



January 17, 2013

## Citron Reports on Intuitive Surgical (NASDAQ:ISRG) : Part II

# Intuitive Surgical: Angel with Broken Wings, or the Devil in Disguise?

Our first report on Intuitive Surgical surveyed some of the major litigation problems the company is facing, and we reviewed some of the academic and peer comparisons of da Vinci surgeries to other treatment approaches.

Part 2 of the investigation focuses on five more key issues that will negatively impact earnings in the near future and put Intuitive's stock at \$300 per share in 2013.

As Wall St. awaits ISRG earnings next week, which are at risk of tipping weakness in its total procedures growth, the real story is the macro picture, which portends enormous headwinds in 2013 for the one-time Wall Street darling. Procedure counts will dramatically soften and new machines sales will flatline, due to:

- heightened awareness of treatment cost differentials to be leveled under Obamacare,
- the consequences of looming litigation, which will
- force hospitals to disclose more completely and accurately the risks of complications in robotic surgeries, including :
  - the specific risks of being exposed to the movements of the robot's instruments
  - the electricity conducted within and through them, and
  - the surgeon's level of skill and training in manipulating the device.

But \$300 is just the first stop. What happens when it becomes clear that insurance companies will no longer pay huge reimbursement premiums for robotic surgeries? Or the FDA initiates an inquest into the patient burns and perforations unique to robotic surgeries, as yet undisclosed in Intuitive's one-sided marketing blitz? Or the litigation against the company from injured and deceased patients gains class action status? It is Citron's belief that **none of these risks** are currently priced into the stock, and they are all very real risks indeed.

In this report Citron has taken source-document research to the next level, and has actually databased every MAUDE (FDA) report on Intuitive, so any investor, doctor, or law firm can search by keyword (i.e. "malfunction", "death", "burn", "laceration", etc.) In this report we also present a roadmap that shows the forces weighing on Intuitive over the next 12 to 18 months, and the challenges they face on the way down.

We also must note that, as well as the tremendous commercial success generated by Intuitive, we respect the company and management for introducing robotic surgery into the vernacular of the medical community, and building one of the great growth stories of the past decade. Da Vinci has even starred on [Grey's Anatomy](#)! Its marketing team has won tremendous share of mind with the public, and its campaign to stimulate public demand for robotic surgeries has been enormously successful. Too bad it has run so far beyond what the science can support.

Citron also does not challenge the view that in the hands of a highly skilled, thoroughly trained surgeon with deep experience in robotic surgery, in cases carefully selected for appropriateness, da Vinci can enable many good surgical outcomes. That is not a topic of debate.

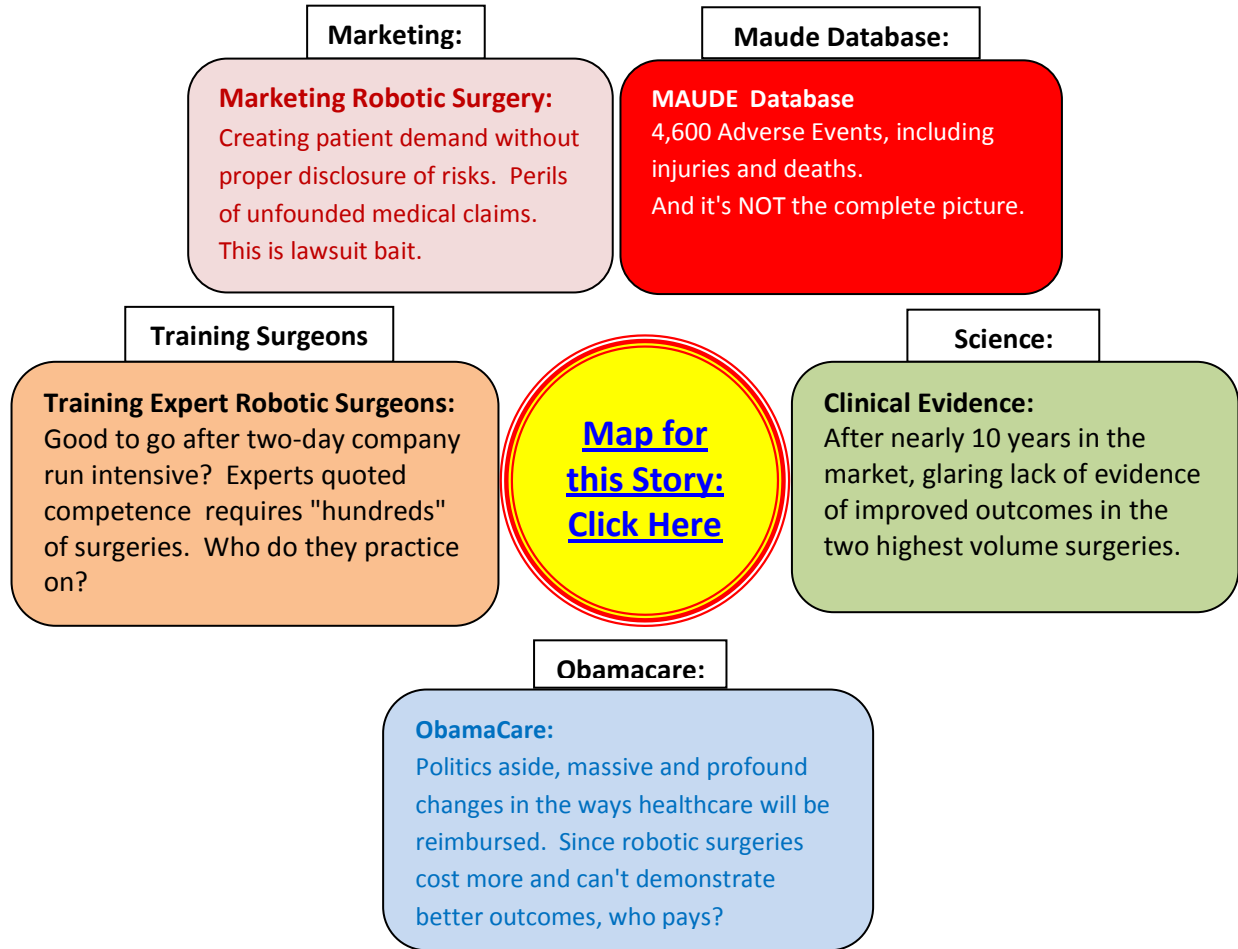
But just like Apple's descent from \$700 to \$500 ... **everyone hits a wall sometime**. Even though we are about to discuss some disastrous outcomes from the da Vinci robot and some significant challenges that the company will face to revenues from reimbursement, as well as from tort litigation and most important from the scientific community, our \$300 figure merely reflects a fair current multiple for Intuitive. It does **not** price in any material changes in the company. And when multiple compression hits, it hits fast.

**ROADMAP TO THIS STORY: ([Click Here](#))**

There are **five** main issues explored in this story. Each is on a collision course to negatively impact Intuitive Surgical's financial future. Some very critical data points are new as of this week, while others date back a few years. However, every point has been corroborated by expert opinion. It is Citron's opinion that nobody has actually assembled all the pieces of the mosaic into a coherent investment thesis, as presented in this report.

Intuitive maintains a \$20 + billion market cap, and buy recommendations from a slew of analysts. It carries a forward EPS of 29, but analysts like Lazard insist on even higher price targets. We believe that their analysis is based on blindly modeling numbers and failing to see the changing fundamentals.

The Big Five Issues Overhanging Intuitive Surgical are:



There are medical, scientific, ethical, and regulatory aspects of this story. The reason it needs a map is because multiple issues bear on very serious litigation risk the company has created for itself, which will only intensify this year and next. However, Citron's remains intensely focused on the bottom line, and the inevitability of profound multiple contraction for Intuitive's Stock. Because the confluence of forces is interconnected, we've drawn a map to illustrate how these issues relate directly to the financial consequences to Intuitive, which will be discussed below.

From these major topics we will address litigation risk, then utilization rate issues and finally financial consequences.

## MAUDE Database:

# Over 4,600 Adverse Events – just the Tip of the Iceberg

## Introduction to the MAUDE database

(NOTE: For each point below, clickable links are provided directly into the referenced MAUDE record: )

The FDA publishes and maintains a database called MAUDE (Manufacturer and user Facility Device Experience) which catalogs medical device malfunctions and adverse outcomes.

Some of these records are truly disturbing. For example, consider this case: [MAUDE 1915208](#)  
(We've copied the entirety of the narrative fields here because the report is so full of contradiction and lacking in credibility. )

### Manufacturer Narrative

On november 30, 2010, an isi clinical sales representative spoke to the surgeon that performed the da vinci hysterectomy on the patient. The surgeon stated that the patient did have an autopsy performed which found that the patient had an injury to her left external iliac artery. The source of the injury was not confirmed. Based on the limited information provided, it is indeterminable if the da vinci system, instruments or accessories contributed to the patient's demise. As of december 3, 2010, no adverse events have been experienced with the site's system.

### Event Description

It was reported that post a successful da vinci hysterectomy procedure, the patient developed an infection and was not discharged as planned. Ten days post op, the patient was given a blood thinner and expired due to an arterial bleed. Reportedly, the patient's demise was unrelated to the da vinci surgical system.

### Manufacturer Narrative

On (b)(4) 2012, isi received a legal summons indicating that the patient expired on (b)(6) 2010, post op a da vinci si hysterectomy with bilateral salpingoo-oophorectomy and pelvic node dissection procedure performed on (b)(6) 2010. Emergency surgical procedures performed on the patient on (b)(6) 2010, revealed that the patient had sustained a burn to the right external iliac artery, pumping blood in the body cavity, causing bowel ischemia incompatible with life.

Following the surgical procedure, pain medication was continually administered to the patient without good affect due to significant pain experienced by the patient.

Remember that hysterectomy surgery is generally very routine. Surgical notes document an injury to the left iliac artery, and a burn to the right iliac artery. We are unsure if there was a left/right error here; if there are two injuries or one. It only took one injury to cause the death of the patient. Clearly there is at least one burn involved. There is no other way for a burn in an arterial wall to occur except from the da Vinci equipment. Nonetheless, the green comments by the company attempt to exonerate the da Vinci by stating a complete denial of the obvious.

It is necessary to understand that participation in MAUDE reporting is voluntary. After reviewing numerous MAUDE records, just a few excerpted examples of which are posted below, it is Citron's opinion that many of these records are not being posted to further scientific inquiry or medical accountability -- they are being posted as an extended CYA exercise.

After surveying patterns in these 4,600 MAUDE records, as we became deeply disturbed at abuses of the da Vinci machine, we also became disturbed by the abuses of the MAUDE database itself. Beyond the burns, perforations and lacerations that appear far too many times, over 90% of the reported incidents are reported by Intuitive Surgical, which inserts in every possible instance, including some that are clearly unfathomable, like the above example, that the complications or problems resulting from the surgery had **nothing to do with the da Vinci device, and/or that the machine appears to be functioning without error**. We'll revisit this line of defense later on in this article.

## Citron Publishes all the Intuitive Surgical adverse outcome records reported in MAUDE

We needed database search capability into MAUDE to really gain insight into what the patterns really tell us about Intuitive's business. The searches on the FDA site were too rudimentary for real analysis. So Citron took the extraordinary step of downloading the entire dataset of Intuitive Surgical adverse events reports into a database search platform. Further, so that researchers can do their own work with it, we have converted the entire dataset into an easy-to-search Excel format. Interested parties can re-import this dataset into their own database tools and see what patterns emerge. And anyone can search Excel and click on the links to read any corresponding MAUDE report.

In the spirit of Citron's underlying conviction that all parties should have access to all relevant information, we have taken the extraordinary step to republish the entire 4.600 record database in Excel format

[Click to Download the Entire MAUDE Dataset Excel file here](#)

(**Excel Note:** Column J contains the hyperlink to each online record at the FDA website; columns E and F (in red) contain the Event Description and Manufacturer's Narrative fields, which can be searched for keywords, and viewed in full by double-clicking.)

Citron invites all parties to examine this database from their own perspectives. Some of Citron's observations are documented below.

## Patterns Citron Identifies in MAUDE

Citron has been analyzing this dataset for some time, and presents some conclusions which should be very troubling for Intuitive investors. There are over 4,600 records in MAUDE which result from adverse events from Intuitive Surgical's da Vinci robot device. The outcomes range from the non-event (error code detected when no surgery was in progress) to severe injuries and deaths.

About 3,900 of these records, or about 82% are from years 2007 to 2012. Investors are free to perform their own analysis, and invited to draw their own conclusions.

Citron has chosen records representatives of the types of issues we are describing, neither the best nor the worst of their class; to stand as examples of the pattern as described:

- **1) This adverse event dataset is built entirely from voluntary entries. That means that by definition, the database will never be a complete catalog of the adverse events from da Vinci surgeries.**

In fact, the FDA states on the [MAUDE homepage](#) that the information cannot be used to determine failure rates. There is no incentive for the main reporting parties, Intuitive and the hospitals who are its primary customers, to enter cases into Maude. **We see many cases in which, as soon as the risk of legal liability emerges in a case, the hospital stops providing further information about the patient outcome and post-failure inquiry findings.**

- **Event Type: "Death":** MAUDE : 2890369

"It was reported 2 days post a successful da Vinci si myomectomy procedure, the patient expired. ... the surgeon who performed the surgical procedure reported to him that a tenaculum forceps instrument being used during the surgical procedure was not moving as it should.... The csr indicated that he instructed the surgeon to have the instrument removed, cleaned and re-installed. The csr indicated that the site proceeded using the instrument and the planned surgical procedure was completed. No patient harm, adverse outcome or injury was reported to have occurred at the time of the surgical procedure. On (b)(6) 2012, the intuitive surgical csr was notified by the surgeon that the patient was re-admitted to the hospital on (b)(6) 2012 due to a perforated bowel and the patient expired on (b)(6) 2012."

"On (b)(6) 2012 an inspection of the site's system was performed by an intuitive surgical field service engineer(fse). Inspection of the site's da Vinci si surgical system by the fse found no issues and that the site's system functioned within specification. The site has indicated to the intuitive surgical clinical sales representative that **the site is currently performing an internal investigation into the reported incident and is unable to provide any other details concerning the incident. Several attempts have been made to verify additional details concerning the reported event; however, no additional information was provided.**"

- **Event Type: "Death"** MAUDE : 2600178

"The delay in reporting is due to an administrative oversight where the aware date was inadvertently not updated by a customer service representative."

**"Several attempts have been made to gather additional information regarding this event from this site without success."**

- **Event Type: “No Answer Provided”** MAUDE : 1985870  
 “Over a week post op, the patient underwent a pelvic exam which resulted in the discover of a tear and an infection.”  
 “As of the date of this report, additional information has not been provided to support the reported event.”
- **Event Type: “Death”:** MAUDE : 2241885  
 “Since receiving this initial report, the site has been contacted to request additional information without success.”
- **Event Type: “Other”** MAUDE : 2559247  
 “Reportedly, during the biopsy procedure, the patient's renal artery was damaged.”  
 “On april 13, 2012, intuitive surgical contacted the surgeon, (b)(6) and he indicated that the intended planned procedure was a da Vinci s partial nephrectomy procedure, however, he is unable to provide any other information concerning the reported event and that I should contact the hospital's risk management department. On april 20, 2012, intuitive surgical was contacted by attorney (b)(6) and she indicated that due to hippa regulations she is unable to provide additional information concerning the reported event to 3rd parties. However, the hospital will comply with any request for additional information directly from the fda.”
- **Event Type: “Other”** MAUDE : 2552349  
 “After 15 minutes of operation the surgeon lost control of psm arm 1, resulting in damage to the patient's stomach.”  
 “Multiple attempts have been made to gain additional information about the event, but the customer has yet to provide further details.”

- **2) Intuitive inserts CYA commentary whenever it can, whether logical or not.**

Over 90% of the records in Maude are posted by Intuitive Surgical. That probably accounts for the frequent assiduous notes stating phrases like "a review of the system logs show no errors occurred", and "no machine malfunctions occurred", or "the field system engineer subsequently tested the system, and found it to be working to manufacturer's specifications with no defect or malfunction". The consistency of these comments appearing, when analyzed in full, will show a pattern of **the company's attempt to exonerate itself from liability at every opportunity.**

**What end does this serve, except to shift blame for adverse events onto the surgeon and the hospital – their own customers.** See the "Legal Liability" discussion below.

- **Event Type: “Death”:** MAUDE : 2890369 (Also above)  
 "Inspection of the site's da Vinci si surgical system by the fse found no issues and that the site's system functioned within specification."
- **Event Type: “Death”** MAUDE : 2548815  
 “It was reported that during a da Vinci si ovarian transposition procedure, a complication occurred and the patient started to bleed. The surgeon attempted to control bleeding ... surgeon attempted to find the source of bleeding. It is unclear on the sequence of events after this. The patient was confirmed to have expired. It is unknown

whether the patient expired during or after the procedure. No further information was provided.”

“The system was tested by a field service engineer and performed to specifications. The account stated the case complications are unrelated to the da Vinci system. Multiple attempts for additional information from the account were made. To date, no further information has been received.”

- **Event Type: “Injury”** MAUDE : 2543963

“It was reported that during a da Vinci si pulmonary lobectomy procedure, the patient's pulmonary artery was lacerated...”

“Several follow up attempts with the site have been made concerning the patient's status, however, no additional information has been provided. As of (b)(4) 2012, there have been no reported recurrences of this issue at this hospital.”

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- **Event Type: “Death”** MAUDE : 2539834

“It was reported that during a da Vinci si bilateral salpingo-oophorectomy procedure, during placement of the uterine manipulator, the patient's bowel was ruptured. The surgeon repaired the patient's bowel, which took approximately 3 hours to repair.”

“Additional information received from the account indicates the patient death was the result of a heart attack and was not related to the surgery in this event. No further information provided.”

**To be discussed later is the obvious conclusion that every time Intuitive inserts one of these CYA comments, they are implicitly or explicitly attempting to shift the blame to the only other parties – the hospital or the surgeon – their primary customer!** This point will be covered in depth later in this report.

- **3) Any death is too many, especially when the majority of surgeries undertaken using da Vinci are supposed to be routine.**

There are 89 records that document the result of death of the patient. (at least two appear to be duplicate entries, but we have not done any editing of the MAUDE data). The most recent was entered 12/29/2012. Some of these deaths are clearly incidental, while others are extremely troubling with regard to injuries apparently caused during the surgery. Set the filter on the Event Type column to “Death” and you can review them all. The point is that very serious, and sometimes lethal outcomes are the result, patients lives hang in the balance, and are exposed to these risks in what are very often the most routine types of surgeries being performed.

- **4) Records appear only when publicized or years after the event.**

Everyone should be troubled to see records appearing years after the adverse outcome, **apparently only because details of the outcome of these cases had been made public in a medical journal. (The cases had occurred 3 to 4 years prior to appearance in MAUDE.) This strongly indicates that there are an unknown number of bad outcomes that have not been posted in MAUDE.**

- **Event type: “Injury”** MAUDE : 2874824

“The following details are related to the **first** patient injury as alleged in the article: ...



cutting-type current set at 35 w sparked through the intact protective sheath of the monopolar scissors onto an adjacent metallic suction irrigator that was retracting the external iliac vein. Conduction through the suction irrigator resulted in a vessel injury..”  
“Isi has contacted the initial reporter concerning the reported event. A follow-up mdr will be submitted if additional information is provided. “

- **Event type: “Injury”** MAUDE : 2884101  
“The following details concerning the **second** patient injury as indicated in the article is as follows: during a da Vinci urological procedure, while performing a retroperitoneal lymphadenectomy using the monopolar curved scissors instrument with the mcs tip cover installed, the patient's small bowel was injured.  
“Isi has contacted the initial reporter concerning the reported event. A follow-up mdr will be submitted if additional information is provided. “
- **Event type: “Injury”** MAUDE : 2884094  
“The following details are related to the **third** patient injury as alleged in the article: During lymphadenectomy, activation of monopolar coagulation-type current, set at 35 w, caused a spark to extrude laterally through the scissors insulating plastic sheath and onto the right external iliac artery.”  
“Isi has contacted the initial reporter concerning the reported event. A follow-up mdr will be submitted if additional information is provided. “
- **Event type: “Injury”** MAUDE : 2781479  
This one is of concern because of the **five-year time lag** between the publication of the **surgical outcome** and the appearance of the record in MAUDE.

- **5) The most common reasons for patient injuries are perforations (organ punctures), lacerations (cuts) and tears.** Most perforations and lacerations are presumably due to doctor error; however, some cases are clearly describing a context of machine malfunction, which itself might be caused by incorrect setup.

- **Event type: “Death”** MAUDE : 2798286  
“It was alleged that during a da Vinci s partial nephrectomy procedure at (b)(6) hospital, the patient sustained cuts and lacerations, causing injury to the aorta, left renal artery, splenic vein and proximal renal vein. It is also alleged that during the surgical procedure the patient sustained perforation of the pancreas.... It is alleged that between (b)(6) 2010 as results of the various injuries and in particular the unrepaired and untreated injury to the pancreas, hemorrhagic debris and fluid accumulated in the contiguous residual cavity, causing and/or contributing to the development of a right pleural effusion and pericardial effusion. On september 28th, 2012, isi became aware that the patient expired on (b)(6) 2010.”  
“At this time it is undetermined as to what caused the patient's death.” [ Citron asks “Really?” ]
- MAUDE : 2890369 "perforated bowel"(above) MAUDE : 2543963 "pulmonary artery was lacerated" (above)
- MAUDE : 2889862 "bowel perforation was discovered " (below)

- **Event type: "Injury"** MAUDE : 2883607  
"it was noted that the patient suffered a bowel tear during the procedure."
- **Event type: "Injury"** MAUDE : 2807226  
"On (b)(6) 2012, intuitive surgical became aware of a bowel perforation that allegedly occurred during a davinci si hysterectomy ... the surgeon believes that the fenestrated bipolar instrument activated by itself, without the surgeon pressing the foot pedal."  
"The instrument has not been returned for evaluation. The root cause of the customer reported failure mode cannot be determined. Several attempts have been made to gather additional information regarding this event without success. As of the date of this report, no additional information has been provided from the site...."
- **Event type: "Death"** MAUDE : 2736219  
"...on (b)(6) 2010, the patient underwent a da Vinci s partial nephrectomy procedure at (b)(6) medical center. During the surgical procedure the patient sustained perforation of the duodenum. Between (b)(6) 2010, the patient developed an abscess, infection and sepsis. The patient deceased on (b)(6) 2010."  
"A review of the site's system log found that no system error codes were generated during the surgical procedure. At this time it is undetermined as to what caused damage to patient's duodenum. Requests for additional information have been made; however no additional information has been received."

• **6) The second-most prominent pattern is electrocautery: burns from electrical discharge.**

Many burns occur due to insulation failures, as documented in medical journals.

( <http://www.ncbi.nlm.nih.gov/pubmed/22825276> ) There appear to be a variety of reasons when electricity is delivered at unintended times or to unintended tissues. One of the main sources is insulation flaws on the equipment. The details of other burn cases leave room for interpretation of doctor error or machine malfunction.

- MAUDE : 2874824 "sparked through the intact protective sheath... vessel injury "  
(also above)
- MAUDE : 2854101 "small bowel was injured" (also above)
- MAUDE : 2884094 "caused a spark...onto the right external iliac artery. The surface of the vessel was visibly charred" (also above)
- **Event type: "Injury"** MAUDE : 2836485  
"It was reported that during a da Vinci s prostatectomy procedure, while the surgeon was performing pedicle dissection, arcing from the mcs tip cover accessory installed on the monopolar curved scissors instrument occurred causing unintentional burning."
- **Event type: "Other"** MAUDE : 2712015  
"It was reported that after a da Vinci si pulmonary wedge resection procedure was completed, a burn was observed at one of the port sites when the cannula accessory was removed from the instrument arm. The burnt skin was excised, however, the patient was burnt all the way through the tissue."  
"Despite multiple requests, no additional information has been received from the

hospital regarding this event. Intuitive surgical investigation has shown that it is possible for the electrosurgical unit (esu) currents to pass through the instrument arms to ground, through the cannula accessory to the patient, if the patient is not properly grounded or if the grounding pad used by the surgical staff is faulty. As of (b)(4) 2012, the site has continued to use their da Vinci si surgical system and there have been no reported recurrences of this issue at this hospital.”

- **7) Numerous cases of injury not categorized as "Injury" Event Type.** There are hundreds of records of "Other" and "Malfunction" event types, **some documented as injury-causing, and others not.** For instance, if a patient's uterus is unintentionally burned, but the purpose of the surgery was to remove the uterus, that record might be categorized as "Malfunction" rather than "Injury".....using "no-harm, no foul" logic we presume.
  - **Event type: "Other"** MAUDE : 2577302 ( Serious outcome nonetheless --why not "Injury"? )  
“During the surgical procedure the patient sustained injuries to her left ureter and bladder. The planned surgical procedure was converted to open laparotomy surgery with repair of the bladder injury.”  
(after three surgeries... ) “Despite this treatment, the patient continues to suffer from nocturea, pelvic pain, dyspareunia, and continued leakage of urine vaginally.”
  - **Event type: "Malfunction"** MAUDE : 2842683  
“During the procedure, the surgeon noted the instrument was arcing unintentionally, and burned the uterus. The tip was changed out and it continued to arc....”
  - **Event type: "Other"** MAUDE : 2712015 (above)  
“It was reported that after a da Vinci si pulmonary wedge resection procedure was completed, a burn was observed at one of the port sites when the cannula accessory was removed from the instrument arm. The burnt skin was excised, however, the patient was burnt all the way through the tissue.”  
**Event type: "Malfunction"** MAUDE : 2671515  
“During robotic hysterectomy, no one was present at console to activate power source to activate pedal. However, upon advancing instruments there was smoke and a burn spot on the bipolar cautery instrument. The active esu cord had been plugged into the esu monopolar output instead of the bipolar output. There was also a burn on the patient's uterus. The robotic unit had instigated the electrical without anyone telling the panel to. The patient was having a hysterectomy so she was not harmed. ... Cord may have been plugged into monopolar port when it should have been in bipolar port.”
  
- **8) In many of the cases with the worst outcomes, the patient's surgery is closed, reported successful , and they are discharged and sent home. Only later do things turn for the worse.**  
A common occurrence within the adverse outcomes is a surgery that is considered successful. The patient is closed up and sent home. This is one of principal , and much-marketed, benefits of robotic surgery. But the patient returns to the hospital days or weeks later, with internal bleeding, infection, parts still inside them, and/or other serious injuries.

- **Event type: "Death"** MAUDE :1915208 (above)  
 "It was reported that post a successful da Vinci hysterectomy procedure, the patient developed an infection and was not discharged as planned. Ten days post op, the patient was given a blood thinner and expired due to an arterial bleed. Reportedly, the patient's demise was unrelated to the da Vinci surgical system."  
 "Emergency surgical procedures performed on the patient on (b)(6) 2010, revealed that the patient had sustained a burn to the right external iliac artery, pumping blood in the body cavity, causing bowel ischemia incompatible with life. Following the surgical procedure, pain medication was continually administered to the patient without good affect due to significant pain experienced by the patient."
- **Event type: "Injury"** MAUDE : 2889862  
 "It was reported that after a da Vinci s hysterectomy procedure, a bowel perforation was discovered post surgery."  
 "There were no patient complications observed during the case. The bowel perforation was discovered after the patient presented with pain at the emergency room, after which a secondary, non-robotic procedure was conducted to treat the injury. The surgeon believes the perforation may have occurred when the camera cannula was inserted, or when cutting through the fascia."
- **Event type: "Injury"** MAUDE : 2781865  
 "It was reported that after a successful da Vinci si sacrocolpopexy procedure, the patient was discharged on day after her postoperative lleus resolved. On the 5th day the patient began experiencing abdominal pain and nausea. The next day the patient went in for emergency care... a 5mm perforation was identified in the sigmoid colon several centimeters distant from the area of operation. The defect in the colon was alleged to be consistent with a cautery injury. It is alleged that this injury is likely associated with arcing/cautery of the robotic instrument."  
 "Neither the tip cover accessory nor the monopolar curved scissors have been returned for evaluation, therefore, the root cause of the customer reported failure mode cannot be determined. The root cause of the surgical complication experienced by the patient is also currently undetermined. On (b)(6) 2012 the initial reporter indicated that the physician involved with this incident had made the determination that arcing had caused the damage; however this determination was made approximately 30 days after the procedure and after the patient had returned complaining of pain. The operating room staff and team did not observe any arcing during the procedure and could not confirm the physician's observation."

### What MAUDE doesn't give the public:

In addition to not serving as a basis to measure failure rates, due to its voluntary nature, MAUDE also lacks the following:

- Except for scattered comments, MAUDE contains **no information** about the experience level of surgeons or staff conducting robotic surgeries. More about this topic in the **training** section – and the litigation risks section.
- At the same time, there are numerous occurrences of notations of hospitals refusing to provide further information, once there is a risk of legal exposure.

- Timeliness: 971 (over 20%) of the records have no event date entered. Many records are submitted well after the event date – 167 records are dated received by FDA more than six months after the event occurred.
- All information about hospital, doctor, and date is redacted.

### **Implications of MAUDE:**

- The consequences of injury created by robotic surgery can be severe.
- There are more adverse outcomes from robotic surgery than appear in MAUDE. Nobody knows how many.
- Some of the worst injuries go undetected during the robotic surgery – the patient is sent home, the surgery having been declared successful.
- Intuitive's attempts to use Maude to exonerate itself have left a trail of commentary that will come back to haunt the company for years – in court. (See litigation risks)

### **Conclusions of reviewing MAUDE:**

If the da Vinci were a drug, the US public would not be so exposed to this uncertain situation. Drugs require double-blind testing for safety and efficacy **before** receiving licensing to enter the marketplace. It is due to the unique regulatory environment for "medical devices" that da Vinci can be deployed so widely in the market for routine use without a full suite of safety and efficacy testing.

## **Clinical Evidence for Robotic Surgery**

It is astonishing that after being in the marketplace for 10 years, Intuitive finds itself with its only product having no scientific justification for widespread use in the 70%+ of its most common applications: Prostatectomies, and gynecological procedures such as hysterectomy and fibroid surgery. Citron can think of no other correlate in the medical field in the last generation.

### **Gynecological Surgery: No better outcomes than conventional or laparoscopic procedures**

Hysterectomy is Intuitive's largest volume procedure. This was published in a position statement by the American Institute of Gynecologic Laparoscopists, yesterday. Need we say more?

" Complications, conversion rate, hospital stay, blood loss, paralytic ileus duration and weight of the surgically treated uterus were similar in both groups. Clinical outcomes with LAVH were comparable to those with VH; however, operative time was longer with LAVH. Currently, VH should be routinely used."

*Journal of Minimally Invasive Gynecology*  
*Laparoscopically Assisted Vaginal Hysterectomy vs Vaginal Hysterectomy: Meta Analysis*  
*January 2013*

[http://www.jmig.org/article/S1553-4650\(12\)01267-8/abstract](http://www.jmig.org/article/S1553-4650(12)01267-8/abstract)

Same story here...it's been developing for years:

<http://www.ncbi.nlm.nih.gov/pubmed/22247802>  
<http://www.ncbi.nlm.nih.gov/pubmed/21666467>

Meanwhile the failure rates continue to run high, weighing down outcomes with adverse events ...

" This study included 454 robot-assisted procedures that were performed over a 7-month period. A 2.6% accessory cover failure rate was observed. More importantly, such instrument malfunction led to 3 significant intraoperative complications..."

*Mues, Box, and Abaza*  
*Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury*  
*Urology (1) 2011*

<http://www.sciencedirect.com/science/article/pii/S0090429510004176>

The studies comparing robotic and conventional laparoscopic surgeries rate the outcomes about equal. But with robotic surgeries bearing a higher cost, taking longer, exposing the patient to more anaesthesia, and having the overhead of the undisclosed adverse outcomes as described elsewhere in this report, what is fueling the massive numbers of these surgeries? Is it the company's marketing campaign to consumers? Is it the company's "arms race" marketing to hospitals? **Again, what are the legal consequences to Intuitive? Same open questions as above. Answers will emerge in 2013.**

## **Prostate Surgery: "No treatment" is the preferred treatment**

Citron observes that while using da Vinci for Prostatectomies adds appx \$4,800 to the cost of each surgery, there is no scientific evidence that it has produced better outcomes (the gold standard being improved cancer survival rates while avoiding incontinence and impotence)

<http://www.nejm.org/doi/full/10.1056/NEJMoa1113162>

Yet da Vinci was used to perform 146,000 prostate surgeries in 2011, but is experiencing a 20% decline in 2012 rates, largely due to the medical impact of the above findings.

"But for the big three outcomes—cancer control, urinary control, and sexual function—there is still no clear answer as to whether one approach is superior to another... [open, laparoscopic or robotic surgery]"

-- Dr. William Lowrance  
Urologic Oncologist

Huntsman Cancer Institute, University of Utah

<http://www.cancer.gov/ncicancerbulletin/080911/page4>

"The critics are right — if they're talking about innovations like the da Vinci robot, which costs more than a million dollars and yet has never been shown by a randomized trial to improve the outcomes of prostate surgery. Indeed, a 2009 study showed that while patients had shorter hospital stays and fewer surgical complications like blood loss when they underwent this kind of robotic surgery, they later "experienced more ... incontinence and erectile dysfunction".

--Ezekiel J. Emanuel

Oncologist and former White House adviser,

is a vice provost and professor at the University of Pennsylvania.

<http://opinionator.blogs.nytimes.com/2012/05/27/in-medicine-falling-for-fake-innovation/>

"Conclusion: Risks of problems with continence and sexual function are high after both procedures. Medicare-age men should not expect fewer adverse effects following robotic prostatectomy".

*Journal of Clinical Oncology*

*Adverse Effects of Robotic-Assisted Laparoscopic Versus Open Retropubic Radical Prostatectomy*

*Among a Nationwide Random Sample of Medicare-Age Men*

*Barry, Gallagher, Skinner and Fowler*

<http://jco.ascopubs.org/content/early/2012/01/03/JCO.2011.36.8621.abstract>

\*The above quotes were reprinted from Citron's December 19<sup>th</sup> report.

What **is new** in this report is the legal impact of this finding in the perspective Intuitive's ongoing marketing campaign on behalf of robotic surgery. See the Marketing section, and also the Legal Liability section. **What will be the legal consequences of actively promoting a surgery to consumers which costs more, doesn't have demonstrably better outcomes than less expensive methods, has extraordinary risks due to potential system malfunction or doctor error, and isn't statistically advantageous to no treatment"? How will juries feel about evaluating injury claims with the underlying reason to engage in the surgery was based on unfounded medical claims?** See the legal liability section.

## **Practicing Experimental Medicine on the Public: A Perspective "The Operation Was a Success, but the Patient Died"**

Citron reiterates that a robotic da Vinci surgery suite, in the hands of a highly skilled and experienced surgeon, and applied to the right case, can produce excellent outcomes. That is not the question at the heart of this inquiry.

But that is **not** how the science of medical care delivery advances in this country. In the regulation of drugs the scientific method demands that all outcomes, the good, the bad, and the ugly, all have to be measured, with safety and efficacy weighed impartially ... BEFORE entry into the marketplace, and the science drives the marketing claims. That is why FDA has such power to determine the labeling of drugs.

For medical devices, however, the world is somewhat different because of the totality of the da Vinci system, and its impact on patients in surgery. It is not a single purpose appliance with a clear path to assess success/failure based on a narrowly defined outcome. That is why we find ourselves in the midst of a high-stakes, real-life quandary described by the old cliché: "The operation was a success, but the patient died".

If Intuitive were clearly disclosing the risks and the overall data to prospective patients, they would be covered by the principle of "informed consent". But from a marketing standpoint, the company has incited tremendous demand from the public with its "glowing testimonial" advertising. Meanwhile, it has incited an "arms race" between hospitals, driven more by the threat of losing "customers" at any cost, than by dedication to delivering the best outcomes for patients, regardless of tools and methods.

Therefore the ultimate judgment on da Vinci's safety and efficacy is shifted from the clinical trial to the courts. That is the essence of the situation the company finds itself in today. Instead of a medical subcommittee of experts determining if the benefits outweigh the risks in a safety and efficacy consideration, it will be juries. And in that context, the company will face steep legal liabilities as consequences of its marketing excesses.



## Obamacare:

Since the Supreme Court upheld Obamacare, Wall Street has turned its attention to those companies that will become casualties of the new health policy (as well as winners).

The methodology for standardizing and bringing transparency to health care costs is a system called "Diagnosis-related Groups ([DRG's](#)). Intuitive investors who don't know what DRG's are, had better educate themselves. DRG is a fundamental shift in the way health care is reimbursed – moving away from simply paying cost-plus on a blank check basis, to paying for outcomes.

Citron presents an unsolicited letter from a gynecological surgeon which makes our point better than we could:

"I work at two large competing hospitals. Both are not for profit in mission statement. They both have individual contracts with upwards of 1200 payers nationwide. The hospitals are fiercely private and non-transparent about both what they charge and what they have agreed as a contract payment. The insurance companies likewise are private and seem little interested in helping each other have a semblance of uniformity in payments, as insurance companies have historically had a much greater focus on market share and maintenance of margin goals than in management or control of costs. Insurance companies do generally use Medicare rates as a starting point, but make concessions in a variety of ways. Rural hospitals, for example, generally have more of their payments on a cost-plus basis. They have fewer beds with harder economies, and they survive, at least in my state, because the major carriers have let them maintain a cost plus agreement. A mammogram in a rural hospital may pay double as an example.

I am a traditional vaginal surgeon. My bread and butter is the vaginal hysterectomy. The retail bill at hospital A is 8,000 with a final payment of 4,000. Hospital B charges 10,000 with a final payment of 5,000. Hospital B has negotiated richer contracts with my region's two big payers who are major insurers. Hospital B supports a teaching program and has the only full time children's hospital which is the alleged reason that their fees are higher and contractually paid better.

Now when a gynecologist surgeon replaces my vaginal hysterectomy with a laparoscopic procedure, the retail bill goes to 15,000 and reimbursement payment goes to 7,500 to 9,000. It took a while for hospitals to get this increase in payment, but it is nationwide now that laparoscopy pays better than traditional. As a general statement about watching the hospital-insurance game for the last 32 years, hospitals support new technology, but immediately begin the negotiation for higher reimbursement as the technology becomes mainstream.

Now to the robot. My hospital a gets the same fees for robot hysterectomy as a laparoscopic hysterectomy. Hospital A eats the extra time and costs. Hospital B is beating the bushes encouraging robot use. They are getting paid 18,000 to 21,000 for robot hysterectomy with the biggest market share carrier in our market. The carrier knows they are getting rooked, but are honoring cost plus contracts and provisions which reward extra time and costs. They are also saddled with a ridiculous contract clause which gives extra money when an admission is outpatient vs inpatient. They are counting the days until they can come back to the table and pay as they do for hospital A.

Facets of Obamacare may finally provide some transparency to the above. The facet i like the best is to pay a set fee based on diagnosis. It's called DRG based payment. This will kill the robot and make low cost surgeons like me go from being low cost-low margin to low cost-high margin.

It has always been pretty obvious to me why we pay so much more per capita for health care than anyone else."

*From a practicing surgeon –  
Name and Phone number confirmed*

This letter is loaded with issues of critical importance overhanging Intuitive Surgical's business prospects for the next decade.

Note the Medicare reference in paragraph 1 and the DRG reference in paragraph 5. DRG is a fundamental shift in the way health care is reimbursed – moving away from simply paying cost-plus on a blank check basis, to paying for outcomes. No it won't happen overnight, but as Citron has seen in its 2012 critique of Questcor, when insurance companies move, they move with certainty and tend to move as a group.

"If the 600,000 hysterectomies performed in the United States were all done robotically, the reported cost increases would result in an extra \$960 million to \$1.9 billion burden on the health care system."

*From the Journal of Minimally Invasive Gynecology  
AAGL Position Statement: Robotic-Assisted Laparoscopic Surgery in Benign Gynecology  
January 2013*

[http://www.jmig.org/article/S1553-4650\(12\)01267-8/abstract](http://www.jmig.org/article/S1553-4650(12)01267-8/abstract)

Obamacare is going to put the country on a path of paying for healthcare **outcomes**, not just **costs**. This shift is inevitable; our health care costs are out of control, and the entire system is completely unsustainable without such a move. No other industry (with the possible exception of national defense) operates on blind cost-plus basis, and it explains why our healthcare costs are rising at double or triple the inflation rate. Medicare doesn't pay that way anymore, and within a few years, insurance companies won't be either.

Then there is the issue of quantifiable outcomes. The stalking horse dogging Intuitive Surgical is that after hundreds of thousands of gynecological surgeries performed over the last decade, the medical community is unable prove any distinct improvement in outcomes over conventional surgical methods: laparoscopic and/or conventional surgery, based on conditions. The above-referenced professional position paper, released yesterday, is the latest and strongest statement of this reality to date. Meanwhile, da Vinci gynecological surgeries take longer, cost more, and expose the patient to more anaesthesia than conventional surgical techniques.

With regard to prostate surgeries, the big decline that started in 2012 is based on recently findings that rocked the medical industry : no treatment has better or equal outcomes to aggressive surgery for most cases.

Hysterectomy and prostate surgeries represent nearly 70% of the utilization of da Vinci machines in US hospitals. While Intuitive likes to say that the other 30% is "other", in fact the preponderance of these are gynecological surgeries also. Only about 7% of da Vinci surgeries are non-gynecological and non-urological.

**Europe:** After initial promises of huge new markets, Intuitive is delivering disappointing results in Europe.

" The credit and sovereign debt issues impacting Europe have slowed capital sales and procedure growth in that region, and our European sales reflect a challenging economic environment."

*From the Q3 2012 10-Q  
Intuitive Surgical, Oct 18, 2012*

<http://www.sec.gov/Archives/edgar/data/1035267/000119312512427223/d410790d10q.htm>

Ask Cramer about the relative credibility of company excuses for earnings disappointments. It is Citron's opinion that this one is just nonsense. The real reason is nationalized health care. After having bought some machines, Europeans are figuring out that results are not better than cheaper methods – and with nationalized health care driving the purchase commitments and the standards of care, the follow-through is simply not happening.

## Training Surgeons to do Robotic Surgery

The preface to this section are points from the MAUDE section above, namely:

- Intuitive takes positions on many MAUDE records that the adverse outcome was not the fault of the equipment. So who's fault are they saying it is?
- Rarely is there information in the MAUDE record that discloses the level of specific robotic surgery training or experience of the surgeon in a case.

Is the root cause of most of the injuries and adverse outcomes in the lawsuits as well as MAUDE are in fact doctor error? Citron admits this is possible. But if it is true, investors had better realize that this determination just as adverse for Intuitive, or possibly even worse than findings of machine malfunction. This goes directly to Achilles heel of the whole thing -- the difficulty of training for real-life surgery on the da Vinci. This topic is so important that in the recent AAGL position statement we read in the conclusion:

" Efforts should be focused on the proper credentialing and privileging of surgeons to use robotic surgical systems"

*Journal of Minimally Invasive Gynecology  
Laparoscopically Assisted Vaginal Hysterectomy vs Vaginal Hysterectomy: Meta Analysis  
January 2013*

[http://www.jmig.org/article/S1553-4650\(12\)01267-8/abstract](http://www.jmig.org/article/S1553-4650(12)01267-8/abstract)

## What is the Training to become a da Vinci Robotic Unit Surgeon?

Investors and patients had better understand the process by which a surgeon becomes trained to perform robotic surgeries. That process takes **two days**, and it is administered and conducted by Intuitive Surgical, and/or cooperating teaching hospitals.

<http://allaboutroboticsurgery.com/images/OSURoboticsTrainingPrograms.pdf>

Yet there are published expert opinions that it takes **hundreds of surgeries** to become truly proficient on the da Vinci.

"However, surgeons with extensive robotic experience say it takes at least 200 surgeries to become proficient at the da Vinci and **reduce the risks of surgical complications**"  
"

*Orlando Sentinel  
June 16, 2010*

[http://articles.orlandosentinel.com/2010-06-16/news/os-robot-surgery-safety-20100616\\_1\\_robotic-surgery-surgical-advancement-quicker-recovery-times](http://articles.orlandosentinel.com/2010-06-16/news/os-robot-surgery-safety-20100616_1_robotic-surgery-surgical-advancement-quicker-recovery-times)

And that is just for a general robotic assisted hysterectomy. **In a staggering piece of research conducted at Cornell Medical School we read that Doctors who perform robotic-assisted prostate cancer surgery aren't proficient until they have done the procedure more than 1,600 times.**

"The surgeons needed to perform more than 1,600 operations before they were able to gauge with at least 90 percent accuracy how much tissue surrounding the tumor they needed to remove to get all the malignant cells. Leaving stray cancerous cells in the margins, at the edge of the tissue removed during surgery, can lead to recurrences of the disease."

*Bloomberg News  
Feb 16, 2011*

[http://articles.orlandosentinel.com/2010-06-16/news/os-robot-surgery-safety-20100616\\_1\\_robotic-surgery-surgical-advancement-quicker-recovery-times](http://articles.orlandosentinel.com/2010-06-16/news/os-robot-surgery-safety-20100616_1_robotic-surgery-surgical-advancement-quicker-recovery-times)

In the same article Intuitive is quick to attempt to cover its liability:

"Every hospital has its own system to train surgeons and it's not up to the company to determine when the doctors reach proficiency," said Calvin Darling, a spokesman for Intuitive Surgical.'

*Bloomberg News  
Feb 16, 2011*

[http://articles.orlandosentinel.com/2010-06-16/news/os-robot-surgery-safety-20100616\\_1\\_robotic-surgery-surgical-advancement-quicker-recovery-times](http://articles.orlandosentinel.com/2010-06-16/news/os-robot-surgery-safety-20100616_1_robotic-surgery-surgical-advancement-quicker-recovery-times)

Again, the company puts itself at the opposite end of the universe from aligning its interest with its customers.

'But Lenihan recalls MultiCare's steep learning curve from 2005 to 2008. At first, MultiCare and other hospital systems pushed surgeons to use the pricey new tool, he said. By 2008, "We saw a big jump in the number of cases, and we also started to see a big jump in the number of complications."  
Urologists needed 200 to 250 cases to get "consistently good," he said, and even laparoscopy-savvy gynecologists took 50 to 100."

*Seattle Times  
July 7, 2012*

[http://seattletimes.com/html/localnews/2018631542\\_robot08m.html](http://seattletimes.com/html/localnews/2018631542_robot08m.html)

So of the tens of thousands of procedures being performed in the US each year, how many of these are performed by surgeons with less than 100 robotic surgeries in their experience? Less than 10? The MAUDE records do not collect information on the level of experience of the surgeon, so there is no way to know if the adverse outcomes are even correlated to surgeon's level of experience.

The lack of training of some doctors has proven deadly as shown in this case

<http://fightforvictims.com/medical-devices/da-vinci-surgical-robot-injury-lawsuit>

**February 2012:** The family of a Chicago man who died following a da Vinci Surgical Robot procedure was awarded \$7.5 million in a medical malpractice lawsuit against his doctors. The man had died in 2007, after doctor using the robot to remove his spleen accidentally punctured the lower intestine. The injury

wasn't discovered for two weeks, and by then, there was no way to save the man's life. The man's surgeon testified it was the first time he had used the robot on a living person, according to court documents

<http://www.mcnabolalaw.com/12373-LB-reprint-Cogan-022112.pdf>

Here's a news article which resulted in a MAUDE record from 2009

MAUDE : 1515425

'He recounted one case of a surgeon who was using the system for the fourth time. After eight hours of surgery, the proctor -- an experienced surgeon who supervises the operation -- told the surgeon that progress was too slow. He recommended the surgeon switch to conventional surgery, where an incision is made from the navel to the pubic bone to access the prostate.

After the proctor left the operating room, the surgeon continued using the robot. The patient later died from complications."

*Reuters  
Sept 18, 2009*

<http://www.reuters.com/article/2009/09/18/us-surgery-robotics-idUSTRE58G7AV20090918>

So is training to qualify as a da Vinci surgeon two days, or hundreds of surgeries?

Imagine if Boeing sold airplanes but also issued pilots licenses. And imagine they could just say "come up to our training partner for the weekend, and we'll get you all set up"... Now worse, imagine if a new pilot flew the plane, but he didn't even have to be on board.

Not surprisingly, the chief medical adviser for Intuitive Surgical, dr. Myriam Curet, stil opines that overall "robotic surgery is safer than open surgery". And she says "you can operate robots safely in the first 25 cases, gaining speed with experience."

Are you confident in this reassurance as an investor? How about as a patient ?

Citron does not believe there is a shareholder or an analyst on the street who thinks it is good for Intuitive's future for the company to put its own interests against the interests of the doctors and hospitals. But now we see that when the patient "expires" the company blames it on the doctor or the facility.

But that is just the tip of the iceberg. In order for Intuitive to push the procedure count and units sold, they must consistently push for new and unskilled doctors to perform surgeries that could have deadly consequences. Now the tort attorneys have caught on to this. In the one piece of litigation that is closest to trial, we see Intuitive pitted against renowned tort attorney Paul Rheingold. In the discovery requests the plaintiff asked for amongst other things:

## **“Training, proctoring, and credentialing the certification of surgeons.”**

[Click to Download the McCalla vs Intuitive Discovery Plan](#)

[Click to Download the McCalla vs Intuitive Complaint](#)

As doctors and hospitals increasingly become the targets of blame and liability for failed surgeries, utilization rates in hospitals of the da Vinci will come under pressure. When the hospitals begin receiving increased scrutiny on their credentialing and certification of surgeons to use this machine, **the numbers of new machines sold will decline along with procedures.**

In the hands of a highly skilled surgeon, the Da Vinci can be a wonderful tool to get to those “hard to reach” places, but in the hands of an unskilled surgeon, the Da Vinci is a weapon....plain and simple. And with the most current read on the benefits of robotic vs. laparoscopic hysterectomies we see that the same skilled surgeon can save money and time and achieve the same results by using a laparoscope.

**Put in the starkest of terms, there are around 1,900 da Vinci units in operation in the US. Say there are just 5 primary surgeons on each unit. That's around 10,000 surgeons. Now if it took 100 surgeries for each of those surgeons to reach competency, that is approximately 1 million surgeries performed while they were in training. Who did they perform those training surgeries on? Did the patients know?**

### **Marketing Robotic Surgery**

If you type "robotic surgery" into Google. You will see a paid link for [davincisurgery.com](http://davincisurgery.com) , reflecting to a long-standing Adwords campaign run by Intuitive Surgical. Clicking through, you'll see an attractive website displaying video testimonials from credible sounding patients of robotic surgery, touting its benefits. (You will also not the separate surgeon referral site, [www.davincistories.com](http://www.davincistories.com) , a further legal problem of notable proportions.) The purpose of this website is clearly to encourage patients to demand robotic surgery for the numerous categories of surgical procedures for which a robotic procedure is available. Similarly, hospitals advertise their new shiny robot with bold claims and wonderful testimonials.

This is strategic marketing from Intuitive Surgical at its most polished ....to increase patient demand for procedures.

If this were a drug, the marketing would have to follow the science. But this being a medical device, regulations have allowed the company to go direct to consumers, to make bold unfounded claims targeted directly to patients facing the frightening prospects of surgery.



**What follows is not the opinion of Citron, it is the opinion of the experts:**

“The vast majority of hospitals provide an incomplete picture of the costs, risks and benefits of robot-assisted gynecologic surgery on their websites”

“Marketing of robotic gynecologic surgery is widespread. Much of the content is not based on high-quality data, fails to present alternative procedures, and relies on stock text and images”

“Many (hospitals) used emotion-laden language such as “you owe it to yourself” and “you or your loved one.

In the study, less than 5% of hospitals included information about the robotic surgery’s costs, complications or operative time. Nearly half of the hospitals that discussed robotic surgery advantages such as “less pain” did not specify whether that was in comparison with open surgery or traditional laparoscopic surgery, which also is minimally invasive.”

*Schiavone, Kuo, Naumann, Burke, Lewin, Neugut et al  
American Journal of Obstetrics and Gynecology  
May 2012*

[http://www.ajog.org/article/S0002-9378\(12\)00664-3/abstract](http://www.ajog.org/article/S0002-9378(12)00664-3/abstract)

“Researchers examined the websites of 432 hospitals with 200 or more beds in six states and found that 44% had content relating to robotic gynecologic surgery. Nearly two-thirds used stock images from the robotic device’s manufacturer, Intuitive Surgical Inc., and 24% used text from the company.

*AmedNews  
American Medical Association  
August 6, 2012*

<http://www.ama-assn.org/amednews/2012/08/06/prsb0806.htm>

## **"Hospitals Misleading Patients About Benefits Of Robotic Surgery, Study Suggests"**

The public regards a hospital's official website as an authoritative source of medical information in the voice of a physician," says Marty Makary, M.D., M.P.H., an associate professor of surgery at the Johns Hopkins University School of Medicine and the study's leader. "But in this case, hospitals have outsourced patient education content to the device manufacturer, allowing industry to make claims that are unsubstantiated by the literature. It's dishonest and it's misleading."

"For example he points out that 33 percent of hospital websites that make robot claims say that the device yields better cancer outcomes — a notion he points out as misleading to a vulnerable cancer population seeking out the best care."

*Johns Hopkins Medicine  
May 18, 2011*

[http://www.hopkinsmedicine.org/news/media/releases/hospitals\\_misleading\\_patients\\_about\\_benefits\\_of\\_robotic\\_surgery\\_study\\_suggests](http://www.hopkinsmedicine.org/news/media/releases/hospitals_misleading_patients_about_benefits_of_robotic_surgery_study_suggests)

"Materials provided by hospitals regarding the surgical robot overestimate benefits, largely ignore risks and are strongly influenced by the manufacturer," the study's authors concluded.

*Journal for Healthcare Quality  
Jin, Ibrahim, Newman Markov Provonost Makary  
November 2011*

<http://onlinelibrary.wiley.com/doi/10.1111/j.1945-1474.2011.00148.x/abstract>

Here is an example of a hospital claiming superior prostate cancer outcomes:

<http://www.rochestergeneral.org/centers-and-services/surgical-services/robotic-surgery/diagnosis-and-treatment/robotic-urologic-surgery/robotic-radical-prostatectomy/>

**Despite the scientific fact**, as published by the National Cancer Institute on August 9, 2011, that stated:

“But for the big three outcomes—cancer control, urinary control, and sexual function—there is still no clear answer as to whether one approach is superior to another”

<http://www.cancer.gov/ncicancerbulletin/080911/page4>

Here is an example of a few hospitals and their claims....these are two of hundreds.

<http://www.stamfordhospital.org/Services/Specialty-Centers/Center-for-Robotic-Surgery/Conditions-We-Treat/Prostatectomy.aspx>

[http://www.ucdmc.ucdavis.edu/urology/specialties/robotic\\_surgery/](http://www.ucdmc.ucdavis.edu/urology/specialties/robotic_surgery/)

The reason for concern about this aggressive marketing is justified. With increased litigation risks to doctors and hospitals, and Intuitive Surgical ready to pass on the blame of adverse surgical outcomes, Citron believes that hospitals will soon tone down their marketing language, and more importantly **require patients to sign informed consent letters** that disclose the risks as well as the of robotic surgery.

The aggressive marketing claims are also a topic in upcoming litigation, as they are specifically identified in the aforementioned discovery demands. It is stated that part of the discovery will focus on the following category of information:

**“Sales, promotion, advertising, doctors, hospitals, and consumers;”**

## So How Does Training Impact Earnings?

Many of the above articles cite a hyperbolic growth rate in Intuitive's highest-volume surgical procedures. It should be clear to all that the reason for this is Intuitive's strategic marketing decisions to market directly to surgical patients. Then it goes into hospitals and fires off an "arms war" as hospitals feel compelled to invest in da Vinci suites in order to compete for patients.

It is Citron's opinion that Intuitive's marketing machine went way off the reservation and kept right on going. It has become a victim of its own success. It is now responsible for hundreds of thousands of surgeries performed by unknown numbers of insufficiently trained surgeons, under the cloud of inadequate disclosure and unsubstantiated medical claims to patients/consumers and hospitals.

And remember, to date, despite the higher costs, there is an absence of clinical proof of superior outcomes for robotic surgeries in the procedures that are Intuitive' Surgical's highest volume procedures.

This is a recipe for a train wreck. The hospitals have been lulled into complicity with this witches brew of bad medical practice and unsubstantiated medical claims, and the consequences will be far-reaching. What the ultimate liability bill will total out to be is anybody's guess, but one of the easiest conclusions to arrive at is that:

- Utilization of da Vinci machines for surgeries is going to decline.
- Sales of new da Vinci units is going to be under pressure.
- Breakthroughs in new types of robotic surgery are going to be subject to higher regulatory bars and much closer scrutiny of marketing claims.

### Utilization:

Now let's look at the critical forward-looking issue of utilization. In a traditional sales business, analysts turn their attention to pipeline. If a manufacturer "stuffs the channel" by selling more goods to distributors than all its customers can absorb, revenues seem healthy...for a while. But eventually those unsold goods boomerang and later quarters disappoint.

In the case of Intuitive Surgical, it has already sold over 1,900 robotic surgery machines into US hospitals. Its two highest-volume procedures are prostatectomies and hysterectomies, both of which are now being overshadowed by negative trends in clinical results: Prostatectomies not showing better outcomes than doing nothing for most cancer types, and hysterectomies not showing better outcomes than less expensive and shorter laparotomies. Prostate surgeries are already falling off, and now da Vinci is no longer the standard of care for hysterectomy. (In fact, there are a large number of additional gynecological procedures affected by the AAGL position paper than just hysterectomies, and it is Citron's belief that the position paper is therefore even more adverse to Intuitive than basing it on 40% of its total procedure count.)

It is Citron's opinion that either this quarter or next, serious under-utilization will begin to appear in the Intuitive's reported results or in the field. This is going to lead inevitably, albeit with a quarter or two delay, to reduced purchases of new systems. After all, if a hospital has three operating units of da Vinci systems, and utilization falls to 70%, it's like they have nearly a single machine going unused. That's a lot of catching up to do just to get to full capacity.

So falling utilization hits Intuitive's revenues twice: it weakens revenue for (recurring) per-procedure revenues, and it deflates demand for new systems.

So what factors are weighing on **Utilization** :

- Prostate surgeries – equal or better outcomes for most types, with less side effects, with no surgery
- Hysterectomies – standard laparoscopic surgery is cheaper, shorter, with equivalent or better outcome rates
- Cholecystectomy – (gall bladder removal) – we anticipate hearing a lot from Intuitive about this surgery, because their numbers are rising and they have a method for entering through the navel. But the market is not nearly large enough to offset the losses to prostate, hysterectomy and other gynecological surgeries for which it is now not the recommended first line option
- Other gynecologic surgeries – fall under the same AAGP position paper conclusions
- Obamacare – will reduce or eliminate premium payments for robotic surgeries vs lower cost alternatives
- Injury Lawsuits – will make the bad outcomes more visible to the public, and ultimate load costs of adverse outcomes into the cost/benefit equation
- Marketing – hospitals are going to be removing or toning down their marketing advocacy for robotic surgeries as the lawsuits pile up
- Informed consent – patients' enthusiasm for robotic surgery will dissolve as requirements as informed consent and risk acknowledgement becomes standard practice
- Intuitive is going to start needing its new procedures to take up slack in existing machine utilization, rather than selling new units.
- MAUDE and litigation turn the relationship between Intuitive and hospitals, its best customers, adversarial

### **New System Purchase Resistance:**

So what factors are weighing on **New System Purchase** decisionmaking ?

- Declining utilization in high volume procedures, leaving existing systems underutilized. Why buy new ones when the existing ones are standing idle ?
- Obamacare – will reduce or eliminate premium payments for robotic surgeries vs lower cost alternatives; hospitals will not want to eat the higher costs.
- Injury Lawsuits – While the first major judgments will hit Intuitive, hospitals will be less eager to expose themselves to the increased litigation risk of continuing to commit to more systems while existing ones are lawsuit magnets
- MAUDE adverse events and litigation turn the relationship between Intuitive and hospitals, its best customers, increasingly adversarial. This in itself influences the purchasing committees.

- Hospitals inevitably deciding to pull or tone down their overly optimistic and disclosure-deficient promotion of robotic surgery.
- With declines anticipated in two major surgery classifications, and possible increases in one with insufficient potential market size to offset the losses, it doesn't seem like the ideal time for hospitals to commit to additional multi-million-dollar da Vinci surgical suites

### Financial Consequences:

It is Citron's opinion that in 2013, the financial pressures of "the law of large numbers" finally catches up with Intuitive. With 93% of its procedures in just two categories, both facing headwinds, the company will have increasing difficulty compensating for revenue growth shortfalls with new procedures. In at least one now-unspecified quarter in 2013, it is Citron's opinion that a revenue disappointment will hit, and the company's stock will immediately seek a new multiple – at least 1/3<sup>rd</sup> below today's lofty price.

The problem at that point is that when a high-growth glam stock disappoints, investors have to decide if it's a one-quarter phenomenon, and the performance will quickly bounce back -- the new low price could be just a temporary "buying opportunity". But if there's no immediate catalyst that will change the causes of weak growth, the market has to begin the process of re-pricing the future opportunities – at a new lower plateau.