.

Instead, lSI actually minimized the danger that new robotic surgeons posed to patients by teaching its CSRs to pressure hospitals to adopt only minimal credentialing and privileging requirements.

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(2) outright telling the hospitals that their proposed credentialing requirements were too high, even if that proposed requirement was as low as five proctored surgeries.[306]"

"Behind every successful robotic surgery program is not only a great deal of effort, but also a strong partnership with Intuitive Surgical.... With this in mind, we would like to be closely involved in the development and execution of your program. [347]
… the CSRs would "never" tell the surgeons that the CSRs had a financial incentive to make sure that the surgeons actually performed procedures on humans with the robot.[348] Likewise, the CSRs would

not tell the hospital steering committees that the CSRs "would be compensated based on the number of procedures done with the robot.,,[349] Rather, lSI's sales force learn to portray itself as entirely altruistic: "Everything we do is for the benefit of the patient.,[350]

… …

After the first meeting, O'Connor privately "expressed some doubt about the potential quality" of Harrison's robotics program to Carson. [382] Carson reminded O'Connor "not to communicate any bias against Harrison" because "Hospitals like Harrison are our future. [383]

He warned O'Connor that his concerns "shouldn't extend beyond you and me. [384]

The toolkit included numerous marketing resources that would allow lSI to help the hospital market da Vinci surgery to nearby patients.[399] Included in these resources were lSI brochures designed to tell potential patients: "Your doctor is one of the growing number of surgeons worldwide who's been ***successfully trained*** in providing leading-edge treatments *such as da Vinci Prostatectomy ,*[400]

A traditional open prostatectomy in the hands of an experienced surgeon would take 2.5 hours.[416] ISI trained its sales persons to tell surgeons who were reluctant to adopt da Vinci that "most da Vinci surgeons today perform quality radical prostatectomy procedures in less than two hours." Dr. Bildsten's first two robotic procedures took 9.5 and 7.5 hours respectively,[417]despite the fact that both patients were relatively easy patients." [418]

… …

lSI had trained Damon Daniels to believe that Bildsten had learned "all necessary skills" to perform da Vinci Prostatectomy. It had trained and authorized Daniels to "partner" with surgical teams ''to review and select appropriate cases." It had financially incentivized Daniels to try to convince surgeons to perform every prostatectomy with the robot.

Intuitive Surgical is going to defend itself on Wall Street, in the popular press, and the courts by claiming that robotic surgery complication rates are low, and comparable to manual laparoscope. Citron disagrees that this is a valid defense. Nobody is going to be suing laparoscope makers for encouraging surgeons to perform surgeries with inadequate training, and for unleashing a massive marketing campaign targeted at consumers to drive demand for this type of surgery, despite data showing that for its two main high-volume surgical procedures, outcomes are not better than alternatives, yet costs are higher.

This problem is serious, systemic, and going to have massive repercussions in the health care and reimbursement system in the years ahead.

Conclusion

Our one regret is that Citron Research is the primary journalistic outlet that has exposed this story. This story is **beyond important** and is a complete object lesson in how profits can displace best practices in health care. This story is begging for a 60 Minutes-type expose to bring it to the awareness of the public and the medical community. The bull case on the stock rests on the words of Dr. Mario Leitao a consultant for Intuitive, who stated to Bloomberg, “the study results won’t change how often he uses the device. It is like asking a jet fighter pilot to go back to a World War II airplane because it is cheaper.”

EXACTLY! How long does it take to become a jet fighter pilot and what happens to an F-18 in the hands of a single engine Cessna pilot?? - Crash and Burn. More importantly, knowing what we know now, how many new F-18s can you sell with these warnings? Unfortunately, Mr. Taylor's analogy places him on the wrong side of the argument.