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Lead Counsel for Plaintiffs and the Proposed Class

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

IN RE INTUITIVE SURGICAL SECURITIES LITIGATION	No. 5:13-cv-01920-EJD CLASS ACTION **SECOND AMENDED CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS**

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Lead Plaintiff Employees' Retirement System of the State of Hawaii ("Hawaii ERS"), together with named Plaintiff, Greater Pennsylvania Carpenters' Pension Fund ("Greater Pennsylvania") (together "Plaintiffs"), individually and on behalf of all other persons and entities who purchased or acquired the common stock of Intuitive Surgical, Inc. ("Intuitive" or the "Company") during the period between February 6, 2012 and July 18, 2013, inclusive (the "Class Period"), and who were damaged thereby, hereby allege the following based upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters. Plaintiffs' allegations are based on Counsel's investigation, which included, among other things: (i) a review and analysis of Intuitive's public filings with the U.S. Securities and Exchange Commission ("SEC"); (ii) a review and analysis of research reports issued by financial analysts concerning Intuitive; (iii) a review and analysis of other publicly available information concerning Intuitive and its senior officers and directors, including Defendants Gary S. Guthart ("Guthart"), Marshall L. Mohr ("Mohr"), and Lonnie M. Smith ("Smith," collectively, the "Individual Defendants"), including but not limited to information publicly available from various publicly filed litigation matters, including but not limited to (a) *Illinois Union Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-4863-JST (N.D. Cal.); (b) *Navigators Specialty Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-5801-JST (N.D. Cal.); and (c) the Derivative Actions[1]; and (iv) documents produced and testimony taken in connection with this litigation. Many of the facts supporting Plaintiffs' allegations are known only by Intuitive and the Individual Defendants (collectively, "Defendants"), or are exclusively within their custody and control.

I. NATURE OF THE ACTION

1. The focal point of this securities class action is Intuitive's flagship product and source of revenues, a robotic surgery system called da Vinci, and Intuitive's concerted efforts to conceal da Vinci's internally-known defects and the injuries it caused to patients, including

[1] The "Derivative Actions" specifically includes the following cases: 1) *City of Birmingham Relief and Ret. Sys.* v. *Guthart et al.*, No. 5:14-CV-01307; 2) *In re Intuitive Surgical, Inc. Shareholder Derivative Litigation*, No. 5: 14-CV-00515; 3) *Public School Teachers' Pension and Ret. Fund of Chicago* v. *Guthart et al.*, No. CIV 526930; and 4) *City of Plantation Police Officers' Emps' Ret. Sys.* v. *Guthart et al.*, C.A. No. 9726-CB.

death and the risk of serious injury. Throughout the Class Period, and for years prior thereto, Intuitive received thousands of malfunction complaints related to surgeries using da Vinci that if recurred were likely to result in serious injury or death. Despite the severity and multitude of reports, Intuitive systematically underreported these reports and their seriousness to the Food and Drug Administration (the "FDA"). At the same time, use of certain of da Vinci's instruments and accessories was resulting in serious injuries, the most dangerous of which arose from burns to internal organs, tissue, and vessels, caused by the discharge of electricity, usually in the form of sparks, caused by the robot's instruments inside the patient. As complaints and undisclosed injury claims continued to increase, however, the FDA finally initiated a probe of Intuitive in 2013, which culminated with the issuance of a warning letter on July 16, 2013 (the "FDA Warning Letter" attached hereto as Exhibit A). The FDA Warning Letter concluded that Intuitive had concealed information from the FDA, secretly recalled defective parts, and ignored known injuries to patients in its design process of critical da Vinci instruments.

2. Da Vinci is not only Intuitive's flagship product, it is the Company's only product. Each da Vinci system principally consists of three or four robotic arms, depending on the model, which performs laparoscopic surgeries through tiny incisions. Sitting at a separate console away from the patient and looking into a viewfinder, the surgeon uses two joystick-like gadgets to control the robotic arms. Attached to the arms are various types of instruments, including forceps, scissors, needles, and scalpels, as well as tiny cameras and lights. The instruments can be easily swapped through quick snap-and-release docks at the ends of the robotic arms. Intuitive sold da Vinci systems to hospitals to perform numerous types of surgeries, including hysterectomies, prostatectomies, and cardiotomies.

3. Intuitive and the Individual Defendants knew well before the Class Period that da Vinci was causing serious injuries to patients. [redacted] The tip cover is an insulating sleeve, inserted at the distal end of certain da Vinci metal

instruments, designed to prevent electricity from escaping in an unintended manner and burning patients (the "Tip Cover"). After inspecting Intuitive's headquarters in April and May 2013, the FDA reported that Intuitive had received hundreds of complaints and reports between July 2009 and December 2011. The vast majority of these reports concerned the Tip Cover. The critical defect consisted of the risk of cracks or holes developing in the Tip Cover that prevented it from properly insulating the metal instruments and allowed electricity or sparks to escape, an effect known as "arcing." Because the arcing usually occurred outside of the surgeon's camera field of vision, blood vessels and organs were burned without the medical team's knowledge. Deaths occurred when patient injuries remained undetected after the surgery, while patients hemorrhaged internally, or developed infections from undetected internal burns.

4. [redacted] At that time, Defendants sent an "Important Product Notification" letter to customers with recommendations or suggestions regarding use of the Tip Cover. The customer letter was an attempt to avoid a public recall and [redacted] served to band aid Intuitive's Tip Cover problems, while the Company quietly worked to replace the defective Tip Covers with a new version aimed at reducing or eliminating arcing events. According to the FDA Warning Letter, "[t]his correction (the October 2011 letter) was in response to complaints and medical device reports (MDRs) for arcing through damaged tip covers that caused patient injuries." Yet, unbelievably, the Tip Cover letter failed to notify customers, as the Warning Letter did several years later, that the so-called corrective action was in response to complaints and MDRs for arcing that caused patient injuries. Instead the Tip Cover letter indicated that it was being sent "based on recent feedback from our customers" and omitted all reference to "arcing," "burning," or associated "dangers" or "patient injuries" that could occur as a result from use of the Tip Cover. Not only was the letter's content deficient in terms of giving surgeons notice of the severe risk of harm that may occur from Tip Cover usage,

in violation of FDA regulations, but Intuitive also failed to report this corrective action to the FDA as required, which the FDA subsequently classified in the July 2013 FDA Warning Letter as a "Class II Recall." [redacted] In addition to the Tip Cover correction, Intuitive initiated two other corrective actions in October 2011, both of which it concealed from the appropriate FDA authorities, [redacted]

5. Rather than inform the FDA, its customers, or the investing public of the severe risk of injury that patients faced from arcing events and Tip Cover usage, Defendants continued to market its top selling Tip Cover accessory, and surgeons continued to use it, unaware of the risk of harm [redacted] Patients, in turn, continued to suffer severe injuries as result of sustaining burns from damaged Tip Covers.

6. Aware of the problems that lay ahead stemming from the injuries that had occurred to patients from da Vinci use, Defendants hired the law firm of Skadden, Arps, Slate, Meagher & Flom LLP in early 2012 as national coordinating counsel in connection with products liability suits and to quietly assist with tolling agreements for injured patients/claimants who had not yet filed suit against Intuitive. The first of thousands of undisclosed tolling agreements entered into between the Company and patients claiming injury were entered into in or around October 2012. By December, hundreds of injured patients had entered into confidential tolling agreements with the Company, and by April, thousands. Later the Company would report that the vast majority of these claims were related to the Monopolar Curved Scissors ("MCS" or "Monopolar Scissors") and the Tip Covers and that they had entered into confidential mediation with many of the claimants. While all of this was taking place, the Company omitted any substantive public disclosure of these tolling agreements until several months after entering into them, and even failed to notify their products liability insurers about them, according to lawsuits later filed by their carriers against Intuitive. This was yet another

attempt to conceal from the market the apparent danger associated with the da Vinci surgical system and its Tip Cover accessory, and evade the related consequences of increased injuries and litigation.

7. Compounding Defendants' failure to report the risk of severe injuries stemming from the Tip Cover and arcing incidents, the so-called corrective actions in October 2011, and the resulting tolling agreements entered into with patients alleging injury, Intuitive also falsely and misleadingly minimized the importance of MDRs that did reach the FDA. As set forth in more detail below, stringent FDA regulations require that hospitals report to the manufacturer (*i.e.* Intuitive) serious injuries arising from the use of da Vinci. In turn, these regulations also require Intuitive to submit these medical device reports, or MDRs, to the FDA. MDRs filed with the FDA are compiled in the FDA's Manufacturer and User Facility Device Experience ("MAUDE") database. To hide the da Vinci defects, however, Intuitive consistently underreported MDRs, misclassified them under the innocuous category of "other," even though scores qualified as "serious injury," and added self-serving disclaimers in the filed MDRs concerning the purported lack of evidence linking the injury or harm to a da Vinci defect.

8. [redacted]

[redacted] Intuitive did not report to the investing public the significant deficiency in its MDR Reporting practices until March 13, 2013. Even then, Defendants grudgingly disclosed only certain information regarding the changes to their MDR Reporting practices, characterizing it as "administrative" in nature and highlighting that "[n]one of these device malfunction MDRs involved reportable injuries or deaths," while omitting that they all involved malfunctions, which could cause or contribute to a death or serious injury, if it were recur. At approximately the same time the March 13, 2013 press release was issued, [redacted] However, investors still did not learn the true number of MDRs Intuitive had filed until many months after such MDRs were filed with the FDA.

9. It was only after these significant changes to Intuitive's MDR reporting practices, and the material rise in serious MDR reports, that in January 2013 the FDA began a safety probe of the Company. The FDA probe suggests that, after the FDA realized in September 2012 that Intuitive had been improperly labeling the MDRs, the FDA did not fully trust the Company's role as a middleman between the hospital reports and those that Intuitive submitted to the agency. The FDA thus sent out a survey directly to hospitals in January 2013 seeking, among other things, information concerning (i) problems or challenges with da Vinci, (ii) complications during surgeries, (iii) problem-causing da Vinci devices, and (iv) surgeons' familiarity with da Vinci recalls and corrective changes. In addition to this written survey, the safety probe also included one-hour interviews with surgeons.

10. The FDA probe was not made public until *Bloomberg News* publicly disclosed it on February 28, 2013, only five minutes before the stock market closed. Investors immediately understood the negative repercussions of the probe and, in those short five minutes, sold substantial amounts of stock. The stock price dropped $63, from about $573 to $510 per share, resulting in the Company losing more than ten percent of its value.

11. Unbeknownst to investors, the Individual Defendants had been heavily selling their Company stock in unusual and suspicious trading. In November 2012, immediately following the September 2012 meeting with the FDA after which Intuitive knew that MDRs would spike, Defendant Smith terminated his 10b5-1 trading plan and sold more than 100,000 shares of Intuitive stock, making just shy of $70 million. Throughout the entire Class Period, Defendant Smith sold more than $100 million of his Intuitive holdings. Similarly suspicious was Defendant Guthart's trading. Guthart had not sold any shares prior to the Class Period since 2008. He then began selling in earnest starting early in the Class Period, in April 2012, ultimately selling more than $8 million of his Intuitive holdings during the Class Period. As to Mohr, he continuously liquidated almost all the shares he had at any one point in time, selling over 27,000 shares during the Class Period, or over 16 times his average holdings.

12. Tellingly, the Individual Defendants made the vast majority of these stock sales at all-time highs exceeding $500 per share, and before the full truth about the true safety and risk profile of the Company emerged. The stock price had reached these historic highs because Intuitive had become a Wall Street darling propped-up by Defendants' false and misleading statements and omissions. Defendants misleadingly emphasized the Company's 20%-plus growth in revenues and number of surgeries, while simultaneously touting da Vinci as "a new generation of surgery" that "combine[d] the benefits of minimally invasive surgery (MIS) for patients with the ease of use, precision, and dexterity of open surgery." Defendants thus pounced on the perception of robotic surgery as the future, with minimal trauma, and the same (if not greater) benefits as open surgery. Defendants, however, did not disclose the known defects, patient injuries, and deaths, and their concerted efforts to conceal all this from the FDA and the public.

13. This concealment, however, was soon to end. After the FDA launched the safety probe in early 2013, it followed with a lengthy inspection of Intuitive's headquarters between April 1 and May 30, 2013. At the end of the inspection, the FDA issued a Form FDA-483 ("Form 483") to Defendant Guthart setting forth the objectionable conditions observed. *See*

Exhibit B (Form 483). There were four such observations, including the discovery by the FDA that Intuitive had carried out the secret recall of the Tip Covers in October 2011, as discussed above. In addition, and equally dangerous to patients' health, Intuitive had known since 2010 that surgeons needed to clean da Vinci instruments while inside the patient's bodies, and that to do so they scrubbed one instrument against another. This had consistently led to tears or holes in the Tip Covers that led to arcing that in turn caused injuries to patients. FDA regulations thus required Intuitive to address this "user need" through a rigorous and heavily regulated design control process. Intuitive entirely ignored this user need, did not document it, and never even sought to address this health risk in flagrant violation of FDA regulations.

14. As news of the FDA safety probe, da Vinci's defects, and the risks posed to health began to spread, patients, surgeons, and hospitals started to cut back on da Vinci purchases and the number of procedures. For the first quarter of 2013, Intuitive thus reported a rare slowdown in the rate of procedure growth. With only the month of March in the first quarter affected by the disclosure on February 28, 2013 of the FDA safety probe, first quarter revenues and sales growth, nevertheless, were lower than expected.

15. The public disclosure of the FDA probe and the rise in MDRs that prompted it also lead investigative journalists to examine da Vinci's record. Lengthy news articles revealing tragic injuries caused by da Vinci increasingly began to surface. On March 5, 2013, for example, *Bloomberg* published a story titled, "Robosurgery Suits Detail Injuries as Death Reports Rise." One such death was that of a 24 year-old woman who had suffered a lacerated artery while undergoing surgery for cervical cancer. The burned artery had not been discovered until eleven days later, which was too late. The autopsy concluded that the patient's death was a "therapeutic complication" resulting in hemorrhage and multi-organ failure.

16. Due to the onslaught of negative reports, in the second quarter ending June 30, 2013, the adverse impact on revenues and procedure growth was substantial. On July 8, 2013, Intuitive reported preliminarily that second quarter 2013 revenues from da Vinci sales had declined six percent to $215 million, compared to $229 million in the second quarter of 2012.

Intuitive also had sold only 143 systems, compared with 150 systems in the second quarter of 2012, and 164 systems in the first quarter of 2013. The Company thus had gone from rapid growth to a steep decline in only one quarter.

17. Wall Street analyst reports reflected surprise at the unexpected decline and its magnitude. JP Morgan's report of July 8, 2013 called it "shocking": "The severity of the top line [revenue] shortfall, with the company posting revenues of $575M vs. consensus of $630 million [$622M JP Morgan] was shocking, and raises more questions than answers."

18. Ten days later, on July 18, 2013 Intuitive revealed that it had received the FDA Warning Letter dated July 16, 2013. A Warning Letter is the most serious agency communication and often the last step prior to seizure, injunction, and/or civil money penalties. The FDA Warning Letter, in large part, formally determined that the observations listed in the Form 483 were violations of the Federal Food, Drug, and Cosmetic Act" ("FDCA"), and thus represented a significant escalation of the FDA's regulatory action.

19. According to the FDA Warning Letter, (i) the Tip Covers constituted "misbranded devices"; (ii) Intuitive knew that the Tip Covers in October 2011 posed a risk to health and, yet, Intuitive proceeded to conduct a secret recall while failing to report this "correction," thereby violating FDA reporting requirements; (iii) Intuitive also knew that the intraoperative cleaning of da Vinci instruments caused the Tip Covers to fail, leading to arcing, and yet ignored the problem, again violating FDA regulations including Current Good Manufacturing Practices; and (iv) after having been notified of these violations pursuant to Form 483, Intuitive had submitted incomplete and inadequate responses to the FDA on June 7, 2013. Tellingly, the FDA Warning Letter added, "[t]he FDA has previously informed you of your firm's correction and removal violations in an untitled letter dated February 19, 2008, and FDA 483 Inspectional Observations issued on December 20, 2002." In saying this, the FDA was confirming that failing to report corrections and removals (*i.e.*, the secret recall) was an ongoing, unsolved issue with Intuitive.

20. The public disclosure of the FDA Warning Letter, after the market closed on July 18, 2013, marks the end of the Class Period and the dramatic decline suffered in the price of the stock. The next day, Intuitive closed at $392 per share, falling under $400 for the first time in almost two years. Investors and the market understood that the risk posed by da Vinci, and the risk profile of Intuitive's stock, had materially and substantially increased, and that the Company's growth potential had materially and substantially decreased. Indeed, the material negative change in the Company's risk profile and growth outlook is best exemplified by the degree to which Intuitive concealed the MDRs from the FDA. The increase in the number of MDRs filed in the year following Intuitive's September 4, 2012 change in MDR Reporting demonstrates that Intuitive suppressed more than 40 percent of all MDRs prior to that time including MDRs for device malfunctions that posed a risk of injury to patients if they reoccurred. Indeed, for the years 2000 - 2012, there were 5,333 da Vinci-related MDRs filed in total. This number grew dramatically to over 8,450 MDRs, after a staggering 3,117 da Vinci-related MDRs were filed with the FDA in the nine months from January 1 to September 30, 2013 alone. This massive cover-up of da Vinci's defects and the extent of patient injuries constitutes securities fraud.

II. JURISDICTION AND VENUE

21. The claims asserted herein arise pursuant to §§ 10(b), 20(a) and 20A of the Securities Exchange Act of 1934 ("Exchange Act") (15 U.S.C. §§ 78j(b), 78t(a) and 78t-1(a)) and Rule 10b-5 promulgated under §10 of the Exchange Act (17 C.F.R. § 240.10b-5).

22. This Court has jurisdiction over the subject matter of this action pursuant to § 27 of the Exchange Act (15 U.S.C. § 78aa). In addition, because this is a civil action arising under the laws of the United States, this Court has jurisdiction pursuant to 28 U.S.C. § 1331.

23. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Intuitive resides and transacts business in this District, and maintains its U.S. headquarters in this District at 1266 Kifer Road, Building 101, Sunnyvale, California 94086. Many of the acts that constitute the violations of law complained of herein,

including the preparation and public dissemination of materially false and misleading statements, occurred in substantial part in this District.

24. In connection with the acts alleged herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the U.S. mails, interstate telephone communications and the facilities of the national securities markets, including NASDAQ.

III. PARTIES

A. Plaintiffs

25. On November 18, 2013, the Court appointed Hawaii ERS as Lead Plaintiff for the Class in this consolidated class action pursuant to the Private Securities Litigation Reform Act of 1995 (the "PSLRA"). ECF No. 50.

26. Hawaii ERS is a qualified defined benefit public pension plan that was established in 1925. Hawaii ERS, which is governed by an eight-member board of trustees, currently provides retirement, disability, survivor, and other benefits to more than 112,000 members. The members of ERS are retirees, beneficiaries, inactive vested members, and active public employees working for the state and counties of Hawaii, and include teachers, professors, police officers, firefighters, judiciary employees, judges, and elected officials. As of June 30, 2012, the ERS had more than $11.9 billion in assets under management. As set forth in its PSLRA certification attached hereto as Exhibit C, Hawaii ERS purchased a total of 26,048 shares, and sold 12,268 shares of Intuitive common stock on the open market during the Class Period and suffered damages as a result of the securities law violations alleged herein.

27. Hawaii ERS purchased Intuitive securities contemporaneously with Defendants Smith's, Guthart's, and Mohr's sales of Intuitive stock during the Class Period. Specifically, on November 20, 2012, Hawaii ERS purchased 11,867 shares of Intuitive common stock. On that same date Defendant Smith sold 23,949 shares of Intuitive common stock. On November 26, 2012, Hawaii ERS purchased 6,000 shares of Intuitive common stock. On that same date, Defendant Smith sold 21,164 shares of Intuitive common stock. Additionally, on January 29,

2013, Hawaii ERS purchased 140 shares of Intuitive common stock. Only one day prior, on January 28, 2013, Defendant Mohr sold 8,000 shares of Intuitive common stock; and only one trading day before that, on January 25, 2013, Defendant Guthart sold 4,500 shares of Intuitive common stock.

28. Greater Pennsylvania is a trustee-administered, multi-employer, defined benefit pension plan for carpenters in Pennsylvania that had more than $800 million in assets as of January 1, 2011. As set forth in its PSLRA certification attached hereto as Exhibit D, Greater Pennsylvania purchased a total of 2,893 shares, and sold 21 shares of Intuitive common stock on the open market during the Class Period and suffered damages as a result of the securities law violations alleged herein.

29. Greater Pennsylvania purchased Intuitive securities contemporaneously with Defendants Smith's, Guthart's and Mohr's sales of Intuitive stock during the Class Period. Specifically, on October 23, 2012, Greater Pennsylvania purchased 1,825 shares of Intuitive common stock. On October 22, 2012, Defendants Smith, Guthart and Mohr sold 17,500, 4,500, and 7,300 shares of Intuitive common stock, respectively.

B. Defendant Intuitive

30. Intuitive was founded in 1995 with the purpose of developing technology that would allow minimally invasive surgery to expand to a broader range of procedures. In January 1999, Intuitive introduced its sole product: the da Vinci surgical system ("da Vinci"). Da Vinci was the first robotic surgical system to be cleared by the FDA for general laparoscopic surgery in 2000. Since then, Intuitive has designed, manufactured and marketed updated models of da Vinci and its related instruments and accessories. In June 2000, Intuitive completed an initial public offering, followed by a second public offering in 2003. Intuitive is incorporated in Delaware. The Company's common stock is publicly traded on NASDAQ under the ticker symbol "ISRG."

C. The Individual Defendants

31. Defendant Gary S. Guthart ("Guthart") joined Intuitive in 1996, was promoted to President in 2007, and has served as Intuitive's Chief Executive Officer since January 2010. Guthart is also a member of Intuitive's Board of Directors. Guthart has a B.S. in Engineering, as well as an M.S. and Ph.D. in Engineering Science. Guthart signed and certified Intuitive's false and misleading Forms 10-K for fiscal 2011 and 2012, and certified Intuitive's false and misleading Forms 10-Q for the quarterly periods ending March 31, 2012, June 30, 2012, September 30, 2012, and March 31, 2013. Guthart also made false and misleading statements on Intuitive Earnings Conference Calls ("Earnings Calls") on April 17, 2012, July 19, 2012, October 16, 2012, January 22, 2013, and April 18, 2013. Further, Guthart made false and misleading statements in the Forms 8-K dated April 17, 2012, July 19, 2012, October 16, 2012, January 22, 2013, and April 18, 2013.

32. Defendant Marshall L. Mohr ("Mohr") joined Intuitive as Senior Vice President and Chief Financial Officer in March 2006. Mohr signed and certified Intuitive's false and misleading Forms 10-K for fiscal 2011 and 2012, as well as its false and misleading Forms 10-Q for the quarterly periods ending March 31, 2012, June 30, 2012, September 30, 2012, and March 31, 2013. In addition, Mohr made materially false and misleading statements during the Earnings Calls on July 19, 2012, October 16, 2012, January 22, 2013 and April 18, 2013. Mohr also signed Intuitive's materially false and misleading Forms 8-K dated April 17, 2012, July 19, 2012, October 16, 2012, January 22, 2013, March 14, 2013, and April 18, 2013.

33. Defendant Lonnie M. Smith ("Smith") joined Intuitive as CEO in June 1997. Smith resigned from his position as CEO in January 2010, but remains, and remained during the Class Period, Chairman of the Board as well as an executive officer of the Company. Smith signed Intuitive's false and misleading Forms 10-K for fiscal 2011 and 2012.

34. Facts that are critical to Intuitive's "core operations" are presumed to be known by its key officers, including each of the Individual Defendants. In addition, during the Class Period, the Individual Defendants, as senior executive officers and/or directors of Intuitive, were

privy to confidential and proprietary information concerning Intuitive, its operations, finances, financial condition, product safety, development and performance, and present and future business prospects. The Individual Defendants also had access to material adverse, non-public information concerning Intuitive, as discussed in detail below. The Individual Defendants' positions at Intuitive further gave them access to non-public information about the Company's business, finances, financial condition, product safety, development and performance, and present and future business prospects through access to internal corporate documents, conversations and connections with other corporate officers and employees, attendance at management and/or board of directors meetings and committees thereof, and through reports and other information provided to them in connection therewith. Because of their possession of such information, the Individual Defendants knew, or were reckless in not knowing, that the adverse facts specified herein were concealed, and thus the Individual Defendants had materially misled investors during the Class Period.

35. The Individual Defendants are liable as direct participants in the wrongdoing complained of herein. The Individual Defendants, by reason of their status as senior executive officers and/or directors, were "controlling persons" within the meaning of Section 20(a) of the Exchange Act, and had the power and influence to cause Intuitive to engage in the unlawful conduct complained of herein. Because of their positions of control, the Individual Defendants could, and did, directly or indirectly, control the conduct of Intuitive's business.

36. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Intuitive's annual reports, quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. They were provided with copies of the Company's reports and press releases alleged herein to be materially false and misleading prior to or shortly after their issuance, and thus the Individual Defendants had the ability and opportunity to prevent their issuance or to correct them. Because of their positions with the Company, and their access to material, non-public information, the Individual Defendants knew that the adverse facts

specified herein had not been disclosed to, and were being fraudulently concealed from, the public. The Individual Defendants are liable for the materially false and misleading statements and omissions alleged herein.

37. As officers and controlling persons of a publicly-held company whose shares are registered with the SEC and traded on NASDAQ, the Individual Defendants had a duty to disseminate prompt, accurate and truthful information with respect to Intuitive, and to correct any previously issued statements that had become materially misleading or untrue, so that the market price of the Company's common stock would be based upon truthful and accurate information. The Individual Defendants each violated these specific requirements and obligations during the Class Period.

38. The Individual Defendants are liable as participants in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Intuitive common stock by disseminating materially false and misleading statements that concealed material adverse facts concerning the safety of da Vinci, undisclosed recall and corrective actions, violations of FDA disclosure and reporting regulations, and the Company's growth and financial success. The scheme: (i) deceived the investing public regarding Intuitive's business, operations, management and the value of Intuitive's common stock; (ii) permitted the Individual Defendants to sell stock and engage in insider sales during a period of stock inflation; (iii) concealed da Vinci's defects and true risk profile; (iv) failed to comply with FDA regulations applicable to da Vinci, *i.e.*, the Company's core business; (v) caused Plaintiffs and other members of the Class to purchase Intuitive common stock at artificially inflated prices; and (vi) caused Plaintiffs to suffer damages.

IV. SUBSTANTIVE ALLEGATIONS

A. Background

39. Intuitive Surgical has been the market leader in robotic-controlled surgery devices before, during, and after the Class Period. The Company conducted an initial public offering in 2000 when the FDA approved its sole product, the da Vinci Surgical System, for laparoscopic surgery. This initial approval was limited to certain procedures, such as gallbladder and

gastroesophageal surgery. In the years following, the FDA approved da Vinci for additional treatments, including thoracoscopic (chest) surgery, cardiac procedures performed with adjunctive incisions, as well as urologic, gynecologic, pediatric, and transoral otolaryngology surgeries. Intuitive now dominates the robot-surgery field as it is the only company whose system is cleared in the United States for soft tissue procedures, which include prostate and gynecological surgery.

40. As the market leader, the Company has been growing rapidly in the last few years. As of December 31, 2012, there were 2,585 da Vinci Systems installed in approximately 2,025 hospitals worldwide. The number of U.S. procedures performed with these robots grew to approximately 367,000 in 2012, up from 292,000 in 2011, and 228,000 in 2010. Total revenue rose from $1.41 billion in 2010, to $1.76 billion in 2011, and $2.18 billion in 2012. Da Vinci system sales rose from 441 da Vinci systems in 2010 to 534 in 2011 and 620 in 2012.

41. Intuitive's revenue is solely generated from the da Vinci Surgical System. In 2012, revenues from sales of da Vinci represented about 43% of the overall revenue in 2012. Each unit costs between $1.0 and $2.3 million. The rest was generated by "recurring revenue," which included sales of da Vinci instruments and accessories (approximately $1,300 to $2,000 per procedure) and sales of da Vinci service agreements. Annual service agreements range between $100,000 and $170,000 per system. During 2012, instrument and accessory revenue contributed 41% and service revenue generated 16%.

B. Defendants Concealed Da Vinci's Defects and Performance Problems

1. Da Vinci's Monopolar Scissors Caused Severe Injuries Due To Defective Tip Covers and Arcing

42. The da Vinci Surgical System consists of several key components, including (i) an ergonomically designed console equipped with a high-definition 3-dimensional vision system where the surgeon sits while operating, (ii) a patient-side cart where the patient lays during surgery, (iii) three or four interactive robotic arms, (iv) proprietary EndoWrist® instruments that attach to the robotic arms, and (v) a hardware console, which houses the computer operating system and software that controls the robotic arms. Together, these

components allow surgeons to operate by manipulating a suite of tiny computer-assisted remote control tools through a small tube inside a patient.

43. The EndoWrist Instruments include a number of endoscopic surgical parts used with da Vinci for a wide range of surgical tasks, such as tissue manipulation, suturing, cutting, coagulation, and clamping. Most instruments have an articulating design at the tips that enter the patient's body, known as a "wrist," and provide various degrees of motion that mimic the human hand and wrist-movements. Quick-release levers facilitate instrument changes during surgical procedures. The instruments also have an electronic tag that identifies each specific instrument and limits the number of uses so that the tag "expires" the instrument after a pre-determined number of uses.

44. The most commonly used Endowrist instrument is the MCS. According to a study entitled "Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury," co-authored by Adam C. Mues, Geoffrey N. Box, and Ronney Abaza, and published in 2011 in the Journal of Urology, 24 surgeons performed 454 robotic procedures between July 2008 and January 2009, and all of the procedures involved the Monopolar Scissors. The use of the Monopolar Scissors is so prevalent because it allows doctors to both cut and cauterize tissue during surgical procedures. Cauterization occurs through the application of monopolar electricity.

45. The MCS is used in [redacted] of gynecological procedures, hysterectomies, urologic procedures and prostatectomies done with da Vinci. It is not to be used without a Tip Cover.[2] The Tip Cover Accessory is an electrically insulating sleeve that is placed over the distal tip of the MCS that acts to insulate the metal parts of the instrument so that only the intended electrode (the scissor blades) is exposed for surgical application.[3] In other words, it

[2] *See* Defendants' Objections and Responses to Plaintiffs' Second Set of Requests for Admission to All Defendants ("Defs.' Admissions"), RFA Nos. 64, 65, 67, 68.

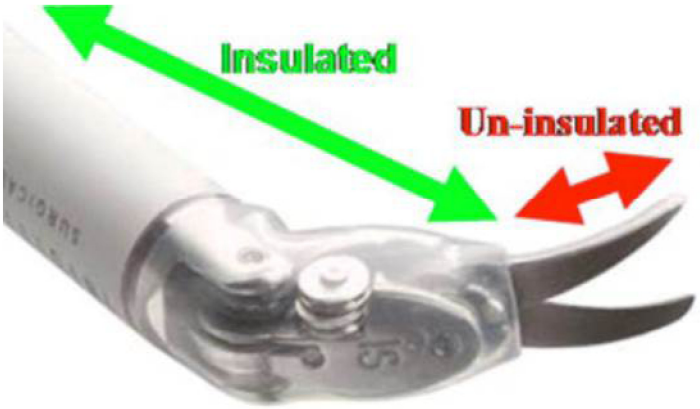
[3] *See* Defs' Admissions, RFA No. 60.

acts to protect the patient against stray electrical energy shooting out at unintended places during surgery and causing harmful burns and other serious injuries.

46. The MCS and Tip Cover over the course of their introduction to the market have had different versions. [redacted]

[redacted]

Monopolar Scissors with Tip Cover Accessory



Damaged Tip Cover Accessory[5]

[redacted]

[5] The images of the Monopolar Scissors and the Tip Cover Accessory were published in "Robotic Instrument Insulation Failure: Initial Report of a Potential Source of Patient Injury." Adam C. Mues, Geoffrey N. Box, and Ronney Abaza, J. of Urology 105 (2011).

47. "The Tip Cover plays an important role in the robotic instrument" because it "serves as an insulation for the metallic segment of the EndoWrist and prevents broad dissipation of monopolar electric current," according to an article published in March 2011 by Yonsei University College of Medicine, entitled "Iliac Vein Injury Due to a Damaged Hot Shears Tip Cover During Robot Assisted Radical Prostatectomy." If the Tip Cover functions properly, the article reported, "[i]t allows safe dissection in proximity to delicate structures such as blood vessels, nerves and bowel." If the Tip Cover fails, however, electricity can escape the MCS and burn or harm patients. This is commonly referred to as "arcing" because a visual arc of electricity is formed from the defect in the insulated portion of the Tip Cover to another instrument or tissue. The tissue is thus burnt and injured.

48. Even more severe injuries occur when the arcing is not in the field of vision of the surgeon and therefore remains undetected. Perforation of internal organs and blood vessels causes internal bleeding and severe injuries that are discovered days after the surgery, and only after the patient's condition has deteriorated rapidly for unknown reasons. One such patient was Sonya Melton. In an interview reported by CNBC on March 19, 2013 ("Robotic Surgery: Growing Sales, but Growing Concerns"), "[Sonya Melton] said she had become so sick almost immediately after her surgery to remove uterine fibroids that she thought she was going to die. Her condition, she said, puzzled doctors so much that within days they sliced open her stomach to find out why she was in excruciating pain and had developed a full-fledged pneumonia. What they found, she said, was a perforation in her small intestine." It turns out, as CNBC reports, Melton's ureters, which carry urine from the kidneys to the bladder, had been "burned."

49. Another such case that went undetected initially involved Michelle Zarick. According to LexisLegalNews Zarick underwent a hysterectomy to remove benign ovarian fibroid tumors.[6] Zarick's da Vinci-assisted hysterectomy was performed on February 2, 2009. Although she initially felt fine, five weeks later she had diarrhea and felt nauseated and feverish,

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[6] *See* http://www.lexislegalnews.com/articles/7771/da-vinci-surgical-robot-case-settles-during-deliberations-by-california-jury.

culminating in about an inch of her bowel prolapsing out of her body when she went to use the bathroom. Zarick filed a lawsuit against Intuitive and during opening arguments on April 7, 2016, Zarick's attorney argued that inadequate insulation on the tip of the monopolar electro-cauterizing scissor device caused Zarick's internal electrical burns. Later, during the course of the same trial, Intuitive's Executive Vice President, Product Operations, Salvatore Brogna, admitted under oath that under certain conditions, there was a "defect" in the Gen I Tip Cover, which could result in arcing.[7] Brogna also described certain circumstances which could result in a hole or tear in the tip cover wherein unintended arcing could occur.[8]

50. Other patients have tragically died as a result of undetected burns. As reported by *Bloomberg* on March 5, 2013, ("Robosurgery Suits Detail Injuries as Death Reports Rise"), Kimberly McCalla underwent surgery with da Vinci to treat early-stage cervical cancer on August 12, 2010. "Eleven days after the operation, she was rushed back into surgery, where doctors found a laceration of the iliac artery near the original operation….The doctors sewed the artery up, but it was too late. After two more emergency operations, Kimberly died on August 25 after suffering [] bowel damage 'incompatible with life,' according to an operative report."

51. A subsequent lawsuit filed on behalf of Ms. McCalla's estate alleged that "there had been a burn of the right external iliac artery."[9] The lawsuit also alleged that the burn to the iliac artery was sustained due to a defective device that used "monopolar energy to cut, burn and cauterize tissue," which had "inadequate insulation" thereby "allowing electrical current to pass into tissue outside of the operative field," and ultimately resulting in death to the patient.

52. The severe injuries suffered by Sonya Melton, Michelle Zarick, and Kimberly McCalla as a result of monopolar current are not isolated cases. Indeed, a review of the MAUDE database shows that there was a substantial and material increase in Tip Cover related

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[7] *See* Brogna Tr. Ex. 202 (Zarick Trial Testimony), at p. 300-304.

[8] *See id.* at 300.

[9] Complaint at 6, *McCalla v. Intuitive Surgical, Inc.*, No. 12-2297 (S.D.N.Y. Apr. 2, 2012), ECF. No. 1.

MDRs in 2011 and 2012 compared to prior years, and that there has been a corresponding increase in Tip Cover reports related specifically to arcing or burning.

2. Intuitive's Long Standing Safety Issues with da Vinci [redacted]

53. [redacted] The most serious injuries arose from burns to patients' internal

[redacted]

organs caused by discharge of electricity that escaped through the tip cover. [redacted] Yet, Defendants did not contain, recall or take other mitigation efforts to notify customers of the product at that time. And as a result, the complaints continued.

54. In direct response to these complaints regarding arcing and burning to patients, [redacted]

55. [redacted]

[redacted]

[19] *Id.*

[redacted]

56. [redacted]

[redacted]

[redacted]

[21] *Id.*

[22] *Id.*

[redacted]

[redacted]

57. [redacted]

58. Later, the Company finally was in a position to submit a request for approval of its new Gen II Tip Cover design in or around August of 2011.[redacted]

59. [redacted]

[redacted]

[redacted]

3. The October 2011 Secret "Class II Recall" of the Tip Covers and Other Concealed Corrective Actions

60. Aware that the Tip Cover failures were causing, and risked causing, significant harm, [redacted] Defendants tried to protect themselves while buying more time before its Gen 2 Tip Cover was approved for release to the market. This came in the form of an "Important Product Notification" letter to customers with recommendations or suggestions regarding use of the Tip Cover.

61. Specifically, on October 10, 2011, Intuitive sent out a letter to hospitals providing modified instructions for the Tip Cover and MCS, requesting that surgeons avoid collisions and more carefully install tip covers.[29] Intuitive also sent two additional letters to hospitals between October 10, 2011 and October 17, 2011, removing the thyroidectomy indication from da Vinci's approved uses, despite the fact that Intuitive had previously marketed da Vinci for that specific procedure,[30] and providing modified instructions for the cannula accessory.[31]

[redacted]

[30] On October 13, 2011, Intuitive sent out a letter notifying da Vinci hospitals that da Vinci was not cleared for thyroidectomy procedures – i.e., the surgical removal of all or part of the thyroid gland. Intuitive had previously marketed da Vinci for these procedures and profited from the revenues generated. Intuitive also did not report this letter to the San Francisco District Recall Coordinator. The FDA, again, later classified Intuitive's corrective action taken on October 13, 2011 as a "Class II Recall."

[31] On October 17, 2011, Intuitive sent a third corrective letter to da Vinci hospitals with information for inspecting instrument cannulas – i.e., a hollow rigid tube inserted into the body that allows the instruments on the robotic arms to access patients' anatomy through the small incisions. Damaged Tip Covers due to defective cannulas was identified in the Form 483 as "one of the root causes" for arcing that resulted in patient injuries. This action was also not

62. The October 2011 Tip Cover letter indicated that it was being sent "based on recent feedback from our customers" and omitted all reference to "arcing," "burning," or associated "dangers," failing to properly alert surgeons and their hospitals of the danger posed by unintended arcing, including risk of patient injury such as "bleeding from major vessels" and even death.[32] Instead, the Tip Cover letter purported to be a reiteration of instructions for use.

63. The FDA Warning Letter issued in July 2013 found that none of the recall letters issued by Intuitive were properly classified as "Class II Recalls" or reported to the FDA district recall coordinator in violation of FDA regulations. Had Intuitive properly classified these as Class II Recalls, the market would have had public disclosure of such events as per FDA regulations and procedures, which publishes Class II Recalls in the FDAs publically available database, providing the market with notice of the risk of serious injury resulting from use of the Tip Cover back in 2011. *See* 21 CFR § 806.10 (2013); 21 U.S.C. § 360i(g) (2012); § 519(g) of the Food, Drug, and Cosmetic Act. [redacted]

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reported to the San Francisco District Recall Coordinator. Again, the FDA later classified Intuitive's corrective action taken on October 13, 2011 as a "Class II Recall."

[redacted]

[redacted]

64. [redacted] which would have required Defendants to send the letters to the local FDA District Recall Coordinator, to give that designated office an opportunity to review and comment during the recall process, and also would have resulted in the FDA publishing the letters for public view.

[redacted]

66. [redacted]

[redacted]

[redacted]

4. Defendants Violated FDA Regulations by Concealing Modifications to the Tip Covers

67. Pursuant to § 519(g) of the FDCA, 21 U.S.C. § 360i(g), and 21 C.F.R. § 806 of the Reports of Corrections and Removals regulation, companies such as Intuitive are required to provide promptly to the FDA a written report "of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated [to] . . . reduce a risk to health posed by the device." 21 C.F.R. § 806.10(a).

(a) The regulation defines a "[c]orrection" as "the repair, modification, adjustment, relabeling, destruction, or inspection (including patient monitoring) of a device without its physical removal from its point of use to some other location." 21 C.F.R. § 806.2(d).

(b) A "[r]isk to health" is defined as "(1) [a] reasonable probability that use of, or exposure to, the product will cause serious adverse health consequences or death; or (2) [t]hat use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote." 21 C.F.R. § 806.2(j).

(c) "Removal" means "the physical removal of a device from its point of use to some other location for repair, modification, adjustment, relabeling, destruction, or inspection." 21 C.F.R. § 806.2(i).

5. The FDA's Approval of the New Tip Cover

68. Before marketing certain devices like the da Vinci, FDA regulations require clearance under section 510(k) of the Act. This allows the FDA to determine whether the device is substantially equivalent to another legally marketed device and if not, whether the new device raises new questions of safety and effectiveness. For an existing device, a new 510(k) is required if the intended use changes or if the technology changes and those changes significantly affect the safety or effectiveness of the device.

69. In the first instance, for changes to an existing device, it is up to the device manufacturer to determine whether a submission is needed to obtain approval of an update on an existing device that the Company plans to market. If the Company determines that no such submission is needed, then it will simply modify the product and internally document in a "letter to file" the changes are being made, with no submission to the FDA. [redacted] In contrast the full 510(k) submission would require attachment of all relevant documentation for the FDA's review. The FDA then has a full 90 days to review. [redacted]

70. Here, despite the significance of the changes being made to the design of the Tip Cover, [redacted]

[redacted]

[redacted] The Special 510k was thereafter submitted to the FDA on or around August 5, 2011, but failed to include all of the relevant information needed to properly assess it. For example, [redacted] The Gen II was cleared by the FDA in October 2011.[46]

6. Intuitive Chooses Not to Remove the Gen I Tip Cover Even after the Gen II Version was Available

71. [redacted]

[redacted]

[redacted] This was true despite the fact that according to Intuitive's internal policies effective during the Class Period, [redacted]

72. On May 30, 2012, the Company finally issued a market withdrawal of the Gen I Tip Cover.[51] In it, Intuitive made clear that the communication is "not a product recall" and that the Gen I Tip Cover (which it refers to as the "-10" version) is both "safe and effective when used in accordance with product labeling."[52] Although the Company asked customers to return the "-10" version of the Tip Cover, they did not require it, nor did they reference any risk of harm stemming from continued use of the "-10" version, such as arcing or burning of tissues, organs or arteries. In other words, they continued to distort the public perception of the safety of the Tip Cover.

73. Unaware of the attendant risks, at least some hospitals continued to use the old version of the Tip Cover and patients continued to get injured. [redacted] MDRs confirm that the Company

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[redacted]

continued to get reportable complaints stemming from Tip Cover failures from its old model, that it failed to recall, into 2013.[53]

7. Tip Cover Failures Continued Even After Gen II Tip Cover Released

74. [redacted] the Company also continued to receive arcing complaints even after it rolled out its Gen II Tip Cover for use.[54] Those complaints, including complaints of arcing, started coming in not long after the general release of the Gen II tip cover in April 2012 [redacted]

75. The significant danger involved in these continued events caused [redacted]

[53] *See, e.g.*, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi__id=3447371 (MDR related to -10 version of the Tip Cover related to an event date of 9/18/13 wherein arcing was reported).

[redacted]

76. This letter stands in stark contrast to Intuitive's own October 2011 customer letters and May 2012 market withdrawal letter, which were devoid of any language about danger, arcing, burning, significant harm or patient injury. [redacted] hospitals were on their own to make sure their doctors understood the risk of harm to patients.

77. [redacted]

78. [redacted]

8. The Severe Injuries Attributed to the Tip Cover Translates into Inevitable Lawsuits and Claims

79. Due to the severe nature of the injuries sustained from the Tip Cover and arcing incidents, there was a notable increase in products liability and/or personal injury lawsuits and claims against Intuitive starting in 2012.[57] While continuously touting the benefits of da Vinci surgery, Intuitive concealed that by the end of the first quarter in 2012, there had been eight da Vinci patient deaths in the short period between December 2011 and March 31, 2012, and at least five personal injury and/or product liability lawsuits filed against the Company. To deal with these products liability cases and other potential litigations, Defendants hired the law firm

[57] Plaintiffs analyzed publicly available data concerning lawsuits filed against Intuitive between March 2010 and August 2013. This analysis reveals there were at least 25 such lawsuits, 18 of which included allegations related to insufficient insulation allowing monopolar current to pass onto patient tissue, resulting in inadvertent burns and other injury. This analysis is further broken down in Section VII (Defendants Made Materially False and Misleading Statements and Omissions).

of Skadden, Arps, Slate, Meagher & Flom LLP in early 2012 ("Skadden"). Skadden was hired to serve as national coordinating counsel in connection with the growing number of products liability suits and to quietly assist with a "tolling project," which was implemented to secure tolling agreements for injured patients/claimants who had not yet filed suit against Intuitive.[58]

80. The vast majority of these private tolling agreements were entered into between individuals claiming injuries stemming from the MCS and the Gen I Tip Cover and Skadden (on behalf of Intuitive). The first of thousands of these undisclosed tolling agreements was entered into in or around October 2012.[59] By December, hundreds of injured patients had entered into confidential tolling agreements with the Company, and by April, thousands.[60] Indeed, documents and testimony confirm that as of December 31, 2012, the master tolling chart listed 193 tolled claims and that the number of tolled claims continued to grow throughout the winter and spring of 2013, reaching 328 tolled claims on January 31, 2013; 734 tolled claims on February 28, 2013; 864 tolled claims by late March; and 2,248 tolled claims by June 27, 2013.[61] Intuitive later reported that the Company entered into (confidential) mediation with many of the claimants, whose approximately ***3,000 claims*** covered the period of 2004 to 2013, resulting in the Company taking a $67 million charge against earnings.[62] Despite the legal and business risk involved with receipt of hundreds and then thousands of claims, Defendants omitted any substantive public disclosure of these tolling agreements until several months after entering into

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[58] [redacted](IRONSHORE0006760-78); [redacted](NAV_003275-324); [redacted]

[59] *See* [redacted](April 8, 2014 ISRG Press Release).

[60] *See* [redacted](IRONSHORE0006760-78) (shows 865 tolled claims as of March 21, 2013) [redacted](NAV_003275) (lists 2,124 claims submitted between 3/1/2013 and 8/20/2013). Both charts make clear that by April 5, 2013 Defendants had entered into thousands of tolling agreements.

[61] *See* Order Denying Partial Summary Judgment, *Illinois Union Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-4863 (N.D. Cal. May 27, 2016) (ECF No. 178); *see also* [redacted](IRONSHORE0006760-78); [redacted]

[62] *See* Intuitive Surgical April 8, 2014 Press Release. Later the Company disclosed additional charges in its 2014 Form 10-K: "During the year ended December 31, 2014, we recorded pre-tax charges of $82.4 million, of which $67.4 million, $9.6 million, and $5.4 million was recorded in the first, second, and fourth quarters of 2014, respectively, to reflect the estimated cost of settling a number of the product liability claims covered by the tolling agreements..."

them, with its first substantive disclosure being in Intuitive's April 19, 2013 Report on Form 10-Q, filed with the SEC. However, even this disclosure omitted how many tolling agreements had been entered into. Investors were not the only ones who were misled about these tolling agreements. Intuitive even failed to notify their products liability insurers while they were securing products liability coverage, according to lawsuits later filed by their carriers against Intuitive.

C. Complaints and Medical Device Reports Also Showed That Defendants Had Notice of the Defects in the Tip Covers for Years

81. The main mechanism through which the FDA is apprised of health risks from medical devices, including da Vinci, are MDRs. The purpose of MDRs is "to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use." 21 C.F.R. § 803.1.

82. MDRs are therefore critical components of the FDA's ability to monitor a device's performance and determine if further FDA actions are necessary, including inspections of facilities and post-market studies. MDRs filed with the FDA are compiled in the FDA's MAUDE data, a publicly available database that summarizes MDR filings.

83. Adverse events and device malfunctions were reported to Intuitive in the form of complaints. [redacted] Complaints that represented reportable events were supposed to be promptly reviewed and investigated to determine, where possible, the underlying cause of the complaint.

84. [redacted]

[redacted]

[redacted]

[redacted]

85. [redacted]

[redacted]

86. Among those complaints that were deemed "reportable complaints," (MDRs), even some of those were misclassified and contained self-serving language disclaiming any

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[redacted]

responsibility for the injury or harm.[68] For example, an MDR filed on the MAUDE database concerning a report of death goes through a description of a patient dying after a "successful da vinci hysterectomy" performed in 2010, after which she later developed an infection. The MDR details that emergency surgical procedures performed on the patient revealed the patient had a burn to her iliac artery. Yet, the MDR still details Intuitive's self-serving position: "Based on the limited information provided, it is indeterminable if the da Vinci system, instruments or accessories contributed to the patient's demise."[69] Another MDR bearing an event date of "6/29/2009" provides details of a da Vinci hysterectomy during which the surgeon noticed a "char mark" on the patient's posterior uterus and sparks from the "instrument sleeve" that also caused a "small thermal char injury" to the patient's "bowel serosa." Yet, Intuitive classified this not as an injury, but as a malfunction.[70]

87. Plaintiffs analyzed the MAUDE database as of October 15, 2013 and the results showed that there had been a substantial and material increase in Tip Cover-related MDRs in 2011 and 2012 compared to prior years. (These MDRs reference Tip Cover model number 400180).

88. The number of Tip Cover-related MDRs for each year between 2007 and 2010 was, respectively, 19, 60, 77, and 68. In 2011 and 2012, the number of MDRs increased to 117 and 104. Accordingly, the annual average between these two periods nearly doubled, from 56 in the 2007- 2010 period to 110.5 between 2011 and 2012.

89. Of these MDRs, the average annual Tip Cover incidence that related to arcing or burning more than doubled when comparing the same periods. Between 2007 and 2010, there were, respectively, 2, 24, 14, and 22 such MDRs. In 2011 and 2012, those MDRs increased to

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[redacted]

[69] *See* 8/12/2010 MDR at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=1915208.

[70] *See* 6/29/2009 MDR at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=1486275.

34 and 38, respectively. Accordingly, the annual average also more than doubled, from 15.5 between 2007 and 2010 to 36 between 2011 and 2012.

90. Issuance of MDRs related to the MCS and Tip Covers (model numbers 400180, 400179, 420179) continued their steep upward trajectory. There was a 54% increase in reported MDRs related to MCS and Tip Covers from 2012 to September 2013 with 128 in 2012 to 197 in 2013.

1. Intuitive Systematically Concealed and Underreported Medical Device Reports to the FDA

91. Strict regulations promulgated by the FDA govern MDR reporting procedures. The FDA relies primarily on the manufacturer's reporting obligations since approximately 94% of the MDRs received by the FDA are reported by the manufacturer.[71] Pursuant to these regulations, when an adverse event related to a serious injury occurs, user facilities, *e.g.* hospitals, are required to report these injuries to the manufacturer: "whenever a device user facility [*e.g.* hospitals] receives or otherwise becomes aware of … information that reasonably suggests that a device has or may have caused or contributed to … a serious injury to a patient of the facility… the facility shall … report the information … to the manufacturer." 21 U.S.C. § 360i(b)(1)(B) (emphasis supplied); *see also* 21 C.F.R. §§ 803.30, 803.50.

92. Manufacturers must then report to the FDA "no later than 30 calendar days after the day that [the manufacturers] receive or otherwise become aware of information, from any source, that reasonably suggests that a device that [the manufacturers] market: (1) [m]ay have caused or contributed to a death or serious injury; or (2) [h]as malfunctioned and this device or a similar device that [the manufacturers] market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a).

93. The obligations of the manufacturers, such as Intuitive, are not limited to merely reporting adverse events, but also include the obligation to further investigate and understand the

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[71] "Adverse Event Reporting for Medical Devices," Department of Health and Human Services, Office of the Inspector General, Oct. 2009 (finding that 94% of medical device adverse event reports filed with the FDA were submitted by device manufacturers in 2007) https://oig.hhs.gov/oei/reports/oei-01-08-00110.pdf.

underlying causes. Manufacturers "are also responsible for conducting an investigation of each event and evaluating the cause of the event." 21 C.F.R. § 803.50(b). If the original report is incomplete, the regulations also require manufacturers to "provide a statement explaining why this information was incomplete and the steps [taken] to obtain the information." *Id.* Further, if the manufacturer later obtains information not available at the time it filed the initial report, the manufacturer must file a supplemental report with the new information. *Id.*

94. Intuitive brazenly violated these FDA regulations by minimizing and underreporting: 1) device malfunctions; and 2) serious injuries arising from da Vinci. A medical journal study of Intuitive's reporting practices to the FDA concluded that the Company underreported robotic surgery complications between January 2000 and August 2012, and highlighted facts that strongly suggest that Intuitive did so intentionally. The study ("Underreporting of Robotic Surgery Complications") was published in the Journal for Healthcare Quality in September 2013.[72] The purpose of the study was to test whether robotic surgery complications may be more common than represented in FDA adverse event reports.

95. The study cross referenced MDRs in the MAUDE database with legal documents retrieved from LexisNexis and PACER. Of the 70 events found in the legal databases, eight, or more than 10%, had not been reported to the FDA, including deaths, perforations, and severe injuries. In five of the cases, no report was ever filed with the FDA. In two cases, the MDRs were filed only after the *Wall Street Journal* and *Reuters* reported the story – one of the MDRs "disputes the death" and only acknowledged that the patient suffered nerve damage. In a separate instance, even though an Intuitive representative had been present during the surgery and witnessed the patient's death, Intuitive still did not report it to the FDA.

2. Intuitive Systematically Under-Reported Serious Injuries

96. In addition to flagrantly failing to report deaths and other serious injuries to the FDA, Intuitive also misclassified the injuries that it actually reported to minimize their import.

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[72] Michol A. Cooper, Andrew Ibrahim, Heather Lyu and Martin A. Makary, *Underreporting of Robotic Surgery Complications*, J. for Healthcare Quality (2013).

[redacted]

97. [redacted] in connection with the March 13, 2013 Press Release, the Company admitted that it had been improperly classifying serious injuries as "other." [redacted] The effect of the reclassification was to almost double the number of serious injuries in 2012 to 131.[75] The Company has still not explained its failure to properly report serious injuries and how serious injuries could possibly have been classified with the innocuous label of "other."

98. The March 13, 2013 Press Release further admitted that Intuitive had not been reporting MDRs properly to the FDA. In a cryptic disclosure, it stated that in September 2012 it had "revised its MDR practices," which had then resulted in "increased reports." Intuitive again did not explain the nature of the revision. Simply put, Intuitive had been withholding MDRs from the FDA in an effort to minimize the number and import of any negative adverse events.

3. Intuitive Systematically Under-Reported Device Malfunctions

99. The March 13, 2013 Press Release also failed to disclose that the Company was

[redacted]

[redacted]

[75] Suntrust Analyst Report, "ISRG-Thoughts on Updated Reporting Practices," dated March 14, 2013.

[redacted]

100. [redacted] Intuitive did not report the significant deficiency in its MDR Reporting practices or the tip cover arcing problems to the market [redacted] or even alert the market until March 2013 that the Company was attempting to align its reporting practices with FDA regulations.[79]

101. [redacted]

4. The Number of Medical Device Reports Increased Dramatically After the Change in Reporting in September 2012 Showing That Intuitive Had Systematically Concealed Adverse Events

102. [redacted]

[redacted]

[79] *See* [redacted] (March 13, 2013 ISRG press release); [redacted]

[redacted]

103. In the midst of changing Intuitive's previously deficient reporting process, ***but before the rise in MDRs was available for public view***, all three Individual Defendants capitalized on their insider knowledge by selling vast amounts of Intuitive stock. Collectively, the Individual Defendants sold an extraordinary sum, exceeding $70 million between late October and early December of 2012. Individually, in late October, Defendants Guthart and Mohr sold 4,500 and 7,300 shares, respectively, reaping proceeds of approximately $2.4 million and $3.9 million respectively. This was particularly striking for Defendant Guthart, who had refrained from selling since August 2008. Defendant Smith sold in late October and all throughout November, on no fewer than eight occasions, more than 125,000 shares of Intuitive common stock for almost $70 million. *See* full discussion of insider trading in section V.A. *infra*.

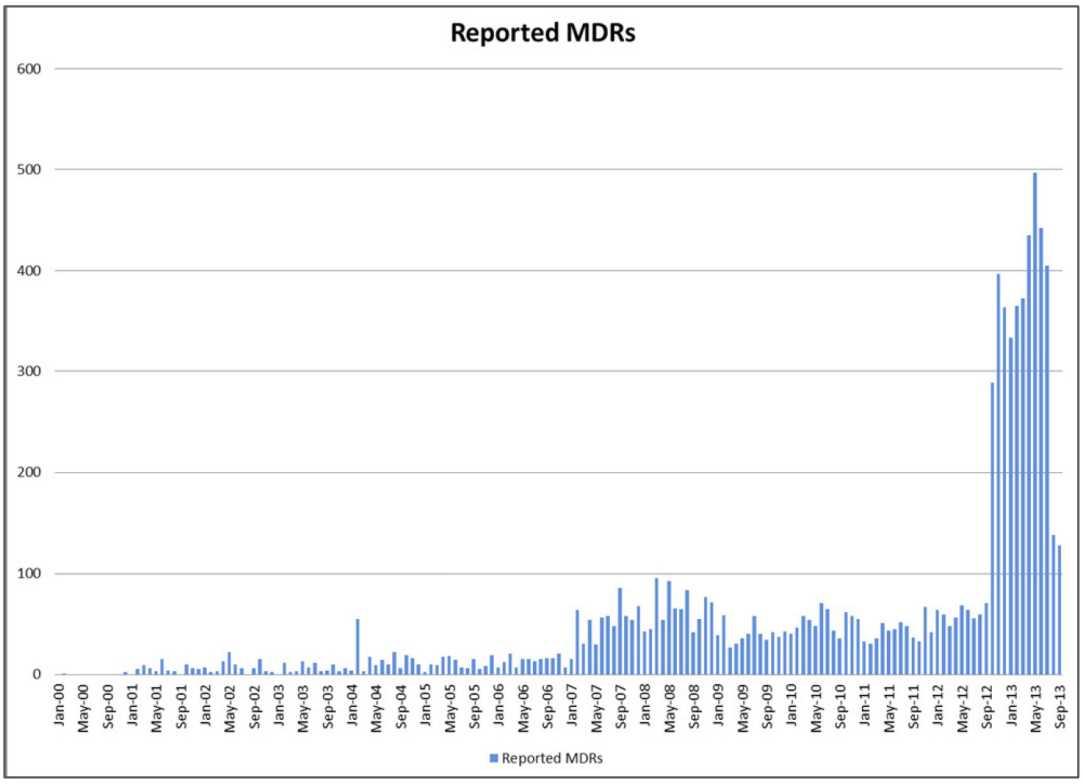
104. Once Intuitive began accurately reporting MDRs in September 2012, the number of MDRs in the MAUDE database skyrocketed.[83] For the prior 12 years, from 2000-2012, there had been 5,333 da Vinci-related MDRs filed. This number grew dramatically to over 8,450 MDRs, after a staggering 3,117 da Vinci-related MDRs were filed with the FDA in the nine months from January 1 to September 30, 2013 alone. This represents an astounding 40 percent

[redacted]

[83] To evaluate the rise in defects and injuries related to da Vinci, Plaintiffs analyzed the MAUDE database as of October 15, 2013 that is publicly available from the FDA website (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm). This analysis is referenced above and is further broken down in Section VII (Defendants Made Materially False and Misleading Statements and Omissions). This analysis was only possible after Intuitive started complying with FDA regulations and stopped underreporting and misclassifying MDRs, as reported by Intuitive in March 2013.

increase in 2013 compared to all prior years cumulatively. In other words, Intuitive had suppressed nearly half of all MDRs.

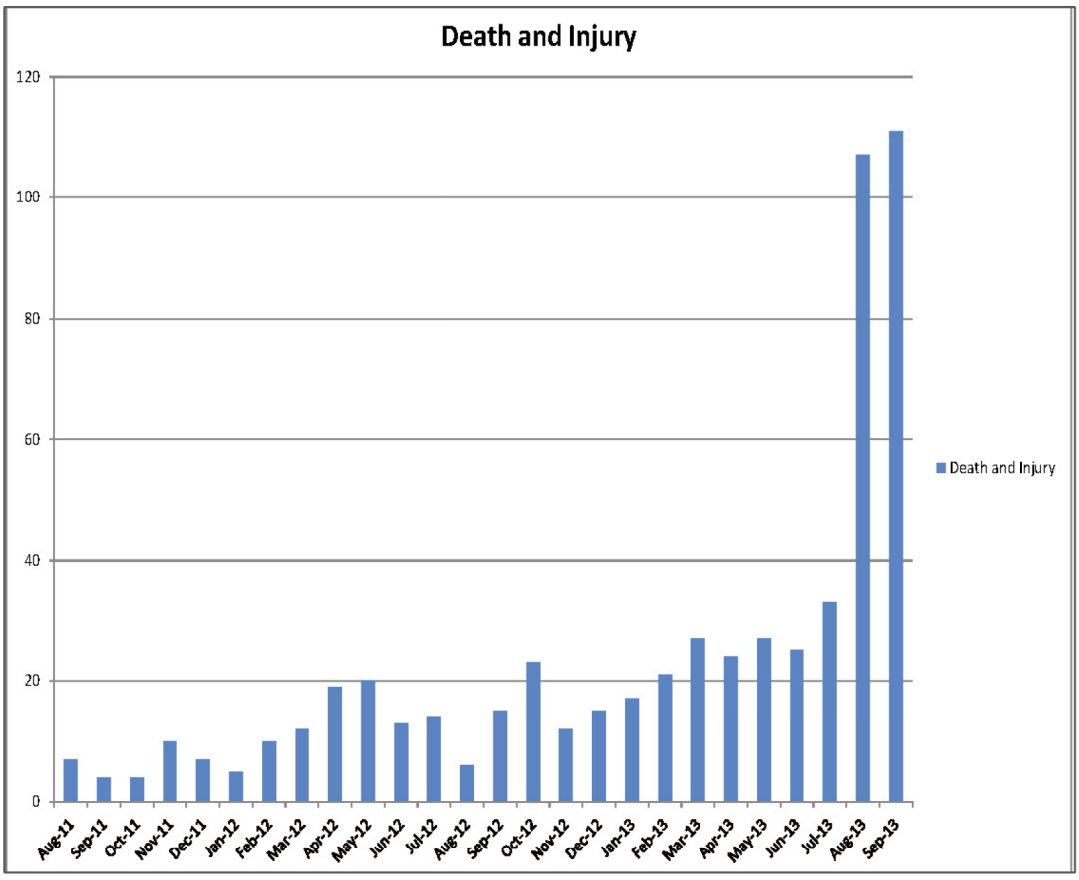
105. The extent of Intuitive's cover-up is also evident in the monthly reporting figures. With an average rate of over 400 MDRs a month filed during the first seven months of 2013, this is more than five times higher than any prior period since da Vinci was introduced in 2000. The chart below, showing the number of MDRs submitted to the FDA on a monthly basis from January of 2000 through September 2013, highlights the stunning increase after the meeting with the FDA in September 2012 left Intuitive no choice but to begin accurate reporting:



106. Further, not only did the total number of MDRs grow on a large scale, so did the number of MDRs reporting "injury" and "death." In August 2013, the number of "injury" and "death" MDRs swelled to more than 100 – more than triple the rate of any other month. These 100-plus MDRs were due to a mass filing of more than 70 "injury" or "death" events which were designated by the Company as part of a "legal mediation effort." Altogether, there were more than 20 such "legal complaint" reports, all "injury" or "death" events, filed between June

2013 and September 2013, most of which show a time lag between event date and date reported of six months to three or more years. In other words, the adverse events had taken place years before and were not reported by Intuitive to the FDA.

107. The chart below visually demonstrates the massive increase in MAUDE "death" and "injury" reports:



108. Equally telling from this chart is the obvious increase in MDRs beginning in November 2012 and the rapid acceleration thereafter. While "death" and "injury" reports between August 2011 and August 2012 averaged about 10 per month, from September 2012 through September 2013 they averaged 35, a more than **three-fold increase** as they continued to rise and exceed 100 by August 2013.

109. [redacted]

110. On March 13, 2013, more than 18 months after first identifying that there was an issue in their MDR Reporting practices, Defendants were finally forced to disclose – because of public inquiries regarding the significant rise of MDRs – that Intuitive had made certain "administrative" changes to their MDR Reporting practices in September 2012 that had resulted in a rise in MDRs and also had made corrections on certain MDRs which would now be reported as "serious injuries" instead of "other."[86] However, this disclosure still concealed continuing problems with the Gen II tip cover and the expanding cadre of lawsuits and tolled claims from da Vinci patients.[87] In addition, at around the time the March 13, 2013 Press Release was issued, Intuitive [redacted]

111. [redacted]

[redacted]

[86] *See* [redacted] (March 13, 2013 ISRG press release); [redacted]

[redacted]

D. The FDA Takes Strong Regulatory Action

1. The 2013 FDA Probe: In January 2013 the FDA Began to Uncover Significant da Vinci-Related Defects and FDA Violations

112. On the heels of the September 2012 reclassification of serious injuries, the FDA noted an increase in the number of reports of adverse events. Given that the Company had previously "down-coded" the adverse reports without providing any justification, the FDA this time leapfrogged Intuitive's role in the reporting chain of custody and went directly to the source, the physicians. In a letter-survey, the FDA asked physicians to provide information about adverse events related to da Vinci directly to the FDA, not Intuitive. The letter further indicated that the survey would not be limited to a question and answer form, but that agency officials would speak with surgeons for up to an hour.

113. "What the FDA [was] trying to determine with the survey [was] whether adverse event reports sent to the agency [were] 'a true reflection of problems' with the robots, or the result of other issues, Synim Rivers, an agency spokeswoman" said in an e-mail reported by *Bloomberg*.[90] According to *Bloomberg*, Ms. Rivers added "[i]t is difficult to know why the reports have increased." In fact, *Bloomberg* broke the news of the FDA probe on February 28, 2013, five minutes before the close of the stock market, causing Intuitive's stock price to fall 11 percent by the close to $509.89.

114. Commenting on the news of the FDA probe, Michael Matson, an analyst with Mizuho Securities in New York, said that a rise in adverse events was a concern because "patients would get scared." "Part of what's driven this market is people seeking out robotic surgery – hospitals market it and the patients seem to think it's better." Matson then concluded that Intuitive's stock was likely going to remain under pressure until the Company could prove that the safety worries were not significant. *Id.*

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[90] *Intuitive Surgical Robots Probed by U.S. in Surgeon Survey* (2), February 28, 2013, released at 18:14.

115. A further drop on March 5 resulted from *Bloomberg News* reporting on the rise in incident reports, deaths related to da Vinci complications, and allegations of product liability suits pending against the Company as related to complications during robotic surgery.

2. First Quarter 2013 Results Were Impacted by the FDA Probe and Reclassification of Serious Injuries

116. News of the FDA probe and the increase in serious injuries had an impact in the number of da Vinci procedures in the first quarter ending March 31, 2013. Analysts surmised that this could happen. A prior analyst report issued by Canaccord Genuity, dated March 18, 2013, revisited the negative headlines associated with Intuitive in the prior months, and concluded that

> **the cadence of negative news** over the past several months has **increased the risk to ISRG's financial performance**….the pullback in ISRG's share price is warranted given the real possibility, in our mind, that system sales and **procedure growth could be impacted** should hospital administrators delay purchasing the robotic system in light of the aforementioned studies and negative press.

117. When Intuitive announced first quarter results on April 18, 2013, "the cadence of negative news" had begun to reduce the number of surgeries using da Vinci. According to a JP Morgan report dated April 19, 2013, "results were decidedly mixed … [with] the all-important procedure growth number falling short." JP Morgan also highlighted the importance of procedure growth, stating, "[w]e have consistently argued that procedure growth is the key metric for investors, and are not changing our tune." (emphasis in original). Other analysts reached the same conclusion. A report by Leerink Swann that same day was titled, "Solid 1Q Beat Overshadowed by Light Procedure Growth."

118. Wall Street thus understood that, although Intuitive had performed well in terms of revenues and profits in the first quarter of 2013, the future did not portend well given that the use of da Vinci surgeries was stalling. Indeed, before the end of the first quarter, Intuitive had forecasted procedure growth for all of 2013 to range between 20 and 23 percent. In fact,

procedures during the first quarter had increased only by 18 percent.[91] Investors agreed with the analysts' dire assessment, causing Intuitive's stock price to drop $8.62 to $484.75 after the announcement.

119. Guthart sought to minimize the negative news and the numerous questions from analysts about the impact of the FDA probe and issues with da Vinci during the earnings conference call that quarter held on April 18, 2013. Guthart attempted to discredit the negative reports by raising the specter of a conspiracy: "we are in the midst of a concerted effort by critics of robotic surgery to challenge the benefit it brings to patients." Guthart then effectively denied the validity of safety concerns with da Vinci, further concealing the action the Company had taken to hide the extent of the actual problems. Guthart stated, "[w]e are confident that those who invest their time in a serious review of the clinical literature on da Vinci will find ample evidence of the benefit it brings to patients, surgeons, hospitals and the medical community at large."

120. Despite Guthart's efforts to preempt the analysts' concerns, the first question on the April 18th earnings call was related to the impact of the da Vinci safety issues on the number of procedures. Evan Lodesen from JP Morgan asked Guthart, "Can you disaggregate the slowdown in benign [hysterectomies] between the seasonal effects that you mentioned such as deductibles and then also the more coordinated efforts that you talked with regards to the robot, specifically?" Guthart admitted that the negative news had impacted the number of procedures, although he was not able to quantify it: "negative press has some hard-to-measure impact on benign hysterectomy, although it doesn't appear to be large. It's also probably not zero."

121. Other analysts on the call made similar inquiries. David Roman from Goldman Sachs asked: "any sort of impact you have had from the recent noise in the marketplace, what is your plan to start to stem that and then how long do you think it might take before we start to see some positive returns from those efforts?" Guthart responded that it was "hard" to assess.

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[91] Total procedures in 2012 had reached approximately 450,000 compared to about 360,000 and 278,000 in 2011 and 2010 respectively. That represented procedure growth of almost 30% in 2011 and 25% in 2012.

122. Amit Hazan, from SunTrust Robinson Humphrey, then asked directly about the FDA probe: "[d]o you know anything about the report [referring to the FDA survey] that might be coming out with what you might be anticipating?" Guthart said, "we have no – nothing to share on that front," stopping himself short of apparently saying "we have no information."

3. The Form 483 Issued In May 2013 Documented Numerous Violations Including the Secret Recall of Tip Covers In 2011

123. Between April 1 and May 30, 2013, the FDA inspected Intuitive's headquarters in Sunnyvale, California. The inspection was conducted under the supervision of FDA investigator, Mary R. Hole. At the end of the inspection Ms. Hole issued a Form 483 addressed specifically to Defendant Guthart. An FDA Form 483:

> is issued to firm management at the conclusion of an inspection when an investigator(s) has **observed any conditions** that in their judgment **may constitute violations of the [FDCA]** and related Acts....The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and **discussed with the company's senior management**.[92]

124. The FDA's Form 483 issued to Defendant Guthart on May 30, 2013, reported four observations ("Observations"). Each of these Observations detailed a deficiency in Intuitive's FDA reporting practices, and Observation Four further detailed the Company's failure to properly address a design failure related to the Monopolar Scissors.

125. **Observation One** documented four instances in which Intuitive had effectively conducted a secret recall, or in the regulatory language of the FDA, initiated a "correction or removal, conducted to reduce a risk to health posed by a device, [and] [had] not reported [it] in writing to the FDA." The first instance was described as follows:

> (i) On 10/10/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with suggestions and recommendations for the proper use of instruments with **tip covers** for the correct generators that should be used with monopolar instruments. This action was not reported to the San Francisco District Recall Coordinator.

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[92] *See* http://www.fda.gov/ICECI/EnforcementActions/ucm250720.htm; http://www.fda.gov/ICECI/EnforcementActions/ucm256377.htm.

This recall of the Tip Covers by Intuitive had been a direct response to "**complaints and MDRs for arcing through damaged tip covers that caused patient injury.**" The Form 483 further observed that Intuitive's recall had been in response to 134 complaints, of which 82 resulted in MDRs related to Tip Cover issues.

126. **Observation One** included three additional instances in which Intuitive had effectively conducted a secret recall:

> (ii) On 10/13/2011, Intuitive Surgical, Inc. sent out a letter notifying da Vinci clients that the da Vinci surgical systems are not cleared for thyroidectomy indication. This **action was not reported** to the San Francisco Recall Coordinator. The thyroidectomy indication was promoted by Intuitive Surgical, Inc.... Between July 2009 and October 2011, Intuitive Surgical received 13 complaints and filed 5 MDRs related to thyroidectomies performed with the da Vinci system.
>
> (iii) On 10/17/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with information for inspecting instrument cannulas, proper flushing instruments, and the proper transportation of the da Vinci between buildings. This **action was not reported** to the San Francisco Recall Coordinator....some of these issues have been previously identified as root causes in other complaints that gave rise to MDRs (for example, damage to the integrity of a tip cover due to defective cannulas was identified as one of the root causes for arcing that resulted in patient injuries). As such these issues represent a risk to the health of patients.
>
> (iv) On 01/24/2013, Intuitive Surgical, Inc. sent out a letter and [a new User Manual Addendum for Transoral Surgery,] (TORS)....the new version [of the manual] warns that da Vinci TORS surgery is not indicated for pediatric patients, therefore the vagueness in the previous version [of the manual] represented a health risk to pediatric patients. (*See* Ex. B at 1-2, attached hereto).

127. **Observation Two** documented an instance in which Intuitive had misleadingly represented to the FDA its "corrective actions" as voluntary, while concealing that they had been the result of adverse event reports. In October 2011, Intuitive withdrew the recommendation that da Vinci be used to conduct thyroidectomies without informing the FDA. Once the FDA began the April-May 2013 inspection, however, Intuitive quickly sought to cover its tracks by reporting the withdrawal of the indication on April 11, 2013. But this belated report, more than 18 months after the fact and prompted by the on-site inspection, was also misleading. The April 2013 report sought to portray the withdrawal as *sua sponte* while concealing that the withdrawal had occurred only after receipt of at least five MDRs and over a dozen complaints.

> Specifically, Intuitive Surgical, Inc. **failed to report** that there were 5 MDRs associated with the field action taken on 10/13/2011 (Thyroidectomy indication withdrawal). The 806 report … that was supplied to the San Francisco District Coordinator on 4/11/2013 indicated 0 MDRs….During my inspection of Intuitive Surgical, Inc. 5 MDRs were represented as related to this correction.

128. **Observation Three** documented that Intuitive had concealed the initial decision to market da Vinci for thyroidectomies. Intuitive sent a "letter to file" instead of submitting a new premarket notification [510(k)], as required by 21 CFR §807.81(a)(3)(ii) for a major change or modification in the intended use of the device. Defendants profited from uncleared da Vinci thyroidectomies for more than two years, between July 2009 and October 2011.

> Specifically, Intuitive Surgical, Inc. **did not document** the decision to add a thyroidectomy indication to the da Vinci system general laparoscopy clearance 510(k) No. K990144 through Letter to File rather than through the submission of a new 510(k) application.

129. **Observation Four** documented that Intuitive concealed an additional health risk created by the Monopolar Scissors. "Intuitive . . . ha[d] received complaints of arcing of energized surgical instruments as a result of surgeons cleaning off instruments [inside the patient's body] by scraping them across other surgical instruments. In the case of … the Monopolar [] Scissors … the scraping led to tears or holes in protective tip covers that led to arcing that in turn led to injuries to patients." This knowledge and awareness of the surgeons' need to clean the instruments inside the patient's body created a duty to design a safe cleaning process, which Intuitive ignored.

4. Second Quarter 2013 Results Reflected the Full Blown Financial Impact of the FDA Probe and da Vinci's Safety Concerns

130. On July 8, 2013, Intuitive issued a press release pre-announcing second quarter results. While Defendants had minimized the impact of da Vinci's safety concerns in the first quarter, they could no longer do so in the second quarter as the wheels came unhinged. The financial results were dismal and the reported number of procedures using da Vinci continued to deteriorate despite prior statements that the first quarter slow down had been temporary.

131. Revenues from da Vinci sales had declined six percent to $216 million in the second quarter of 2013, compared to $229 million in the same quarter in 2012. Intuitive had sold

only 143 systems compared with 150 system in the second quarter of 2012, and 164 systems in the first quarter of 2013. And the number of procedures again grew only by 18 percent, so that, after six months, Intuitive's projected growth of 20 to 23 percent was no longer feasible.

132. The analyst reports reflected surprise at the unexpected nature and magnitude of the decline. JP Morgan's report of July 8 called it "shocking": "The severity of the top line [revenue] shortfall, with the company posting revenues of $575M vs. consensus of $630 million [$622M JP Morgan] was shocking, and raises more questions than answers."

133. Analysts also remained skeptical that the severe decline was due to the excuse provided by Intuitive. Intuitive claimed that the negative results were due to economic factors and hospitals cutting capital expenditures, such as the purchase of da Vinci systems. Morgan Stanley's July 17, 2013 report evidences skepticism: "We are less convinced a material change in the US CapEx [capital expenditure] environment explains the system shortfall in the quarter. Our Q1 and Q2 surveys showed a declining interest in robotics and hesitance to purchase a da Vinci despite a stable broader CapEx environment." Put simply, hospitals were not reducing expenditures. They were just not buying da Vinci systems, and one of the reasons was the "safety of robotic surgery," as Morgan Stanley explained in a subsection entitled, "A Review of Recent Pressures on da Vinci Procedures."

134. Canaccord's report dated July 9, 2013 expressed similar views: second quarter "results usurped our most bearish scenario; represented ISRG's worst system performance (-6% [year over year]) since the height of the financial crisis in [the third quarter of 2009]; and most notably, exhibited a significant deviation from historic growth trends – ISRG had reported system sales growth >15% for 9 consecutive quarters."

135. Canaccord also no longer viewed the negative results as cyclical or due to external factors, but systemic. "What's more, the factors cited by ISRG for the systems miss strike us as more systemic than isolated, thus could take longer to resolve, in our estimation." Canaccord then noted that in the second quarter press release Intuitive had blamed "economic pressures on hospitals which led to some deferred system purchases." Like Morgan Stanley,

Canaccord remained skeptical. "This [the claim that hospitals had cut back] comes just three months after the company reported Q1/13 system sales that were quite strong (+24% Y/Y), making the magnitude and speed with which this negative deviation from historical placement growth trends unprecedented in the company's history….We expect management to provide greater clarity on the factors impacting sales during the Q2 conference call on July 18, but for now we are left with many more questions than answers."

136. On this news, Intuitive's stock price suffered a severe blow. It dropped $80.78 from $500.08 to $419.30, almost 20 percent. *Bloomberg* reported that the Company's stock price "**fell the most since 2008** after reporting preliminary results that missed analysts' estimates as sales slowed for its surgical robots, which have faced **safety** and cost-efficiency questions."[93]

5. The FDA Warning Letter

a. On July 16, 2013 the FDA Issued a Warning Letter to Intuitive

137. Intuitive's Form 483 escalated into a Warning Letter in record time, between the end of the inspection on May 30 and July 16, when the FDA issued it. The FDA Warning Letter was addressed directly to Defendant Guthart.

138. Pursuant to the FDA's Regulatory Procedures Manual ("RPM"), "**Warning Letters are issued only for violations of regulatory significance**. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected. A Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the FDCA." RPM § 4-1-1. Accordingly, Warning Letters establish that a violation of the FDCA has occurred. Importantly, "**[r]esponsible officials in positions of authority** in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities comply with the law. Under the law, such individuals **are presumed to be fully aware of their responsibilities**." *Id.*

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[93] *Intuitive Surgical Declines on Falling da Vinci Robot's Drop in Sales* (2) issued July 9, 2013 at 4:36 p.m.

139. The Agency issued the FDA Warning Letter after it received Intuitive's response on June 7, 2013 to the Form 483. The FDA found that the June 7 response was "incomplete and inadequate," and reached other significant findings and conclusions.

140. First, the FDA Warning Letter concluded that the Tip Cover Accessory and Cannula 8mm Regular were "misbranded devices" under § 502(t)(2) of the FDCA, 21 U.S.C. 352(t)(2). Intuitive had "failed or refused to furnish material or information respecting the device." This referred to Intuitive's failure to notify the FDA of the changes to the Tip Covers and Cannulas set forth in Observation One of Form 483.

141. Second, and most importantly, the FDA determined that the four unreported corrections in Observation One of the Form 483 in which Intuitive had concealed changes to the Tip Covers and other procedures from the FDA constituted "Class II recall[s]." In each of the four instances the FDA Warning Letter stated: "Your report of this recall on April 19, 2013 has been classified by [the] FDA as a Class II recall." Accordingly, the FDA had determined that Intuitive had carried out four secret recalls, which the Company concealed during the Class Period, including recalling the Tip Covers.

142. The FDA Warning Letter further explained that Intuitive's belated excuse for not reporting the recalls was unacceptable. Intuitive claimed that it had changed an internal standard operating procedure so that "corrections, removals and labeling reiterations" (as Intuitive carried out here with respect to the Tip Covers) would be reported to the FDA local district director "or 3rd party expert." This 3rd party expert option was nothing but a subterfuge. According to the FDA Warning Letter, such an option made it impossible for the FDA to evaluate the information to be provided to the FDA because that option allowed for no information at all to be reported and did not explain Intuitive's basis for choosing between informing the FDA and the supposedly "3rd party expert."

143. Third, regarding Intuitive's failure to report these four corrections and removals, the FDA Warning Letter added, "[t]he FDA has previously informed you of your firm's correction and removal violations in an untitled letter dated February 19, 2008, and FDA 483

Inspectional Observations issued on December 20, 2002." In saying this, the FDA confirmed that failing to report corrections and removals was an ongoing, unsolved issue with Intuitive.

144. Fourth, the FDA Warning Letter found that Intuitive's devices were adulterated under § 501(h) of the FDCA, 21 U.S.C. § 351(h), because Intuitive had failed to fully implement the Quality System regulation regarding Design Control, as required by 21 C.F.R. § 820.30. Specifically, Intuitive knew "of patient injuries" concerning the Monopolar Scissors that required changes to the design of the Tip Covers and Cannulas but completely ignored those injuries and did nothing. The FDA Warning Letter added, "you informed our investigator that you are aware of patient injuries associated with intraoperative cleaning of energized instruments such as Monopolar Curved Scissors and Fenestrated Bipolar Scissors evidenced by at least [redacted] complaints and 82 MDRs during calendar years 2010 and 2011, and 15% of the MDRs reviewed by our investigator. You also informed our investigator that you are aware that cleaning instruments inside patients during surgery is a common practice and have included a label warning in the Instructions-for-Use (IFU) against the practice. When our investigator asked you to provide the design input documentation and design resolution of this known user need you failed to provide the requested documentation."

145. Intuitive failed to provide the "design input documentation" and "design resolution" to the FDA because it had not even attempted to fix the actual design defect and had limited itself to merely adding a label warning in the IFU. This "fix" shifted the burden for preventing device related injuries to Intuitive's customers (*i.e.*, surgeons), instead of providing an adequately designed product that would not fail. It depended on surgeons reading the changes and adequately modifying their behavior while Intuitive continued to distribute the problematic devices. Intuitive stated that they had adequately considered the cleaning requirement and the risks without going through the design control process. However, failing to properly determine the root cause of the problem by not following the design control process resulted in continued failure of the device with resulting injuries. The FDA concluded that this was "inadequate."

146. The term inadequate does not sufficiently describe the number and importance of FDA design control regulations that Intuitive violated. Regulations over the design process required Intuitive to institute procedures "to ensure that the design requirements relating to a device are appropriate and address the intended use of the device, including the needs of the user and patient." 21 C.F.R. § 820.30(c). In this case, surgeons needed to clean the accumulated debris off of the Tip Covers during surgery without removing them from the patient. This recognized need is referred to in the regulations as "design input." The FDA Warning Letter concluded that Intuitive had never even attempted to address the problem, having never documented the design input.

147. Failing to even document the design input, Intuitive never continued with the subsequent requisite design process and was thus unable to show the FDA the appropriate "design resolution" documentation. Under FDA regulations, had Intuitive identified and documented the design input, it would have then had to translate it into a "design output." 21 C.F.R. § 820.30(d). If the "user need" consisted of cleaning the Monopolar Scissors intraoperatively, as in this instance, then the design output required Intuitive to institute a procedure or a redesign of the equipment to clean intraoperatively without damaging the protective covering in order to prevent arcing.

148. After implementing a design output, Intuitive was required to document the "design verification," whereby Intuitive would have had to confirm that the design output met the design input requirements. 21 C.F.R. § 820.30(f). In this instance, if the design input constituted the surgeons' need to clean the Tip Covers, then Intuitive was required to design a fix to the problem that allowed for cleaning the Tip Covers without causing arcing – the design output. And after verifying the design, Intuitive was required to validate that the Tip Covers worked, *i.e.*, validate that the Tip Covers "conformed to defined user needs and intended uses," or intraoperative cleaning. 21 C.F.R. § 820.30(g) ("design validation").

149. Intuitive ignored all of these design regulations rendering the Tip Cover Accessory and Cannula 8mm Regular "adulterated devices." The FDA Warning Letter

admonished that the "Tip Cover Accessory and Cannula 8mm Regular are adulterated devices under section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements for devices which are set forth in the Quality System regulation," 21 C.F.R. § 820.

150. The FDA Warning Letter concluded with a stern admonition that the issues identified were not an all-inclusive list. "Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facilities." The letter further warned that the issues identified could be "symptomatic of serious problems." "The specific violations noted in this letter and in the Inspectional Observation, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance."

b. The FDA Warning Letter Caused a Sharp Decline in Intuitive's Stock Price

151. After the July 8, 2013 press release announcing preliminary financial results for the second quarter, analysts did not expect any surprises in Intuitive's earnings conference call on July 18, 2013 after the market close. "Due to preannouncement, there should be no surprises in 2Q13 results," said Janney Capital Market's report of July 18, 2013. Yet, there was. Guthart disclosed that Intuitive had received an FDA Warning Letter.

152. JP Morgan's July 19, 2013 report characterized the confluence of events resulting in the FDA Warning Letter as a "Perfect Storm." Likewise, an analyst report by Trefis that day said, the "company was dealt another blow in the form of a FDA warning letter, which could hinder approval of new products/procedures going forward." "The warning letter from the FDA will only worsen conditions as it will make it harder for the company to sell the system," it continued.

153. A subsequent *Bloomberg* headline that day also focused on Intuitive's lack of candor with the FDA: "Intuitive Reeling as FDA Cites Lack of Visibility on Problems." It then

summed up the situation, stating: "Intuitive … has lost about $6 billion in value over five months after disclosures about adverse events with its products, a recent recall, and now, a regulatory warning it hasn't adequately reported on issues concerning the devices." In addition, a "review of Food and Drug Administration records now shows the reports of injuries involving robot procedures have doubled in the first six months of 2013, compared with a year earlier."

154. Intuitive's stock price declined by $28.81 on July 19, 2013 to close at $392.67. It had not dropped below $400 since October 2011, before the beginning of the Class Period. *Bloomberg*'s headline on July 20, 2013 said it all: "Intuitive Surgical Declines On Warning Letter From FDA." The article focused on Intuitive's FDA reporting violations: "FDA inspections in April and May found a number of deficiencies, including that the [Sunnyvale, California-based] company in some cases hadn't adequately reported device corrections and patient adverse events."

155. A review of the MAUDE database actually reveals that it is far worse than *Bloomberg* reported. For the prior 12 years, from 2000-2012, there were 5,333 da Vinci- related MDRs filed. This number has dramatically grown to over 8,450 MDRs, after a staggering 3,117 da Vinci related MDRs were filed with the FDA in the nine months from January 1, 2013 to September 30, 2013 alone. With an average rate of over 400 MDRs a month filed during the first seven months of 2013, this is more than five times higher than any prior period since da Vinci was introduced. This staggering increase in reported da Vinci-related defects, patient injuries, and deaths in 2013 alone—in comparison to the prior 12 years—was hidden by Intuitive through its dramatic underreporting of MDRs.

E. Post Class Period: Intuitive's Product Liability Insurers Claim They Too Were Misled

156. In October 2013, the Company was named as a defendant in an insurance action brought by Illinois Union Insurance Co. ("Illinois Union") in the United States District Court for the Northern District of California. Illinois Union sought to rescind the policy it issued to the Company, which provided coverage for product liability claims made during the period March 1, 2013 to March 1, 2014. In December 2013, the Company was named as a defendant in another

insurance action brought by Navigators Specialty Insurance Co. ("Navigators") also seeking to rescind its excess policy issued to Intuitive for product liability claims made against the Company during the same policy period. As Defendants disclosed in their Report on Form 10-Q for the period ended September 30, 2016, filed on October 19, 2016, "[b]oth plaintiffs generally allege that the Company did not disclose the existence of tolling agreements or the number of claimants incorporated within those agreements, and allege that those agreements were material to plaintiffs' underwriting processes." In the insurance litigation, Navigator's asserted that

> During the insurance application process, ***Intuitive held in its hand a Master List of 734 tolled claims that it never disclosed to Navigators***. Intuitive was obligated to disclose those tolled claims under Insurance Code section 332. Having withheld information from its insurers regarding the existence of 734 tolled claims, ***which burgeoned into liabilities "north of 50 million dollars" to date***, Intuitive now attempts to blame Navigators for failing to conduct sufficient internet research to discover information that Intuitive already had in its possession but actively concealed.[94]

157. It was not until Intuitive secured insurance coverage from these insurance companies that they disclosed the hundreds of tolling agreements to them, according to the insurers. Of course, this was too late for the insurers to consider the related risk associated with these claims prior to issuing the relevant policies, similar to Intuitive's public disclosures regarding the risk of injury stemming from the Tip Covers themselves.

V. ADDITIONAL EVIDENCE OF SCIENTER

A. The Individual Defendants' Stock Sales During the Class Period Were Highly Unusual and Suspicious

158. Each of the Individual Defendants engaged in stock sales during the Class Period that were suspiciously timed and dramatically out of line with their prior trading practices. As a result of these Class Period trades, the Individual Defendants profited from the artificial inflation embedded in the trading price of Intuitive stock caused by their false and misleading statements and omissions to investors during the Class Period. Many of these insider sales occurred immediately after the Company's undisclosed discussions with the FDA starting in September

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[94] *See* Plaintiff Navigators Reply Brief to Intuitive's Opposition to Motion for Summary Judgment at 1, Illinois Union v. Intuitive, No 13-4863 (N.D. Cal. Apr. 19, 2016) (ECF No. 155).

2012 regarding MDR reporting requirements, as detailed above. Many other sales took place in late January 2013, just before the first Corrective Disclosures, while Intuitive stock was trading near Class Period highs, and shortly before substantial declines in the price of the stock.

1. The Value and Amount Were Highly Unusual

159. The Class Period sales of Intuitive stock by Defendants Guthart, Mohr, and Smith were highly unusual and suspicious as measured by (i) the total amount and percentage of shares sold, (ii) the contrast with the Individual Defendants' own prior trading history, and (iii) the timing of the sales. Such sales therefore raise a strong inference of scienter.

160. To evaluate the Individual Defendants' selling activity, Plaintiffs used the publicly-available trading data that the Individual Defendants are required to report to the SEC on Form 4. Plaintiffs analyzed the trading by the Individual Defendants during the Class Period and during the equal-length period immediately preceding the Class Period beginning August 26, 2010 and ending February 5, 2012 (the "Control Period"). The Form 4s filed during the Class Period and Control Period are hereby incorporated by reference, and a summary of the relevant transactions are set forth in Exhibit E, annexed hereto.

161. To analyze the Individual Defendants' sales, Plaintiffs calculated the total sales by each of the Individual Defendants, together with the cash proceeds from such sales, during the Control and Class Periods. Those totals were then compared to identify whether Individual Defendant's sales during the Class Period were consistent with their sales during the Control Period. The Individual Defendants' specific trading dates were also evaluated compared to Corrective Disclosure dates. All of these analyses reveal that the Individual Defendants' Class Period sales were extremely large, highly unusual, and suspicious.

a. The Nominal Amount and Percentage of Holdings Sold Were Extraordinary

162. The amount and percentage of shares sold during the Class Period by Defendants Mohr, Guthart, and Smith were extraordinarily large. Defendant Smith's sales during the Class Period totaled **$100,068,631**, which represented approximately 40% of the total shares he had available for sale during the Class Period. Defendant Mohr sold 27,400 shares during the Class

Period. He held 1,191 shares at the beginning of the Class Period and 1,242 shares at the end of the Class Period. Hence, his Class Period sales of 27,400 shares represent approximately **16 times** his average shareholdings. Mohr practically sold every share that he acquired during the Class Period for proceeds of **$15,274,248**. Defendant Guthart's sales during the Class Period totaled $8,743,264, representing approximately 30% of the total shares he had available for sale during the Class Period.

b. The Stock Sales Were Inconsistent With Prior Trading Practices

163. The Individual Defendants' Class Period stock sales were not only large in absolute terms, but also inconsistent with the Individual Defendants' own prior selling activity during the Control Period.

164. Collectively, the Individual Defendants increased their stock sales approximately **three-fold**, from 78,000 shares to more than 230,000 shares. Separately, each Individual Defendant's sales also increased sharply. During the Control Period, Defendant Guthart did not sell **a single share** of Company stock. Yet he sold approximately 16,000 shares, or **one-third** of his entire Intuitive holdings, during the Class Period. This is an infinite increase over the Control Period. Defendant Smith more than tripled his sales, from 62,000 to nearly 190,000 shares. Defendant Mohr's share volume also increased significantly, from 16,000 shares sold during the Control Period to over 27,000 during the Class Period.

165. The contrast between the Individual Defendants' sales during the Control Period and the Class Period is also striking when measured in dollars. Collectively, the Individual Defendants' sales increased more than **four-fold** during the Class Period, from approximately $29 million during the Control Period to over $124 million during the Class Period.

166. Separately, each of the Individual Defendant's individual sales, as measured in dollars, also increased dramatically. As noted, Defendant Guthart did not sell any shares during the Control Period, in comparison to the nearly $9 million worth of stock that he sold during the Class Period. Defendant Smith's trading also increased exponentially, more than **quadrupling** from $23 million during the Control Period to $100 million during the Class Period. And

Defendant Mohr's individual sales **more than doubled** during the Class Period, from $6 million during the Control Period to over $15 million during the Class Period.

c. The Timing of the Stock Sales Was Suspicious

167. The Individual Defendants' sales of stock were suspiciously timed in large measure because they sold a vast number of shares after they learned of materially adverse information but before the public disclosure of that same adverse information.

168. All three Individual Defendants sold massive amounts of stock immediately after the meeting with the FDA and the Company's revision of its MDR Reporting practices in September 2012 which caused a substantial increase in MDRs. Between late October and early December 2012 the Individual Defendants sold an extraordinary sum that exceeded $70 million.

(a) Defendant Smith sold more than 125,000 shares of Intuitive common stock for almost $70 million on no fewer than eight occasions. Importantly, almost 110,000 shares were sold after Smith terminated his 10b5-1 Plan, as discussed further below.

(b) In late October 2012, Defendants Guthart and Mohr sold 4,500 and 7,300 shares, respectively, reaping proceeds of approximately $2.4 and $3.9 million, respectively. The Individual Defendants thus sold and profited before the impact of the new MDR reporting requirements would be made public and would negatively impact the stock price, as it ultimately did towards the end of the Class Period.

169. Defendants Guthart and Mohr also sold shares immediately after Intuitive learned of the FDA safety probe on or before January 18, 2013, but before the FDA probe became public. Defendant Guthart sold 4,500 shares on January 25, 2013, when Intuitive stock was trading at $577.82 per share. Guthart's sale occurred only 34 days prior to the first Corrective Disclosure date of February 28, 2013, upon which the Company's share price tumbled $63.63 to $509.89. Defendant Mohr sold around the same time as Defendant Guthart, divesting himself of 8,000 shares on January 28, 2013. At that time Intuitive stock was trading for $577.93 per share. Suspiciously, after trading consistently throughout the Class Period, these January 2013

transactions by Defendants Guthart and Mohr constituted their final sales of the Class Period and were executed at historic highs.

170. These January 2013 sales are also suspicious because they took place within one trading day of each other, apparently in concert, given the Individual Defendants' regular contact and shared knowledge of undisclosed material information about the Company. Only three days later, on February 1, 2013, Smith entered into a new 10b5-1 Plan, as discussed further below. Accordingly, the proximity in time of the last sales by Defendants Guthart and Mohr with Smith's execution of a new 10b5-1 Plan raises a strong inference that they acted in concert and discussed the transactions.

2. The Stock Sales Generated Enormous Abnormal Profits

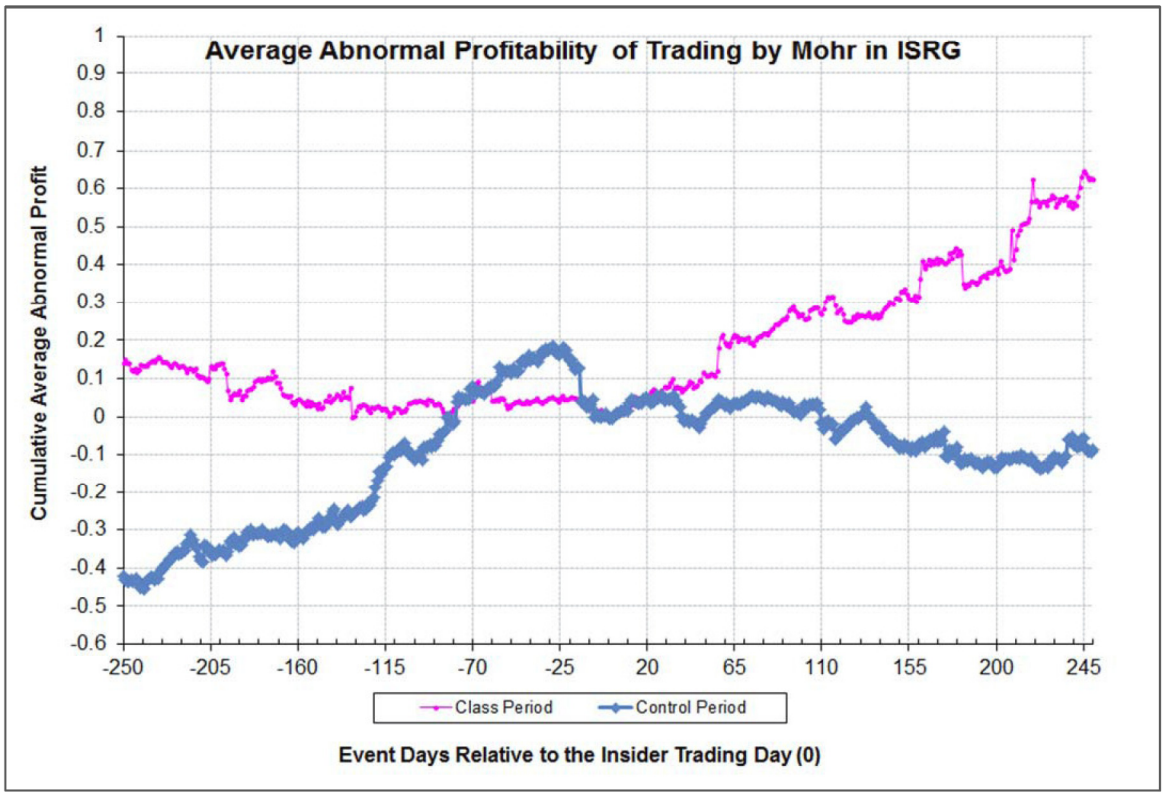
171. Plaintiffs also analyzed whether the Individual Defendants' sales of Intuitive stock during the Class Period generated abnormal (above-average) profits as compared to the Control Period. Defendants did generate abnormal profits from their stock sales during that time, further suggesting suspicious trading activity that raises a strong inference of scienter.

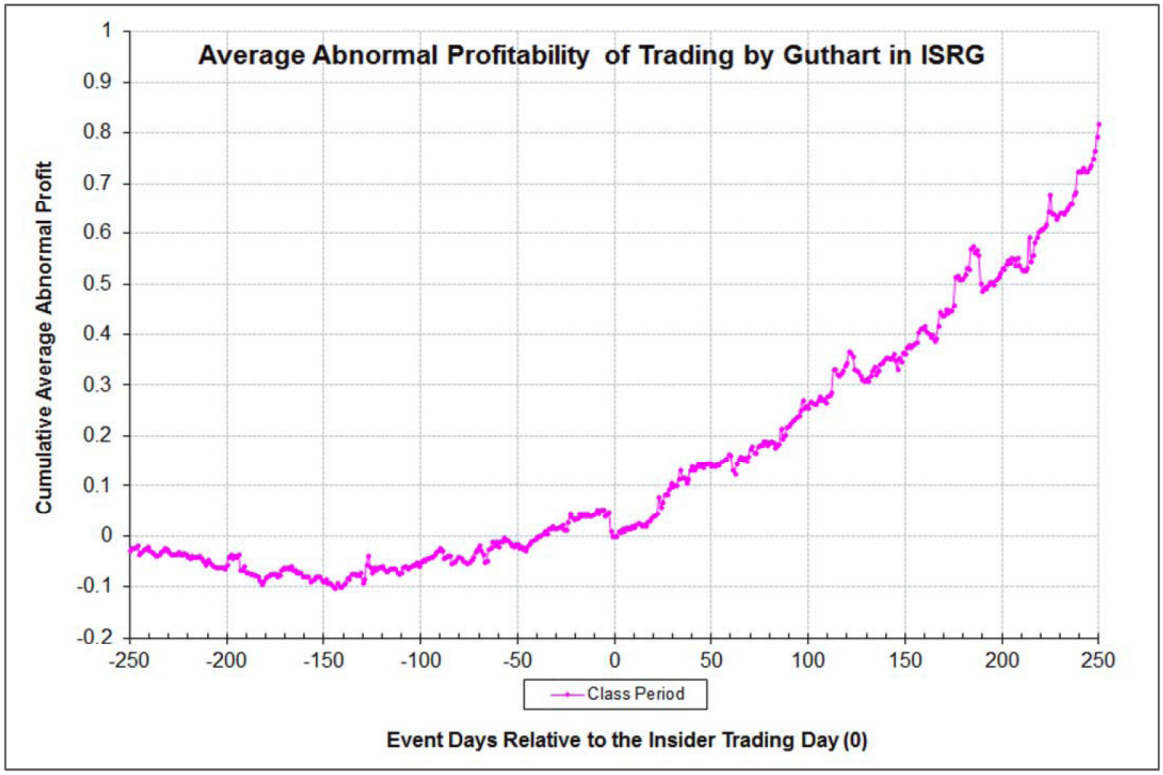
172. Plaintiffs evaluated abnormal profits by using an event study methodology called the "market-model method," which computes cumulative shareholder returns not explained by the market. Under this approach, first, a prior period is used to estimate the relation between Intuitive stock and the market index. Next, this relation is used to estimate the abnormal profits during the relevant Period. To consider a simple example of the analysis, assume that the sensitivity of Intuitive stock to market index is one (beta is one). In that case, if an insider buys a share of Intuitive stock, which then increases in price from $100 to $120 (20%), and the market index increases from 1000 to 1010 (1%) during the same period, then the abnormal profit would be 19%. Similarly, if a company's stock price declines subsequent to a sale by a greater amount than the relevant benchmark index, then the sale enabled the insider to generate an abnormal profit by avoiding the decline. This methodology is widely-accepted, having been used extensively in academic literature studying the profitability of insider trading. *See, e.g.*, Fishe, R.P.H. and M.A. Robe, "The Impact of Illegal Insider Trading in Dealer and Specialist

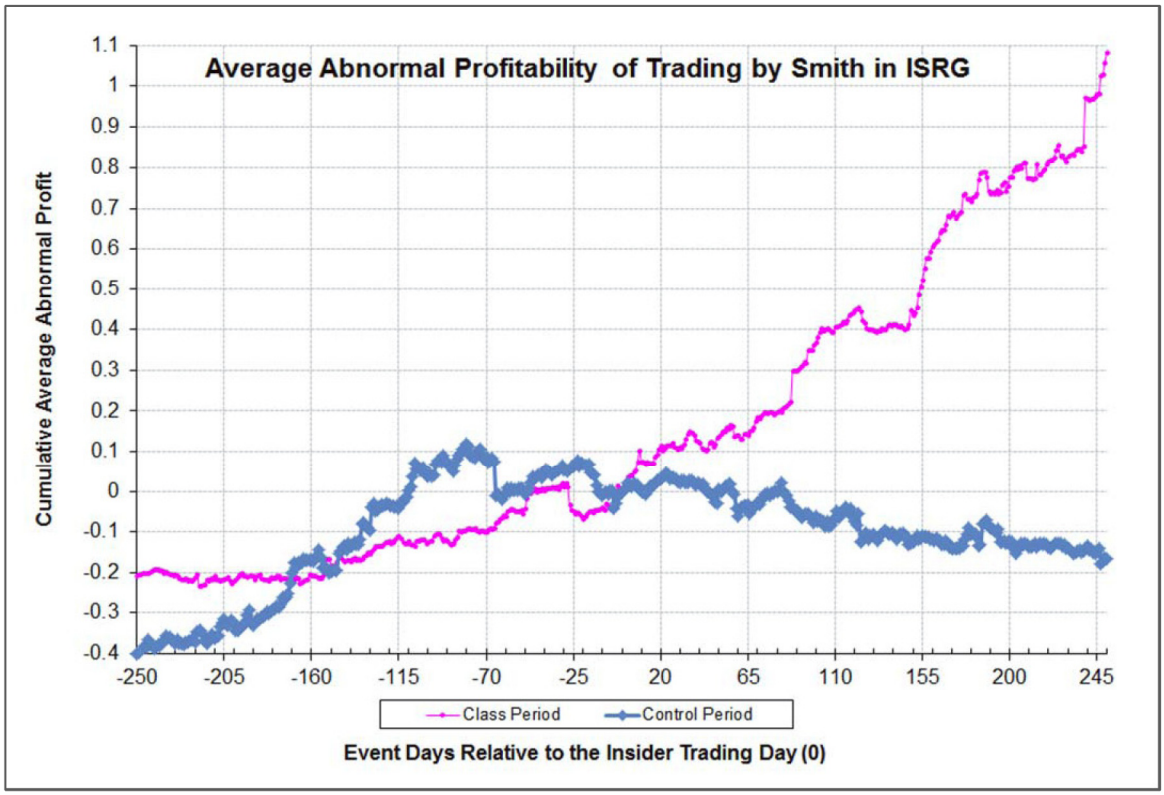
Markets: Evidence from a Natural Experiment," 71 J. of Fin. Econ. 461-488 (2004). Abnormal profits were calculated using a value-weight index of NYSE, AMEX, and NASDAQ stocks as the market index during the Control Period and Class Period.

173. To determine whether the unusual profits were the result of random chance, Plaintiffs used equally-rated prediction errors from the market-model method for the 250 trading days before (approximately one year) and the 250 trading days after the day of the trade, and then Plaintiffs equally averaged these residuals across event days for each Individual Defendant. This data was then used to compute a t-statistic to infer the probability that the observed cumulative abnormal profits were due to random chance.

174. Applying this methodology, it is clear that the Individual Defendants each generated extremely large abnormal profits on their transactions in Intuitive stock during the Class Period, particularly when compared to their trading behavior during the Control Period, as reflected in the following charts:

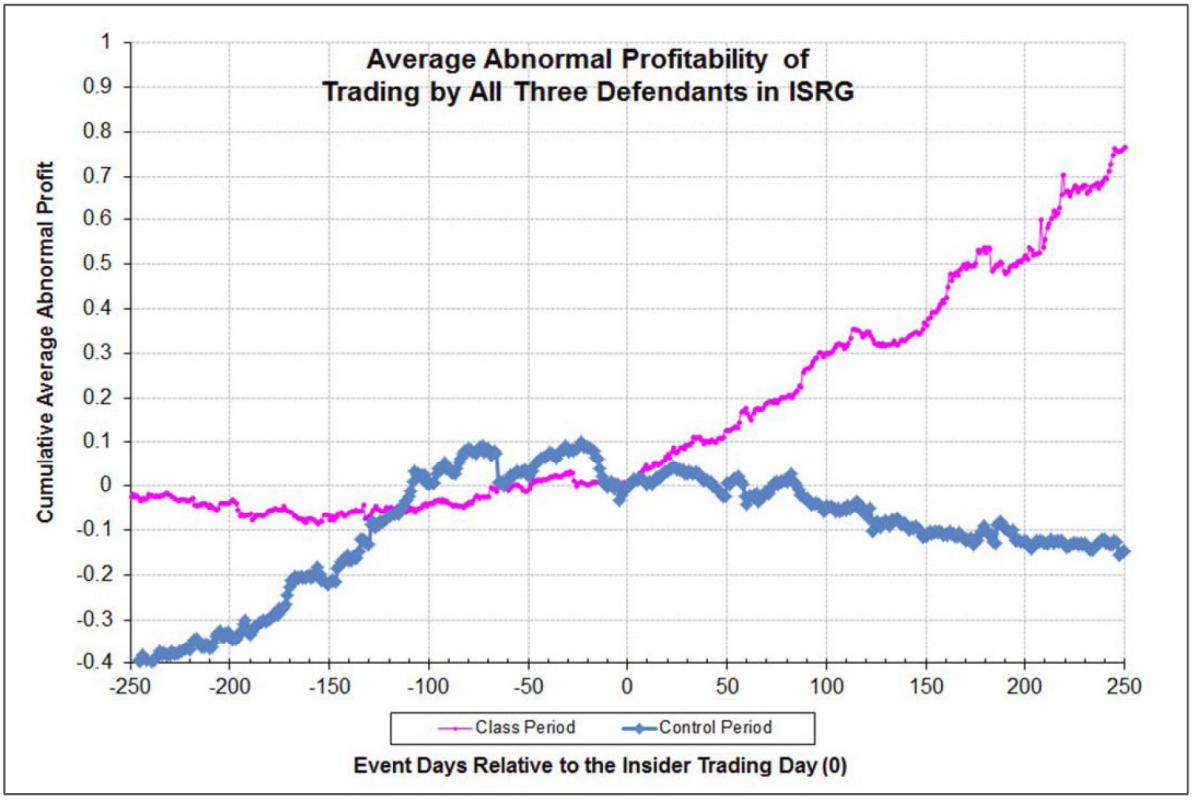



Average Abnormal Profitability of Trading by Guthart in ISRG
Cumulative Average Abnormal Profit
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
-0.1
-0.2
-250
-200
-150
-100
-50
0
50
100
150
200
250
Class Period
Event Days Relative to the Insider Trading Day (0)


Average Abnormal Profitability of Trading by Smith in ISRG
Cumulative Average Abnormal Profit
1.1
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
-0.1
-0.2
-0.3
-0.4
-250
-205
-160
-115
-70
-25
20
65
110
155
200
245
Class Period
Control Period
Event Days Relative to the Insider Trading Day (0)

175. As shown above, based on the timing of the Individual Defendants' Class Period trades, (i) Mohr generated average annual returns that exceeded the benchmark index by more than 62% after about one year, (ii) Guthart's profits exceeded the benchmark by more than 81% after about one year, (iii) and Smith's trades delivered abnormal annual profits of 108% after about one year. Further, using the market-model method described above, it is clear that the possibility that these abnormal profits resulted from random chance is extremely remote: the probability of these profits occurring randomly is less than one percent for Defendants Guthart and Smith and less than five percent for Defendant Mohr. The results are therefore strongly statistically significant.

176. Collectively, all three Individual Defendants' trades delivered abnormal profits in excess of 76% after about one year. The timing and extent of these abnormal profits, as well as the contrast between Control Period and Class Period trades, are reflected graphically in the chart below. Again, the chart compares trades for the Control and Class Periods for the Individual Defendants, and depicts cumulative abnormal profit (or loss) on all trades occurring during each period, calculated daily for one to 250 days following the day of trade. As reflected in the chart below, trades during the Class Period immediately generated abnormal profits, demonstrating them to be extraordinarily well-timed and therefore highly suspicious, particularly when compared to the lack of abnormal profits generated during the Control Period.



3. The Timing of the 10b5-1 Plans Adopted by the Individual Defendants During the Class Period is Suspicious

177. Rule 10b5-1, 17 C.F.R. § 240.10b5-1 provides that a person will be deemed to have traded "on the basis of" material nonpublic information if the person engaging in the transaction was "aware of" that information at the time of the trade. To provide a safe harbor under the "aware of" standard, the SEC created an affirmative defense to insider trading claims for trades made pursuant to a binding agreement or plan ("10b5-1 Plans" or "Plans"). *See* Selective Disclosure and Insider Trading, 65 Fed. Reg. 51,716, at 51,727-28 (Aug. 24, 2000). Pursuant to SEC Rule 10b5-1(c), a 10b5-1 Plan is a defense to insider trading liability **only** if it is entered into by an insider "**[b]efore becoming aware**" of inside information, and was established "in good faith and not as part of a plan or scheme to evade the prohibitions" against insider trading.

178. Because of this, insiders are advised to "design a trading plan with the intention that it will not be modified or amended frequently, since changes to the plan will raise issues as

to a person's good faith." Thomson West, Corporate Counsel's Guide to Insider Trading and Reporting § 12:26 (2006). Conversely, the adoption and/or modification of these Plans while in possession of material non-public information is highly suspicious and supports a strong inference of scienter.

179. [redacted] Defendants Smith and Guthart sold Intuitive stock on April 20, 2012 – [redacted] in possession of the material, non-public information described herein. Defendant Mohr, [redacted] sold Intuitive stock on April 30, 2012 in possession of the material, non-public information described herein.

180. [redacted]

[redacted] (Form 4 dated 4/23/12); [redacted] 4s) [redacted] (Form 4 dated 4/23/12). [redacted] (Form 4 dated 5/2/12).

[redacted]

[redacted]

[redacted]

[redacted] (Smith Form 4 dated 4/23/12).

[redacted]

[102] *See* Defs.' Admissions, RFA No. 94.

[redacted]

[redacted]

182. Although some of the Individual Defendants' stock sales were made pursuant to these 10b5-1 Plans, the circumstances of those sales are sufficiently suspicious to overwhelm any exculpatory inference that might otherwise have been available to pre-planned sales based on such Plans. [redacted] In these circumstances, Defendant Guthart's trades according to a 10b5-1 Plan are highly suspicious and indicative of insider trading behavior.

183. Defendant Mohr's trading suffers from the same deficiency as Defendant Guthart's trading. [redacted] Defendant Guthart's and Mohr's coordinated activity – entering 10b5-1 Plans on exactly the same day during the Class Period, as well as their synchronized trading as discussed above – is further suggestive of suspicious trading activity. Defendant Smith's behavior also appears to have been part of the Individual Defendants' concerted effort to take advantage of their inside information.

184. Defendant Smith enacted a 10b5-1 Plan only days prior to Defendants Guthart and Mohr, on March 8, 2012, approximately a month after the beginning of the Class Period, and transacted according to the plan on April 20, 2012, July 24, 2012, and October 22, 2012. As if the enactment of a 10b5-1 Plan after the start of the Class Period were not suspicious enough, Defendant Smith's trading evidences two other peculiarities: (i) the majority of Defendant Smith's Class Period transactions were not pursuant to his 10b5-1 Plan, and in fact those transactions correspond with the FDA's investigation of Intuitive, as discussed above, and

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105 [redacted]

106 [redacted]

[redacted]

(a) [redacted][107]

(b) Between November 20, 2012 and December 31, 2012, Defendant Smith sold 109,922 shares of Intuitive stock not pursuant to any 10b5-1 trading plan.[108]

(c) [redacted][109]

(d) Smith sold 25,000 shares on March 4, 2013 [redacted][110]

(e) [redacted][111]

185. Casting further doubt, none of the Individual Defendants traded later in the Class Period once the Corrective Disclosures came out and Intuitive's stock price started to drop. This suggests that each Individual Defendant chose to suspend his 10b5-1 Plan to avoid selling at lower prices, after having taken advantage of the Plan to sell stock earlier for higher returns. This manipulation epitomizes the behavior that has prompted regulators to call into question the ethics of these Plans.

186. Indeed, even if the Individual Defendants had entered into 10b5-1 Plans prior to the Class Period and traded within them consistently throughout the Class Period, such plans are under heavy SEC scrutiny in light of a recent *Wall Street Journal* investigation that found that insiders who were trading pursuant to 10b5-1 Plans were still trading at opportune times and

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[107] *See* Defs.' Admissions, RFA No. 87 [redacted]

[108] *See* Defs.' Admissions, RFA No. 92; *see also* [redacted] (Form 4 – 12/5/12); [redacted] (Form 4 – 11/28/12); [redacted] (Form 4 – 11/26/12).

[109] *See* Defs.' Admissions, RFA No. 88 [redacted]

[110] *See* Defs.' Admissions, RFA No. 94.

[111] *See* Defs.' Admissions, RFA No. 89.

reaping better-than-expected results. According to the November 27, 2012 *Wall Street Journal* article entitled "Executives' Good Luck in Trading Own Stock," executives trading pursuant to 10b5-1 Plans are still able to time their trades to avoid losses and increase earnings because trading plans are not public and can be canceled or amended at any time without disclosure.

187. Accordingly, the Individual Defendants' behavior in entering into Class Period Plans, and in some circumstances modifying those Plans or trading outside them, as well as their apparent decisions to suspend their Plans upon the decline of the Company's stock price, and to violate the terms of the Plans, further raises a strong inference of suspicious and unusual trading activity.

B. Defendants Knew, or Were Deliberately Reckless in Not Knowing, That Intuitive Had Been Violating FDA Regulations

188. Defendants knew, or were deliberately reckless in not knowing, of Intuitive's FDA violations and the continuous nature of the violations cited herein. Indeed, the FDA reported in its July 2013 FDA Warning Letter to Defendant Guthart and Intuitive:

> The FDA has previously informed you of your firm's correction and removal violations in an untitled letter dated February 19, 2008, and FDA 483 Inspection Observations issued on December 20, 2002.

189. The February 19, 2008, "Untitled Letter" referenced in the FDA Warning Letter (the "2008 Untitled Letter") was addressed to Defendant Smith. The FDA issues Untitled Letters to companies for violations of the FDCA. The letter provides companies with an opportunity to take voluntary and prompt action to correct the violation before FDA initiates an enforcement action. The FDA will issue either a Warning Letter or an Untitled Letter, depending upon the nature of the violation.[112]

190. The 2008 Untitled Letter cited Intuitive for its "[f]ailure to submit a written report to FDA within 10 working days of any correction or removal of a device if the correction or removal was initiated to reduce the risk to health posed by the device or to remedy a violation of the act which may present a health risk," including:

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[112] *See* http://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/ucm284105.htm.

(a) Intuitive's **failure to properly report** to the FDA the removal of a cautery instrument as a "Class II [r]ecall"; and

(b) Intuitive's **failure to properly report** a field correction of all da Vinci units manufactured from May 2005 through March 2006, also classified by the FDA as a "Class II [r]ecall."

191. The FDA also took the opportunity in the FDA Untitled Letter to remind Defendant Smith and Intuitive that the Agency had previously informed them of correction and removal violations in the December 20, 2002 Form 483 (the "2002 Form 483"). The 2002 Form 483, addressed to Defendant Smith, cited the Company for "four unreported field corrections and removals." In addition, it specifically noted that Intuitive had not documented any "justification for not reporting to the agency," and that "[m]anagement reviews [did] not ensure that the quality system satisfie[d] the requirements of part 820," which governs Intuitive's obligation to ensure that a device is designed to meet user requirements.

192. Separately, but equally significant, the 2002 Form 483 cited Intuitive for failing to implement "[c]omplaint handling procedures for receiving, reviewing, and evaluating complaints." The 2002 Form 483 observed that Intuitive was turning a blind eye to problems with the da Vinci even then: "Of eleven complaints I reviewed at least five Case Report Forms do not indicate the date of the event being complained about, even though this information is available in two written complaints received from complainants and should have been available from three incidents where a company representative was present at the event."

193. Together, the 2002 Form 483 and the 2008 Untitled Letter demonstrate that Defendants, including Defendant Smith, knew of Intuitive's precise regulatory violations during the Class Period, including: (i) secretly issuing Class II Recalls without properly reporting those corrections to the FDA (21 C.F.R. § 806.10); and (ii) failing to report, or timely report, complaints or reports of adverse events through the MDR mechanism (21 C.F.R. § 803.50). Defendants' systematic and unresolved misconduct over the years and throughout the Class Period concerning these regulatory violations raises a strong inference of scienter.

194. This strong inference is further supported by the FDA's own language concerning Form 483s and Warning Letters:

(a) "The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management"; and

(b) "Responsible officials in positions of authority in regulated firms have a legal duty to implement whatever measures are necessary to ensure that their products, practices, processes, or other activities comply with the law. Under the law, such individuals are presumed to be fully aware of their responsibilities." RPM § 4-1-1.

195. That the FDA considered Defendants Smith and Guthart to be the "responsible officials in positions of authority," pursuant to RPM § 4-1-1, is clear from the Agency's designation of Defendants Smith and Guthart as two of the FDA's primary Intuitive contacts.

196. Over the last decade and through the Class Period, Defendants Smith and Guthart have been primary contacts for the FDA in communications with Intuitive concerning all regulatory matters, including (i) Form 483s, Warning Letters, and Untitled Letters; (ii) field corrections, and (iii) instrument recalls. For example, Defendant Guthart was the named recipient of the July 16, 2013 FDA Warning Letter and the May 30, 2013 Form 483; and Defendant Smith was the recipient of the 2008 Untitled Letter, the 2002 Form 483, and an April 12, 2001 Warning Letter. Prior to the Class Period, both Defendants Smith and Guthart were also copied on or were recipients/senders of the following correspondence with the FDA: (i) March 13 and May 9, 2012, FDA letters to Defendant Guthart concerning recalls; (ii) a February 11, 2011, FDA letter to Defendant Smith concerning a recall; (iii) a January 9, 2008, Intuitive letter to the FDA, copying Defendants Smith and Guthart, concerning a field correction; (iv) July 2 and November 20, 2007, FDA letters to Defendant Smith concerning recalls; and (v) a February 14, 2007, Intuitive letter to the FDA, copying Defendant Guthart, concerning a recall.

197. Indeed, Defendants Smith and Guthart have had a long tradition of being at the forefront of all communications with the FDA, commencing with their participation in the open

session in the FDA's June 16, 1999 Medical Devices Advisory Committee when seeking initial FDA clearance for da Vinci.

C. The Individual Defendants Monitored Reports of Adverse Events

198. While simultaneously touting the safety and efficacy of da Vinci, Intuitive failed to disclose that for years da Vinci posed a material health risk to patients. The Individual Defendants' knowledge of the rise in MDRs, adverse/reportable events, and complaints is further supported by the following information:

1. Internal Documents and Testimony

199. As set forth below, the Individual Defendants' knowledge of the rise in MDRs and adverse/reportable events, and complaints is supported by documents and testimony [redacted]

200. [redacted]

201. [redacted]

(a) [redacted][114]

(b) [redacted]

(c) [redacted]

(d) [redacted]

(e) [redacted]

(f) [redacted]

[redacted]

---

[113] [redacted]

[114] [redacted]

(g) [redacted]

[redacted]

(h) [redacted]

[redacted]

(i) [redacted]

[redacted]

(ii) [redacted]

[redacted]

(iii) [redacted]

[redacted]

(iv) [redacted] and

(v) [redacted]

[redacted]

202. [redacted]

[redacted]

[redacted]

203. [redacted]

[redacted][120]

204. [redacted]

[redacted][121]

[redacted]

[redacted][122]

205. [redacted]

[redacted]

(a) [redacted][123]

(b) [redacted][124]

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120 [redacted]

121 [redacted]

122 [redacted]

123 [redacted]

124 [redacted]

(c) [redacted][125]

(d) [redacted][126]

(e) [redacted][127]

(f) [redacted][128]

(g) [redacted][129]

(h) [redacted][130]

(i) [redacted][131]

(j) [redacted][132]

(k) [redacted][133] and

(l) [redacted][134]

[redacted]

(a) [redacted][135]

(b) [redacted][136]

[redacted]

[125] [redacted]

[126] [redacted]

[127] [redacted]

[128] [redacted]

[129] [redacted]

[130] [redacted]

[131] [redacted]

[132] [redacted]

[133] [redacted]

[134] [redacted]

[135] [redacted]

[redacted]

[136] [redacted]

(c) [redacted][137]

(d) [redacted][138]

(e) [redacted][139]

(f) [redacted][140]

(g) [redacted][141] and

(h) [redacted][142]

[redacted]

[redacted][143]

207. [redacted][144] [redacted]

[redacted][145] [redacted]

[redacted]

137 [redacted]

[redacted]

138 [redacted]

[redacted]

139 [redacted]

140 [redacted]

[redacted]

141 [redacted]

142 [redacted]

[redacted]

143 [redacted]

[redacted]

144 [redacted]

[redacted][146]

[redacted][147]

[redacted][148]

[redacted][149]

[redacted][150]

[redacted]

[redacted][151]

[redacted][152]

208. Intuitive also had instant access to data from the da Vinci standard, da Vinci S and da Vinci Si Systems through a feature called "OnSite" which allows Intuitive to remotely monitor da Vinci in "real time."[redacted] According to Intuitive's website, OnSite also permitted "automatically upload[ed] system logs "to be sent to the Company following each procedure.

[redacted][145]

[redacted]

[redacted][146]

[redacted][147]

[redacted][148]

[redacted][149]

[redacted][150]

[redacted][151]

[redacted]

[redacted][152]

[redacted][153]

[redacted][154] [redacted][155] [redacted][156]

2. Public Source Information

209. Following the conclusion of the Class Period, multiple public sources have also described the Individual Defendants' involvement in discussions regarding the problems with the tip cover and MCS and the Company's MDR Reporting.

210. In a recent publicly accessible court filing, Defendants admit their ongoing involvement with the tip cover accessory and MDR reporting issues. Most notably, in support of their motion for summary judgment seeking dismissal of failure-of-oversight claims in a derivative action predicated on the same conduct as that alleged here, Defendants filed a Statement of Undisputed Material Facts and Undisputed Evidence.[157] Therein, Defendants not only admit the ongoing involvement of Intuitive's officers and directors with regulatory issues generally, but also admit their oversight and direct involvement in the issues surrounding the tip cover accessory and MDR reporting, noting that (1) "at every Intuitive Board meeting, the Board discussed regulatory compliance, including FDA reporting practices;" (2) "the Board regularly discussed design and manufacturing issues, including the tip covers;" (3) "Intuitive's directors met in special sessions to address the issues;" (4) "Intuitive directors received updates from Dr. Guthart, Intuitive's CEO, regarding the issues;" (5) "Intuitive's directors independently spoke with Dr. Guthart and others within the company outside of Board meetings;" (6) "the officer defendants . . . were similarly diligent;" (7) "the directors and officers oversaw Intuitive's

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[redacted][154]
[redacted][155]
[redacted][156]

[157] *See* Separate Statement in Support of Defendants' Motion for Summary Judgment, or in the Alternative, Summary Adjudication at 5, *Pub. Sch. Teachers' Pension & Ret. Fund of Chicago v. Guthart,* CIV-526930 (Super. Ct. Cal. June 1, 2016).

decision to devote significant engineering resources to investigating the issue;" (8) "Intuitive officers . . . came to believe that the company should classify certain incidents involving da Vinci differently, thereby making them reportable," and; (9) "Dr. Guthart notified the Directors of this determination, and kept [the Board] updated as Intuitive brought the issue to the FDA's attention." As the Individual Defendants were officers of Intuitive during the relevant period and Defendant Smith also served as Chairman of Intuitive's Board of Directors during the relevant period, the Individual Defendants admit their direct involvement in issues surrounding the tip cover accessory and MDR reporting.[158]

211. Moreover, information derived from the *Illinois Union Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-4863 (N.D. Cal.) and *Navigators Specialty Ins. Co. v. Intuitive Surgical, Inc.*, No. 15-cv-5801-JST (N.D. Cal.), ECF No. 1 rescission litigation further supports Plaintiffs' allegations that Defendants actively concealed the massive tolling project in late 2012 and early 2013. Illinois Union and Navigators both sought to rescind underlying insurance policies based on Intuitive's alleged concealment of the tolling agreements which Intuitive had entered into with parties claimed to have been injured by da Vinci. The parties to those cases dispute when Intuitive first disclosed the existence of the tolling agreements to Illinois Union and Navigators. In the "Undisputed Facts" section of the Court's Order Denying Illinois Union's Motion for Partial Summary Judgment, the Court recited the following facts:

> Beginning in late 2012, Intuitive authorized outside counsel to enter into "tolling agreements" with plaintiffs' attorneys for individuals who had contacted Intuitive regarding potential injury claims related to the da Vinci Surgery System. The tolling agreements took the form of letters from Intuitive's outside counsel to the plaintiffs' attorneys, stating that Intuitive agreed to "toll the applicable statute of limitations with regard to potential claims involving the da Vinci Surgical System by [the Claimant]" in exchange for the claimants' agreeing to, among other things, delay in filing suit. Intuitive's outside counsel retained a master chart listing each of the claims involving the da Vinci Surgical System that were currently subject to the tolling agreements. Intuitive's Assistant General Counsel periodically received updates from outside counsel regarding which claims were currently subject to the tolling agreements. As of December 31, 2012, the master chart listed 193 tolled claims. The number of tolled claims continued to grow throughout the winter and spring of 2013, reaching 328 tolled claims on January 31, 2013; 734 tolled claims on February 28, 2013; 864 tolled claims by late

[158] *See id.* at 5-10, Defendants' Undisputed Material Facts and Undisputed Evidence Nos. 17, 18, 20, 21, 22, 23, 30, 39, 40.

> March; and 2,248 tolled claims by June 27, 2013. On March 21, 2013, Intuitive notified Ironshore for the first time of the existence of the tolling agreements. The first public disclosure of any tolling agreements was made in Intuitive's April 19, 2013 Form 10-Q, filed with the SEC. …The document did not indicate how many tolling agreements had been entered into and went on to explain that Intuitive "does not . . . know how many of such individuals will ultimately file lawsuits . . ."[159]

D. Imputed Knowledge of Facts Critical To Core Operations

212. Each of the Individual Defendants was a top executive involved in Intuitive's daily operations and with access to all material information regarding the Company's core operations. Therefore, each of the Individual Defendants is presumed to have had knowledge of all material facts regarding Intuitive's core da Vinci business.

213. Here, Intuitive has one product: the da Vinci Surgical System, which generates 100% of its revenue. Given the centrality of da Vinci to Intuitive's operational and financial success, the Individual Defendants knew and should have known that throughout the Class Period that its only product contained known defects that compromised patient safety, and that Defendants were systematically underreporting to the public and the FDA material information regarding those defects and safety concerns in violation of critical FDA regulations.

VI. LOSS CAUSATION AND ECONOMIC LOSS

214. During the Class Period, as detailed herein, Defendants engaged in a course of conduct that artificially inflated the price of Intuitive common stock and operated as a fraud or deceit on the Class Period purchases of Intuitive common stock by making materially false and misleading statements and omissions concerning (i) the fact that Intuitive had been systematically violating FDA reporting and other regulations and ignoring significant objectionable conditions existing since at least 2010, as noted in the Form 483 and the FDA

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[159] *See, e.g.*, Order Denying Partial Summary Judgment, *Ill. Union Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-4863 (N.D. Cal. May 27, 2016) (ECF No. 178); [redacted] (IRONSHORE0006760-78); Declaration of Charles Wheeler In Support of Partial Summary Judgment, at Exhibit 40, *Ill. Union Ins. Co. v. Intuitive Surgical Inc.*, No. 13-4863 (N.D. Cal. Apr. 6, 2016) (ECF No. 146-29) ("tolling agreements as early as November of 2012"); [redacted]

Warning Letter issued to Intuitive, and (ii) the health risks and design defects in the da Vinci device, that posed previously unknown safety concerns for the public.

215. When Defendants' prior materially false and misleading statements and omissions began to be disclosed and became known to the market, the price of Intuitive common stock declined precipitously as the prior artificial inflation was removed from the price of Intuitive common stock. As a result of their purchases of Intuitive common stock at artificially inflated prices during the Class Period, Plaintiffs and other members of the Class suffered a substantial economic loss (*i.e.*, damages under the federal securities laws) as the truth was revealed. For purposes of alleging loss causation, the price decline in Intuitive common stock, as detailed herein, was a direct result of the nature and extent of materially false and misleading statements and omissions revealed to investors and the market, as follows:

216. **On February 28, 2013**, five minutes before the market closed, *Bloomberg* reported that a U.S. regulator had initiated a probe over the safety of Intuitive's products. According to *Bloomberg*, a regulator had commenced a survey of surgeons asking them to list any complications they may have seen with Intuitive's robots, causing the stock price to immediately drop by more than 10%. As reported by *MarketWatch* on the same day, Intuitive shares "plunged more than 11%, or $63.63 a share, in the final five minutes of trading Thursday, just as a news report circulated saying the company's devices were under federal scrutiny. *Bloomberg News* issued the two-paragraph report right before the close, saying that an unidentified U.S. regulatory body was looking into whether Intuitive Surgical's robotic devices were causing any complications for surgeons."

(a) Commenting on the FDA probe, Michael Matson, an analyst with Mizuho Securities in New York, said that a rise in adverse event reports caused concern that "patients would get scared." "Part of what's driven this market is people seeking out robotic surgery – hospitals market it and the patients seem to think it's better," he added.[160] Matson then

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[160] Bloomberg, *Intuitive Surgical Robots Probed by U.S. in Surgeon Survey* (2), February 28, 2013, released at 18:14.

concluded that Intuitive's stock was likely going to remain under pressure until the Company could prove that the safety worries were not significant. *Id.*

(b) Intuitive's common stock closing price fell from $573.52 on February 27, 2013 to $509.89 on February 28, 2013. Trading volume exceeded 900,000 shares, more than five times the prior day's volume of just over 168,000, and more than double the average daily Class Period trading volume of approximately 400,000 shares.

217. **On March 5, 2013**, another *Bloomberg* article entitled "Robosurgery Suits Detail Injuries as Death Reports Rise" reported that incident reports sent to U.S. regulators linked the da Vinci to at least 70 deaths since 2009. The report lent credence to the allegations of product liability suits pending against the Company, in particular that complications during robotic surgery caused serious injuries and, in some cases, death. Moreover, the article quoted a surgeon at John Hopkins Hospital in Baltimore, Martin Makary, saying that he was concerned that some complaints may not have been reaching the public because they were being kept quiet by hospitals, which often had been using the machines as a draw to gain additional customers. "No one knows the numbers now," said Makary. According to the *Bloomberg* article, at least one product-liability lawsuit pending against Intuitive at the time alleged that da Vinci instruments had insufficient insulation, which resulted in electrical burns. The report also noted that as the number of robotic surgery procedures increased, injury reports involving da Vinci had increased from 24 in 2009 to at least 115 in 2012.

(a) On the same day, an analyst at Janney Capital Markets issued a report detailing Intuitive shares being under pressure as a result of "business journal articles continue[ing] to harp on potential safety concerns on da Vinci."

(b) Intuitive's share price dropped $22.78, approximately 3%, from a closing price of $541.32 on March 4, 2013 to a closing price of $525.72 on March 5, 2013. Trading volume almost doubled from the prior day, as it exceeded one million shares, more than double the average daily Class Period trading volume of approximately 400,000 shares.

218. **On April 18, 2013**, Intuitive reported its 1Q 2013 financial results after the market closed. Intuitive reported procedure growth of 18%, below consensus expectations of 21%, and guided total 2013 procedure growth to the lower end of its range.

(a) Analysts focused on the news concerning weak procedure growth in the first quarter of 2013. As part of Leerink Swann's April 19th analyst report titled, "Solid 1Q Beat Overshadowed by Light Procedure Growth," analyst Richard Newitter reported, "light procedures and a more cautious 2013 procedure outlook could overshadow the strong 1Q performance—especially given recent negative press/journal articles/lawsuit attention that, in our view, have heightened investor sensitivity around da Vinci's utilization." In reports dated April 19, 2013, other analysts also attributed the troubling lack of procedure growth to the recent "negative press," including Janney Capital Markets and Suntrust Robinson Humphrey.

(b) *Bloomberg Businessweek* issued a *headline* on April 19, 2013 stating that, "Intuitive Surgical Slumps on da Vinci Growth." The article reported that "Shares of Intuitive Surgical Inc. slumped Friday [April 19] after the company reported slower growth than expected in surgical procedures performed with its da Vinci robotic system."

(c) Intuitive's common stock fell by $8.62, approximately 3%, from a closing price of $493.37 on April 18, 2013 to a closing price of $484.75 on April 19, on trading volume exceeding 1.5 million shares, approximately double the prior day's trading volume, almost four times the average daily Class Period trading volume of approximately 400,000 shares.

219. **On July 8, 2013**, Intuitive reported preliminary 2Q 2013 financial results after the market closed. Intuitive's preliminary Q2 2013 results fell well below expectations, reflected in part by weaker-than-expected da Vinci system sales. Intuitive's announced revenue of $575 million was far short of the Street's $629.6 million projection and analysts' estimates of growth.

(a) The new revelations about the financial results were described by *Bloomberg* as leading to the largest single day stock price decline "since 2008 after reporting preliminary results that missed analysts' estimates as sales slowed for its surgical robots, which

have faced safety and cost-efficiency questions." According to *Bloomberg*, the results caused at least four analysts to initiate downgrades, including Raymond James, JMP Securities, Goldman Sachs and Canaccord Genuity.[161]

(b) Analyst reports reflected surprise at the unexpected nature of the magnitude of the decline. JP Morgan's report of July 8 called it "shocking": "The severity of the top line [revenue] shortfall, with the company posting revenues of $575M vs. consensus of $630 million [$622M JP Morgan] was shocking, and raises more questions than answers."

(c) Other analysts remained skeptical that the severe decline was due to economic factors and hospitals cutting capital expenditures, such as the purchase of da Vinci systems. According to Morgan Stanley's July 17, 2013 report: "We are less convinced a material change in the US CapEx [capital expenditure] environment explains the system shortfall in the quarter. Our Q1 and Q2 surveys showed a declining interest in robotics and hesitance to purchase a da Vinci despite a stable broader CapEx environment." Customers were simply not buying da Vinci, and one of the reasons was the "safety of robotic surgery," as Morgan Stanley explained in a subsection entitled, "A Review of Recent Pressures on da Vinci Procedures."

(d) Similar views were expressed by Canaccord Genuity's report dated July 9, 2013, and entitled "Q2 Results Deviate Disconcertingly From Trend Line; Downgrade To Hold." The Canaccord analysts reported second quarter "results usurped our most bearish scenario; represented ISRG's worst system performance (-6% [year over year]) since the height of the financial crisis in [Q3 2009]; and most notably, exhibited a significant deviation from historic growth trends – ISRG had reported system sales growth >15% for 9 consecutive quarters."

(e) Canaccord also no longer viewed the negative results as cyclical or due to external factors, but systemic. "What's more, the factors cited by ISRG for the systems miss strike us as more systemic than isolated, thus could take longer to resolve, in our estimation."

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[161] Bloomberg, *Intuitive Surgical Falls on da Vinci's Robot's Drop in Sales* (2), July 9, 2013, issued at 16:36.

Canaccord then noted that in the second quarter press release Intuitive had blamed "economic pressures on hospitals which led to some deferred system purchases." Like Morgan Stanley, Canaccord remained skeptical. "This [the claim that hospitals had cut back] comes just three months after the company reported Q1/13 system sales that were quite strong (+24% Y/Y), making the magnitude and speed with which this negative deviation from historical placement growth trends unprecedented in the company's history….We expect management to provide greater clarity on the factors impacting sales during Q2 conference call on July 18, but for now we are left with many more questions than answers."

(f) The media was also skeptical about the Company's stated reasons for the slowed da Vinci sales. On July 9th, in response to Company statements claiming that the decline in U.S. system sales was due to reduced hospital budgets, *Benzinga* reported that,

> [w]hat the company failed to mention were the lawsuits filed where patients alleged they were injured during surgeries with the device. It also failed to mention that U.S. regulators were surveying surgeons about the use of the system after 70 deaths were reported since 2009 and a rise in adverse events was reported in conjunction with the system.
>
> Then there are doctors who question the need for the machine. Robotic surgery costs significantly more than traditional surgeries and doctors point out that there is a lack of large-scales studies to prove the benefits of the system.
>
> **All of this** has caused the stock to plummet more than 17 percent in early morning trading Thursday and 30 percent since late January.[162]

(g) On July 9, 2013, in response to the negative news, Intuitive's share price dropped $80.78, or almost 20%, from a closing price of $500.08 on July 8, 2013, to a closing price of $419.30 on July 9, 2013. Trading volume in excess of 5.5 million shares was the largest figure in almost four years (since July 23, 2009) and was almost 14 times the prior day's volume of just over 400,000 shares, also almost 14 times the average daily Class Period trading volume of approximately 400,000 shares.

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[162] *Benzinga*, "Intuitive Surgical Plunging after Negative Pre-Announcement (ISRG)" 2013 WLNR 16668188 (July 9, 2013). *Benzinga* is an internet based financial media outlet. www.benzinga.com.

220. **On July 18, 2013**, after the market close, Intuitive reported 2Q 2013 financial results consistent with its July 8, 2013 pre-announcement and also disclosed an FDA Warning Letter received as a result of an FDA onsite audit of the Company conducted during the quarter and related to observations in a Form 483.

(a) Analysts focused on the reporting of the FDA Warning Letter and its ramifications. On July 19th, Morningstar reported that the FDA warning letter, combined with the pending litigation and claims of inadequate surgeon training "holds the potential to disrupt the company's operations." JP Morgan characterized the confluence of events resulting in the FDA Warning Letter as a "Perfect Storm" in its July 19 report. Likewise, on the same day, Trefis issued an analyst report reporting that the "company was dealt another blow in the form of a FDA warning letter, which could hinder approval of new products/procedures going forward." Trefis added: "[t]he warning letter from the FDA will only worsen conditions as it will make it harder for the company to sell the system."

(b) Media reports also attributed Intuitive's immediate common stock price drop to the FDA Warning Letter. For example, on July 19th, the MotleyFool reported "it wasn't the numbers that sent Intuitive's stock nuclear on Thursday after the closing bell. The FDA has picked and prodded at the robotic surgical device maker for some time, but regulators' investigations came to a big climax that culminated in a gut-wrenching one-two punch for investors." The article further warned that "the slump in system sales means that the increasing talk regarding safety and legal issues at the company are catching up to Intuitive's financials – and investors. Thursday's warning [letter] by the FDA may only exacerbate that trend."

(c) On the same day, a subsequent *Bloomberg* article, "Intuitive Reeling as FDA Cites Lack of Visibility on Problems," reported: "Intuitive … has lost about $6 billion in value over five months after disclosures about adverse events with its products, a recent recall, and now, a regulatory warning it hasn't adequately reported on issues concerning the devices." In addition, a "review of Food and Drug Administration records now shows the reports of

injuries involving robot procedures have doubled in the first six months of 2013, compared with a year earlier."

(d) Intuitive's common stock price fell by $28.80 per share, approximately 7%, from a closing price of $421.47 on July 17, 2013 to a closing price of $392.67 on July 19, 2013. Trading volume exceeded 4.6 million shares, which was 6 times the prior day's volume, almost 12 times average daily Class Period trading volume of approximately 400,000 shares.

(e) *Bloomberg*'s headline on July 20 said it all: "Intuitive Surgical Declines On Warning Letter From FDA." The article focused on Intuitive's FDA reporting violations: "FDA inspections in April and May found a number of deficiencies, **including that the [Sunnyvale, California-based] company in some cases hadn't adequately reported device corrections and patient adverse events**."

221. An article published in *Seeking Alpha* on October 6, 2013, and entitled "Wait For The Next Shoe To Drop Before Buying Intuitive Surgical," succinctly summed up the impact of the FDA regulatory actions on Intuitive's common stock price:

> Intuitive Surgical (ISRG), the dominant manufacturer of robotic surgical devices, has had a difficult 2013 and its troubles may continue. . . . **ISRG's woes are directly and almost exclusively due to the** Food and Drug Administration ("FDA") **warning letter and the related investigation into the efficacy, safety and use of the company's "da Vinci" surgical robot**, which the company disclosed last quarter.
>
> . . . the **company's development shall be stunted until the conclusion of FDA scrutiny. Hospitals will refrain from purchasing new da Vinci robots**, whether or not they want or can afford them, while this overhanging regulatory concern persists.
>
> **Hospital** administrators are effectively handcuffed, which will **restrict ISRG's near-term growth rates**.

222. Each of the declines discussed above in the Company's common stock price was statistically significant at a high level after taking into account changes on the same days in the overall securities market and in relevant industry indices. Furthermore, as set forth above, each of the price declines in Intuitive common stock is attributable to the disclosure of previously concealed information relating to the materially false and misleading statements and omissions alleged herein. The timing and magnitude of Intuitive's common stock price declines negate any

inference that the losses suffered by Plaintiffs and other Class members were caused by other changed market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to Defendants' fraudulent conduct. As the truth about Defendants' fraud was revealed, the Company's common stock price declined, the artificial inflation came out of the price of the common stock, and Plaintiffs and other members of the Class suffered damages.

VII. DEFENDANTS MADE MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

223. Throughout the Class Period Defendants made materially false and misleading statements and omissions about the safety of da Vinci and Intuitive's compliance with FDA regulations. These statements and omissions were false and misleading because they failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, (b) deficient design control processes, and (c) reportable field actions, including the October 2011 recall letters; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death; (iii) additional unreported complaints; and (iv) the growing number and nature of products liability claims (including tolling agreements) brought against the Company during the Class Period. These false and misleading statements and omissions thereby concealed the severity and likelihood of the risks to health posed by da Vinci. The ultimate public disclosure of the true severity and likelihood of the risks to health had a negative and material impact in procedure growth, the financial results, and the Company's stock price.

A. Defendants Made Materially False and Misleading Statements and Omissions That Concealed Dangerous da Vinci Defects and Performance Problems in Violation of FDA Regulations

1. Intuitive's February 6, 2012 Form 10-K Annual Report (Ending December 31, 2011)

224. On February 6, 2012, Intuitive filed its Form 10-K for the year ending December 31, 2011 (the "2011 Form 10-K"), Defendants stated:

(a) "[w]e believe that this new generation of surgery, which we call da Vinci Surgery, combines the benefits of minimally invasive surgery (MIS) for patients with the ease of use, precision and dexterity of open surgery;" and

(b) "The ***da Vinci Surgical System enables surgeons to extend the benefits of MIS*** to many patients typically receiving open surgery by using computational, robotic and imaging technologies to overcome many of the limitations of conventional minimally invasive surgery."

225. In touting the benefits of the "da Vinci Surgical System," Defendants concealed that far from "extend[ing] the benefits of MIS," da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects resulting in:

(a) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci (¶¶ 60-66);

(b) the filing of at least 508 MDRs in 2011 and receipt of tens of thousands of complaints including (i) complaints reporting material health risks to patients as a result of da Vinci, (ii) ten death-related reports, and (iii) a material increase in device malfunction MDRs in 2012-2014 compared to prior years (¶¶ 91-111); and

(c) at least four personal injury and/or product liability lawsuits filed against Intuitive between March 18, 2010 and December 31, 2011 (¶¶ 79-80).

226. Defendants also failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, and (b) deficient design control processes; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death;

(iii) additional unreported complaints; and (iv) the growing number and nature of products liability claims brought against the Company during the Class Period.

2. Intuitive's April 19, 2012 Form 10-Q (Ending March 31, 2012)

227. On April 19, 2012, Intuitive filed its first quarter Form 10-Q for the period ending March 31, 2012 (the "1Q12 Form 10-Q"), which detailed that da Vinci surgery represents "a new generation of surgery" that "combines the ***benefits*** of minimally invasive surgery (MIS) for patients with the ease of use, precision and dexterity of open surgery."

228. In touting the benefits of the "da Vinci Surgical System," Defendants concealed that far from "extend[ing] the benefits of MIS," da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects resulting in:

(a) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci (¶¶ 60-66);

(b) the filing of a substantial number of MDRs and receipt of tens of thousands of complaints including (i) complaints reporting material health risks to patients as a result of da Vinci, (ii) eight death-related reports in the three month period between December 31, 2011 and March 31, 2012, and (iii) a material increase in device malfunction MDRs in 2012-2014 compared to prior years (¶¶ 91-111); and

(c) at least five personal injury and/or product liability lawsuits filed against Intuitive between March 18, 2010 and March 31, 2012 (¶¶ 78-80).

229. Defendants also failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, and (b) deficient design control processes; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death; (iii) additional unreported complaints; and (iv) the growing number and nature of products liability claims brought against the Company during the Class Period.

3. Intuitive's July 23, 2012 Form 10-Q (Ending June 30, 2012)

230. On July 23, 2012, Intuitive filed its second quarter Form 10-Q for the period ending June 30, 2012 (the "2Q12 Form 10-Q"). In the 2Q12 Form 10-Q Defendants repeated the representations from Intuitive's 1Q12 Form 10-Q, set forth *supra* in paragraph 227, describing, *inter alia*, the da Vinci as a "a new generation of surgery" which "combines the **benefits** of [MIS]" with those of open surgery.

231. In touting the benefits of "da Vinci Surgery," Defendants concealed that far from "combin[ing] the benefits of [MIS]" (including shorter recovery times and fewer complications) with those of open surgery, da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects present in da Vinci, resulting in:

(a) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci (¶¶ 60-66);

(b) the filing of a substantial number of MDRs and receipt of tens of thousands of complaints including (i) complaints reporting material health risks to patients as a result of da Vinci, (ii) 11 death-related reports in the three months between March 31, 2012 and June 30, 2012; and (iii) a material increase in device malfunction MDRs in 2012-2014 compared to prior years (¶¶ 91-111); and

(c) at least eight personal injury and/or product liability lawsuits against Intuitive filed between March 18, 2010 and June 30, 2012, at least three of which allege injuries associated with Microcracks/insufficient insulation - Monopolar current (¶¶ 78-80).

232. Defendants also failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, and (b) deficient design control processes; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death; (iii) additional unreported complaints; and (iv) the growing number and nature of products liability claims brought against the Company during the Class Period.

4. Intuitive's October 18, 2012 Form 10-Q (Ending September 30, 2012)

233. On October 18, 2012, Intuitive filed its third quarter Form 10-Q for the period ending September 30, 2012 (the "3Q12 Form 10-Q"). In the 3Q12 Form 10-Q, Intuitive made the same representations set forth *supra* in paragraph 227 describing da Vinci as a "a new generation of surgery" which "combines the benefits of [MIS]" with those of open surgery.

234. In touting the benefits of "da Vinci Surgery," Defendants concealed that far from "combin[ing] the benefits of [MIS]" (including shorter recovery times and fewer complications) with those of open surgery, da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects present in da Vinci, resulting in:

(a) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci (¶¶ 60-66);

(b) the filing of a substantial number of MDRs and receipt of tens of thousands of complaints including (i) complaints reporting material health risks to patients as a result of da Vinci, (ii) six death-related reports in the three months between June 30, 2012 and September 30, 2012 and (iii) a material increase in device malfunction MDRs in 2012-2014 compared to prior years (¶¶ 91-111); and

(c) the filing of at least **12** personal injury and/or product liability lawsuits against Intuitive between March 18, 2010 to September 30, 2012, five of which alleged injuries associated with Microcracks/insufficient insulation - Monopolar current (¶¶ 78-80).

235. Defendants also failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, and (b) deficient design control processes; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death; (iii) additional unreported complaints; and (iv) the growing number and nature of products liability claims (including tolling agreements) brought against the Company during the Class Period.

5. February 4, 2013 Form 10-K Annual Report (Ending December 31, 2012)

236. On February 4, 2013, Intuitive filed its Form 10-K for the year ending December 31, 2012 (the "2012 Form 10-K"). In its 2012 Form 10-K, Intuitive repeated the representations in paragraphs 224 and 224(a) calling the "da Vinci Surgical Systems . . . a new generation of surgery" and touting it as "combin[ing] the benefits of minimally invasive surgery ("MIS") for patients with the ease of use, precision and dexterity of open surgery." Intuitive further represented that "[o]ver the past two decades, **MIS ha[d] reduced trauma to the patient** by allowing selected surgeries to be performed through small ports rather than large incisions, often **resulting in shorter recovery times, fewer complications** and reduced hospitalization costs."

237. In touting the benefits of the "da Vinci Surgical System," Defendants concealed that far from "extend[ing] the benefits of MIS" (including shorter recovery times and fewer complications), da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects, resulting in:

(a) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci (¶¶ 60-66);

(b) the filing of at least 1,597 MDRs in 2012 and receipt of tens of thousands of complaints including (i) complaints reporting material health risks to patients as a result of da Vinci, (ii) 32 death-related reports, being filed in 2012 related to da Vinci, reflecting a disproportionate 214 percent increase from 2011, and (iii) a material increase in device malfunction MDRs in 2012-2014 compared to prior years (¶¶ 91-111); and

(c) the filing of at least 14 personal injury and/or product liability lawsuits filed against Intuitive between March 18, 2010 and December 31, 2012, half of which alleged injuries associated with Microcracks/insufficient insulation – Monopolar current (¶¶ 78-80); and

(d) the FDA commencing a safety probe in January 2013 in response to the increase in number of da Vinci-related MDR reports (¶¶ 112-115).

238. Defendants also failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, and (b) deficient

design control processes; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death; (iii) additional unreported complaints; (iv) that Intuitive had engaged in a massive project to enter into undisclosed tolling agreements with hundreds of injured patients beginning in early December 2012. The number of tolled claims continued to grow throughout the winter and spring of 2013, reaching 328 tolled claims by January 31, 2013;[163] and (v) Intuitive also had commenced confidential mass mediation efforts with injured patients to make sure that details concerning tip cover related injuries and deaths were not publicly reported or detailed in litigation complaints. This was yet another attempt to conceal the apparent danger associated with the da Vinci surgical system, and evade the related consequences of increased injuries and litigation from the market.

6. Defendants' March 13, 2013 Press Release

239. The March 13 Press Release stated: "[i]n response to general inquiries regarding a recent rise in Medical Device Reports (MDR) filed by Intuitive Surgical, the company explained that the noted rise [did] not reflect a change in product performance but rather a change in MDR reporting practices." Intuitive further characterized the change in reporting practices as an "administrative change in how MDRs previously reported as adverse events were subcategorized. This change has not increased the total number of adverse event reports. This will result in an increase in events in the 'serious injury' subcategory and a corresponding decrease in the 'other' subcategory. Total adverse event rates have remained low and in line with historical trends."

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[163] *See, e.g.* Order Denying Partial Summary Judgment, *Illinois Union Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-4863 (N.D. Cal. May 27, 2016) (ECF No. 178); [redacted] (IRONSHORE0006760-78); [redacted]

240. Intuitive's statements were materially false and misleading because they failed to disclose that:

(a) Defendants had been aware of issues with Intuitive's MDR reporting for device malfunctions that posed a risk of injury to patients for at least 18 months prior to the issuance of the March 13 Press Release.

(b) [redacted]

(c) [redacted]

(d) In 2012 there had been a 214% increase in MDRs related to product performance compared to 2011, which exceeded "historical trends" and the increasing use of the da Vinci products; and

(e) that this increase in MDRs had caused the FDA to initiate a safety probe to find the root cause for the increase and evaluate da Vinci product performance.

7. Intuitive's April 18, 2013 Form 8-K and Earnings Call

241. On April 18, 2013, Intuitive filed with the SEC a Form 8-K attaching a press release announcing the Company's Q1 2013 financial results (the "April 18th Press Release"). In the release, Guthart commented: "Despite a concerted effort by vocal critics of robotic surgery, support remains strong among patients, surgeons and hospitals. . . . da Vinci Surgery has clinically proven benefits in offering a minimally invasive option to a broader group of patients than traditional technologies."

242. During Intuitive's April 18, 2013 earnings conference call (the "April 18th Earnings Call"), Defendant Guthart stated:

(a) "As you know, we are in the midst of a concerted effort by critics of robotic surgery to challenge the benefit it brings to patients…[w]e are confident that those who invest their time in a serious review of the clinical literature on da Vinci will find ample evidence of the benefit it brings to patients, surgeons, hospitals and the medical community at large."

(b) Defendant Guthart further stated that "**da Vinci surgery has proven safety, efficacy, economic and ergonomic benefits** when compared to the open surgical procedures it is replacing."

243. Defendant Guthart's statements were materially false and misleading because they denied the validity of the safety issues even though Defendants knew and failed to disclose that da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects, resulting in:

(a) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci (¶¶ 60-66);

(b) the filing of a substantial number of MDRs and receipt of tens of thousands of complaints including (i) complaints reporting material health risks to patients as a result of da Vinci, (ii) an increase in death-related reports related to da Vinci, and (iii) a material increase in device malfunction MDRs in 2012-2014 compared to prior years (¶¶ 91-111);

(c) the filing of at least 16 personal injury and/or product liability lawsuits had been filed against Intuitive between March 18, 2010 and April 18, 2013, nine of which alleged injuries associated with Microcracks/insufficient insulation – Monopolar current (¶¶ 78-80);

(d) the FDA commencing an inspection of Intuitive's facilities on April 1, 2013 during which numerous safety related violations were found (¶¶ 123-129);

(e) 864 undisclosed tolled claims by late March 2013;[164] and

(f) [redacted] This was yet another attempt to conceal the apparent danger associated with the da Vinci surgical system, and evade the related consequences of increased injuries and litigation from the market.

244. Defendants also failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, and (b) deficient design control processes; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death; (iii) additional unreported complaints.

8. Intuitive's April 19, 2013 Form 10-Q (Ending March 31, 2013)

245. On April 19, 2013, Intuitive filed its first quarter 2013 form 10-Q for the period ending March 31, 2013 (the "1Q13 Form 10-Q"). In the 1Q13 Form 10-Q, Intuitive,

(a) repeated the representations in Intuitive's 3Q12 Form 10-Q, set forth *supra* in paragraph 227, describing da Vinci as a "a new generation of surgery" and touting its advantages of combining the benefits of both open surgery and MIS; and

(b) reported that "during the first quarter of 2013, there have been articles published and papers written questioning patient safety and efficacy associated with da Vinci Surgery…We believe that **da Vinci Surgery continues to be a safe and effective surgical method**…"

246. The 1Q 2013 Form 10-Q representations were materially false and misleading because Defendants knew and failed to disclose that da Vinci was causing serious patient injuries and deaths as a direct result of performance problems and dangerous defects, resulting in:

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[164] *See, e.g.* Order Denying Partial Summary Judgment, *Illinois Union Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-4863 (N.D. Cal. May 27, 2016) (ECF No. 178); [redacted] (IRONSHORE0006760-78); [redacted]

(a) Intuitive instituting three secret recalls in October 2011 to reduce risks to health posed by da Vinci (¶¶ 60-66);

(b) the filing of a substantial number of MDRs and receipt of tens of thousands of complaints including (i) complaints reporting material health risks to patients as a result of da Vinci, (ii) an increase in death-related reports related to da Vinci, and (iii) a material increase in device malfunction MDRs in 2012-2014 compared to prior years (¶¶ 91-111); and

(c) the filing of at least 16 personal injury and/or product liability lawsuits had been filed against Intuitive between March 18, 2010 and April 18, 2013, nine of which alleged injuries associated with Microcracks/insufficient insulation – Monopolar current (¶¶ 78-80);

(d) the FDA commencing an inspection of Intuitive's facilities on April 1, 2013 during which numerous safety related violations were found (¶¶ 123-129);

(e) 864 undisclosed tolled claims by late March 2013;[165] and

(f) [redacted] This was yet another attempt to conceal the apparent danger associated with the da Vinci surgical system, and evade the related consequences of increased injuries and litigation from the market.

247. Defendants also failed to disclose: (i) Intuitive's failure to comply with FDA regulations, including: (a) the failure to properly classify and report MDRs, and (b) deficient design control processes; (ii) long-standing defects and performance problems in da Vinci instruments and accessories which resulted in injury and death or the risk of injury and death; (iii) additional unreported complaints.

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[165] *See, e.g.* Order Denying Partial Summary Judgment, *Illinois Union Ins. Co. v. Intuitive Surgical, Inc.*, No. 13-cv-4863 (N.D. Cal. May 27, 2016) (ECF No. 178); [redacted] (IRONSHORE0006760-78); [redacted]

VIII. CLASS ACTION ALLEGATIONS

248. Plaintiffs brings this action on behalf of themselves and as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3), consisting of all persons and entities who purchased or acquired the publicly traded common stock of Intuitive Surgical, Inc. during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are (i) Defendants Intuitive, Gary S. Guthart ("Guthart"), Marshall L. Mohr ("Mohr"), and Lonnie M. Smith ("Smith") (collectively, "Defendants"); (ii) members of the immediate families of Guthart, Mohr, and Smith; (iii) any subsidiaries and affiliates of Defendants; (iv) any person who is or was an officer or director of Intuitive or any of Intuitive's subsidiaries or affiliates; (v) Defendants' directors' and officers' liability insurance carriers, and any affiliates or subsidiaries thereof; (vi) Intuitive's employee retirement and benefit plan(s); and (vii) the legal representatives, heirs, successors and assigns of any such excluded person or entity.

249. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Intuitive stock was actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Intuitive or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

250. Plaintiffs' claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law complained of herein.

251. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation. Plaintiffs have no interests that are adverse or antagonistic to the Class.

252. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) Whether the SEC filings, press releases, reports and other public statements disseminated to Intuitive's investors during the Class Period contained materially false and misleading statements or omissions;

(c) Whether and to what extent the market price of the Company's common stock was artificially inflated during the Class Period due to the non-disclosures and/or false and misleading statements complained of herein;

(d) Whether Defendants acted with scienter;

(e) Whether reliance may be presumed pursuant to the fraud-on-the-market doctrine; and

(f) Whether the members of the Class have sustained damages as a result of the misconduct complained of herein, and, if so, the proper measure thereof.

253. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this case as a class action.

IX. PLAINTIFFS ARE ENTITLED TO A PRESUMPTION OF RELIANCE

254. Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute v. United States*, 406 U.S. 128 (1972), because the claims asserted herein against Defendants are primarily predicated upon omissions of material fact for which there was a duty to disclose.

255. Plaintiffs are also entitled to a presumption of reliance under the fraud on the market doctrine on Defendants' material misrepresentations and omissions for the following reasons:

- Intuitive's common stock was actively traded in an efficient market on NASDAQ during the Class Period;
- As a regulated issuer, Intuitive filed periodic public reports with the SEC;
- Intuitive regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services;
- The market reacted promptly to public information disseminated by Intuitive;
- Intuitive was covered by numerous securities analysts employed by major brokerage firms who wrote reports which were distributed to the sales force and certain customers of their respective firms. Each of these reports was publicly available and entered the public marketplace; and
- Without knowledge of the misrepresented or omitted material facts alleged herein, Plaintiffs and other members of the Class purchased Intuitive stock between the time Defendants failed to disclose material facts and the time the true facts were disclosed.

256. In addition to the foregoing, Plaintiffs are entitled to a presumption of reliance because, as more fully alleged above, Defendants failed to disclose material information regarding da Vinci's defects throughout the Class Period.

X. THE SAFE HARBOR PROVISION IS INAPPLICABLE

257. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to the allegedly false statements pled in this complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and circumstances. To the extent certain of the statements alleged to be false and misleading may be characterized as forward-looking, they were not adequately identified as "forward-looking" statements when made, and were not accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor is intended to apply to any forward-looking statements pled herein, Defendants are liable for those false and misleading forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false and misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of Intuitive who knew that those statements were false and misleading when made.

XI. CAUSES OF ACTION

FIRST CAUSE OF ACTION

For Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

258. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

259. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate and maintain inflated the market price of Intuitive common stock; and (iii) cause Plaintiffs and other Class members to purchase Intuitive common stock at artificially inflated prices.

260. In furtherance of this unlawful scheme, plan and course of conduct, Defendants took the actions set forth herein. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain artificially high market prices for Intuitive's common stock in violation of §10(b) of the Exchange Act and SEC Rule 10b-5. All of the Individual Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

261. Defendants, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about da Vinci's defects, Intuitive's corrective action related to those defects, and the Company's failure to comply with applicable disclosure and reporting laws and regulations.

262. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to falsely and misleadingly assure investors of da Vinci's safety and continued substantial growth, which included the making of, or the participation in making of, untrue statements of material fact and omitting to state material facts necessary in order to make the statements made about da Vinci and Intuitive's compliance with applicable disclosure and reporting laws and regulations, in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of Intuitive common stock during the Class Period.

263. Defendants' Guthart, Mohr, and Smith's primary liability, and controlling person liability as set forth in Count II, arises from the following facts: (i) they were each senior executives and/or directors during the Class Period and members of the Company's management

team or had control thereof; (ii) each of these Defendants, by virtue of his responsibilities and activities as a high-level executive and/or director of the Company, was privy to and participated in the creation, development, and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these Defendants was advised of, and had access to, other members of the Company's management team, internal reports, and other data and information about da Vinci and Intuitive's compliance with applicable disclosure and reporting laws and regulations; and (iv) each of these Defendants was aware of the Company's concealment of information from the investing public, which they knew or recklessly disregarded was materially false and misleading.

264. Defendant Guthart signed and certified Intuitive's materially false and misleading Forms 10-K for fiscal 2011 and 2012, and certified the Company's materially false and misleading Forms 10-Q for the quarterly periods ending March 31, 2012, June 30, 2012, September 30, 2012, and March 31, 2013. Defendant Guthart also made materially false and misleading statements and omissions on Intuitive Earnings Calls on April 17, 2012, July 19, 2012, October 16, 2012, January 22, 2013, and April 18, 2013. Further, Defendant Guthart made materially false and misleading statements and omissions in the April 17, 2012, July 19, 2012, October 16, 2012, January 22, 2013, and April 18, 2013 Forms 8-K.

265. Defendant Mohr signed and certified Intuitive's materially false and misleading Forms 10-K for fiscal 2011 and 2012, as well as its materially false and misleading Forms 10-Q for the quarterly periods ending March 31, 2012, June 30, 2012, September 30, 2012, and March 31, 2013. Defendant Mohr also signed Intuitive's materially false and misleading Forms 8-K filed on April 17, 2012, July 19, 2012, October 16, 2012, January 22, 2013, March 14, 2013, and April 18, 2013. Defendant Mohr also made materially false and misleading omissions during the Earnings Calls on July 19, 2012, October 16, 2012, January 22, 2013, and April 18, 2013.

266. Defendant Smith signed Intuitive's materially false and misleading Forms 10-K for fiscal 2011 and 2012.

267. In addition to the duties of full disclosure imposed on Defendants as a result of making affirmative statements and reports, or participation in the making of affirmative statements and reports to the investing public, they had a duty to promptly disseminate truthful information that would be material to investors, including truthful, complete and accurate information with respect to the Company's operations and performance so that the market prices of the common stock would be based on truthful, complete and accurate information.

268. Defendants had actual knowledge of the false and misleading statements and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and disclose such facts, even though such facts were available to them. Defendants' materially false and misleading statements and omissions were done knowingly or recklessly and for the purpose and effect of concealing Intuitive's true financial condition from the investing public and supporting the artificially inflated price of its common stock. As demonstrated by Defendants' materially false and misleading statements and omissions about da Vinci and Intuitive's compliance with applicable disclosure and reporting laws and regulations, Intuitive and the Individual Defendants, if they did not have actual knowledge of the materially false and misleading statements and omissions alleged, were reckless in failing to discover such materially false and misleading statements and omissions by deliberately refraining from taking those steps necessary to discover the facts concealed.

269. As a result of the materially false and misleading statements and omissions, as set forth above, the market price of Intuitive's common stock was artificially inflated during the Class Period. Unaware that the market price of Intuitive common stock was artificially inflated, and relying directly or indirectly on the materially false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock traded, and/or on the absence of material adverse information that was known to, or recklessly disregarded by, Defendants but not disclosed publicly during the Class Period, Plaintiffs and the other members of the Class purchased or otherwise acquired Intuitive common stock during the Class Period at artificially inflated prices and were damaged thereby.

270. At the time of said omissions, Plaintiffs and other members of the Class were unaware of the concealed information. Had Plaintiffs and the other members of the Class and the marketplace known the truth regarding da Vinci and Intuitive's compliance with applicable disclosure and reporting laws and regulations, Plaintiffs and other members of the Class would not have purchased or otherwise acquired Intuitive common stock, or, if they had acquired such stock during the Class Period, they would not have done so at the artificially inflated prices which they paid.

271. By virtue of the foregoing, Defendants have violated §10(b) of the Exchange Act, and Rule 10b-5 promulgated thereunder.

272. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's common stock during the Class Period.

SECOND CAUSE OF ACTION

For Violation of Section 20(a) of the Exchange Act Against Defendants Guthart, Mohr, and Smith

273. Plaintiffs repeat and reallege each and every allegation contained above as if fully set forth herein.

274. Defendants Guthart, Mohr, and Smith acted as controlling persons of Intuitive within the meaning of §20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions, and their ownership and contractual rights, substantial participation in and/or awareness of the Company's operations and/or intimate knowledge of the materially false and misleading financial statements filed by the Company with the SEC and disseminated to the investing public, these Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including its omissions, which Plaintiffs contend were materially false and misleading. These Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings and other statements alleged by Plaintiffs to be materially false and

misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

275. In particular, Guthart, Mohr, and Smith each had direct and supervisory involvement in the day-to-day operations of the Company, particularly with respect to da Vinci, the Company's sole product, and, therefore, are presumed to have had the power to control or influence the particular false and misleading statements and omissions giving rise to the securities violations alleged herein.

276. As set forth above, Intuitive violated §10(b) and Rule 10b-5 by the acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act. As a direct and proximate result of Intuitive's wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

THIRD CAUSE OF ACTION

For Violation of Section 20A of the Exchange Act on Behalf of Plaintiffs

277. Plaintiffs repeat and re-allege each and every allegation contained above as if fully set forth herein.

278. This claim is asserted against Defendants Guthart, Mohr, and Smith and is brought on behalf of Plaintiffs and members of the Class who purchased Intuitive common stock contemporaneously with the Individual Defendants and who sold Intuitive common stock at inflated prices during the Class Period.

279. On November 20, 2012, Hawaii ERS purchased 11,867 shares of Intuitive common stock. On that same date, while in possession of material, adverse nonpublic information, Defendant Smith sold 23,949 shares of Intuitive common stock.

280. On November 26, 2012, Hawaii ERS purchased 6,000 shares of Intuitive common stock. On that same date, while in possession of material, adverse nonpublic information, Defendant Smith sold 21,164 shares of Intuitive common stock.

281. On January 25, 2013, while in possession of material, adverse nonpublic information, Defendant Guthart sold 4,500 shares of Intuitive common stock. One trading day later, on January 28, 2013, Defendant Mohr, while also in possession of material, adverse nonpublic information, sold 8,000 shares of Intuitive common stock. On January 29, 2013, merely two trading days after Defendant Guthart's sale and only one day after Defendant Mohr's, Hawaii purchased 140 shares of Intuitive common stock.

282. In addition, on October 23, 2012, Pennsylvania Carpenters purchased 1,825 shares of Intuitive common stock. On October 22, 2012, while in possession of material, adverse nonpublic information, Defendants Smith, Guthart, and Mohr sold 17,500, 4,500, and 7,300 shares of Intuitive common stock, respectively.

283. Defendants Guthart, Mohr, and Smith violated §10(b) of the Exchange Act, as described herein.

284. As a result of the foregoing, Defendants Guthart, Mohr, and Smith violated §20A of the Exchange Act and are each liable to Plaintiffs and other Class members who purchased shares of Intuitive common stock contemporaneously with the Individual Defendants' insider sales, and who seek disgorgement of the Individual Defendants' profits and avoided losses from their transactions in Intuitive common stock.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

A. Determining that this action is a proper class action and certifying Plaintiffs as co-class representatives under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiffs and the other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiffs hereby demand a trial by jury of all issues so triable.

DATED: November 2, 2016

/s/ Serena S. Hallowell
LABATON SUCHAROW LLP
MICHAEL W. STOCKER (179083)
JONATHAN GARDNER (*pro hac vice*)
MARK S. ARISOHN (*pro hac vice*)
SERENA P. HALLOWELL (*pro hac vice*)
CHRISTINE M. FOX (*pro hac vice*)
ALEC T. COQUIN (*pro hac vice*)
140 Broadway
New York, NY 10005
Telephone: 212-907-0700
Facsimile: 212-818-0477

Counsel for Plaintiffs and the Proposed Class

Exhibit A

Inspections, Compliance, Enforcement, and Criminal Investigations

Intuitive Surgical, Inc. 7/16/13

Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94501-7070
Telephone: (510) 337-6700

WARNING LETTER

July 16, 2013

VIA UNITED PARCEL SERVICE

Gary S. Guthart, President and CEO
Intuitive Surgical, Inc.
1266 Kifer Road, Bldg 100
Sunnyvale, CA 94086-5304

Mr. Guthart

During an inspection of your facility located at 1266 Kifer Road, Sunnyvale, CA between April 1, 2013 and May 30, 2013, and investigator from the United States Food and Drug Administration (FDA) determined that your firm manufactures computer controlled endoscopic surgical systems and associated accessories. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

The inspection revealed that your da Vinci System IS1000, da Vinci System IS1200, da Vinci System IS2000, da Vinci System IS3000, Tip Cover Accessory, and Cannula 8mm Regular are misbranded devices under section 502(t)(2) of the Act, 21 U.S.C. 352(t)(2), in that you failed or refused to furnish material or information respecting the device that is required by or under section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR 806-Medical Devices; Reports of Corrections and Removals regulation. Significant deviations include, but are not limited to the following:

Failure to submit a written report to FDA within 10 working days of any correction or removal of a device if the correction or removal was initiated to reduce the risk to health posed by the device or to remedy a violation of the act which may present a risk to health as required by 21 CFR 806.10 (b).

Examples of these failures include but are not limited to the following:

1. In October 2011, Intuitive Surgical, Inc. initiated a field correction by sending letters to da

Vinci Surgical System clients with suggestions and recommendations for the proper use of the Tip Cover Accessory and for the correct generators that should be used with monopolar instruments. This correction was in response to complaints and medical device reports (MDRs) for arcing through damaged tip covers that caused patient injuries. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1425-2013.

2. In October 2011, Intuitive Surgical, Inc. initiated a separate field correction by sending letters to da Vinci Surgical System clients to notify them that the da Vinci Surgical Systems promoted for thyroidectomy indications is not cleared for that use. You are aware of complaints and MDRs related to thyroidectomies performed with the da Vinci Surgical System. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1426-2013.

3. In October 2011, intuitive Surgical, Inc. initiated a separate field correction by sending letters to da Vinci Surgical System clients with information for inspecting the instrument cannulas, proper flushing of the instruments, and proper transportation of the da Vinci Surgical System between buildings. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1428-2013.

4. In January 2013, Intuitive Surgical, Inc. initiated a field correction by sending letters and replacement user manual addendum titled “da Vinci, da Vinci S, and da Vinci Si Surgical Systems User Manual Addendum for Transoral Surgery (TORS) P/N 552003-02 Rev.B 2012.09” to da Vinci Surgical System clients. The replacement addendum includes changes to the types of patients and conditions for which da Vinci TORS is indicated, such as warning against use in pediatric patients. Though the field action was undertaken to reduce a risk to health posed by the device, you failed to report the field action to the FDA as required. Your report of this recall on April 19, 2013 has been classified by FDA as a Class II recall, Z-1424-2013.

We have reviewed your response dated June 7, 2013 and find it incomplete and inadequate. Your standard operating procedure titled Field Actions, document 853012, revision T indicates that all corrections, removals, and labeling reiterations will be reviewed with the local district recall coordinator or 3rd party expert. We are unable to assess the adequacy of this change as we cannot evaluate the extent of the information that will be submitted to the local FDA recall coordinator. Nor can we assess how you will implement this new requirement in your SOP.

In addition, Section 6.3 of your work instruction titled Regulatory Notifications, document 859179, revision F intended to be used after a determination is made to file a field correction/removal indicates that Class I and Class II actions are to be reported, and Class III actions will be directed to the Head of Regulatory Affairs. This work instruction appears to contradict your Field Actions SOP, document 853012, which indicates that all corrections, removals, and labeling reiterations will be reviewed with the local district recall coordinator or 3rd party expert.

The FDA has previously informed you of your firm’s correction and removal violations in an untitled letter dated February 19, 2008, and FDA 483 Inspectional Observations issued on December 20, 2002.

A follow-up inspection will be required to assure that your corrections and/or corrective actions are adequate and properly implemented.

The inspection also revealed that your da Vinci System IS1000, da Vinci System IS1200, da Vinci System IS2000, da Vinci System IS3000, Tip Cover Accessory, and Cannula 8mm Regular are adulterated devices under section 501(h) of the Act, 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements for devices which are set forth in the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. Significant deviations include, but are not limited to the following:

Design input requirements were not adequately documented as required by 21 CFR 820.30(c). Specifically, you informed our investigator that you are aware of patient injuries associated with intraoperative cleaning of energized instruments such as the Monopolar Curved Scissors and Fenestrated Bipolar Scissors as evidenced by at least **(b)(4)** complaints and 82 MDRs during calendar years 2010 and 2011, and 15% of the MDRs reviewed by our investigator. You also informed our investigator that you are aware that cleaning instruments inside patients during surgery is a common practice and have included a label warning in the Instructions-for-Use (IFU) against the practice. When our investigator asked you to provide the design input documentation and design resolution of this known user need you failed to provide the requested documentation.

We have received your response dated June 7, 2013 and find your response to this observation inadequate. Your modification to section 8.1 of document number 823033, revision H in that you are concluding that the IFU adequately consider the known intraoperative cleaning of instruments and the associated risks without going through your design control processes. You response is also inadequate in that you do not provide a response to the root cause of this critical missing design input in your design documentation.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the awarding of contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to: Lawton W. Lum, Director of Compliance, 1431 Harbor Bay Parkway, Alameda, CA 94502. Refer to the Unique Identification Number 406661 when replying. If you have any questions about the contents of this letter, please contact: Compliance Officer Sergio Chavez at 510-337-6886.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Elizabeth A. Kage
Acting District Director

Page Last Updated: 07/31/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Exhibit B

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510) 337-6700 Fax:(510) 337-6702 Industry Information: www.fda.gov/oc/industry	04/01/2013 - 05/30/2013* FEI NUMBER 3001675293

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Gary S. Guthart, President and Chief Executive Officer

FIRM NAME	STREET ADDRESS
Intuitive Surgical, Inc.	1266 Kifer Rd Bldg 100
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Sunnyvale, CA 94086-5304	Medical Device Manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

A correction or removal, conducted to reduce a risk to health posed by a device, was not reported in writing to FDA.

Specifically, Intuitive Surgical, Inc. undertook four field actions on 10/10/2011, 10/13/2011, 10/17/2011, and 01/24/2013 without notifying the San Francisco District Recall Coordinator of these actions.

On 10/10/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with suggestions and recommendations for the proper use of instruments with tip covers and for the correct generators that should be used with monopolar instruments. This action was not reported to the San Francisco District Recall Coordinator. This correction was in response to complaints and MDRs for arcing through damaged tip covers that caused patient injury. Between January 2010 and December 2011, Intuitive Surgical, Inc. received 134 complaints and filed 82 MDRs related to tip cover issues.

On 10/13/2011, Intuitive Surgical, Inc. sent out a letter notifying da Vinci clients that the da Vinci surgical systems are not cleared for thyroidectomy indication. This action was not reported to the San Francisco District Recall Coordinator. The thyroidectomy indication was promoted by Intuitive Surgical Inc. after the firm filed a "Letter to File" under the da Vinci general surgery clearance (K990144) but after questions from CDRH, the firm (b) (4) (b) (4) Between July 2009 and October 2011, Intuitive Surgical received 13 complaints and filed 5 MDRs related to thyroidectomies performed with the da Vinci system.

On 10/17/2011, Intuitive Surgical, Inc. sent out a letter to da Vinci clients with information for inspecting instrument cannulas, proper flushing of instruments, and the proper transportation of the da Vinci between buildings. This action was not reported to the San Francisco District Recall Coordinator. Between January 2010 and September 2011, Intuitive Surgical Inc. received 2 complaints related to instrument flush ports and 17 complaints related to cannulas. There were no MDRs directly associated with these complaints, however some of these issues had been previously identified as root causes in other

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complaints that gave rise to MDRs (for example, damage to the integity of a tip cover due to defective cannulas was identified as one of the root causes for arcing that resulted in patient injuries). As such these issues represent a risk to the health of patients.

On 01/24/2013, Intuitive Surgical, Inc. sent out a letter and "da Vinci, da Vinci S, and da Vinci Si Surgical Systems User Manual Addendum for Transoral Surgery (TORS) P/N 552003-02 Rev.B 2012.09" to da Vinci clients to replace "da Vinci, da Vinci S, and da Vinci Si Surgical Systems User Manual Addendum for Transoral Surgery (TORS) P/N 552002-01 Rev.C 2011.04". The letter sent to clients clarified the types of patients and conditions for which daVinci TORS is indicated. For example, the new version of the IFU warns that da Vinci TORS surgery is not indicated for pediatric patients, therefore the vagueness in the previous version of the IFU represented a health risk to pediatric patients.

OBSERVATION 2

Illnesses or injuries that have occurred with use of devices subject to corrections or removals have not been reported.

Specifically, Intuitive Surgical, Inc. failed to report that there were 5 MDRs associated with the field action taken on 10/13/2011 (Thyroidectomy indication withrdawal). The 806 report No. 2955842-101311-004 that was supplied to the San Francisco District Coordinator on 04/11/2013, indicated 0 MDRs in Section 8 on page 3 of 7 of the report. During my inspection of Intuitive Surgical, Inc. 5 MDRs were represented as related to this correction. Intuitive Surgical Inc. failed to report these 5 MDRs on the 806 report provided to the San Francisco District Coordinator on 04/11/2013.

OBSERVATION 3

Procedures for design change have not been adequately established.

Specifically, Intuitive Surgical, Inc. did not document the decision to add a thyroidectomy indication to the da Vinci system general laparoscopy clearance 510(k) No. K990144 through Letter to File rather than through the submission of a new 510(k) application. At the time that this decision was made there were no procedures in place to document this design change issue. Effective as of 04/02/2012, Intuitive Surgical, Inc. has such a procedure in place as illustrated by Section 6.8.4 of Design Control SOP, Document: 854005, that requires that regulatory decisions for design changes be documented using DOP 853226 - Global Regulatory Asessment. However there was no retrospective analysis done to determine how to prevent this error from reoccuring, or to assess if the decision to add a thyroidectomy indication to the da Vinci system general laparoscopy clearance 510(k) No. K990144 through Letter to File, or any other regulatory decisions made for any other design changes done before the addition of this section, should have been reassessed utilizing a DOP 853226 - Global Regulatory Assessment to determine if new regulatory submissions should have been filed for those design changes.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mary R. Hole, Investigator	05/30/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Sunnyvale, CA 94086-5304	Medical Device Manufacturer

The promotion of the da Vinci thyroidectomy was questioned by the Center for Devices and Radiologic Health, and Intuitive Surgical, Inc. (b) (4)
(b) (4)

OBSERVATION 4

Design input requirements were not adequately documented.

Specifically, the user need for intrasurgical cleaning of surgical instruments was not part of the user needs included in the design of surgical instruments, such as Intuitive Surgical, Inc. Fenestrated Bipolar Forceps Part No. 400205/420205 that are commonly known to need cleaning during surgery. Intuitive Surgical, Inc. has received complaints of arcing of energized surgical instruments as a result of surgeons cleaning off instruments intrasurgically by scraping them across other surgical instruments. In the case of energized surgical instruments, such as Intuitive Surgical, Inc. Monopolar Curved Scissors (MCS) Part No. 420179/400179, the scraping led to tears or holes in protective tip covers that led to arcing that in turn led to injuries to patients.

AMENDMENT 1

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mary R. Hole, Investigator	05/30/2013

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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Observation Annotations

Observation 1:	Reported corrected, not verified.	Observation 2:	Reported corrected, not verified.
Observation 3:	Reported corrected, not verified.	Observation 4:	Reported corrected, not verified.

*** DATES OF INSPECTION:**
04/01/2013(Mon), 04/02/2013(Tue), 04/03/2013(Wed), 04/04/2013(Thu), 04/05/2013(Fri), 04/08/2013(Mon), 04/09/2013(Tue), 04/10/2013(Wed), 04/11/2013(Thu), 04/18/2013(Thu), 04/19/2013(Fri), 04/22/2013(Mon), 04/24/2013(Wed), 04/29/2013(Mon), 05/02/2013(Thu), 05/03/2013(Fri), 05/08/2013(Wed), 05/10/2013(Fri), 05/13/2013(Mon), 05/14/2013(Tue), 05/15/2013(Wed), 05/16/2013(Thu), 05/17/2013(Fri), 05/29/2013(Wed), 05/30/2013(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mary R. Hole, Investigator	05/30/2013

Exhibit C

CERTIFICATION

I, Wesley K. Machida, as Executive Director of the Employees' Retirement System of the State of Hawaii (the "ERS"), hereby certify as follows:

1. I am fully authorized to enter into and execute this Certification on behalf of the ERS. I have reviewed the Amended Class Action Complaint for Violations of the Federal Securities Laws prepared against Intuitive Surgical, Inc. ("Intuitive Surgical") alleging violations of the federal securities laws;

2. The ERS did not purchase securities of Intuitive Surgical at the direction of counsel or in order to participate in any private action under the federal securities laws;

3. The ERS is willing to serve as a lead plaintiff or representative party in this matter, including providing testimony at deposition and trial, if necessary;

4. The ERS' transactions in Intuitive Surgical securities during the Class Period are reflected in Exhibit A, attached hereto;

5. The ERS sought to serve as a lead plaintiff in the following class actions filed under the federal securities laws during the last three years;

Abrams v. Intuitive Surgical, Inc., No. 13-cv-1920 (N.D. Cal.)
In re Medtronic, Inc. Securities Litigation, No. 13-cv-1686 (D. Minn.)

6. The ERS is currently serving as lead plaintiff in the following class action filed under the federal securities laws during the last three years:

In re Medtronic, Inc. Securities Litigation, No. 13-cv-1686 (D. Minn.)

7. Beyond its pro rata share of any recovery, the ERS will not accept payment for serving as a lead plaintiff on behalf of the Class, except the reimbursement of such reasonable costs and expenses (including lost wages) as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 10 day of October, 2013.

Wesley K. Machida
Executive Director of the Employees' Retirement System of the State of Hawaii

EXHIBIT A

TRANSACTIONS IN INTUITIVE SURGICAL, INC.

Transaction Type	Trade Date	Shares	Price Per Share	Cost / Proceeds
Sale	02/13/12	-20.00	$498.53	$9,970.60
Purchase	08/07/12	270.00	$495.57	($133,804.25)
Purchase	08/08/12	130.00	$500.76	($65,098.61)
Purchase	08/08/12	100.00	$500.76	($50,075.85)
Purchase	08/10/12	200.00	$494.61	($98,921.00)
Purchase	08/10/12	100.00	$495.85	($49,584.50)
Purchase	08/10/12	2,589.00	$495.87	($1,283,804.32)
Sale	08/13/12	-2,889.00	$508.31	$1,468,507.59
Purchase	11/13/12	1,733.00	$536.17	($9,291,821,.61)
Purchase	11/13/12	1,733.00	$536.17	($9,291,821,.61)
Purchase	11/20/12	11,867.00	$538.18	($6,386,591.55)
Purchase	11/26/12	6,000.00	$532.64	($3,195,834.00)
Sale	11/30/12	-50.00	$529.31	$26,465.34
Sale	12/27/12	-220.00	$486.04	$106,927.77
Purchase	01/29/13	140.00	$574.57	($80,440.16)
Purchase	02/01/13	170.00	$582.19	($98,972.73)
Purchase	02/07/13	140.00	$569.86	($79,780.90)
Purchase	02/20/13	300.00	$565.00	($169,499.61)
Purchase	03/13/13	576.00	$509.33	($293,374.08)
Sale	03/18/13	-576.00	$476.92	$274,705.40
Sale	03/21/13	-500.00	$490.10	$65,673.95
Sale	03/22/13	-500.00	$490.00	$244,998.50
Sale	03/22/13	-600.00	$485.39	$291,236.64
Sale	03/27/13	-340.00	$492.26	$167,368.03
Sale	04/03/13	-360.00	$497.83	$179,218.98
Sale	04/11/13	-350.00	$509.91	$178,469.27
Sale	04/15/13	-370.00	$510.41	$188,851.29
Sale	04/17/13	-430.00	$503.71	$216,596.89
Sale	04/19/13	-1,690.00	$472.65	$798,776.47
Sale	05/17/13	-300.00	$482.99	$144,896.82
Sale	06/18/13	-390.00	$506.29	$197,452.28
Sale	07/09/13	-100.00	$413.82	$41,382.00
Sale	07/09/13	-200.00	$414.45	$82,889.08
Sale	07/09/13	-483.00	$414.43	$200,170.75
Sale	07/09/13	-600.00	$410.73	$246,440.40

Transaction Type	Trade Date	Shares	Price Per Share	Cost / Proceeds
Sale	07/09/13	-1,300.00	$418.40	$543,923.25

Exhibit D

CERTIFICATION

I, James R. Klein, as Administrative Manager of Greater Pennsylvania Carpenters' Pension Fund ("GPCPF"), hereby certify as follows:

1. I am fully authorized to enter into and execute this Certification on behalf of the GPCPF. I have reviewed the Amended Class Action Complaint for Violations of the Federal Securities Laws prepared against Intuitive Surgical, Inc. ("Intuitive Surgical") alleging violations of the federal securities laws;

2. The GPCPF did not purchase securities of Intuitive Surgical at the direction of counsel or in order to participate in any private action under the federal securities laws;

3. The GPCPF is willing to serve as a class representative in this matter, including providing testimony at deposition and trial, if necessary;

4. The GPCPF's transactions in Intuitive Surgical securities during the Class Period are reflected in Exhibit A, attached hereto;

5. The GPCPF sought to serve as a lead plaintiff in the following class action filed under the federal securities laws during the last three years;

In re Chemed Corp. Securities Litigation, No. 12-cv-00028 (S.D. Ohio)

6. The GPCPF is currently serving as lead plaintiff in the following class action filed under the federal securities laws during the last three years:

In re Chemed Corp. Securities Litigation, No. 12-cv-00028 (S.D. Ohio)

7. Beyond its pro rata share of any recovery, the GPCPF will not accept payment for serving as a lead plaintiff on behalf of the Class, except the reimbursement of such reasonable costs and expenses (including lost wages) as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 11th day of October, 2013.

James R. Klein
Administrative Manager of Greater Pennsylvania Carpenters' Pension Fund

EXHIBIT A

TRANSACTIONS IN INTUITIVE SURGICAL, INC.

Transaction Type	Trade Date	Shares	Price Per Share	Cost / Proceeds
Purchase	10/23/12	1,825.00	$546.58	($997,508.50)
Sale	12/05/12	-21.00	$523.75	$10,998.75
Purchase	12/19/12	190.00	$515.10	($97,869.00)
Purchase	03/14/13	213.00	$493.51	($105,117.63)
Purchase	04/19/13	39.00	$475.42	($18,541.38)
Purchase	04/19/13	219.00	$477.92	($104,664.48)
Purchase	07/09/13	407.00	$411.45	($167,460.15)

Exhibit E

Non-Derivative Securities Disposed of by Gary S. Guthart During Control Period (Aug. 26, 2010 - Feb. 5, 2012) and Class Period (Feb. 6, 2012 - July 18, 2013)

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	4/20/2012	688	575.042
Common Stock	4/20/2012	1312	575.042
Common Stock	4/20/2012	1500	574.979
Common Stock	7/24/2012	2000	473.468
Common Stock	7/26/2012	1500	490
Common Stock	10/22/2012	1500	542.979
Common Stock	10/22/2012	1000	545.632
Common Stock	10/22/2012	2000	544.477
Common Stock	1/25/2013	1500	577.674
Common Stock	1/25/2013	1000	578.068
Common Stock	1/25/2013	2000	577.571

Non-Derivative Securities Disposed of by Marshall Mohr During Control Period (Aug. 26, 2010 - Feb. 5, 2012) and Class Period (Feb. 6, 2012 - July 18, 2013)

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	2/1/2011	100	335.28
Common Stock	2/1/2011	300	335.26
Common Stock	2/1/2011	300	335.25
Common Stock	2/1/2011	100	335.08
Common Stock	2/1/2011	185	335.01
Common Stock	2/1/2011	717	335
Common Stock	2/10/2011	1000	335.75
Common Stock	2/10/2011	100	335.79
Common Stock	2/10/2011	100	335.78
Common Stock	2/10/2011	200	335.77
Common Stock	2/10/2011	100	335.7
Common Stock	2/10/2011	100	335.68
Common Stock	2/10/2011	100	335.65
Common Stock	2/10/2011	100	335.56
Common Stock	2/10/2011	100	335.44
Common Stock	2/10/2011	100	335.31
Common Stock	2/10/2011	100	335.23
Common Stock	2/10/2011	2900	335.2
Common Stock	7/22/2011	9298	403.51

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	4/30/2012	100	580.495
Common Stock	4/30/2012	700	581.495
Common Stock	4/30/2012	200	582.495
Common Stock	4/30/2012	400	583.495
Common Stock	4/30/2012	200	584.495
Common Stock	4/30/2012	500	585.495
Common Stock	4/30/2012	500	586.495
Common Stock	4/30/2012	1000	581.495
Common Stock	4/30/2012	300	582.495
Common Stock	4/30/2012	1200	583.495
Common Stock	4/30/2012	400	584.495
Common Stock	4/30/2012	400	585.495
Common Stock	4/30/2012	400	586.495
Common Stock	4/30/2012	300	580.495
Common Stock	4/30/2012	700	581.495
Common Stock	4/30/2012	600	583.495
Common Stock	4/30/2012	300	584.495
Common Stock	4/30/2012	400	585.495
Common Stock	4/30/2012	200	586.495
Common Stock	7/25/2012	3300	478.58
Common Stock	10/22/2012	4000	543.023

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	10/22/2012	3300	543.223
Common Stock	1/28/2013	3200	574.122
Common Stock	1/28/2013	3600	574.575
Common Stock	1/28/2013	1200	574.575

Non-Derivative Securities Disposed of by Lonnie M. Smith During Control Period (Aug. 26, 2010 - Feb. 5, 2012) and Class Period (Feb. 6, 2012 - July 18, 2013)

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	1/27/2011	400	334.81
Common Stock	1/27/2011	6	334.78
Common Stock	1/27/2011	300	334.785
Common Stock	1/27/2011	100	334.79
Common Stock	1/27/2011	200	334.8
Common Stock	1/27/2011	100	334.82
Common Stock	1/27/2011	450	334.84
Common Stock	1/27/2011	500	334.95
Common Stock	1/27/2011	100	336.2
Common Stock	1/27/2011	2144	336.33
Common Stock	1/27/2011	200	336.56
Common Stock	1/27/2011	500	336.65
Common Stock	1/27/2011	1000	336.68
Common Stock	1/27/2011	5000	336.902
Common Stock	1/27/2011	2000	337.01
Common Stock	1/27/2011	2000	337.14
Common Stock	4/26/2011	1919	351.41
Common Stock	4/26/2011	100	351.46
Common Stock	4/26/2011	200	351.72

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	4/26/2011	2000	351.74
Common Stock	4/26/2011	2000	351.74
Common Stock	4/26/2011	2139	352
Common Stock	4/26/2011	300	352.01
Common Stock	4/26/2011	600	352.07
Common Stock	4/26/2011	110	352.11
Common Stock	4/26/2011	110	352.12
Common Stock	4/26/2011	2	352.14
Common Stock	4/26/2011	200	352.15
Common Stock	4/26/2011	100	352.17
Common Stock	4/26/2011	100	352.82
Common Stock	4/26/2011	100	352.27
Common Stock	4/26/2011	300	352.31
Common Stock	4/26/2011	100	352.32
Common Stock	4/26/2011	100	352.37
Common Stock	4/26/2011	100	352.39
Common Stock	4/26/2011	1000	352.41
Common Stock	4/26/2011	1000	352.49
Common Stock	4/26/2011	9	352.5
Common Stock	4/26/2011	200	352.52
Common Stock	4/26/2011	200	352.53

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	4/26/2011	100	352.68
Common Stock	4/26/2011	100	352.71
Common Stock	4/26/2011	100	352.77
Common Stock	4/26/2011	75	352.78
Common Stock	4/26/2011	200	352.81
Common Stock	4/26/2011	200	352.82
Common Stock	4/26/2011	100	352.83
Common Stock	4/26/2011	100	352.86
Common Stock	4/26/2011	400	352.91
Common Stock	4/26/2011	10	352.96
Common Stock	4/26/2011	6	352.98
Common Stock	4/26/2011	10	353.02
Common Stock	4/26/2011	10	353.06
Common Stock	4/26/2011	600	353.11
Common Stock	4/26/2011	200	353.12
Common Stock	4/26/2011	188	353.61
Common Stock	4/26/2011	466	354
Common Stock	4/26/2011	2	354.02
Common Stock	4/26/2011	844	354.14
Common Stock	4/26/2011	300	354.15
Common Stock	7/26/2011	15000	397.121

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	10/25/2011	15000	419.707
Common Stock	4/20/2012	17500	575.088
Common Stock	7/24/2012	12500	473.178
Common Stock	7/24/2012	5000	473.178
Common Stock	10/22/2012	17500	543.285
Common Stock	11/20/2012	23949	536.673
Common Stock	11/21/2012	2906	534.625
Common Stock	11/21/2012	13551	534.625
Common Stock	11/23/2012	20899	536.867
Common Stock	11/26/2012	21164	534.343
Common Stock	11/27/2012	1422	528.149
Common Stock	11/27/2012	25031	528.149
Common Stock	12/3/2012	1000	525.98
Common Stock	3/4/2013	2766	536.495
Common Stock	3/4/2013	634	537.495
Common Stock	3/4/2013	1500	539.495
Common Stock	3/4/2013	4255	540.495
Common Stock	3/4/2013	6800	541.495
Common Stock	3/4/2013	6200	542.495
Common Stock	3/4/2013	300	543.495
Common Stock	3/4/2013	500	546.495

Security	Transaction Date	Shares Sold	Sale Price
Common Stock	3/4/2013	2000	549.495
Common Stock	3/4/2013	45	550.495