

Citron Updates Intuitive Surgical Price Target to \$200

"You can't solve a problem with the same mind that created it."

-- Albert Einstein

A woman on vacation takes a walk on the beach, recovering from a recent hysterectomy. All of a sudden, her colon falls out of her vagina down to her knees – but think on the bright side, the procedure helped meet the Clinical Sales Rep's quarterly quota!

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Detail.CFM?MDRFOI_ID=3305519

As much as this report is about a publicly traded company, it is about the conflict between the practice of medicine and the profit motive. Our government is currently shut down over a debate about healthcare. It is widely known that our per capita healthcare costs are the highest in the world – in fact [2.5 times the costs of wealthy European countries](#), consuming 17.6% of our GDP. However, our health outcomes are mediocre by all quality measures compared to many European countries.

In over 12 years of publishing probative stock research, Citron is most proud of the work we published on Intuitive Surgical (NASDAQ:ISRG) starting last December. Not because the stock suffered a decline of over 30% amidst a record-setting bull market, but rather because we helped raise to the forefront of public awareness the undisclosed dangers of robotic surgery and the subsequent dilemma: what happens when medical best practices collide with unbridled thirst for profits. At the time, we suggested a stock price of \$250 – prompting even Goldman Sachs to weigh in, claiming that Citron was overstating concerns.



Since then, the issues at Intuitive have only intensified, but the company shows no signs of acknowledging them yet. To preserve their long-term future, they unavoidably must confront making the difficult strategic decisions to serve the medical community in alignment with the best practices of medicine, rather than manipulate it for short-term profits. **Citron now believes that a generous valuation of Intuitive would be at 12 – 14x 2014 earnings, or around \$200 per share. And this is being overly generous to a company we can genuinely argue is not investable til it gets its house in order.**

In the ensuing nine months since the initial Citron reports, the company has received FDA warning letters, criticism from numerous medical associations, and confessed a large earnings miss. With analysts clamoring for the company to “Do something about the negative press”... as though that is the illness, rather than just a symptom, it’s understandable that investors are left to wonder: “Is the bad news behind us?”... With this piece, Citron affirmatively shows why the answer is a definite NO!

Citron did not plan on revisiting this story but what we found will shock you.

Massive Increase in MAUDE Reports Submitted in 2013

In its groundbreaking report January 17, 2013, Citron took the unprecedented step of publishing the FDA’s entire MAUDE database for Intuitive Surgical, spanning 12 years of adverse event reporting on the da Vinci. **This represents the only public source of information on adverse events for da Vinci on patients in the U.S.** Even [CNBC tipped its hat to Citron](#) in its March 19 coverage of the name. Citron’s Maude database download is now being used by robotic surgery committees in hospitals nationwide as a crosscheck for concerns about the device.

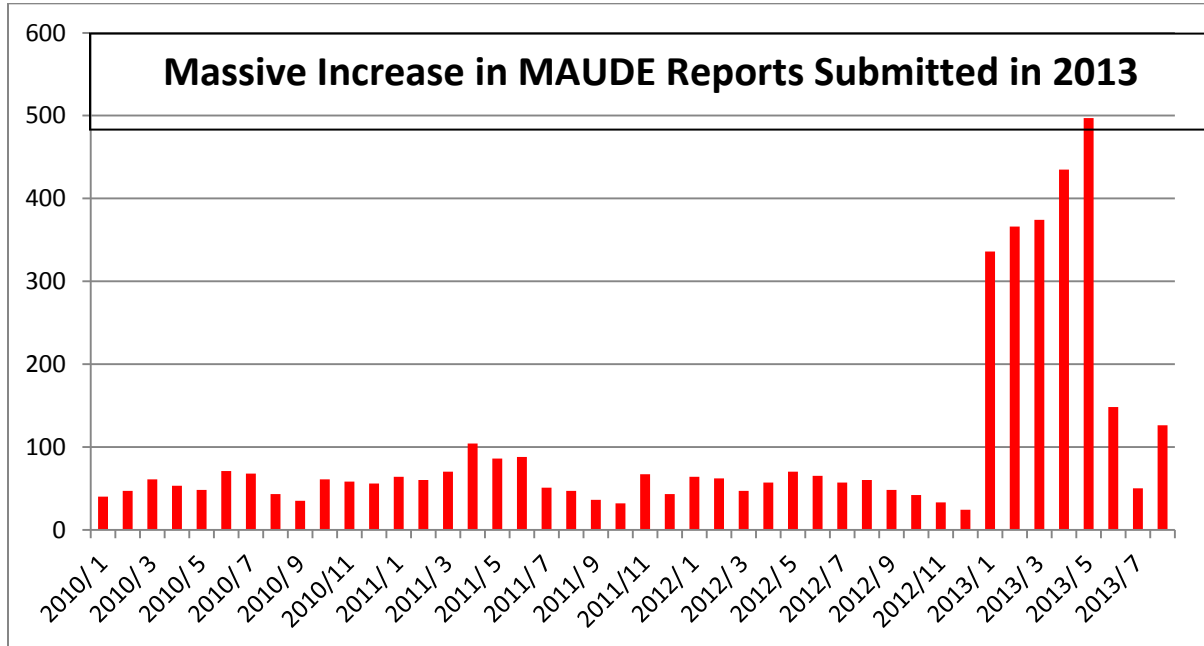
But something scary happened this year:

In the first 8 months of 2013, **2332 Adverse Event records were posted** – compare to **4603** records posted in the entire 12 year period since the first Adverse Event tracking for da Vinci appeared in MAUDE in 2000.

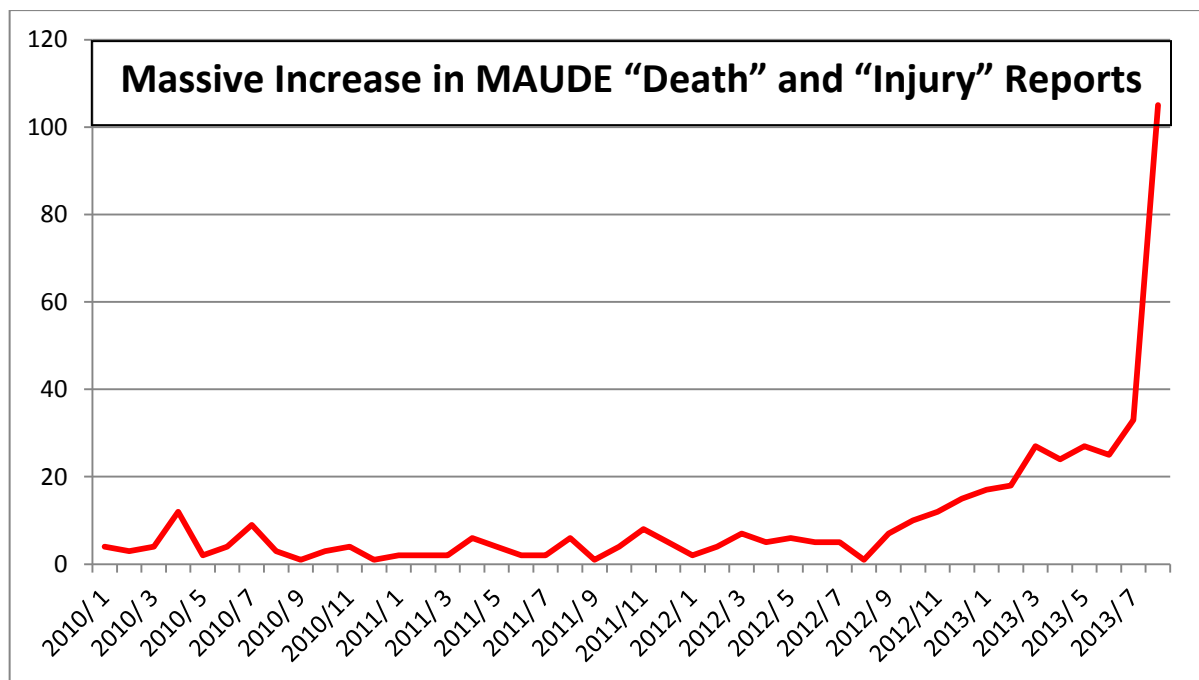
	Number of Adverse Events Reported	Link to Excel format of MAUDE database
Jan 2013 – August 2013	2332	[Click to Download]
FY 2000 – 2012	4603	[Click to Download]

So in this piece, Citron publishes an update of the Maude database for 2013. There are some noteworthy observations here:

We observe a huge increase in the number of MAUDE reports as 2013 begins – 2,008 filings – a rate of over 400 a month, during the first five months of 2013 alone. This rate is more than **five times** higher than any prior period since the da Vinci was introduced. Then notice a precipitous falloff to just 50 reports in July – with no explanation.



Meanwhile, surprisingly, the number of “Injury” or “Death” type events skyrockets in August to 105 – more than triple the rate of any prior month. This suggests drastic policy and procedure changes at Intuitive. While its motives remain unclear, the inconsistency raises obvious doubts.



August's 105 injury and death reports are apparently due to a mass posting of 73 "Injury" or "Death" events which are annotated "As part of a legal mediation effort..." in the company's inserted notes. Altogether there are 40 such "legal complaint" reports, all "Injury" or "Death" event types, filed in the last four months, **all of which show a time lag between event date and date reported of one to four years or more.**

Why has the FDA not opened a formal investigation into this? This is real and dangerous.

A reasonable investor would anticipate that reams of litigation disclosure will be made public in the company's 10-Q filing due this month. There are so many disturbing questions opened up by this dataset that Citron's commentary only scratches the surface.

"We think that based on the sample, the 245 reported cases represent a small fraction of the true events out there,... The number of reported cases seems very low, given the discussion of these events in the surgical community.

-- Dr. Martin Makary
associate professor of surgery
Johns Hopkins University School of Medicine
Baltimore, Maryland

<http://www.medscape.com/viewarticle/810490>

This Excel format allows analysts, decision makers and individual investors alike to inspect this data, pose their own questions and seek their own answers.

Here are a few pointers for viewing the MAUDE data in Excel format:

- Filters can be set on each column for any data value or expression (for example, event types of "Death", "Injury" or "Malfunction").
- Keywords can be searched across all records, or set as filters in any column.
- The red highlighted columns are the textual narratives, which contain the most depth of detail. They can be read most conveniently by dragging the lower edge of the cell contents window vertically so several lines of text are visible, or by formatting free text columns E and F with word wrap turned on, and widening those columns.
- The data can also be imported into your database of choice.
- Column J, the MDR Report Key, is a hyperlink to the entire report record online at the FDA site.

Here are just a few of the questions that stand out to us:

- How can so many bowel punctures and burns be occurring in highly routine surgeries such as hysterectomy and prostatectomy?
- Why does the company **insist** on appending every injury and death record with one of its 'don't blame us' annotations, such as "no machine failure", "no system errors", "system functioned within specification" or "no anomalies detected during the surgery", etc. ?
- Is death a reasonable risk factor from a routine cholecystectomy (gall bladder removal), one of the simplest and most routine surgical procedures?
- Why are patients with serious septic aftereffects of da Vinci surgery discharged from the hospital, only to be readmitted to the emergency room in life threatening conditions?

Before the analysts jump to their feet with their blindfolds on and your wallets open, they should ask themselves: did any of these events ever happen to one of their loved ones? It is the opinion of Citron that the only reason there is not a national outcry is because the da Vinci robot has yet to kill or injure "the right person" – like the next of kin of a congress member or a celebrity.

Questions Investors Should Demand Answers to:

What is the actual change in the legal liability landscape due to all these new suits being filed? What will be the impacts on Intuitive's client hospitals – their purchasing choices and their professional practice oversight?

Why are so many of these reports backdated – disclosing just now the adverse events from surgeries conducted years ago? How far back in time does the liability extend? How many such cases are being spawned right now, on a track where the investing public won't find out about them for years to come? How many reports are applicable to current surgeries? Is the frequency of reporting Adverse Events increasing? Why?

There are between 55 and 60 cases of punctured, burned or lacerated bowel injuries logged during 2013 alone. Some of these were caught and repaired by the surgeon during the procedure, but in many other cases, the patient was sent home, returning to the hospital later with serious or life threatening abdominal infections. Considering that the majority of these cases are relatively simple hysterectomies or prostatectomies, these cases are extremely disturbing. There should be no such risk with these types of surgeries.

(Because the MAUDE reporting system is voluntary, it cannot ever be used as a quantitative measure of outcomes. See the FDA site for its cautionary comments about use of the MAUDE data.)

The truth is now coming out – one local paper at a time.

The commercial success of da Vinci can be attributed to patients demanding robotic surgery – having been the targets of intensive direct marketing and PR. Over the past ten years local newspapers have touted the local hospital who just purchased their robotic surgery machine. But now the tides have begun to turn. Here is a recent article that is reflective of many around the country which now discuss the dangers that have been expressed by Citron et al...

Vanderbilt's Dr. Joseph Smith reported that it took him **150** surgeries before he got results as good as when he performed open prostatectomies. He said it took him **250** surgeries before he was comfortable and confident using the machine.

<http://www.ncregister.com/articles/robot-527186-ahlering-company.html>

The Bottom Line

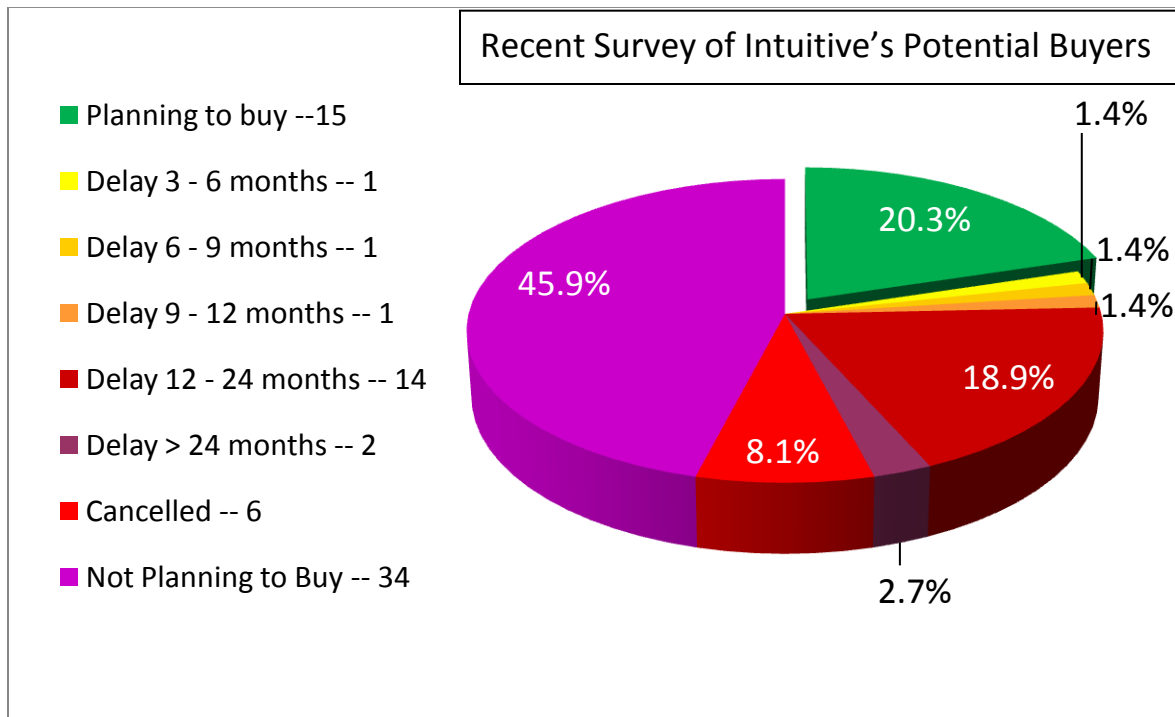
- Intuitive's entire business is driven by just two benchmarks: the number of new surgical suites sold, and the number of procedures performed using installed da Vinci's.
- Last quarter clearly demonstrated new surgical suite sales far below guidance.
- The company procedure counts are vulnerable to declining use for prostatectomy and hysterectomy. Management claims they are going to shore up the losses in these mainline procedures with ... gall bladder surgeries ([cholectystectomy](#)), while touting a new da Vinci model that runs all the robot arms through a single incision port. But gall bladder removal surgery is an easy, hour-or-less procedure performed by a surgeon skilled in handheld laparoscopic technique ... So does using da Vinci genuinely add value, or is it just a way of amortizing the costs of underutilized and oversupplied da Vinci's, while shoring up the company's income statements?
- Note the repeating pattern: the company touts medical breakthroughs that will purportedly drive its growth, but its business strategy is to target high-volume routine surgeries for which its technology represents a solution looking for a problem. Again, there's no established medical benefit here, other than fewer and smaller incisions. For a few single women, smaller abdominal scar marks is a plus. But gall bladder surgery is extremely common, and widely recognized as one of the simplest surgeries to perform...so it should be done by robot, because ?

- Analysts at industry conferences clamor to ask the company: “When will the bad news stop?” ... completely missing the point – that the real battleground is not fighting for headlines, but rather determined by the actual clinical outcomes. That drives the business model of the company, and ultimately the financials. Can Intuitive really maintain double-digit growth through the decade, as forecast by nearly every analyst?
- The amazing thing about the analyst coverage of Intuitive is that it seems utterly inconceivable to anyone on Wall Street that this company could **stop growing entirely** for the foreseeable future. A few analysts have shaved a few points off the growth trajectory. But Citron asks a deeper question: **are the best days of Intuitive Surgical behind it, or ahead of it?**

Citron suggests that the market for da Vinci devices and procedures is already at or near saturation, and the safety concerns and negative news flow need only take the top off already weakening utilization rates, to stifle the demand for new units.

What about this quarter?

A recent survey by SunTrust of Intuitive’s sales pipeline was spun as positive, but in Citron’s opinion it is **could hardly be worse**. Intuitive’s penetration among addressable U.S. hospitals (over 100 beds) already exceeds 54%, so the number of cancellations plus long delays in its pipeline outpacing “planning-to-buys” has to be of tremendous concern.



It is Citron's opinion that a delay of greater than 12 months qualifies as a virtual **cancellation**. The survey has 4 separate choices for 0-3, 3-6, 6-9, and 9-12 month delays, all of which were bypassed by 16 out of 19 respondents.

So either this quarter clearly demonstrates declining revenue growth at Intuitive, or the company has found a creative way to make its numbers at the expense of patients globally.

Further Research

In the near future Citron will put out further research clearly demonstrating the absence of an acceptable **return on investment** for hospitals considering ponying up for more da Vinci units. We did not want to comingle that research with this current body of work because of the importance of this message. We believe that the many robotic surgery committees at hospitals worldwide are already performing this analysis -- and we will confirm their conclusions.

Conclusion

Again, Citron is **not** saying that, for some patient conditions, the da Vinci is **not** an effective tool in the hands of a skilled surgeon **highly** experienced in its use. But the choice to use it in a given surgery should be a matter of the doctor's judgment, after impartially weighing **all** options, armed with the best clinical science with regards to standards of care, in light of the specifics of the patient's condition. It should **never** be influenced by a salesperson who has access to patient charts. And it is **past time** to stop one-sided and misleading marketing to patients, without full disclosure of the risks.

Note to Intuitive management: It is about time that Intuitive takes a step back from its aggressive sales and share repurchase practices. Use your money instead to establish proper training centers for surgeons.

Additional reading -- We are sure than many of you have already read:

- The [statement by the American Congress of Obstetricians and Gynecologists](#) (ACOG) that robot-assisted Hysterectomy (**Intuitive's #1 highest-volume procedure**) is not clinically superior to handheld laparoscopic surgery for routine hysterectomy ... with higher costs and longer operating times, and should not be the standard of care.
- The [statement by the National Cancer Institute of the National Institutes of Health](#) that radical prostatectomy, (**Intuitive's #2 highest-volume procedure**) is not the standard of care for the vast majority of prostate cancers. Conservative care (watching, without aggressive treatment) has better overall outcomes than surgery for all but the most aggressive cancer sub-types.

- An [FDA Warning Letter](#) about failure to furnish material information about possible product safety defects and misbranded devices.
- The many recent articles bring to the public's attention [increased awareness](#) about the [undisclosed risks](#) of robotic surgery; tremendous increase in the number of adverse events with injuries and deaths as reported in the only publicly available source of such information.

Cautious Investing to All