UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

CAMBRIDGE RETIREMENT SYSTEM, on behalf of Itself and all Others Similarly Situated, Plaintiff, v. INVACARE CORPORATION, *et. al.*, Defendants.	Case No. 1:13-cv-1165-CAB CLASS ACTION

AMENDED COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

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I. INTRODUCTION

Lead Plaintiff, the Government of Guam Retirement Fund ("Lead Plaintiff" or "Guam"), brings this action individually and on behalf of all persons or entities who purchased or otherwise acquired the publicly traded common stock of Invacare Corporation ("Invacare" or the "Company") between February 27, 2009 and December 7, 2011, inclusive (the "Class Period") and were damaged thereby (collectively, the "Class"). Excluded from the Class are Defendants (as defined herein), present or former executive officers of Invacare and their immediate family members.

Lead Plaintiff alleges the following based upon personal knowledge as to itself and its own acts and upon information and belief as to all other matters. Lead Plaintiff's information and belief is based on, *inter alia*, the independent investigation of Lead Counsel, Bernstein Litowitz Berger & Grossmann LLP. Lead Counsel's investigation includes, but is not limited to, a review and analysis of: (i) Invacare's public filings with the U.S. Securities and Exchange Commission ("SEC"); (ii) publicly available filings and reports by government law enforcement and regulatory agencies relating to investigations and legal actions concerning Invacare, including in the action captioned *United States of America v. Invacare Corporation, et al.*, No. 1:12-cv-03086 (DAP) (N.D. Ohio); (iii) documents and information disclosed in other litigation naming Invacare and/or its directors as defendants or nominal defendants; (iv) research reports by securities and financial analysts regarding Invacare; (v) transcripts of Invacare investor conference calls; (vi) press releases and media reports; (vii) economic analyses of the historical movement, pricing and trading data for publicly traded Invacare common stock; (viii) consultation with relevant experts; (ix) interviews with former employees of Invacare (identified herein as Confidential Witness ("CW_")); and (x) other publicly available material and data identified herein. Lead Counsel's investigation into the factual allegations contained herein is

ongoing, and many of the relevant facts are known only by the Defendants named herein, or are exclusively within their custody or control. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

II. NATURE AND SUMMARY OF THE ACTION

1. This is a class action against Invacare, a manufacturer and distributor of home and long-term care medical products, Gerald B. Blouch ("Blouch"), its President and Chief Executive Officer ("CEO"), and A. Malachi Mixon, III ("Mixon"), its Chairman, founder and former CEO, (collectively, "Defendants"), for violation of the federal securities laws. Invacare's best-selling products are power and manual wheelchairs, and homecare bed systems.

2. This action arises from Defendants' numerous, serious and pervasive violations of FDA regulations and current Good Manufacturing Practices ("cGMP") beginning as early as 1996 and continuing throughout the Class Period. Invacare and its senior management were repeatedly notified by the U.S. Food and Drug Administration ("FDA") of these regulatory deficiencies yet, unbeknownst to investors, deliberately refused to take obvious yet costly steps that were necessary to correct the severe problems. Instead, Defendants embarked on an aggressive growth campaign and publicly touted to investors the Company's impressive financial results, while, at the same time, consistently and falsely assuring investors that Invacare was "adhering to high standards of quality and safety" and "continu[ing] to strengthen its programs to better ensure compliance with applicable regulations" – including, specifically, by addressing the FDA's concerns. Ultimately, the foreseeable risk of Defendants' intentional disregard of federal law and the FDA's repeated warnings began to materialize in January 2011, when the Company announced that the FDA intended to seek a consent decree of injunction against the Company.

Ultimately, Invacare was forced to enter into the consent decree, which required the Company to shut down all design, manufacturing, and distribution of products at its corporate headquarters and adjacent wheelchair manufacturing plant, literally bringing the Company to its knees. To restore its good standing with the FDA and finally address the quality and safety problems, Invacare was forced to spend more than $40 million to date, hire numerous outside consultants, and undergo a rigorous three-phase independent audit process.

3. Invacare operates in an intensely regulated industry. In particular, the manufacture and sale of Invacare's medical devices are extensively regulated by the FDA, which is charged with protecting the public health by, among other things, assuring the safety, effectiveness, quality and security of medical devices.

4. Invacare, like other medical device manufacturers, is subject to periodic inspections by the FDA to ensure compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and other applicable laws and regulations. If a FDA inspection identifies "objectionable conditions" – *i.e.*, conditions that may constitute violations of the FDCA and related implementing regulations – the FDA issues a Form FDA-483 directed to company management. According to the FDA, Forms 483 are reserved for "significant" conditions that indicate that a device has been or is being manufactured in a manner that may be injurious to health. Also according to the FDA, at the conclusion of an inspection, Forms 483 are "*presented and discussed with the company's senior management*." The issuance of a Form 483 is a very serious matter and represents a risk that the FDA may take corrective action against a company, including imposing measures that have material adverse effects on the company's operations and financial condition, as Invacare has long acknowledged in its SEC filings.

5. Even more serious than a Form 483 is the receipt of a Warning Letter from the FDA. Warning Letters are one of the FDA's principal means of achieving prompt corrective action before the FDA initiates an enforcement action. Warning Letters are reserved for substantial violations of FDA regulations. Importantly, Warning Letters typically will not be issued if the FDA finds that adequate corrective actions have been implemented following the initial notification of observed noncompliance, usually by way of Form 483.

6. According to documentation that has only recently become publicly available, prior to and during the Class Period, Invacare was subject to numerous FDA inspections and received not less than ***twelve Forms 483*** and ***five Warning Letters***, which collectively identified at least ***71 violations of FDA regulations*** – dozens of which were "repeat" or "recurring" violations that the FDA had previously raised with Invacare as early as 1996 but which Defendants failed to correct. Among other deficiencies, these Forms 483 cited the Company's mishandling of complaints about its products, including incidents of fatal suffocation in Invacare beds and wheelchairs that burst into flames immolating helpless occupants.

7. Despite their knowledge of these systematic and serious operational, quality control and regulatory deficiencies, Defendants either concealed the Forms 483 from investors or, to the extent they were disclosed, Defendants repeatedly falsely assured investors during the Class Period that it was "addressing" or had "addressed" the issues raised by the FDA, and otherwise was strengthening its programs "to better ensure compliance with applicable regulations, particularly those which could have a material adverse effect on the company." These and other material misrepresentations were included in every Annual Report filed by the Company during the Class Period. In addition, the same or similar misstatements were contained or incorporated in a series of other public statements issued by Defendants during the Class

Period, including quarterly reports, press releases, earnings conference calls, news articles, and the Company website.

8. In truth, however, Defendants were not undertaking any serious effort to ensure remediation and compliance. Numerous former Invacare employees interviewed in connection with Lead Counsel's investigation confirmed that the Company had a deeply-ingrained culture of contempt for the FDA, and begrudgingly adopted only the most superficial measures in an attempt to pacify the FDA and avoid undertaking the costly, systemic, and company-wide reforms necessary to bring the Company into compliance with FDA requirements. One former 17-year Invacare employee described Invacare's token efforts to appease the FDA as a ***"smokescreen"*** and explained that, despite the numerous FDA warnings, ***"[n]one of the business processes or paperwork or prints ever really changed."***

9. While Defendants told investors and regulators that Invacare was taking appropriate corrective measures to address problems identified by the FDA, in reality the Company refused to hire additional personnel or make the improvements necessary to comply with FDA requirements. According to one longtime Invacare manufacturing employee at the impacted Taylor Street Facility, ***"Invacare knew we had problems [but] it was just all about making money. We weren't addressing or fixing the problem, we were too busy making money."*** Similarly, another 17-year Invacare employee confirmed that: ***"They were not following FDA regulations . . . . All it was [about] was do your numbers, get the product out the door and that's it."*** This veteran machinist, who also worked at the Taylor Street Facility, emphasized that Invacare management "***always wanted to go beyond [Wall Street] expectations from the previous year***. ***It was more about sales, not safety."***

10. On December 17, 2010, Invacare received two more Forms 483 detailing numerous regulatory violations at Invacare's Corporate Headquarters and the Taylor Street Facility, which Defendants concealed from investors for almost a year. Because Defendants failed to take appropriate measures to address the numerous, systemic problems personally observed by FDA inspectors and communicated to the Company's top executives, the FDA issued a formal "Warning Letter" on December 15, 2010, which was released to the public on January 4, 2011. That disclosure immediately caused Invacare's stock price to drop by 4.5%, or $1.38 per share.

11. Nevertheless, Defendants continued to make false and misleading statements downplaying the significance of the Warning Letter and assuring investors that it was taking adequate steps necessary to address the problems and avoid more serious consequences. In truth, Defendants continued their campaign of delay and obfuscation. For example, employees were instructed not to speak with FDA inspectors; to take vacation days or "lack of work" days to avoid having to interact with FDA inspectors; or production lines were simply shut down during FDA inspections. According to a former Invacare employee, ***"We were told that . . . if they knew the FDA was coming in, they would have certain people there staged, and a lot of times they would shut down the machinery."*** If the FDA became suspicious, the former employee recounted, the plant manager would just lie to the inspectors that Invacare did not have any orders for the product that day or could only run that line on other days. Defendants went to even greater extremes to avoid the FDA and the Company's regulatory compliance obligations. For example, in anticipation of the FDA demanding the Company shut down its Taylor Street Facility, Defendants relocated entire manufacturing lines to Mexico and Canada. In addition, one former Invacare employee described how the Company moved sewing machines under cover

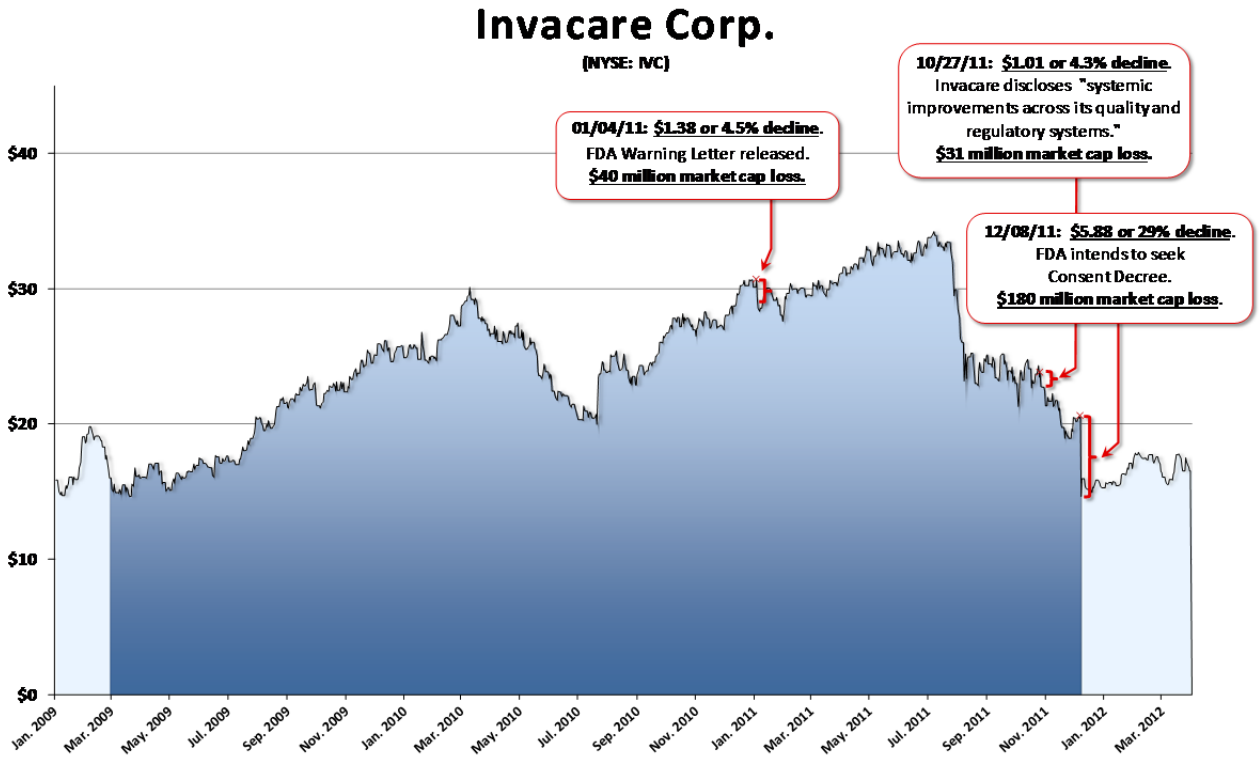
of night from the wheelchair upholstery department at the Taylor Street Facility to the Cleveland Street Facility so the Company could maintain production even after the Consent Decree was imposed.

12. Ultimately, on December 8, 2011, Invacare shocked investors by issuing a press release announcing that the FDA intended to seek a consent decree of injunction against the Company, which would shut down the Company's design and manufacturing operations. Thereafter, the Department of Justice, acting at the FDA's direction, filed a Complaint For Permanent Injunction against the Company. The resulting consent decree between Invacare and the U.S. Government (the "Consent Decree") has had a devastating impact on the Company's business, operations and financial condition. As discussed below, Invacare has incurred, and continues to incur, substantial declines in both sales volume and margins, delays in new product launches, interruption of its strategic "Globalization Initiative," and more than $40 million in additional "quality and regulatory costs" thus far as the Company struggles to comply with terms of the Consent Decree and belatedly implement systemic compliance processes across the Company. In addition, as a result of the Consent Decree, more than 40% of Invacare's Taylor Street workforce (approximately 200 employees, many of whom had worked for the Company for decades) have been permanently laid off to date.

13. Revelations about Invacare's serious and systemic regulatory failings also caused substantial losses to the Company's investors. When the market learned about the FDA Warning Letter and its implications on January 4, 2011, the market price for Invacare's common stock declined by $1.38 per share or 4.5%. Similarly, when the market learned more about the true scope and consequences of Invacare's problems on December 8, 2011, when the Company disclosed that the FDA was demanding that it enter into a consent decree. This shocking

revelation caused the price of Invacare stock to plummet nearly 29%, from $20.58 per share on December 7, 2011, to close at $14.70 per share on December 8, 2011, eliminating over $180 million in market capitalization in a single day.

14. In total, investors incurred hundreds of millions of dollars in market capitalization losses as a result of Defendants' material misrepresentations and omissions regarding Invacare's regulatory compliance deficiencies, as set forth on the stock price chart below:



15. Scienter is beyond reasonable dispute. Although Invacare is the world's largest home medical equipment product supplier, it is a close knit company with less than 6,000 employees at its peak. The Company's design and complaint/recall nerve center was located within its corporate headquarters at One Invacare Way, Elyria, Ohio and the manufacturing facility where the majority of the regulatory violations occurred was literally just across the street. Both Defendants Blouch and Mixon were intimately involved in the Company's dealings with the FDA. Indeed, most of the FDA's Forms 483 were addressed directly to Blouch and,

according to several former Invacare employees, Blouch monitored all compliance issues at Invacare. Less than a month after the FDA's intention to seek a consent decree was announced, the Company assured investors that Blouch would remain ***"very involved in the process."*** Similarly, Mixon was known for being a "hands-on" manager, even after suffering a mild stroke in 2010. Indeed, after his stroke, Mixon confirmed that he continued to be immersed in all aspects of the Company's operations, claiming, ***"Nothing goes on [at Invacare] that I don't know about."***

16. Unquestionably, Defendants were aware throughout the Class Period of the Invacare's extensive and repeated violations of FDA regulations and cGMP requirements. Indeed, the Consent Decree came as no surprise to Invacare's top executives. According to the Department of Justice's complaint, the FDA had previously inspected Invacare's corporate headquarters in September 2002, October 2004, April 2005, December 2008, and December 2010. The FDA also had inspected Invacare's manufacturing facility in March 2003, December 2008 and December 2010. According to the Government's complaint, "At these inspections, [the] FDA ***repeatedly observed and documented violations of the QS [Quality System] regulations"*** similar to the violations cited in the FDA's 2011 inspections, as well as ***"numerous violations of the MDR regulations*** at the majority of the previous inspections."[1] At the conclusion of every inspection, the FDA met with Invacare management, including specifically Blouch, issued a Form 483 detailing the numerous violations found "and discussed the documented observations with them." Moreover, according to the Government's complaint, Invacare and Blouch ***"promised corrections at the conclusion of each inspection."*** As the complaint stated plainly, based on these prior investigations and extensive record of citations,

[1] All emphasis added throughout unless otherwise noted.

Forms 483, and meetings with Invacare management, Invacare and Blouch were ***"well aware that their practices violate the Act"*** as the FDA has ***"repeatedly warned Defendants, both orally and in writing about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act."***

17. In sharp disparity to the substantial shareholder wealth lost as a result of Defendants' fraudulent conduct, Defendants Mixon and Blouch realized over $45 million in proceeds from insider stock sales during the Class Period. The trading records of Mixon and Blouch reveal that, at the very same time they were asserting Invacare's "substantial compliance" with FDA regulations and assuring investors that the "costs associated with making the process improvements" identified by the FDA were "not expected to be material" and were "eminently manageable," Mixon and Blouch were quickly disposing their personal holdings of stock in the Company. In particular, Invacare's founder, Chairman and former Chief Executive Officer, Defendant Mixon, reaped over ***$39 million*** from the sale of Invacare stock during the Class Period, including from trades made just weeks before the Invacare revealed to the public that the FDA intended to seek a consent decree against the Company.

III. JURISDICTION AND VENUE

18. The claims asserted herein arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"); 15 U.S.C. §§ 78j(b) and 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

19. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. Section 1331 and Section 27 of the Exchange Act.

20. Venue is proper in this District pursuant to 28 U.S.C. Section 1391(b) and Section 27(a) of the Exchange Act because, at all relevant times, Invacare has conducted business in this

District and has maintained its principal executive office in this District at One Invacare Way, Elyria, Ohio, and because many of the false and misleading statements were made in or issued from this District.

21. 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 communications and facilities of the national securities markets.

IV. PARTIES

A. Lead Plaintiff

22. Lead Plaintiff, the Government of Guam Retirement Fund, was appointed by the Court as Lead Plaintiff by Order dated October 1, 2013. Lead Plaintiff is a public pension plan, based in Maite, Guam, that provides retirement, disability and survivor benefits for members who complete a prescribed number of years in government service, their surviving spouses, and minor children. Established in 1951, Guam maintains over $1.4 billion in net assets held in trust for pension benefits. As set forth in the certification previously filed with this Court on July 23, 2013, and as incorporated by reference herein, Guam purchased 18,000 shares of Invacare common stock on the New York Stock Exchange ("NYSE") at artificially inflated prices during the Class Period alleged herein and suffered losses of approximately $177,000 from its Class Period purchases of Invacare common stock. Lead Plaintiff has reviewed this Amended Complaint and authorized its filing.

B. Defendants

23. Defendant Invacare, an Ohio corporation, is one of the world's leading manufacturers and distributors of medical devices for use in the home and extended care settings, including custom manual and power wheelchairs, and manual and electric homecare beds.

Invacare sells its products principally to home health care and medical equipment providers and distributors, and also serves as a contractor to the Veterans Administration and other government agencies.

24. Invacare's corporate headquarters are located at One Invacare Way, Elyria, Ohio ("Corporate Headquarters"), and its principal manufacturing facilities are located at 1200 Taylor Street, Elyria, Ohio ("Taylor Street Facility"), which is directly adjacent to the Corporate Headquarters, and in Sanford, Florida (the "Sanford Facility"). Among other things, the Corporate Headquarters serves as the design and complaint/recall nerve center for all of the Company's operations worldwide. The Taylor Street Facility produced manual and powered wheelchairs, while the Sanford Facility principally produced homecare beds. Together, these products accounted for approximately half of Invacare's sales and revenue. In addition, Invacare maintains a warehouse and shipping/receiving facility located a mile away at 899 Cleveland Street (the "Cleveland Street Facility") that is not subject to the Consent Decree. Invacare's common stock trades under the symbol "IVC" on the NYSE.

25. Defendant Blouch is Invacare's President and CEO. As CEO, Blouch oversees Invacare's product development, product management, and international relations and sales. Blouch previously served as interim CEO of Invacare from April 30, 2010, through December 31, 2010. Blouch joined the Company in 1990 as its first Chief Financial Officer ("CFO"), and became the Company's Chief Operating Officer in 1994. Blouch has also served as President and a Director of Invacare since November 1996. During the Class Period, Blouch disposed of over 190,000 shares of Invacare common stock in insider sales for proceeds totaling over $4.2 million.

26. Defendant Mixon has served as Chairman of the Board of Directors of Invacare ("Board") since 1983. As Chairman, Mixon focuses on government relations, strategic initiatives, and research and development. Mixon previously served as Invacare's President and CEO, from 1979 through 1996 and 2010, respectively.

27. On April 30, 2010, Invacare announced that Defendant Mixon was taking a temporary medical leave as Chairman and CEO of the Company due to a mild stroke, and that Defendant Blouch would serve as Invacare's interim CEO while Mixon recovered. In the press release, Mixon stated that his condition was stable, "my doctors have told me the prognosis for a full recovery is favorable," and "I look forward to returning to Invacare soon to full duty." Less than three months later, on July 17, 2010, Invacare issued a press release announcing the return of Defendant Mixon as Chairman of the Board.

28. In November 2010, Mixon stepped down as CEO after 30 years leading the Company. On November 19, 2010, Invacare announced that Blouch, the Company's interim CEO since April 30, 2010, had been named by the Board as President and CEO of the Company, effective January 1, 2011. However, the Company also stated that Mixon would "continue to be actively engaged with the Company as Chairman of the Board," in particular, with a "focus on government relations, strategic issues and research and product innovation."

29. Defendants Blouch and Mixon are collectively referred to herein as the "Individual Defendants." The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Invacare's quarterly reports, press releases, and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. During the Class Period, the Individual Defendants signed and certified the Company's SEC filings, including, but not limited to, Invacare's Forms

10-Q and 10-K. They were provided with copies of the Company's reports, press releases, conference call transcripts, and presentations alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. 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 concealed from the public and that the positive representations being made were materially false and misleading. The Individual Defendants are liable for the misstatements pleaded herein.

V. CONFIDENTIAL WITNESSES

30. The allegations herein are supported, in part, by first-hand accounts of confidential witnesses, including persons who were employed by Invacare during the Class Period. As set forth below, the confidential witnesses were each in a position to know the information alleged, and many corroborate the allegations of one another as well as information that is publicly available, as well as the complaints of consumers and findings of the FDA. The confidential witnesses have been identified with particularity but without disclosing identities in order to address concerns about retaliation or career injury.

31. CW1 was employed as Invacare's Manager of Regulatory Affairs from September 2010 through July 2013. As Manager of Regulatory Affairs, CW1 was intimately familiar with the issues with the FDA and the Company's responses. CW1 worked at Invacare's Corporate Headquarters and reported to Ronald J. Clines ("Clines"), Invacare's Director, Product Risk and Quality Engineering (previously Director of Regulatory Affairs and Quality Systems until 2011) until October 2012 and to William Hoffman, Invacare's Director, Pre- and Post-Market Regulatory and CAPA Management thereafter. Regulatory Affairs fell under Jeff Craigo

("Craigo") who reported to Blouch. However, Craigo did not have a regulatory background, so Clines had primary responsibility for regulatory affairs worldwide.

32. CW2 worked for Invacare for more than 18 years, most recently as Director of Operations, until being terminated in the mass "Christmas layoffs" – two days after Christmas 2012 – when 40% of the Taylor Street Facility's workforce (143 employees), including many long-term employees, were fired by Invacare (the "2012 Christmas Layoffs"). For most of those 18 years, CW2 ran the manufacturing operations for Invacare at various facilities, including the Taylor Street Facility in Elyria. CW2 was intimately involved in many of the FDA investigations of Invacare, particularly in Elyria. CW2 was knowledgeable about the FDA inspections at the Sanford, Florida facility but was not responsible for running that facility. CW2 reported to the Invacare's Vice President of Operations.

33. CW3 was employed by Invacare from September 1989 until retiring in December 2011. During the Class Period, CW3 worked as a Regional Vice President of Sales reporting to Rob Boeye ("Boeye"), Invacare's Vice President of Sales. CW3 was responsible for five to six states surrounding Texas – over one third of the Company's sales – and 42 direct reports.

34. CW4 was employed at Invacare as the General Manager for North America Business at Invacare from October 2012 through April 2013. CW4 also was a member of Invacare's Executive Committee from January 2013 through April 2013. The Executive Committee also included Blouch, Louis Slangen (SVP), Doug Uelman (SVP Quality/RA), John Remmers (SVP, Global Supply Chain, Operations & Engineering), Patti Stumpp (SVP, Human Resources), Anthony LaPlaca ("LaPlaca") (SVP, General Counsel), Dave Mewes (Global Chief Information Officer, Senior Global Leadership Team), Gordon Sutherland (VP General Manager,

Commercial Operations, Invacare International SARL/heads up commercial operations in Europe), as well as Rob Gudbranson ("Gudbranson") (CFO).

35. CW5 worked at Invacare for almost 28 years, including most recently as an Associate 1 working on many different FDA projects related to compliance and reporting to Aaron Sherban and Stephanie Shank, both of whom are currently employed by the Company. CW5 was laid off from Invacare in April 2013. CW5 initially worked at the Cleveland Street Facility but transitioned to the Taylor Street Facility several years ago.

36. CW6 was employed by Invacare from 1991 through February 1, 2011, most recently as a National Accounts Manager. CW6 reported to Linda Bell, Invacare's Director of HCS billing practices, and Boeye, Vice President of Sales.

37. CW7 was a machinist at Invacare's Taylor Street Facility for almost 17 years from 1997 until she was terminated in the mass 2012 Christmas Layoffs. CW7 worked on various production lines, including working on parts for Invacare's power and manual wheelchairs during the last three years at Invacare (*i.e.*, 2009-2012).

38. CW8 was employed as a welder for 17 years, first at Invacare's Cleveland Street Facility then at the Taylor Street Facility, until being terminated in the 2012 "2012 Christmas Layoffs." Most recently, CW8 reported to Alan Sfranze (phon.) who reported to Racquel Walsh and later to Danielle Walsh.

39. CW9 worked for Invacare for 35 years until being terminated in the "2012 Christmas Layoffs," after Invacare entered into the Consent Decree. CW9 was a machine operator and job setter at the Taylor Street Facility and reported to Joe Dutko, a Process Engineer and Supervisor. CW9 worked on the Solara line (high-end custom manual wheelchairs), which

was transferred to Reynosa, Mexico, but also made parts for all of Invacare's wheelchairs, both power and manual.

VI. DEFENDANTS' VIOLATIONS OF THE FEDERAL SECURITIES LAWS

A. Company Background

40. Invacare is one of the world's largest manufacturers of medical equipment and supplies used in the home and extended care environments. According to the Company, Invacare became a standalone business in December 1979, when a group of investors, including Mixon and Joseph B. Richey II ("Richey"), Invacare's Senior Vice President of Electronic and Design Engineering, purchased the Company for $7.8 million from Technicare, a Johnson & Johnson subsidiary. Mixon had been Vice President of Marketing at Technicare. At that time, Invacare had $19.5 million in net sales and a limited product line of lifestyle wheelchairs and patient aids.

41. After separating from Technicare, Invacare embarked on an aggressive growth campaign, entering new markets and expanding its product lines through numerous acquisitions. In particular, between 1995 and 2008, Invacare acquired not less than 35 new companies, increasing its product lines to include ambulatory infusion pumps, oxygen concentrators, beds, and patient furniture. Invacare's net sales grew from $19.5 million in 1979 to approximately $1.8 billion by 2012. Similarly, the Company grew from 300 associates to over 6,100, transforming from small privately-owned enterprise to a NYSE corporation listed on the "Fortune 1000."

42. However, as explained more fully below, Invacare failed to develop its compliance infrastructure or cultivate a culture of compliance among its employees to keep pace with the Company's rapid growth.

43. Invacare currently operates in three principal geographic regions: North America, Asia/Pacific, and Europe. During the Class Period, the North America region was by far the

Company's largest geographical segment by revenue, accounting for over 40% of the Company's annual revenues in 2009, 2010, and 2011.

44. Invacare maintains three product categories for the North America region: North America/Home Medical Equipment ("NA/HME"), Invacare Supply Group, and Institutional Products Group. The NA/HME segment includes the "Rehab," "Standard" and "Respiratory" product lines. The Standard product line includes manual wheelchairs, homecare beds (manual, semi-electric, and fully-electric), personal care products (including crutches, canes, and walkers), and other products. The Rehab product line includes power wheelchairs (both standard and customizable), custom manual wheelchairs, personal mobility products (compact scooters), and other products. The Respiratory product line includes oxygen therapy systems, including portable oxygen cylinders, and transportable and home-based oxygen concentrators.

45. The Company operates four major North American factories: the Taylor Street Facility, the Sanford Facility, and manufacturing facilities in Canada and Mexico. These factories focus on, among other things, the production of powered mobility and custom manual wheelchairs and seating products, the fully integrated manufacture of homecare and institutional care beds, and final assembly of a variety of standard manual wheelchairs. The Company's NA/HME segment is Invacare's largest segment by revenue. Indeed, manual wheelchairs, powered wheelchairs, scooters and similar products accounted for 66% of Invacare's sales.

46. All of Invacare's device design specifications for powered wheelchairs and for powered beds are developed at its Corporate Headquarters. Invacare's Corporate Headquarters also handles complaints and other aspects of the Company's Quality Assurance program.

B. Invacare Products Are Strictly Regulated

47. Invacare's products are subject to extensive regulation by the FDA because they are "medical devices" under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C.

§ 332(a). As stated in Invacare's SEC filings, "the FDA regulates virtually all aspects of a medical device's development, testing, manufacturing, labeling, promotion, distribution and marketing." In addition, unless an exemption applies, certain Invacare products, including its wheelchairs and respiratory products, generally must receive pre-clearance from the FDA before they can be marketed in the United States. The FDA also may require Invacare to obtain a clearance to market modified versions of the Company's existing products or market its existing products for new indications. Such submissions may be time consuming and costly, and require extensive supporting data. Moreover, Invacare is subject to ongoing medical device reporting regulations that require the Company to file reports with the FDA if its products cause or contribute to death or serious injury, or if the Company's products malfunction and would be likely to cause or contribute to death or serious injury if the malfunction were to recur.

48. Specifically, the Act provides that a medical device must be manufactured, packed, stored, and installed in conformity with good manufacturing practice to ensure its safety and effectiveness. 21 U.S.C. § 360j(f). The statutory good manufacturing practice requirement is set out in the quality system ("QS") regulation for devices, 21 C.F.R. Part 820. A device that has been manufactured, packed, stored, or installed in violation of this requirement is deemed to be adulterated. 21 U.S.C. § 351(h). The introduction or delivery for introduction into interstate commerce of an adulterated article of device is a violation of the Act, 21 U.S.C. § 331(a).

49. The Act further provides that every manufacturer of a medical device must submit certain reports and other information to the FDA as may reasonably be required "to assure that the device is not adulterated or misbranded and to otherwise assure its safety and effectiveness." 21 U.S.C. § 360i. However, every medical device manufacturer is required to submit to the FDA a Medical Device Report ("MDR") within thirty days of receiving or otherwise becoming aware

of information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, and to conduct an adequate investigation into MDR reportable events. 21 C.F.R. §§ 803.50(a), 803.50(b)(3). If a manufacturer fails or refuses to submit to the FDA the required MDRs, the medical device at issue is deemed to be misbranded. 21 U.S.C. § 352(t)(2), 21 C.F.R. § 803. Under the Act, the introduction of a misbranded device into interstate commerce is a violation of the Act, 21 U.S.C. § 331(a), as is the adulteration or misbranding of a device while it is held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k).

50. FDA regulations explicitly make senior company management responsible for ensuring adherence to cGMP. When evaluating quality controls, FDA inspectors are required to evaluate, among other things, "whether management with executive responsibility ensures that an adequate and effective quality system has been established and maintained." FDA Guide To Inspections Of Quality Systems, at 18. The FDA treats management responsibility for adherence to cGMP as a very serious matter; in fact, when the FDA concludes that management is not providing sufficient oversight of the procedures used in a manufacturing facility, it may impose a requirement that top officers personally sign off on every procedure used in the facility. If the procedures and quality control systems are not adequate, are ineffective, and/or are not being maintained, then a company's executive management is not upholding its responsibilities under the Act.

51. Defendants were well aware of FDA policy with respect to cGMP. For example, as stated in each of Invacare's annual reports to shareholders during the Class Period, the Company acknowledged that "The United States Food and Drug Administration (the "FDA") regulates the manufacture and sale of medical devices. Under such regulation, medical devices

are classified as Class I, Class II or Class III devices. The company's principal products are designated as Class I or Class II devices. In general, Class I devices must comply with labeling and record keeping requirements and are subject to other general controls. In addition to general controls, certain Class II devices must comply with product design and manufacturing controls established by the FDA."

52. Likewise, Defendants understood the ramifications of Invacare's failure to comply with FDA requirements. As stated in each of Invacare's annual reports to shareholders during the Class Period, "The company's failure to comply with the regulatory requirements of the FDA and other applicable U.S. regulatory requirements may subject the company to administrative or judicially imposed sanctions. These sanctions include warning letters, civil penalties, criminal penalties, injunctions, product seizure or detention, product recalls and total or partial suspension of production."

53. While regulated facilities are typically inspected by the FDA once every three years as a matter of course, inspections may be more frequent if the FDA has cause for concern. According to FDA procedures, if an FDA inspector discovers "significant" deviations from cGMP during an inspection, he or she delivers a report on FDA Form 483 to senior management at the conclusion of the inspection. "The Form FDA 483 Inspectional Observations is intended for use in ***notifying the inspected establishment's top management*** in writing of significant objectionable conditions, relating to products and/or processes, or other violations of the FD&C Act and related Acts which were observed during the inspection." FDA Investigations Operations Manual 2009 § 5.2.3.

54. According to FDA Field Management Directive No. 120, "Inspectional Observations (FDA 483) are of critical importance to both the Agency and regulated industry."

Inspectors are instructed that "Observations which are listed should be significant and correlate to regulated products or processes being inspected," and that "Observations of questionable significance should not be listed on the FDA 483." The Directive also requires that copies of each Form 483 be sent to "the top management official of the firm inspected." Moreover, FDA investigators conduct exit or close out interviews at inspection sites with company personnel to ensure that senior management at the company has notice of the nature and seriousness of the findings, ensure that the company understands the issues identified in the observations and confirm that the facts underlying the observations are correct and that relevant documentation has been collected (if the inspection is of a serious nature). Thus, senior management of companies whose facilities are inspected by the FDA, such as Invacare, are immediately made aware of any problems at the conclusion of the on-site inspection process.

55. A "repeat" or "recurring" observation listed on a Form 483 occurs when, on two or more successive investigations, FDA investigators observe continuing problems with the same quality system(s). Repeat observations often form the basis for a Warning Letter or other enforcement action by the FDA.

56. A company will typically respond to the Form 483 within fifteen days by providing the FDA with a detailed plan to remedy the deficiencies. If the significant deviations from cGMP noted in a Form 483 are not remedied, the FDA may then issue a "Warning Letter" to the organization. A Warning Letter is a communication to the company that has been reviewed within several levels of the FDA, including the district office and FDA headquarters. The letter generally states that the company has made products that are adulterated or misbranded, violating the Act, and that the company has a very limited amount of time to address the problem(s) before the FDA takes further regulatory action against the firm, the adulterated

product, and responsible individuals. Warning Letters are only "issued for significant regulatory violations that require prompt and adequate corrective actions." U.S. Food and Drug Administration, Regulatory Procedures Manual, Ch. 4 - Advisory Actions (July 2012).

57. Warning Letters are one of the FDA's principal means of achieving prompt corrective action before the FDA initiates an enforcement action. Warning Letters are issued to achieve voluntary compliance with the Act and its implementing regulations and to establish prior notice. The issuance of a Warning Letter is widely considered to be a more serious regulatory action than the issuance of a Form 483. According to the FDA, Warning Letters should only be issued for violations of regulatory significance, *i.e.*, those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected. Warning Letters are thus reserved for more significant violations of FDA regulations. Importantly, Warning Letters typically will not be issued if the FDA finds that adequate corrective actions have been implemented following the initial notification of observed noncompliance, usually by way of Form 483. Warning Letters are relatively rare and are reserved for serious, repeat offenders. Indeed, for the entire fiscal years 2009, 2010 and 2011, the Center for Devices and Radiological Health ("CDRH"), the department of the FDA responsible for reviewing medical devices, issued annually only 136, 204 and 175 Warning Letters, respectively.

58. In exceptionally infrequent occasions when a company has ignored previous warnings by the FDA and continues to produce and distribute medical devices in significant violation of the Act, the Justice Department, at the request of the FDA, will file a complaint for injunctive relief in federal court. According to FDA guidelines, in considering an injunction, the FDA must evaluate the seriousness of the offense, the actual or potential impact of the offense on

the public, whether other possible actions could be as effective or more effective, the need for prompt judicial action, and whether it will be able to demonstrate the likelihood of the continuance of the violation in the absence of a court order. Injunction will be the action of choice when, among other things, there has been a history of prior violations, and previous attempts to correct them through alternative warnings or sanctions have not been effective. Injunctions are considered a drastic measure and are filed in only the most egregious cases. For the fiscal years 2009 through 2012, the CDRH sought a total of only **four** injunctions against medical device manufacturers, one of which was filed against Invacare.

C. The U.S. Government's Complaint For A Permanent Injunction

59. On December 20, 2012, the United States filed a Complaint For Permanent Injunction in this District (the "FDA Complaint") (attached as Exhibit 1) against Invacare, Blouch and Clines, Invacare's Director, Product Risk and Quality Engineering. The FDA Complaint sought to force the Company and any of its agents to, among other things, cease manufacturing or selling any products from the Company's Corporate Headquarters and Taylor Street Facility "unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices" comply with requirements of the FDCA. The lawsuit was the culmination of years of FDA inspections and Forms 483 violation observations at Invacare, many of which cited numerous repeat violations of the same provisions of the Act.

60. The FDA Complaint established that the Company had been violating the FDCA and, in particular, failed to comply with cGMP since at least September 2002.[2] According to the

[2] Indeed, prior to the commencement of the Class Period, the FDA inspected Invacare's Corporate facility in September 2002, October 2004, April 2005 and December 2008, and inspected the Taylor Street facility in March 2003 and December 2008. At the conclusion of

FDA Complaint, Defendants Invacare and Blouch knew of these violations since at least 2002 and had discussions and written communications with the FDA throughout the Class Period regarding the violations. Additionally, as CEO, Defendant Mixon was directly involved in communications with the FDA regarding the violations prior to and during the Class Period.

61. The violations detailed within the FDA Complaint and related FDA documentation demonstrates a pervasive pattern of systemic operational, quality and safety deficiencies and Defendants' failure to take the necessary and appropriate corrective measures at the Company's Corporate Headquarters and Taylor Street Facility.

1. Invacare Sold Adulterated Products

62. According to the FDA Complaint, the FDA inspected Invacare's Corporate Headquarters over an approximately one-month period from July 18, 2011 to August 11, 2011. "During the August 2011 inspection, the FDA investigators documented numerous violations of the QS regulations at the Corporate Headquarters. Many of these violations related directly to the manufacture [sic] powered wheelchairs at Invacare's Taylor Street facility." FDA Complaint, Ex. 1 at ¶17.

63. Specifically, the FDA investigators determined that Defendants failed to establish and maintain adequate procedures for implementing corrective and preventive action ("CAPA"), including failing to use appropriate statistical methodologies to detect recurring quality problems. *Id*. at ¶17.A. According to the FDA Complaint, Invacare also failed to establish and

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each of the prior inspections, the FDA investigators issued a Form FDA 483 detailing numerous Quality System Regulation violations, including, but not limited to, violations involving: design controls; complaint handing; corrective and preventive action; nonconforming products; and production and process controls. In addition, each of the Forms 483 documented numerous violations of the MDR regulations.

maintain procedures for receiving, reviewing, and evaluating complaints (*id*. at ¶17.F.) and failed to adequately maintain complaint files (*id*. at ¶17.H.), among other FDCA violations.

64. Defendants' FDCA violations – and efforts to avoid taking appropriate corrective action – are corroborated by accounts of former Invacare employees with first-hand knowledge of the events at issue in this action.

65. CW1, Invacare's Manager of Regulatory Affairs from September 2010 through July 2013, was initially responsible for nearly all of Invacare's regulatory affairs activities, which primarily included approval of design controls and handling complaints and recalls. However, CW1 noted that during the interview for the job, it was clear that Invacare did not want someone who was "a real stickler" for rules. To this end, CW1 was asked a couple of questions during the interview about where he/she "draws the line." It was explained that Invacare was looking for a Manager of Regulatory Affairs who could "do more with less" because Regulatory Affairs was "a cost center." CW1 was told that Invacare needed to keep costs low with respect to compliance.

66. CW1 was directly involved with the Quality Control and cGMP problems at Invacare's manufacturing facilities. CW1 also supported the Sanford, Florida facility, including all complaints and design control approvals, because there was no regulatory personnel there. CW1 confirmed that the CEOs at Invacare, *i.e.*, Defendants Blouch and Mixon, received every Form 483 sent to the Company, as the FDA purposefully addresses Forms 483 directly to a company's CEO. CW1 further confirmed that all of the issues identified in the Forms 483 and the Warning Letter that ultimately led to the FDA Complaint were legitimate, long-standing problems at Invacare.

67. For example, as noted in the FDA Complaint, Invacare's design controls were inadequate, and Invacare's 510(k) decisions were inaccurate primarily because of the Company's misunderstanding of the 510(k) requirements as to when a 510(k) should be filed.[3]

68. Similarly, according to CW1, Invacare was doing very few CAPAs, and those that were being done were not to the standard the rest of the industry would expect. CAPA is a concept within Good Manufacturing Practices ("GMP") that focuses on the systematic investigation of discrepancies (failures and/or deviations) to prevent their recurrence. Furthermore, according to CW1, there were essentially no statistical techniques being used at Invacare; something that was pretty standard to do. Invacare did not introduce a procedure for statistical techniques until one of the early 2011 (either February or March) responses to the FDA. As a result, Invacare's techniques were still "broken" throughout the Class Period.

69. Similarly, according to CW1, Invacare had failed to establish adequate procedures to track and analyze product returns and complaints to identify trends. Due largely to the size of the Company, there were numerous product returns that came in every month. Invacare was not trending those because there was no trending procedure. The Company was not trending them as complaints and was not looking to see if those returns had issues that needed Corrective and

[3] According to the FDA, "Section 510(k) of the Food, Drug and Cosmetic Act requires device manufacturers who must register, to notify FDA of their intent to market a medical device at least 90 days in advance. This is known as Premarket Notification - also called PMN or 510(k). This allows FDA to determine whether the device is equivalent to a device already placed into one of the three classification categories. Thus, "new" devices (not in commercial distribution prior to May 28, 1976) that have not been classified can be properly identified. Specifically, medical device manufacturers are required to submit a premarket notification if they intend to introduce a device into commercial distribution for the first time or reintroduce a device that will be significantly changed or modified to the extent that its safety or effectiveness could be affected. Such change or modification could relate to the design, material, chemical composition, energy source, manufacturing process, or intended use." http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/510kclearances/default.htm.

Preventative Actions or CAPAs. According to CW1, these were very big problems and "pretty systemic issues."

70. CW1 confirmed that Invacare was not cooperative with the FDA or at least had a strained relationship with them. In CW1's experience, the best policy is to give the FDA what they ask for when they are in-house, when they ask for it, as quickly as possible. By contrast, at Invacare, things were much more argumentative.

71. CW1 also confirmed that Blouch was directly involved in customer complaints at Invacare. Complaints came in through Customer Service, which was located in the same complex as headquarters just down the street. The paperwork would get entered into TrackWise, a complaint handling software. Any complaint that had to do with injury or death went to a group called the Safety Committee, which consisted of Blouch, Richey, and LaPlaca, and even CFO Gudbranson on many cases, as well as outside counsel. The Safety Committee would look to see if there were any trends. If the committee felt comfortable with what they heard, the complaint could be closed out on TrackWise. CW1 also attended Safety Committee meetings.

2. Invacare Sold Misbranded Devices

72. Under the FDCA, every manufacturer is required to submit a MDR to the FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a product may have caused or contributed to a death or serious injury, and to conduct an adequate investigation into MDR reportable events. FDA Complaint, Ex. 1 at ¶12. A device is deemed "misbranded" if a device manufacturer fails or refuses to submit MDRs to the FDA as required. *Id*. at ¶13. According to the FDA Complaint, Invacare sold misbranded products in violation of the FDCA during the Class Period. *Id*. at ¶18.

73. CW1 related that the Company's definition of what requires an MDR was contrary to the FDCA. Invacare interpreted the provision to mean that an MDR does not have to

be filed unless the company can demonstrate that their device has malfunctioned and, thus, Invacare could avoid filing MDRs unless they knew for a fact that the device had malfunctioned. According to CW1, the bar set by Clines prior to the FDA Complaint was that until Invacare could get the device back and demonstrate through their own testing that it malfunctioned, Invacare would not file an MDR. In particular, Invacare would not file an MDR if it believed that the injury or death was attributable to an accident instead of a product malfunction. However, based on his/her experience, CW1 said that most companies would have filed the MDRs in these situations, unlike Invacare. Most companies realize that there is little harm in filing an MDR if it is written properly. Most companies figure, "Why mess with it?" They would rather just file the MDR and move on.

3. Invacare Repeatedly Violated Good Manufacturing Practices

74. The FDA's August 2011 inspections also identified numerous violations of cGMP and QS regulations at Invacare's Taylor Street Facility, including failure to establish and maintain proper controls and procedures regarding "nonconforming" product and the adjustment, cleaning, maintenance and calibration of manufacturing equipment. FDA Complaint, Ex. 1 at ¶19.

75. Invacare's longstanding violations of cGMP and failure to implement appropriate remedial measures are further corroborated by the accounts of former employees. Indeed, several former manufacturing employees interviewed in connection with Lead Counsel's investigation confirmed that Invacare failed to appropriately segregate nonconforming parts and products.

76. CW2 recalled that beginning in 2010, the FDA "basically camped out" at Invacare – an unusual change from prior years. They had more auditors and stayed five to six months inspecting the Taylor Street Facility and Invacare Way Corporate Headquarters located

approximately 100 feet away. Invacare was disputing issues with the FDA and not conforming to compliance requirements. For example, the FDA required that every time Invacare performed maintenance on a machine, it had to validate the process. Invacare had never done this and did not know an easy way to do it so the FDA would say "well, you've got a problem."

77. CW5 was responsible for building and auditing both power and manual wheelchairs, and worked on every assembly line at the Taylor Street Facility. In particular, CW5 was working on the custom power wheelchair line where Invacare had problems with the FDA. According to CW5, the FDA inspections were in response to complaints (*i.e.*, they were not just regular inspections), including in response to incidents in which a couple of people had "burned up" in the wheelchairs because of issues with the electronics. "Invacare knew we had problems [but] it was just all about making money. We weren't addressing or fixing the problem, we were too busy making money." In 2009 and 2010, "everything was just business as normal." No one on the floor knew there was a problem [with the FDA]. Every so often employees would hear that "someone burned up in a chair or something," but they never heard Invacare was in trouble or having any problems with the FDA. Employees were expected to just build their chairs and go home.

78. CW5 stated that Invacare did not do a good job of segregating non-conforming parts. One day Quality Control would say that the parts were no good and could not be used. However, if the end of the month came and they needed to get chairs out, then all of a sudden those parts were good again. A part could be rejected as "no good" one day, but a few weeks, or even less, the parts were suddenly considered "good" if Invacare was not making its numbers. CW5 knew of instances where managers overrode Quality Control's nonconformance decisions. In 2012, after the FDA requested that the Company enter into a consent decree, Invacare created

cages made of chain-link fence for defective parts at each department within the Taylor Street Facility.

79. CW6 described Invacare's failure to track the serial numbers for wheelchairs, beds and other products it sold, which violated cGMP. Invacare had no way of tracking the devices it sold at the end-user level. "[T]here was no way to track recalls with the product." "Ideally, it's supposed to work that we sell a piece of equipment, write down all of the features and benefits, and that gets received by the provider. The serial number gets attached to the purchase order, and once it's issued to the provider, a serial number is sent to the provider who then keeps a record of the serial number. That's the way it's done now." When asked if Blouch, Lou Slangen ("Slangen") and Mixon were aware of the serial number and quality control issues that occurred at Invacare, CW6 stated, "They were intimately aware of it. It's their baby and it goes right on their desk. They're pulling all the strings at Invacare. Everything. Everything. They trickle the information up to the Board and Mal Mixon, and then trickle it down to everybody under them. Again, why they are still there is absolutely beyond me."

80. Invacare regional managers convened conference calls in which CW6 and other sales managers were instructed "not to say anything" about the serial number issues. Apparently, the FDA had contacted providers (Invacare customers) who in turn contacted Invacare to say "Hey, I got a call from the FDA about this." According to CW6, Blouch, Mixon and Slangen directed their regional sales managers to instruct the sales force that "it's not that big of a deal, don't worry, and this will be taken care of in no time. It's simply not that big of a deal." "The message on these calls was, 'Don't have the conversation with providers. We're taking care of this internally. Tell them not to worry, that it's not that big of a deal, and we'll get it all taken care of.'"

81. When asked to identify specific quality control problems at the Taylor Street Facility, CW7 stated: "They were not following FDA regulations . . . . All it was [about] was do your numbers, get the product out the door and that's it." CW7 confirmed that, at Invacare, nothing that was manufactured was documented," as required by FDA regulations. "All we did at the end of a shift was turn in how much numbers you did." Specifically, workers were required to report only the part number, description of the part, and how many were manufactured each day. There was no requirement to document "print numbers" (*i.e.*, the blueprint used to manufacture the part). The only thing that manufacturing employees were required to document was the part number, "never the print number," as was required by FDA regulations.

82. CW7 explained that each manufacturing department had an information center with a file cabinet organized by part number, from lowest to highest, and that for each part number a corresponding print could be found. "All you did was look up the part you were going to work with in that filing cabinet, then pull out the print." Invacare did modifications from time to time on certain parts, and when that happened, the corresponding print was supposed to be updated as well. However, CW7 explained that after manufacturing a part, and doing a quality check and "first piece inspection," if the dimensions on the part did not match the dimensions on the print, then it was apparent that the print had not been updated and the part was "out of tolerance." This happened frequently at Invacare. When parts were found to be out of tolerance, they were raised up to engineering. According to CW7, the FDA found most of their errors at Invacare's engineering department.

83. According to CW7, the quality control team at Invacare met as often as daily with Mixon and other members of Invacare upper management. When asked how involved Blouch

and Mixon were in the manufacturing process, CW7 stated, "of course they knew what was going on, of course." They were "the ones who ignored everything" with the FDA. Indeed, despite the discrepancies in manufacturing tolerances, accounting to CW7, parts still went out the door because Invacare was more concerned about meeting sales goals. "***They always wanted to go beyond [Wall Street] expectations from the previous year. It was more about sales, not about safety."***

84. CW8 confirmed information related by CW7 that Invacare employees informed supervisors and engineers time after time that blueprints were incorrect and also submited papers indicating what the engineers needed to change, the Company would never make corrections to the prints or changed them. When employees discovered a problem with the print, they filled out a "corrective action" form, which was submitted to the supervisor and in turn given to the engineers. Copies were also supposed to be provided to Invacare executive management. CW8 also confirmed that Invacare was not taking serious steps to address the problems identified by the FDA: "every time the FDA would tell Invacare what they needed to do, they weren't doing anything." As for the prints, the FDA told Invacare they were wrong but nothing was corrected or fixed until the FDA shut Invacare down.

85. According to CW8, Invacare also refused to fulfill basic, simple FDA requirements for good manufacturing practices. For example, if the Company decided to move a CNC machine to another part of the building, the machine had to be recalibrated and recertified, which Invacare would not do. Similarly, Invacare was supposed to but did not have the "check gauges" recalibrated. In fact, the FDA found that Invacare had stated in its quality [control] system that a check gauge had been recalibrated when in reality it was sitting under a desk.

86. CW8 stated that employees were forbidden from talking with any FDA inspector. Employees were instructed before the FDA came in not to address the inspector. If the inspector had any questions, only Chris Carter ("Carter") (plant manager at the Taylor Street Facility in 2011) and a select few chosen by Carter were permitted to speak to the FDA. Furthermore, CW8 explained, when the FDA inspectors were onsite, Invacare shut down certain production lines. ***"We were told that . . . if they knew the FDA was coming in, they would have certain people there staged, and a lot of times they would shut down the machinery."*** Employees were told that they had to take either a vacation day or a "lack of work" day. If the FDA became suspicious, Carter would just tell them that Invacare did not have any orders for the product that day or that the Company could only run that line on Tuesdays and Thursdays and the FDA came on a Wednesday. Decisions to shut down machinery would have come from upper management, CW8 stated.

87. According to CW8, Invacare started making small changes. ***"The Company basically just created a smokescreen because nothing ever really changed. Employees were instructed to keep running the lines the way they were . . . ."*** The Company assumed that if it made these small changes, the FDA would "back off." However, the inspector became "ticked off" when it was discovered that Invacare had moved production machinery from the Taylor Street Facility over to the Cleveland Street Facility to avoid FDA scrutiny in anticipation of the consent decree. In truth, Invacare had been moving production out of the Taylor Street Facility to other facilities to avoid FDA scrutiny since at least 2009, including, for example, moving production for a patient lift or "trapeze" to Mexico because there was no way the line would ever pass FDA inspection. In 2009, Invacare started receiving more stern warnings from the FDA and, as a result, Invacare started moving old machinery that could not hold a tolerance and would

not pass FDA inspection. CW8 confirmed that Blouch, Jim Dowdell ("Dowdell") and Rich Schwartz ("Schwartz") were at meetings in 2010 in which it was decided that Invacare would move production lines out of the Taylor Street Facility because it knew a consent decree was coming that would shut down production. Indeed, Invacare continued moving production machinery out of the Taylor Street Facility even after the FDA issued the Warning Letter in January 2011. Employees were told that because Invacare could not correct the issues cited by the FDA, the Company knew that a consent decree was coming. Employees were told by their supervisors that they had to get stuff out of Taylor Street because Invacare could not make the plant FDA compliant. These decisions to move machinery and production lines could only be made by plant managers with approval from upper management, including Blouch and Mixon. By the end of 2011, the Company had moved almost all of its assembly lines from the Taylor Street Facility to other facilities that were not being inspected by the FDA. The only lines that were left at the Taylor Street Facility were some of the power wheelchairs, recounted CW8.

88. CW8 further described efforts made by Invacare to appease the FDA as a ***"paper trail"*** and ***"smokescreen"*** and recounted that ***"[n]one of the business processes or paperwork or prints ever really changed."*** For example, Invacare repeatedly failed to segregate non-conforming product, as required by cGMP. "They did not have nonconforming bins for material that was bad, and the FDA did not like how it was segregated. The FDA went out on the [production] line and found wheelchairs that were missing parts or that were nonconforming sitting with chairs that were supposedly good [and readied for sale]." The FDA told Invacare to fix their nonconforming area, but when they returned, they found the same issue. Invacare had merely painted a yellow line on the floor to separate the nonconforming from conforming parts, which the FDA determined was insufficient.

89. In short, Invacare was merely going through the motions to create a superficial appearance of compliance but, in reality, potentially dangerous products continued to be shipped out to customers with Defendants' knowledge or conscious disregard.

D. Defendants Repeatedly Violated The FDCA And Failed To Take Appropriate Corrective Action Prior To And Throughout The Class Period

90. Defendants' violations of the FDCA commenced prior to and continued throughout the Class Period, including the very same violations that resulted in the FDA Complaint and Consent Decree. Indeed, Defendants knew about numerous, severe and pervasive problems since at least January 1996, when the FDA inspected the Company's Sanford Facility, which resulted in a detailed Warning Letter issued in May 1996 ("May 1996 Warning Letter") addressed directly to Defendant Mixon. The May 1996 Warning Letter admonished Invacare for its failure to comply with cGMP and MDR principles. Specifically, the FDA found serious deficiencies in the Company's quality controls relating to complaint-handling procedures and process and testing validation and component procedures.

91. On August 20, 1998, the FDA issued another Warning Letter to Invacare addressed to Defendant Mixon ("August 1998 Warning Letter") concerning an FDA inspection of Invacare's Sanford, Florida facility on July 22, 1998. The August 1998 Warning Letter identified a host of "serious regulatory problems involving electric patient beds, lift out chairs, and adjustable, automatic air mattresses," and noted the violations caused these medical devices to be adulterated. The August 1998 Warning Letter observed that Invacare failed: (1) to validate and document significant manufacturing processes and quality assurance tests to assure specific requirements were met; (2) to establish and maintain device history records ("DHR's") demonstrating devices are manufactured and tested in accordance with DHR and other requirements of the QS regulation; (3) to establish and maintain procedures for implementing

correct and preventive actions; and (4) to establish procedures for identifying training needs and ensuring that all personnel are trained to adequately perform their assigned responsibilities and that all training is documented. The August 1998 Warning Letter concluded by demanding that Invacare take prompt action to correct these deviations, and warned that failure to do so may result in regulatory action, including an injunction.

92. On August 26, 2003, the FDA issued another Warning Letter to Invacare ("August 2003 Warning Letter"), detailing a number of quality control deficiencies observed during March 2003 inspections of Invacare's Taylor Street Facility, Cleveland Street Facility, and Corporate Headquarters. The August 2003 Warning Letter – which was addressed to Defendant Mixon – observed violations relating to Invacare medical devices causing them to be adulterated. The August 2003 Warning Letter found that Invacare had failed to establish proper design controls and acceptance activities. In addition, the August 2003 Warning Letter observed that Invacare failed to maintain a complaint handling process ensuring "that all complaints involving the possible failure of a device to meet any of its specifications are adequately reviewed, evaluated, and investigated, as required by 21 C.F.R. 820.198(c)." The FDA inspector reviewed all forty-one complaints pertaining to alleged fire-related incidents that Invacare received from October 1, 2002, to March 10, 2003, the majority of which involved smoking caused by a faulty gearbox seal. The FDA inspector noted that "[t]here was no documentation to show that Invacare investigated and evaluated these complaints to determine whether the smoking gearboxes are a safety concern," and there was no indication that Invacare planned to perform a safety assessment for these complaints. The August 2003 Warning Letter concluded by demanding that Invacare take prompt action to correct these deviations, and warned that failure to do so may result in regulatory action, including an injunction.

93. In December 2008, just prior to the start of the Class Period, the FDA conducted inspections of Invacare's Corporate Headquarters and Taylor Street Facility and observed MDR reporting violations at both locations. On November 29, 2009, following those inspections, the FDA issued an untitled letter to Invacare, addressing the MDR reporting violations and warning Defendants that further enforcement actions could occur if they did not correct the violations.

94. On August 18, 2010, after completing no less than twelve separate inspections of Invacare's Sanford, Florida facility between August 2, 2010 and August 18, 2010, the FDA issued a twelve-page Form 483 addressed to Chris K. Carter, Director of Operations, making ten separate observations. *See* Ex. 2. These observations identified serious safety, recordkeeping, and compliance deficiencies at nearly every level of the Sanford, Florida facility – from the Company's failure to respond adequately to recurring reports that its electric beds had caught fire and caused patients to become trapped between the rail and the mattress, to inadequate design validation procedures, and the lack of sufficient training of plant employees.

95. The FDA's observations in the August 2010 Form 483 identified serious quality control failures that were entirely consistent with previous FDA Warning Letters. The FDA's observations included, among other deficiencies, the following:

- Failure to evaluate complaints involving the possible malfunction or mislabeling of its devices. In particular, between February 19, 2009 and April 13, 2010, Invacare received at least nine separate complaints regarding patients getting trapped in the mattress and railing of Invacare's bed systems that may have caused or contributed to their deaths. In addition, between February 23, 2010 and June 25, 2010, the Company received thirteen separate complaints of Invacare control systems shooting sparks or beds catching fire, including two such incidents reportedly resulting in death to the users. Nevertheless, with respect to each complaint, the Company failed to document the root cause of the incident;

- Failure to document corrective and preventive actions in response to reports of entrapment involving Invacare medical beds sometimes resulting in death;

- Failure to complete proper risk analysis on the patient entrapment issue;

- Failure to establish and maintain adequate design validation procedures, particularly with respect to assuring that labeling adequately communicates to patients that use of non-Invacare mattresses could lead to higher risk of death;

- Failure to submit an MDR report to the FDA on at least two occasions regarding received complaints concerning entrapment of patients in Invacare beds; and

- Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities, particularly with respect to complaint handling procedures.

96. As a result of the August 2010 inspections and Invacare's inadequate response, the FDA issued another Warning Letter to Invacare on December 15, 2010 ("December 2010 Warning Letter"), detailing numerous problems at the Sanford Facility that had been identified in the August 18, 2010 Form 483 following the FDA inspections. *See* Ex. 3. The December 2010 Warning Letter – which was addressed to Defendant Mixon – described Invacare's pervasive lack of quality control procedures and called for Invacare to conduct "systemic corrective action."

97. The December 2010 Warning Letter stated that Invacare's manual, electric, and semi-electric beds were adulterated within the meaning of the FDCA based on five separate violations of the cGMP, as follows:

- *First*, the December 2010 Warning Letter found that Invacare failed to establish and maintain adequate procedures for analyzing complaints, including those related to entrapment and potential fire hazard.

- *Second*, the December 2010 Warning Letter stated that Invacare failed to establish and maintain adequate procedures for implementing corrective and preventive actions because, although Invacare had received numerous complaints relating to potential sparks/fires associated with the beds, as well as complaints relating to entrapment with the use of Invacare's bed rails, the Company had failed to implement effective corrective or preventative actions to prevent the recurrence of nonconforming products.

- *Third*, the December 2010 Warning Letter stated that Invacare failed to maintain an adequate record of its investigations, including the dates and results of the investigations, in connection with fire and entrapment issues. Moreover, Invacare's response to the August 18, 2010 Form 483 "did not discuss how [it] will conduct a

> ***systemic corrective action*** that involves re-assessing all complaints to ensure that the investigations were adequately completed and documented."

- *Fourth*, the December 2010 Warning Letter stated that Invacare failed to establish and maintain adequate device design validation procedures in that Invacare had not performed a risk analysis related to entrapment, bed rails and mattress. The FDA again noted that Invacare's response to the August 18, 2010 Form 483 did not discuss how it "will conduct ***a systemic corrective action*** that includes a retrospective review and reevaluation of other types of complaints to ensure that the risk analysis has been appropriately updated."

- *Fifth*, the December 2010 Warning Letter stated that Invacare failed to ensure that all personnel are trained to adequately perform their assigned responsibilities, particularly with respect to complaint handling and analysis.

98. In addition, the December 2010 Warning Letter stated that Invacare's medical bed devices were misbranded in that Invacare failed to comply with the regulations regarding the submission of MDRs. The December 2010 Warning Letter stated that on at least two occasions, Invacare received complaints from consumers regarding fire issues with Invacare beds, but neglected to report this information to the FDA.

99. Tellingly, the FDA concluded its December 2010 Warning Letter with the following admonition:

> The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of the inspection ***may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violation(s), and take prompt actions to correct the violations and to bring your products into compliance***.

100. Significantly, the May 1996, August 1998, and August 2003 Warning Letters all described quality control violations substantially similar to those described in the December 2010 Warning Letter, including adulterated devices and failure to validate and document processes and quality assurance tests. Defendants failed, however, to take appropriate action and reasonably respond to the substantial warnings they received over a course of nearly fifteen years.

101. On December 17, 2010, two days after transmitting the December 2010 Warning Letter, the FDA issued two additional Forms 483 relating to deficiencies at Corporate Headquarters and the Taylor Street Facility. *See* Ex. 4. These new Forms 483 memorialized FDA inspector observations from more than fifty inspections at these facilities between August 11, 2010, and December 17, 2010.

102. In those Forms 483, the FDA documented numerous QS violations, which were nearly identical to those cited in the May 1996, August 1998, August 2003, and December 2010 Warning Letters, including, but not limited to, violations involving: design controls (21 C.F.R. § 820.30); complaint handling (21 C.F.R. § 820.198); corrective and preventive action (21 C.F.R. § 820.100); nonconforming products (21 C.F.R. § 820.90); and production and process controls (21 C.F.R. § 820.70). In addition to these QS violations, FDA investigators documented numerous violations of the MDR regulations similar to those cited in the May 1996, August 1998, August 2003, and December 2010 Warning Letters, including, but not limited to, violations involving: failure to submit an MDR report to the FDA within thirty days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury. Indeed, a disturbing twelve of the nineteen total observations made by FDA inspectors in the December 17, 2010 Forms 483 of the Corporate Headquarters and Taylor Street Facility were deemed "Repeat Observations."

103. Notably, the Company did not immediately disclose receipt of the December 2010 Warning Letter, or the two new Forms 483, to investors. Instead, the market learned of the December 2010 Warning Letter on January 4, 2011, when the FDA released a copy of the Warning Letter to the public. In response, Invacare common stock dropped from $30.67 per

share on January 3, 2011, to close at $29.29 per share on January 4, 2011, a decline of 4.5% or $1.38 per share, on usually high trading volume.

104. From July 18, 2011 through August 11, 2011 ("August 2011 Inspections"), the FDA inspected Invacare's Corporate Headquarters and the Taylor Street Facility. During these inspections, the FDA investigators documented numerous violations of the QS regulation at the Corporate Headquarters facility. Many of these violations related directly to the powered wheelchairs manufactured at Invacare's Taylor Street Facility.

105. During the August 2011 Inspections of the Corporate Headquarters, FDA inspectors observed that Invacare had failed to perform the following quality controls: (1) establish and maintain adequate procedures for implementing corrective and preventive action, including using appropriate statistical methodology where necessary to detect recurring quality problems; (2) establish and maintain adequate design validation procedures to ensure that devices conform to defined user needs and intended uses, to complete proper risk analysis, and to document the results of the validation; (3) establish and maintain adequate procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements; (4) establish, maintain, and document adequate procedures to ensure that the design inputs are appropriate and address the intended use(s) of the device, including the needs of the user and the patient; (5) establish and maintain procedures for receiving, reviewing, and evaluating complaints; (6) document corrective and preventive actions; (7) to adequately maintain complaint files by a designated unit to include a record of the complaint investigation; (8) ensure that all personnel are trained to adequately perform their assigned responsibilities; and (9) have sufficient personnel with experience to assure that all activities required by cGMP are correctly performed.

106. At the August 8, 2011 inspection of Corporate Headquarters, FDA investigators also determined that Invacare had failed to comply with the regulations regarding the submission of MDRs and the maintenance of an adequate MDR procedure that provides for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements. Specifically, the FDA observed that Invacare's MDR reporting procedures failed to describe how it will submit supplemental or follow-up reports, define how Invacare will conduct an investigation and evaluation of each event, or establish documentation and record keeping requirements, as required by cGMP.

107. Similarly, during the August 2011 inspections of Invacare's Taylor Street Facility, where Invacare manufactures powered wheelchairs and accessories, the FDA investigators documented the following violations of the QS regulation: (1) failure to validate certain manufacturing processes; (2) failure to review, validate, and document changes or process deviations and perform revalidation where appropriate; (3) failure to establish and maintain adequate procedures for implementing corrective and preventive actions; (4) failure to establish and maintain adequate procedures to control product that does not conform to specified requirements; (5) failure to establish, maintain and document adequate procedures for rework, to include retesting and reevaluation of the nonconforming product after rework, to ensure the product meets its current approved specifications, and to document the rework and reevaluation activities, including a determination of any adverse effect from the rework on the product; (6) failure to adequately establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met; and (7) failure to establish and maintain adequate procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities.

108. On August 8, 2011, Invacare received two additional Forms 483 relating to objectionable conditions at its Corporate Headquarters and the Taylor Street Facility. *See* Ex. 5. The August 8, 2011 Form 483 relating to the Taylor Street Facility set forth eight violations, five of which were repeats from the previously issued Form 483. The August 8, 2011 Form 483 relating to Corporate Headquarters was perhaps even more troubling. The Form 483 contained thirteen violations, ten of which were "repeat observations" of unremedied quality control deficiencies expressed in from the December 17, 2010 Form 483. Indeed, the FDA inspector noted that Invacare's quality controls were so deficient that corrective and preventative actions were not initiated for five observations listed on the FDA's December 17, 2010 Form 483. Moreover, in detailing Invacare's risk analysis deficiencies, the FDA inspector pointed out that Invacare had failed to properly evaluate 132 out of 137 Risk Analysis Records (or 96%). Further, in explaining Invacare's complaint handling deficiencies, the FDA inspector noted that all 35 out of the 35 complaint calls reviewed were not properly documented. Despite these clear messages from the FDA concerning Invacare's continued and blatant noncompliance—especially in light of the significant number of repeat violations—the Company did not reveal its receipt of the August 8, 2011 Forms 483 to investors.

109. On October 24, 2011, representatives of Invacare attended a regulatory meeting with FDA's Center for Devices and Radiological Health and Cincinnati District Office. At this meeting, Defendants acknowledged that they were aware of the violations at their facilities and promised to correct them.

110. Three days later, on October 27, 2011, Invacare issued a press release announcing its third quarter financial results, which disclosed that the Company was "actively making systemic improvements across its quality and regulatory systems" in response to the deficiencies

cited by the FDA over the course of the preceding year. In response, Invacare's stock price dropped from $23.81 per share on October 26, 2011, to close at $22.80 per share on October 27, 2011, a decline of 4.3% or $1.01 per share, on usually high trading volume.

111. Notwithstanding the FDA's intensified scrutiny of Invacare's operations, Defendants failed to correct the pervasive quality-related issues that ailed the Company. On November 8, 2011, Invacare revealed for the first time that it received the Forms 483 in connection with 2010 and 2011 inspections of the Company's Corporate Headquarters and the Taylor Street Facility. The Company continued to assure investors that it was "working with the FDA to resolve the inspectional observations identified in the warning letter and in the FDA-483s for the Sites."

112. One month later, on December 8, 2011, Invacare shocked investors by issuing a press release announcing that the FDA intended to seek a consent decree of injunction against Invacare relating to its Corporate Headquarters and the Taylor Street Facility. The Company's press release acknowledged that the consent decree was the result of the FDA's prior inspections, and would require the suspension of most operations at the Taylor Street Facility – the Company's most profitable power wheelchair business – as well as Corporate Headquarters until those facilities became compliant with FDA regulations. In addition, the press release stated that "Invacare has confirmed that it intends to enter into discussions with the FDA regarding the terms of the consent decree."

113. As a result of Invacare's shocking disclosure, Invacare stock plummeted nearly 29%, or $5.88 per share, from $20.58 per share on December 7, 2011 to close at $14.70 per share on December 8, 2011, destroying over $180 million in shareholder market capitalization in a single trading day.

E. Post-Class Period Events

114. The announcement of the FDA's intent to seek a consent decree to halt the normal design and manufacturing activities at Invacare's Taylor Street Facility and Corporate Headquarters, and Invacare's extraordinary efforts to comply with the terms of the Consent Decree – including enormous amounts of time and expenses to implement long overdue, company-wide improvements in the Company's regulatory compliance processes – have had a devastating impact on the Company's business, operations and financial condition. As discussed below, Invacare has incurred, and continues to incur, substantial declines in both sales volume and margins, substantial delays in new product launches, and more than $40 million in additional "quality and regulatory costs" related to the Consent Decree to date. Indeed, belatedly making regulatory compliance a priority, Invacare has been forced to delay even new product development – a decision that Defendants acknowledge "had a ripple effect on the performance of the organization" and will continue to have profound effects for years to come. As recently as two weeks ago, Invacare reported to shareholders that "the limitations in the consent decree had, and likely will continue to have, a material adverse effect on the company's business, financial condition and results of operations."

115. Nearly two years have passed since December 2011, the end of the Class Period, when Invacare announced that the FDA intended to seek the Consent Decree. During this time, Invacare negotiated the terms of the Consent Decree and has begun to undertake the steps necessary to bring the Company into full regulatory compliance. Despite these systemic improvements and the attendant substantial expenditure of funds and diversion of management resources, Invacare has not returned to normal operations and has not removed itself from the Consent Decree. Moreover, during this time, in both words and deeds, Defendants have tacitly admitted that their prior efforts during the Class Period to respond to the FDA's serious concerns

about the Company's systemic compliance deficiencies were not only woefully inadequate, but essentially negligible.

116. On December 9, 2011, the day after the FDA's proposed Consent Decree was revealed, the *Chronicle-Telegram* published an article titled, "FDA May Idle Invacare Plant." The article quoted Invacare spokesperson and Director of Investor Relations and Corporate Communications, Lara Mahoney ("Mahoney"), regarding the expected consequences of the Consent Decree. "It's highly likely there will be some suspension of production," Mahoney stated, explaining that the FDA's proposed Consent Decree contained provisions that would require suspension of certain operations and functions at the Taylor Street facility and Corporate Headquarters until they are certified to be in compliance with federal regulations. Defendant Blouch was overseeing the remediation process, the article stated.

117. On January 4, 2012, the Company announced that it had hired a new Senior Vice President of Quality Assurance and Regulatory Affairs to help Invacare work through its quality control issues with the federal government. The new hire, Doug Uelman ("Uelman"), joined the Company in late December and had more than 30 years of experience in quality-control and regulatory roles, principally in the medical device industry. Commenting on the hire in a January 6, 2012 article in the *Chronicle-Telegram*, Company spokesperson Mahoney said that Uelmen reports directly to Blouch and that Blouch would remain "very involved" in the remediation process.

118. On March 26, 2012, Invacare filed with the SEC its Annual Report on Form 10-K for 2011 ("2011 Annual Report"). The 2011 Annual Report disclosed that once the terms of the Consent Decree were negotiated, "they will result in the suspension of a portion, which could be substantial, of the company's operations at its wheelchair manufacturing facility in Elyria, Ohio."

In addition, the 2011 Annual Report stated, a suspension of operations "likely would have adverse effects on the company's business, including loss of revenues, harm to the company's reputation and customer dissatisfaction." Moreover, the 2011 Annual Report warned investors, the Company's diversion of "substantial financial, management and engineering resources to making the systemic improvements necessary to comply with the terms of the consent decree and maintain compliance in the future . . . could impact other areas of the company's business, such as, for example, delays in new product development and cost reduction and globalization activities. All of these factors could result in material adverse consequences to the company's business, performance, prospects, value, financial condition, and results of operations."

119. The 2011 Annual Report further noted that the FDA, in connection with its December 2010 Warning Letter regarding similar deficiencies in quality system processes and procedures at Invacare's Sanford Facility, had "refused to provide new export certificates for company products until the matters covered in the warning letter are resolved."

120. On April 26, 2012, Invacare issued a press release and Form 8-K announcing the Company's first quarter 2012 financial results. For the first quarter of 2012, the Company reported a 22% decrease in earnings per share compared to the same period a year ago, "[p]rimarily as a result of . . . incremental regulatory and compliance costs." Contributing to the disappointing financial results were declining sales at Invacare's North American/HME segment, including a 3.0% decrease in organic net sales compared to the same quarter a year ago. Commenting on the disappointing financial results, Defendant Blouch explained that, "Throughout the first quarter of 2012, Invacare continued to dedicate significant resources to its regulatory and quality systems improvements, including those related to observations made by the United States Food and Drug Administration (FDA)." Moreover, "[i]n addition to the

incremental costs," Blouch added, "the Company has diverted internal resources to accelerate progress on quality systems improvements" which "temporarily impacted other areas of the Company's business, including delays in new product introductions and progress on its Globalization initiative." Blouch noted that while the Company was negotiating with the FDA the terms of the proposed Consent Decree, "it is working expeditiously to make systemic improvements to ensure full compliance with the FDA's Quality System Regulation (QSR)"—thus admitting that the Company did not make the systemic improvements necessary to ensure QSR compliance during the Class Period.

121. On the earnings conference call later that day, Defendant Blouch stated that the Company had incurred $4.1 million in incremental costs related to regulatory and compliance in the first quarter of 2012, or roughly twice the $2.1 million that the Company spent in the fourth quarter of 2011 before the FDA indicated its intent to seek the Consent Decree. Blouch emphasized that the remediation efforts were now Invacare's number one priority—even if it meant putting aside key strategic initiatives and foregoing valuable growth opportunities. For example, in response to an analyst's question about whether the Company might pursue acquisitions, including as part of the Invacare's globalization initiative, Blouch replied:

> My current thoughts are it would have to be extraordinary to cause me to want to gamble on our remediation efforts which I don't want to do. That's first and foremost. It's not that there are opportunities out there. We continue to work on that portfolio, right now, there are few parts of organization that aren't actively involved in the remediation and HR is working on training and recruiting, finance is working on dashboards and integrations. So everybody is in the game. So throwing an acquisition of any consequence wouldn't be wise at the moment.

122. On May 7, 2012, Invacare filed its Form 10-Q for the first quarter of 2012. In it, the Company again disclosed that it was "devoting additional substantial financial, management and engineering resources to make the systemic improvements necessary to comply with the terms of the consent decree [and the warning letter issued with respect to the Sanford Facility]

and maintain compliance in the future." Likewise, the Form 10-Q disclosed that Invacare was diverting additional "internal resources to accelerate progress on quality systems improvements" which "temporarily impacted other areas of the company's business, including delays in new product introductions and progress on its Globalization initiative."

123. On May 15, 2012, Defendant Blouch addressed investors regarding the proposed consent decree at the Bank of America Merrill Lynch 2012 Health Care Conference in Las Vegas. Blouch stated that he expected that a "significant portion" of the Taylor Street Facility "would be curtailed" while Invacare "remediate[d] the deficiencies." Blouch was unusually frank in admitting that the Company was working much harder to resolve the deficiencies than it had in 2011. Blouch explained that after the FDA indicated that it would pursue a Consent Decree, the Company "significantly increased the scope of our remediation efforts," including the "redesign" of quality compliance and implementation, training, and effectiveness checks for "12 individual work streams." "Once you have a consent decree," Blouch commented, "the scope of what you need to do increases." Blouch added that Invacare now expected "to be on the Good Citizens List with the FDA."

124. Significantly, however, Defendant Blouch did not explain at the May 15 investor conference why Invacare had waited until it received a consent decree from the FDA to initiate such "global" remediation efforts, and why Invacare had not implemented such remedial measures earlier in response to the FDA's repeated issuance of Forms 483 and Warning Letters directed to individuals at the highest levels of the Company, including Blouch himself. Nor did Blouch explain why management expected "to be on the Good Citizens List with the FDA" simply because it had belatedly implemented compliance improvements to address deficiencies that the FDA had been hounding Invacare management about for years.

125. On July 26, 2012, Invacare issued a press release and Form 8-K announcing the Company's financial results for the second quarter and first half of 2012. In the press release, Defendant Blouch stated that the Company was continuing to invest in QS improvements "related to previously disclosed observations made by the United States Food and Drug Administration (FDA)" and that "primarily as a result of the related regulatory and compliance costs, adjusted earnings per share decreased 33% . . . in the second quarter of 2012" compared to the second quarter of 2011. In addition, stated Blouch, there were "multiple pressures facing the Company" including "the previously disclosed delay of new product introductions due to the Company's diversion of internal resources in order to accelerate the progress on its remediation effort." Moreover, because the Company was still negotiating the terms of the Consent Decree, Invacare could not provide any guidance for 2012. Blouch reassured investors, however, that "remediation remains the Company's first priority."

126. The remediation efforts necessary were not limited to any single Invacare department or facility but – like the problems that necessitated remediation – were systemic, pervasive and Company-wide. On September 22, 2012, the *Chronicle-Telegram* reported on the ongoing Company-wide effort at Invacare to address its pervasive regulatory compliance deficiencies in preparation for a third-party audit scheduled for the fourth quarter. In the article, Company spokesperson Mahoney commented on the extensive personnel changes and significant efforts needed to rebuild Invacare's quality infrastructure. While refusing to disclose how many new quality control experts the Company had hired, spokesperson Mahoney explained that, "It's in the double digits and a significant effort to rebuild our quality system" and the improvements would be "company-wide." "It's more than a plant — it's a quality system transformation," Mahoney emphasized. "It covers everything from how a customer service department collects

and tracks customer quality data information to how equipment is validated — which means making sure a piece of equipment is going to do what it's supposed to do and document it."

127. Like Defendant Blouch, however, Mahoney did not explain to the *Chronicle-Telegram* why Invacare had not attempted to make such comprehensive, Company-wide improvements to its quality system during the Class Period – including in response to years of adverse FDA Forms 483 and multiple Warning Letters detailing substantially the same or similar deficiencies at Invacare's U.S. manufacturing facilities and Corporate Headquarters – to ensure that something as basic as that a medical device "is going to do what it's supposed to do" and to "document it."

128. On October 25, 2012, Invacare issued a press release and Form 8-K announcing financial results for third quarter and first nine months of 2012, including earnings per share of $0.09 as compared to $0.40 a year ago—a 79% decline. In addition, net sales at the North America/HME segment decreased 9.3% compared to the same period last year, driven by declines in all three product categories principally as a result of delays in new product introductions as a result of Company-wide remediation efforts. Moreover, the press release continued, "[u]ncertainty regarding the resolution of the Company's consent decree with the FDA impacted the Company's ability to renegotiate existing contracts that require uninterrupted supply and likely led some providers to be cautious in their spending with Invacare." Commenting on the third quarter financial results, Defendant Blouch emphasized that, "The Company's first priority continues to be focused on making improvements to its quality systems related to previously disclosed observations made by the United States Food and Drug Administration (FDA)." Blouch continued, "Throughout the year the Company has faced several internal and external challenges that have lowered the Company's sales and margins.

Internally, one of the key pressures is the delay of new products, particularly higher margin products. The Company has temporarily ceased most new product development, because the majority of its engineers are currently focused on remediation."

129. On December 20, 2012, the FDA announced that it had completed its negotiations with the Company and had entered into a formal Consent Decree with Invacare that would sharply curtail the Company's research, development and manufacturing activities. As stated in the FDA's press release, the ***"consent decree of permanent injunction require[es] the company to stop manufacturing, designing, and distributing manual and powered wheelchairs and wheelchair components . . . until it corrects all violations listed in the consent decree and it has been notified by the FDA that it is in compliance with the Federal Food, Drug, and Cosmetic Act."***

130. Under the terms of the Consent Decree, which was signed by Defendant Blouch, Invacare is prohibited, with limited exception,[4] from the manufacture and distribution of custom power and manual wheelchairs, wheelchair components and wheelchair sub-assemblies at or from the Taylor Street Facility. In addition, the Consent Decree restricts design activities related to wheelchairs and power beds at the Taylor Street Facility and Corporate Headquarters. In explaining the basis for the Consent Decree, the FDA stated that, "Seven FDA inspections of the Invacare facilities subject to the consent decree since 2002 have documented violations of FDA's Quality System regulations, along with failures to properly report adverse events to the agency."

[4] The Consent Decree permits Invacare to continue to produce from the Taylor Street facility certain medically necessary products, as well as ongoing replacement, service and repair of products already in use, and fulfill purchase orders and quotes that were in the Company's order fulfillment system prior to the effective date of the Consent Decree.

131. Pursuant to the Consent Decree, Invacare must successfully complete a three-step expert certification audit process, with each step followed by an FDA inspection of the Company's QSR compliance, in order to resume full operations at the Company's impacted facilities. In the first step, a third-party expert must inspect the Taylor Street facility and review its validation procedures as well as the documentation for equipment and processes. In the second step, the third-party expert must review the Company's controls over its designs. In the third step, another third-party audit will be conducted to confirm improvements from the first two reviews. After each of these steps, the expert certification report must be reviewed by the FDA, which completes its own review procedures. Finally, once satisfied with the Company's compliance, the FDA is to provide written notification that the Company is in compliance, and only then will the impacted Invacare facilities be able to resume operations.

132. The following day, December 21, 2012, *The Plain Dealer* reported on the Consent Decree's negotiation and strict terms. "After more than a decade of questions about the safety of Invacare Corp.'s powered wheelchairs, the company has signed an agreement with federal regulators that narrowly avoids a federal shutdown of its Elyria plant," the article began. The article then sets forth a laundry list of quality and safety problems at Invacare over the past decade, including recalls, lawsuits, and multiple FDA inspections that "documented numerous violations" at Invacare's U.S. facilities. Quoting the FDA's Complaint for Permanent Injunction, *The Plain Dealer* reported that during years of previous FDA inspections – including in 2002, 2004, 2005, 2008, and 2010 – the "FDA repeatedly observed and documented violations" to quality regulations similar to those cited in the 2011 FDA inspections.

133. On December 27, 2012, just days after Christmas, Invacare issued a press release announcing that the Company had initiated an "immediate workforce reduction" as a result of the

Consent Decree, including the termination of 40% of the employees at the Taylor Street Facility, or 143 of 365 jobs. The terminations would require the Company to incur restructuring charges "not to exceed $1.25 million," the press release stated. According to an article published the next day by the *Chronicle-Telegram*, "employees said when they returned just one day after Christmas they were handed a notice informing them of when they could return the next day to meet with company officials. Upon returning the next day, the 143 employees were notified they were being laid off." The article noted that many of the terminated employees "had more than 15 years of seniority" at the Company.

134. On March 15, 2013, Invacare filed with the SEC its Annual Report on Form 10-K for 2012 (the "2012 Annual Report"), which was accompanied with a letter to shareholders from Defendants Blouch and Mixon. At the beginning of the letter, Blouch and Mixon acknowledged that "2012 was a challenging year for Invacare" as the Company incurred ***"more than $20 million in incremental quality and regulatory costs"*** and was forced to ***"delay most new product development to allow its design engineers to focus on quality systems remediation"*** in order to address the FDA's concerns. Blouch and Mixon stressed this was a "concerted effort to update and implement a comprehensive portfolio of processes" compliant with the FDA's QSR and that the improvements "will be standardized across all of the Company's FDA registered facilities." The Defendants also noted that the need to delay new product development while the Company addressed its regulatory compliance deficiencies ***"had a ripple effect on the performance of the organization."***

135. In particular, the letter stated, the Consent Decree had a deleterious impact on the business and financial performance of Invacare's core North American/HME segment. Under a section titled "Consent Decree," Defendants Blouch and Mixon explained that "[d]uring consent

decree negotiations last year, and now during the decree's effectiveness, the Company experienced pressures on its net sales and operating results principally in its North American/Home Medical Equipment (HME) mobility and seating segment." The Defendants noted that the adverse effects of the Consent Decree would continue into 2013, and possibly beyond. "In 2013, the Company expects continued pressure on its organic net sales, cash flow and operating profitability," the letter continued. "The key drivers of these pressures include the ongoing quality systems remediation costs, the related diversion of resources and the limited production resulting from the consent decree." Finally, the letter to shareholders explained that in order for the Consent Decree to lift, Invacare would have to complete "three expert certification audits followed by a comprehensive FDA inspection and receipt of the FDA's confirmation of compliance" – all of which were ongoing and the Company did not expect to complete until sometime "within the first half of 2013."

136. The 2012 Annual Report detailed the devastating impact of the Consent Decree on the Company's business, operations and financial condition – including "an additional $22,757,000 in 2012 for regulatory and compliance costs to quality systems improvements compared to 2011" – and the Company's expectation that "these challenges could negatively impact the company's operating results in 2013 to an even greater degree than was experienced in 2012":

> During the pendency of the consent decree negotiations, and now during its effectiveness, the company has experienced pressures on its net sales and operating results from this segment. While, at the time of this filing, the consent decree had been effective for only approximately two months and thus, the effect on customer orders and net sales was not yet clear, the company expects to experience further declines in net sales as a result of the limitations imposed by the consent decree . . . . The company expects to continue to experience decreased net sales and challenged profitability in the North America/HME segment until it has successfully completed the previously described third-party expert certification audit and FDA inspection and has received written notification from

> the FDA that the company may resume full operations. ***For example, the company expended an additional $22,757,000 in 2012 for regulatory and compliance costs to quality systems improvements compared to 2011.*** Even after the company receives the FDA notification, it is uncertain as to whether, or how quickly, the company will be able to rebuild net sales to more typical historical levels, irrespective of market conditions. ***Accordingly, the company expects that these challenges could negatively impact the company's operating results in 2013 to an even greater degree than was experienced in 2012.***

137. On April 9, 2013, the *Chronicle-Telegram* reported that "less than six months after cutting 40 percent of its workforce," Invacare was laying off an additional 68 hourly workers at its Taylor Street Facility. The article stated that the layoffs "mimic[] the scene just days after Christmas when 143 employees were let go and comes several weeks after some hourly employees saw their work week reduced from five days to three days" and quoted Elyria's Finance Director regarding the "ripple effect" on the city's general fund. According to Invacare's spokesperson, the workforce reduction took effect immediately and were indefinite. "When 143 Invacare employees were cut in December, it accounted for nearly $200,000 in revenue. Another 68 employees lost could be upward of $50,000 more," the *Chronicle-Telegram* reported. "Ouch, can't take losing too many employees," the article quoted the City Finance Director, Ted Pileski.

138. On April 25, 2013, Invacare issued a press release reporting its financial results for the first quarter of 2013. For the first quarter of 2013, Invacare's first quarter under the agreed-upon Consent Decree, the Company's financial results were "dramatically impacted" by the Consent Decree, Defendant Blouch stated. "Principally as a result of this pressure on the Company's higher margin custom power wheelchair product category, adjusted earnings per share decreased to a loss of $0.36 in the first quarter of 2013 compared to adjusted earnings per share of $0.15 in the first quarter of 2012. Organic net sales declined by 5.6% compared to the same period last year with a strong performance from Europe being more than offset by lower net sales for all other segments," Blouch explained. In addition, Blouch discussed in the press

release a "comprehensive cost reduction program" that Invacare had developed and was starting to implement, including aggressive workforce reductions at the Taylor Street Facility "to more closely align it with current production volume," "project delays," and reductions in "general expense[s]" – all of which were expected to "stabilize the business." Blouch added that the Invacare Board and management team were "committed to making the right decisions to ensure the Company is well-positioned to re-establish profitability and shareholder value when we emerge from the injunctive phase of the consent decree."

139. Later that day, the Company held an earnings conference call to discuss the Company's first quarter financial results. In response to analyst's question regarding how much Invacare had spent during the quarter "to resolve some of the issues with the consent decree," Invacare CFO Gudbranson disclosed that the Company had spent "a little more than $7 million in the first quarter of 2013," – *i.e.*, in addition to the $22.75 million spent by the Company in 2012.

140. On May 14, 2013, Invacare announced that the FDA had approved the first of the three audits required under the terms of the Consent Decree, allowing the Company to resume certain limited production activities at the Taylor Street Facility. As reported by *HME News*, an industry newspaper for home medical equipment providers, "[t]he company's consent decree with the FDA has wreaked havoc on its North American/HME segment."

141. On July 16, 2013, Invacare announced that it had passed the second third-party certification audit under the Consent Decree, and had a set a timetable for the third and most comprehensive certification audit which involves a top-to-bottom check of Invacare's compliance with FDA quality system rules. Originally, Invacare had set a target date of June 30, 2013, for passing the third audit. However, the Company's press release stated, "[i]n light of the

scope and complexity of the audit, the Company is re-evaluating its expected timing of when the report will be completed and filed with the FDA." Commenting on the audit, Defendant Blouch stated that, "While we were pleased with the progress that we had made on the final third-party certification audit, we have identified a few areas in our quality system that require additional work. We need to take the time now to reassess these sections of our quality system to ensure the processes we have put in place are sustainably compliant."

142. On July 25, 2013, Invacare issued a press release and Form 8-K announcing its financial results for the second quarter of 2013. For the second quarter of 2013, the Company reported a per share loss of $0.62 compared to a per share loss of $0.14 for the prior year period, ***a decline of over 440%***. Contributing to the losses was a substantial 11.6% decrease in net sales at the Company's core North America/HME segment as a result of the Consent Decree. Commenting on Invacare's dismal second quarter 2013 results, Defendant Blouch said, ''Three of our four business segments experienced continued pressure, primarily related to the consent decree, lack of new product introductions and unfavorable sales mix favoring lower margin products." Blouch added that, "our financial results continue to be significantly impacted by the consent decree, which limits the Company's ability to manufacture high-margin, custom power wheelchair products at our Taylor Street Facility in Elyria, Ohio, and ongoing costs related to improvements to our quality system."

143. On July 27, 2013, the *Chronicle-Telegram* reported that Invacare had laid off an additional 25 employees at its Taylor Street facility, bringing the total number of terminated employees at the plant to 235 since December 2012. According to Company spokesperson Mahoney, Invacare permanently terminated these hourly manufacturing associates due to the Company's declining production caused by the Consent Decree. "These are top-rate associates,

and these decisions are difficult to make," stated Mahoney, noting that there were now only 115 employees left at the Taylor Street facility.

144. Most recently, on October 24, 2013, Invacare issued a press release and Form 8-K announcing financial results for the third quarter of 2013 and providing an update on the status of the Consent Decree. For the third quarter of 2013, the Company reported another loss per share of $0.17, as compared to (positive) earnings per share of $0.02 in the third quarter of 2012. For the first three quarters of 2013 the Company reported an astounding per share loss of $1.12, compared to (positive) earnings per share of $0.01 for the same period in 2012. The losses were driven by continuing declines in sales volumes and margins, and increased expenditures as a result of the Consent Decree. In particular, Invacare reported that net sales had decreased by 5.6% both for the third quarter of 2013 and for the first three quarters of 2013, compared to the same period a year ago – including substantial 11.5% and 12.3% decreases in net sales for the third quarter and first nine months of 2013 at the North American/HME segment. In the press release, Invacare explained that the declining net sales (and organic net sales) were principally due to the "North America/Home Medical Equipment (HME) segment, primarily in mobility and seating products, principally due to the reduced order volume at the Company's Taylor Street manufacturing facility resulting from the FDA consent decree." Indeed, the press release stated that estimated sales of products manufactured from the Taylor Street Facility were only $43.7 million for the first nine months of the year compared to approximately $114.2 million for the first nine months of 2012 year, a decline of over 38%.

145. In addition to reporting substantial and continuing declines in sales volumes as a result of the Consent Decree, the October 24 press release reported increased expenses and decreased margins as a result of the Consent Decree. In particular, the Company reported that

gross margin as a percentage of net sales for the third quarter had decreased by almost 2% compared to the third quarter of 2012, principally because of "the North America/HME sales decline in custom power wheelchairs, which is one of the Company's higher margin product lines" and "the negative impact of reduced order volume through the Taylor Street manufacturing facility" which caused "an unfavorable absorption of fixed costs for this facility." Additionally, the Company reported that it had incurred restructuring charges at the North American/HME segment of $4.8 million for the first nine months of 2013 (in addition to $2.2 million for the same period in 2012), and "unfavorable absorption of fixed costs at the Taylor Street manufacturing facility related to the impact of the consent decree."

146. With respect to the status of the Consent Decree, Defendant Blouch stated in the October 24 press release that while the Company had made "significant progress on the final, most comprehensive third-party certification at the Corporate and Taylor Street facilities," Invacare did not expect that the third-party certification report stating that the Company is QSR compliant to be filed with the FDA for several additional weeks. Moreover, as Blouch acknowledged, even if the third-party audit certifies the Company's QSR compliance, ultimately the Company must demonstrate its QS compliance to the FDA and obtain the agency's independent approval and written notification that the Company is in compliance.[5]

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[5] Invacare's regulatory compliance deficiencies have also resulted in a variety of civil lawsuits against the Company. For example, on August 23, 2011, the City of Lansing Police and Fire Retirement System ("City of Lansing"), filed a shareholder derivative action in the Court of Common Pleas in Lorain County, Ohio against the Company's board of directors and the Company nominally, in connection with the FDA's December 2010 Warning Letter. Likewise, on February 2, 2012, another shareholder derivative lawsuit filed by Colleen Witmer asserting similar claims to those asserted by the City of Lansing was filed against substantially all of the directors and the Company nominally in the Northern District of Ohio. The Witmer complaint also alleged claims of unjust enrichment and waste of corporate assets, as well as requesting specific corporate governance reforms. Invacare's SEC filings confirmed that the costs of these

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

147. As discussed above, Defendants made a series of materially false and misleading statements and omissions during the Class Period regarding Invacare's compliance with FDA regulations and cGMP concerning, among other things, control and manufacturing systems for the quality and safety of Invacare's wheelchairs, bed systems, and other medical devices. These statements failed to disclose, among other things, that Invacare was plagued by numerous, serious and pervasive regulatory and cGMP violations, including at its major U.S. manufacturing facilities and Corporate Headquarters, and was able to report positive financial results and project continued earnings growth only by systemically violating these federal laws and regulations and refusing to implement even basic compliance processes. These statements, among other adverse facts detailed herein, became part of the total mix of information impacting Invacare's stock price, and caused Invacare shares to trade, or continue to trade, at artificially inflated prices throughout the Class Period.

148. Defendants' materially false and misleading statements and omissions generally fall within three broad categories: (1) statements and purported "risk factors" regarding Invacare's compliance with the FDCA and relevant regulations, and the programs maintained by the Company to ensure compliance;[6] (2) statements that Invacare was strengthening its compliance programs and taking measures to address, or had in fact addressed, FDA concerns and observed violations of the FDCA; and (3) misrepresentations regarding the nature, extent

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shareholder derivative actions were borne by the Company. In July 2012, the Company settled these derivative suits by agreeing to certain corporate governance improvements, including expanding the duties of the Audit Committee to oversee compliance with regulations on manufacturing medical devices, and amending the Company's whistleblower policy.

[6] Such statements are contained in each of Invacare's quarterly and annual reports filed with the SEC during the Class Period.

and seriousness of the violations identified in the December 2010 Warning Letter, and purported corrective measures being undertaken at the Company to remediate those and other violations identified by the FDA, including the materiality of the costs to and impact on the Company's business and financial performance.

149. Defendants' statements within each of these categories were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons set forth below and in Section VI. In particular, these statements were false and misleading because, among other things:

150. ***Invacare's regulatory violations were numerous, serious and pervasive***. Falsity is further demonstrated by the numerous, serious and pervasive regulatory deficiencies cited by the FDA through Forms 483 and Warning Letters prior to and throughout the Class Period. Defendants' repeated false assurances to investors that Invacare was in "substantial compliance" with laws and regulations, "adhering to high standards for quality and safety," and "strengthening" its compliance programs are belied by the contemporaneous fact that the Company was plagued with serial, repeat violations of the same FDA Quality System regulations and cGMP requirements.

Numerous: since as early as January 1996, when the FDA inspected Invacare's Sanford Facility, Invacare had been on notice of a myriad of recurring deficiencies in its quality system and medical device reporting programs, including, but not limited to, violations involving: design controls (21 C.F.R. § 820.30); complaint handing (21 C.F.R. § 820.198); corrective and preventive action (21 C.F.R. § 820.100); nonconforming products (21 C.F.R. § 820.90); production and process controls (21 C.F.R. § 820.70); and MDR mandatory reporting requirements. According to documentation that has only recently become publicly available,

prior to and during the Class Period, Invacare was subject to hundreds of FDA inspections and received not less than twelve Forms 483 and five Warning Letters, which collectively identified at least 71 violations of FDA regulations – dozens of which were "repeat" or "recurring" violations that the FDA had previously raised with Invacare as early as 1996 but which Defendants failed to correct. As opposed to "strengthening" its quality control and reporting programs, taking the FDA's concerns seriously and "working hard" to "address all of the FDA's concerns" in a timely manner, for well over a decade, Invacare undertook no comprehensive evaluation of its manufacturing operations or made any concerted effort or meaningful commitment in dollars or resources to address the FDA's observed violations.

Serious: During the Class Period, Defendants also downplayed the seriousness of the FDA-cited violations of Quality System Regulations, claiming, for example, that the December 15, 2010 Warning Letter "focuses on internal documentation and procedural processes . . . . [and] does not call into question the safety of efficacy of Invacare products." However, according to the FDA, the very purpose of the FDCA and related regulations is to serve the dual purpose of ensuring the quality, safety, and effectiveness of a manufacturer's medical devices and safeguarding public health. *See* A. Lowery, J. Strojny, and J. Puleo, Medical Device Quality Systems Manual: A Small Entity Compliance Guide, HHS Publication FDA 97-4179 (1st ed. 1996). In truth, as demonstrated by the Forms 483, Invacare's citations related to very grievous incidents of patients burning or suffocating – including fatalities of children – involving Invacare wheelchairs and beds. The FDA repeatedly cited Invacare for failing to properly evaluate and report these incidents, including finding that Invacare lacked proper procedures to determine whether the injuries and deaths were caused by Invacare products and/or whether a product recall was necessary. As a result, the FDA deemed Invacare wheelchairs and beds "adulterated" and

"misbranded" under the FDCA and related regulations. Furthermore, Defendants knew that their continuing failure to comply with cGMP requirements would have serious business consequences, including an injunction to stop production and sales of its best-selling products. As stated at the conclusion of each of the five Warning Letters received by Invacare prior to and during the Class Period, the FDA demanded that Invacare take prompt action to correct these deviations, and warned that failure to do so may result in further regulatory action, including an injunction.

Pervasive: Defendants also mischaracterized Invacare's deficient quality control and reporting systems as confined to the Company's Sanford Facility. In truth, Invacare's regulatory non-compliance was systematic and company-wide, emanating from its design and complaint/recall nerve center at Corporate Headquarters to Invacare's Taylor Street and Sanford Facilities. Indeed, as reflected in the Forms 483 and Warning Letters, Invacare's pattern of regulatory violations was "symptomatic of serious problems in [the] firm's manufacturing and quality assurance systems" that required "systemic corrective action."

151. ***The accounts of numerous long-time Invacare employees***. The eyewitness accounts of numerous former Invacare employees, each of which corroborates the other, confirm the falsity of Defendants' Class Period misstatements. Contrary to Defendants' repeated statements that the Company "respects the FDA's role," that compliance was "among the highest priorities," and that Invacare "continues to strengthen its [compliance] programs" and "had addressed" or "was addressing" FDA concerns, including "actively making systemic improvements," in truth, Invacare and the Individual Defendants fostered a deeply ingrained culture of non-compliance and contempt for the FDA and regulatory requirements. This long-standing culture of non-compliance was set by the tone at the top of the Company, borne of

Defendant Mixon's "hatred" for the FDA and determination to "fight" against agency regulation. Indeed, Mixon was "not supportive" of compliance enhancement efforts and "undermined at every step" the measures recommended by the very same people hired to implement reform at Invacare. Moreover, instead of addressing known problems, Defendants' waged a campaign of delay and misdirection with the FDA, undermining inspections, instructing employees not to cooperate with investigators, and relocating production lines and manufacturing equipment from the Taylor Street Facility to other Invacare sites in advance of the consent decree so the Company could continue to manufacture and sell products despite the impending near-complete shutdown of its Corporate Headquarters and principal manufacturing operation. In truth, Defendants' purported efforts to comply with FDA demands were a "smokescreen" made up of "Band-Aids" and a "paper trail" without any real, substantive changes.

152. Indeed, the absence of genuine reform by Defendants – despite their repeated assurances to the FDA and investors – is further confirmed by former Invacare employees who were "shocked" by the Consent Decree and were otherwise unaware of any FDA problems and described the token gestures toward compliance, such as painting lines to segregate non-conforming parts from being included in wheelchair production. By way of further example, when Invacare finally was forced to create a Chief Compliance Officer position (which did not previously exist at Invacare) and hire other compliance professionals, it did so only reluctantly and half-heartedly, making clear that it did not want anyone who was a "real stickler" for rules and, instead, wanted someone who could "do more with less" because, in Defendants' view, Regulatory Affairs was a "cost center" that did not benefit the Company's bottom line. Indeed, the Company only created a new Chief Compliance Officer position to "sugarcoat" the FDA problems and hoped to hire a "yes person" who would be complicit in their ongoing fraud. ¶251.

However, the new Chief Compliance Officer – a very experienced lawyer and compliance professional – lasted less than three weeks before abruptly resigning. Another highly-experienced medical device professional with deep compliance expertise (CW4) who was hired to help develop a culture of compliance at Invacare also left the Company after only about approximately seven months, after finding that Invacare's leadership – Mixon and Blouch – felt they knew better than the FDA and would do whatever necessary to "bypass" the FDA and "fly under [its] radar screen," particularly to avoid spending money on compliance that, in management's view, "doesn't add value to the customer or the product."

153. ***The comparatively massive expenditure of resources after the Class Period on regulatory compliance and remediation.*** Finally, the falsity of Defendants' Class Period misstatements is further confirmed by the fact that the steps taken and costs incurred by the Company on regulatory compliance activities during the Class Period pale in comparison to the enormous resources expended by the Company after the Class Period to remediate existing deficiencies and ensure full compliance with the FDA's QSR in the future. As discussed in Section VI above, before and throughout the Class Period Defendants intentionally disregarded federal law and the FDA's repeated warnings of FDCA and cGMP violations at Invacare's major U.S. manufacturing facilities and its Corporate Headquarters. Rather than undertaking any serious effort to correct these widespread deficiencies in its operational, design, and record keeping processes, Invacare generally attempted to create a "smokescreen" and "paper trail" in hopes of appeasing the FDA. For example, even after the December 2010 Warning Letter was disclosed and the Company reassured investors that it took the FDA's concerns "very seriously" and was "work[ing] with the FDA" to resolve these and other FDA concerns, the Company spent only $2 million during the third quarter of 2011, and only $4.1 million during the fourth quarter

of 2011 on compliance-related activities. In contrast, since the end of the Class Period, the Company has incurred over $40 million in regulatory compliance costs, including over $7 million in the first quarter of 2013 alone—more than three and a half times the amount spent in the third quarter of 2011, and almost twice the amount spent in the fourth quarter of 2011. The Company continues to incur substantial costs related to quality and compliance remediation that are millions in excess of amounts incurred during the Class Period.

154. Likewise, since the end of the Class Period, Invacare has devoted a far greater amount of internal resources to remediate compliance deficiencies that existed but went uncorrected during the Class Period, and to ensure full QSR compliance across the organization in the future. According to the Company, this includes virtually all parts of the organization, including engineering, finance, HR, as well as Invacare's top management. This substantial diversion of internal resources has resulted in, among other things, delay of new product development, foregoing acquisitions and other business opportunities, and interruption of the Company's strategic Globalization initiative.

155. More specifically, Defendants made the following materially false and misleading statements and omissions (identified in bold, italics) during the Class Period.

A. 2008 Annual Report

156. The Class Period begins on February 27, 2009, when Invacare filed with the SEC its Form 10-K for the fourth quarter and fiscal year ended December 31, 2008 ("2008 Annual Report"). The 2008 Annual Report, which was reviewed, authorized and signed by Defendants Mixon and Blouch (among other Invacare directors and officers), touted Invacare's remarkable growth over the past several decades to become the "world's leading manufacturer and distributor in the estimated $8.0 billion worldwide market for medical equipment and supplies used in the home." The 2008 Annual Report attributed Invacare's success in part to the

Company's focus on quality. According to the 2008 Annual Report, "Invacare is committed to design, manufacture and deliver the best value in medical products, which promote recovery and active lifestyles for people requiring home and other non-acute health care. Invacare pursues this vision by . . . continually striving for total quality throughout the organization."

157. At the same time, the 2008 Annual Report stated that the Company was "subject to extensive government regulation," including by the FDA, and "if the company fails to comply with applicable laws or regulations, the company could suffer severe criminal or civil sanctions or be required to make significant changes to the company's operations that could have a material adverse effect on the company's results of operations." The 2008 Annual Report disclosed that the FDA had conducted "periodic" inspections during the past two years at the Company's Taylor Street Facility, and assured investors that the Company was ***"currently addressing"*** the observations that the FDA had documented on the Form 483 as a result of the inspections. The 2008 Annual Report further assured investors of Invacare's "reputation for adhering to high standards of quality and safety" and that the Company was continuing to ***"strengthen its programs to better ensure compliance with applicable regulations, particularly those which could have a material adverse effect on the company."***

158. In particular, the 2008 Annual Report contained the following materially false and misleading statements and/or omissions of material fact:

GOVERNMENT REGULATION

> The company is directly affected by government regulation and reimbursement policies in virtually every country in which it operates . . . .
>
> The United States Food and Drug Administration (the "FDA") regulates the manufacture and sale of medical devices . . . . ***During the past two years, the FDA inspected the Taylor Street manufacturing facility in Elyria, Ohio. The FDA documented its inspectional observations on FDA Form 483 which the company is currently addressing*** . . . .

> From time to time, the company may undertake voluntary recalls or field corrective actions of our products to maintain ongoing customer relationships and to enhance our reputation for adhering to high standards of quality and safety. None of the company's actions has been classified by the FDA as high risk (Class I). ***The company continues to strengthen its programs to better ensure compliance with applicable regulations, particularly those which could have a material adverse effect on the company.***

159. Additionally, the "Risk Factors" section of the 2008 Annual Report further assured investors regarding the extent and adequacy of Invacare's regulatory compliance procedures, and the critical importance of such policies to the Company's operations:

> The company is subject to extensive government regulation, and if the company fails to comply with applicable laws or regulations, the company could suffer severe criminal or civil sanctions or be required to make significant changes to the company's operations that could have a material adverse effect on the company's results of operations.
>
> . . . . Violations of law or regulations can result in severe criminal, civil and administrative penalties and sanctions, including disqualification from Medicare and other reimbursement programs, which could have a material adverse effect on the company's business. ***The company has established numerous policies and procedures that the company believes are sufficient to ensure that the company will operate in substantial compliance with these laws and regulations.***

160. The 2008 Annual Report also contained a certification signed by Defendant Mixon that he reviewed the report and it "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."[7] In addition, Mixon signed a certification pursuant to the Sarbanes-

[7] The certification also represented that Mixon and Invacare's CFO were responsible for "establishing and maintaining disclosure controls and procedures" and "internal control over financial reporting" for the Company, and that they had "[d]esigned such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant … is made known to us

Oxley Act of 2002 that the Form 10-K "fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934," and that "[t]he information contained in the [Form 10-K] fairly presents, in all material respects, the financial condition and results of operations of the company."

B. First Quarter 2009

161. On April 23, 2009, Invacare issued a press release announcing its financial results for the first quarter of 2009. For the first quarter of 2009, Invacare reported earnings per share of $0.08 compared to earnings per share of $0.07 for the same period of 2008, an increase of over 14%. In addition, the Company reported an increase in organic net sales of 2.1% over the same period of 2008 "driven primarily by organic net sales performance in North America/Home Medical Equipment (NA/HME), which grew 7.1%." According to the press release, the significant sales increase at the North America/HME segment was "driven by sales increases in Respiratory, Standard and Rehab product lines," including custom power and custom manual wheelchairs, manual wheelchairs, and beds.

162. Analysts generally reacted positively to these and other statements contained in Invacare's April 23, 2009 press release. For example, that same day, analysts at Natixis Bleichroeder Equity Research ("Natixis") issued a report noting the Company's "strong results" for the United States and North America, which offset lower than expected sales in Europe and Asia. The Natixis analysts highlighted the Company's higher gross margins and cost-cutting, including management's continued focus on "cutting costs, sourcing cheaper materials and

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by others within those entities, particularly during the period in which this report is being prepared."

inputs." "Profitability Continues to Be Management's Focus – And They Appear to Be Executing," the report stated, confirming the analysts' "buy" recommendation.

163. At the same time, however, Natixis noted several significant risks facing Invacare, including: (1) "Manufacturing: Manufacturing controls may be weak . . . . If the current Good Manufacturing Practices are not maintained, the FDA could refuse to approve marketing applications"; and (2) "Regulatory: The FDA may not approve a product, manufacturing, or an indication, and can change a product's label. The government may not like a firm's marketing practices and penalize it. Manufacturing sites could be deemed unsuitable." Indeed, Natixis identified these same risks in all of their reports on Invacare during the Class Period, a total of approximately 17 different analyst reports.

164. On May 7, 2009, Invacare filed with the SEC its Form 10-Q for the first quarter of 2009, confirming the financial results previously announced by the Company in its April 23, 2009 press release. ***The first quarter 2009 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2008, and directed investors to "carefully consider the risk factors disclosed."*** The second quarter 2009 Form 10-Q contained a certification by Defendant Mixon that attested to the purported accuracy and completeness of the report.

C. Second Quarter 2009

165. On July 23, 2009, Invacare issued a press release announcing its financial results for the second quarter of 2009. For the second quarter of 2009, Invacare reported earnings per share of $0.24 compared to earnings per share of $0.17 for the same period of 2008, an increase of over 41%. In addition, the Company reported an increase in net sales of 0.5% compared for the North America/HME segment compared to the same period in 2008, driven by a 13.4% net sales increase in standard product lines, including increased volumes in manual wheelchairs and

beds, and a 1.8% increase in Rehab product line net sales, including increased volumes in customer power wheelchairs.

166. On August 6, 2009, Invacare filed with the SEC its Form 10-Q for the second quarter of 2009, confirming the financial results previously announced by the Company in its July 23, 2009 press release. ***The second quarter 2009 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2008, and directed investors to "carefully consider the risk factors disclosed."*** The second quarter 2009 Form 10-Q contained a certification by Defendant Mixon that attested to the purported accuracy and completeness of the report.

D. Third Quarter 2009

167. On October 22, 2009, Invacare issued a press release announcing its financial results for the third quarter of 2009. For the third quarter of 2009, Invacare reported earnings per share of $0.42 compared to earnings per share of $0.33 for the same period of 2008, an increase of over 27%. In addition, the Company reported that gross margins as a percentage of net sales for the third quarter was higher by 1.9% compared to the third quarter of 2008 and 1.7% compared to the prior quarter, noting that "[t]he margin improvement compared to the prior year in virtually all segments was the result of cost reduction activities."

168. Analysts reacted favorably to these and other statements contained in Invacare's October 22, 2009 press release. For example, that same day, analysts at Natixis reiterated their "buy" recommendation based on the Company's "very strong 3Q09" earnings due to "higher than expected net sales . . . and gross margins," and management's increased earnings outlook. "Profitability Thesis Still Has Legs," the report emphasized, noting that "IVC should continue to boost its profitability through continued cost-cutting measures."

169. On November 5, 2009, Invacare filed with the SEC its Form 10-Q for the third quarter of 2009, confirming the financial results previously announced by the Company in its October 22, 2009 press release. ***The third quarter 2009 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2008, and directed investors to "carefully consider the risk factors disclosed."*** The third quarter 2009 Form 10-Q contained a certification by Defendant Mixon that attested to the purported accuracy and completeness of the report.

170. **Reasons Why False:** The foregoing statements contained in ¶¶156-59, 163, 165, and 168 regarding Invacare's (1) regulatory compliance and compliance programs; and (2) measures taken to strengthen its compliance programs and address the FDA's concerns and observed violations were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in Section VI and ¶¶149-51 above. Additionally, the statements were false and misleading because Invacare was not "currently addressing" the FDA's observed violations at the Taylor Street Facility during 2007 and 2008, or "continu[ing] to strengthen its programs to better ensure compliance with applicable regulations," because, in December 2008, the FDA also inspected Invacare's Corporate Headquarters and repeatedly observed and documented violations of the QS and MDR mandatory reporting regulations almost identical to those cited in the December 2008 Taylor Street inspection, as well as in past and future inspections. At the conclusion of each of the these inspections, the FDA investigators issued a Form 483 detailing Defendants' numerous significant violations, and discussed their concerns with Defendants. As detailed in the FDA Complaint, the FDA had cited Invacare in Forms 483 and Warning Letters for numerous violations of QS regulations and other FDCA provisions, including many "repeat" or "recurring" violations dating

to as early as 2002. According to the FDA Complaint, "At these inspections, [the] FDA ***repeatedly observed and documented violations of the QS [Quality System] regulations"*** similar to the violations cited in the FDA's 2011 inspections, as well as ***"numerous violations of the MDR regulations*** at the majority of the previous inspections." Moreover, as multiple former Invacare employees have confirmed the Company was not "strengthening" its compliance programs or established and maintained policies and procedures sufficient to ensure compliance. For example, according to CW5, the Company did not take the inspectional observations in the Forms 483 seriously. CW5 stated, "Invacare knew we had problems [but] it was just all about making money. We weren't addressing or fixing the problem, we were too busy making money." In 2009 and 2010, "everything was just business as normal."

E. 2009 Annual Report

171. On February 4, 2010, Invacare issued a press release announcing its financial results for the fourth quarter and full year of 2009. For the fourth quarter of 2009, Invacare reported earnings per share of $0.55 compared to earnings per share of $0.52 for the same period of 2008, an increase of over 6%. For the full year, Invacare reported earnings per share of $1.29 versus $1.09 for 2008, an increase of 18%. In addition, the Company reported an increase in net sales at the NA/HME segment of 0.6% for the fourth quarter and 0.9% for the full year compared to 2008, driven by sales increases in Standard and Rehab product lines.

172. On February 26, 2010, Invacare filed with the SEC its Form 10-K for the fourth quarter and fiscal year ended December 31, 2009 ("2009 Annual Report"). The 2009 Annual Report, which was reviewed and authorized by Defendants Mixon and Blouch (among others), confirmed the financial results previously announced by the Company in its February 4, 2010 press release. The 2009 Annual Report, like the 2008 Annual Report, touted Invacare's rapid growth over the past several decades to become the "world's leading manufacturer and

distributor in the estimated $8.0 billion worldwide market for medical equipment and supplies used in the home." Likewise, the 2009 Annual Report touted the Company's "approximately $1.7 billion in net sales" in 2009, "representing a 16% compound average sales growth rate since 1979." The 2009 Annual Report attributed Invacare's success in part to the Company's focus on quality.

173. Also like the 2008 Annual Report, the Annual Report for 2009 disclosed that the Company was "subject to extensive government regulation," including by the FDA. The report represented that, ***"[t]he company has established numerous policies and procedures that the company believes are sufficient to ensure that the company will operate in substantial compliance with these laws and regulations.***"

174. The 2009 Annual Report also disclosed that the FDA had conducted "periodic" inspections during the past two years at Invacare's Taylor Street Facility and its Sanford Facility and "[a]t the conclusion of each inspection the FDA issued its inspectional observations on FDA Form 483." However, the 2009 Annual Report assured investors that Invacare ***"has addressed"*** the FDA's inspectional observations on the Form 483 and ***"continues to strengthen its programs to better ensure compliance with applicable regulations."*** Invacare's 2009 Annual Report contained certifications by Defendant Mixon that were substantively the same as those identified in ¶160, above.

175. **Reasons Why False:** The foregoing statements contained in Invacare's February 4, 2010 press release and 2009 Annual Report regarding Invacare's (1) regulatory compliance and compliance programs; and (2) measures taken to strengthen its compliance programs and address the FDA's concerns and observed violations were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in

Section VI and ¶¶148-153, above. Additionally, the statements were false and misleading because Invacare had not "addressed" the FDA's observed violations at the Taylor Street Facility and the Sanford Facility during 2008 and 2009, or "continu[ing] to strengthen its programs to better ensure compliance with applicable regulations," because, in December 2008, the FDA also inspected Invacare's Corporate Headquarters and repeatedly observed and documented violations of the QS and MDR mandatory reporting regulations almost identical to those cited in the December 2008 Taylor Street inspection, as well as in past and future inspections. At the conclusion of each of the these inspections, the FDA investigators issued a Form 483 detailing Defendants' numerous significant violations, and discussed their concerns with Defendants. Moreover, on November 29, 2009, the FDA issued a letter to Defendants, following the December 2008 inspections of the Corporate Headquarters and Taylor Street Facility. The letter addressed the MDR reporting violations observed at both facilities, and warned Defendants that further enforcement actions could occur if they did not correct the violations. As detailed in the FDA Complaint, the FDA had cited Invacare in Forms 483 and Warning Letters for numerous violations of QS regulations and other FDCA provisions, including many "repeat" or "recurring" violations dating to as early as 2002. According to the FDA Complaint, "At these inspections, [the] FDA ***repeatedly observed and documented violations of the QS [Quality System] regulations"*** similar to the violations cited in the FDA's 2011 inspections, as well as ***"numerous violations of the MDR regulations*** at the majority of the previous inspections." Moreover, as multiple former Invacare employees have confirmed Invacare lacked the necessary processes and procedures to track complaints and potential product defects. For example, CW6 described Invacare's failure to track the serial numbers for wheelchairs, beds and other products it sold,

which violated cGMP. According to CW6, Invacare had no way of tracking that the devices it sold at the end-user level. "[T]here was no way to track recalls with the product," CW6 stated.

F. First Quarter 2010

176. On April 22, 2010, Invacare issued a press release announcing its financial results for the first quarter of 2010. For the first quarter of 2010, Invacare reported earnings per share of $0.09 compared to earnings per share of $0.08 for the same period of 2009, an increase of 13%. In addition, the Company reported that gross margins as a percentage of net sales for the first quarter was higher by 2% compared to the first quarter of 2009. Regarding the outlook for 2010, Defendant Mixon stated, "We are confident that the combination of strong gross margin improvements and the benefits of globalization initiatives will continue throughout the year. As a result, the Company is confirming its previous guidance . . . ."

177. On May 6, 2010, Invacare filed with the SEC its Form 10-Q for the first quarter of 2010, confirming the financial results previously announced by the Company in its April 22, 2010 press release. ***The first quarter 2010 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2009, and directed investors to "carefully consider the risk factors disclosed."*** The first quarter 2009 Form 10-Q contained a certification by Defendant Mixon that attested to the purported accuracy and completeness of the report.

G. Second Quarter 2010

178. On July 22, 2010, Invacare issued a press release announcing its financial results for the second quarter of 2010. In the press release, Invacare reported strong financial results for the second quarter of 2010, including year-over-year earnings growth of approximately thirty percent, and a 2.7% increase in organic net sales over the second quarter of 2009. Invacare's positive earnings announcement and outlook caused the price of the Company's common stock

to rise from $20.00 per share on July 21, 2010, to close at $23.48 per share on July 22, 2010, an increase of over 17%.

179. On August 6, 2010, Invacare filed with the SEC its Form 10-Q for the second quarter of 2010, confirming the financial results and increased earnings guidance previously announced by the Company in its July 22, 2010 press release. ***The second quarter 2010 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2009, and directed investors to "carefully consider the risk factors disclosed."*** The second quarter 2010 Form 10-Q contained a certification by Defendant Blouch attesting to the purported accuracy and completeness of the report.

H. Third Quarter 2010

180. On October 28, 2010, Invacare issued a press release and Form 8-K announcing its financial results for the third quarter of 2010 and the nine months ended September 30, 2010. The Company recorded another strong quarter, beating analysts' earnings estimates and reporting 8% quarterly earnings growth and 2.4% quarterly organic sales growth, over the same period in the last year. The Company attributed net sales growth in the North America/Home Medical Equipment business line to increased rehabilitation and standard product line sales, "driven primarily by higher sales of custom power and consumer power products" and "standard wheelchair and bed products."

181. Analysts again reacted favorably to the Company's strong third quarter financial performance. For example, Joshua Zable, an analyst at WJB Capital, noted that Invacare's "fundamentals are improving . . . . Management is executing on all fronts. They are boosting sales growth and continue to focus on leveraging the infrastructure and controlling expenses," according to an October 28, 2010 article in *The Plain Dealer*.

182. On November 5, 2010, Invacare filed with the SEC its Form 10-Q for the third quarter of 2010, confirming the financial results previously announced by the Company in its October 28, 2010 press release. ***The third quarter 2010 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2009, and directed investors to "carefully consider the risk factors disclosed."*** The third quarter 2010 Form 10-Q did not mention the August 18, 2010 Form 483 or any of the significant compliance, recordkeeping, or safety issues that the FDA inspectors raised therein. The third quarter Form 10-Q contained a certification by Defendant Blouch (among others) attesting to the purported accuracy and completeness of the report.

183. **Reasons Why False:** The foregoing statements contained in Invacare's July 27, 2010 press release, second quarter 2010 conference call, second quarter Form 10-Q, October 28, 2010 press release, and third quarter Form 10-Q, including statements in purported "risk factors" adopted by reference regarding Invacare's compliance with the FDCA and relevant FDA regulations, and the programs maintained by the Company to ensure compliance were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in Section VI and ¶¶148-153, above. Additionally, the statements were false and misleading because, on August 18, 2010, the FDA concluded a sixteen-day inspection period at the Company's Sanford Facility. After completing the inspection, the FDA issued a Form 483 to Invacare listing significant QS and MDR reporting regulations observed by FDA investigators that were substantially similar to those cited in the past and in the future, such violations included failure to evaluate and report complaints of very grievous incidents of patients burning or suffocating – including fatalities of children – involving Invacare wheelchairs and beds. Invacare did not disclose to investors that it had received the August 18, 2010 Form 483. Nor

did Invacare disclose the significant quality, safety, recordkeeping and overall regulatory compliance problems that pervaded the Sanford Facility and the Company's other major U.S. manufacturing facilities in Elyria, Ohio. Moreover, as multiple former Invacare employees have confirmed that Invacare failed to adopt measure to comply with FDA documentation requirements. For example, according to CW7, "Nothing was documented, and that was it. [It was] just about the numbers – you've got to get this [product] out . . . [but] there was no official documentation of what we were doing." CW7 further stated, "They were not following FDA regulations . . . . All it was [about] was do your numbers, get the product out the door and that's it." CW7 confirmed that, at Invacare, nothing that was manufactured was documented," as required by FDA regulations. "All we did at the end of a shift was turn in how much numbers you did." Specifically, workers were required to report only the part number, description of the part, and how many were manufactured each day. There was no requirement to document "print numbers" (*i.e.*, the blueprint used to manufacture the part). The only thing that manufacturing employees were required to document was the part number, "never the print number."

I. Defendants' Statements Regarding The FDA Warning Letter

184. On January 4, 2011, the FDA released a copy of the December 15, 2010 Warning Letter to the public. As discussed above, the Warning Letter stated that the FDA had inspected the Sanford Facility in August 2010 and found practices that violated several of the cGMP requirements set forth in the Quality System Regulation – for example, failing to evaluate recurring complaints involving the alleged malfunction and mislabeling of Invacare's electric beds, including mishandling of complaints of patient entrapment in bed rails and bed control systems shooting sparks or causing fire, resulting in injury and death, as well as the failure to document corrective and preventive actions in response to reports of entrapment. The December 2010 Warning Letter stated, among other things, that the Company repeatedly failed to meet its

reporting obligations to the FDA by refusing to submit MDR reports regarding the patient entrapment complaints. The regulatory violations identified in the December 2010 Warning Letter were thus the same compliance issues observed by the FDA several months earlier in the August 18, 2010 Form 483, which the Company had failed to address.

185. As a result of Invacare's quality control violations, the FDA's December 2010 Warning Letter concluded that certain of Invacare's medical devices manufactured at the Sanford Facility were "adulterated" within the meaning of section 501(h) of the FDCA. Similarly, the December 2010 Warning Letter found that Invacare's medical bed devices were "misbranded" within the meaning of Section 352(t)(2) in that Invacare failed to comply with the regulations regarding the submission of MDRs.

186. The December 2010 Warning Letter called for Invacare to conduct "systemic corrective action" and stated that the observations made at inspections "may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems." The December 2010 Warning Letter concluded by demanding that Invacare take "prompt actions to correct the violations and to bring [its] products into compliance."

187. Breaking with Invacare's past practice of non-disclosure of adverse FDA communications regarding the Company's regulatory compliance (or lack thereof), Invacare immediately issued a press release following the FDA's public disclosure of the December 2010 Warning Letter. In the January 4, 2011 press release, set forth in full below, Defendants discounted the significance of the December 2010 Warning Letter by characterizing the serious quality, safety, recordkeeping and other regulatory compliance deficiencies cited by the FDA as relating to mere "documentation procedures," while assuring investors that the Company was attempting in earnest to address the FDA's concerns:

Invacare Corporation Comments on FDA Warning Letter Related to Its Documentation Procedures

ELYRIA, Ohio--(BUSINESS WIRE [1])--Today Invacare Corporation (NYSE: IVC) commented on an FDA warning letter related to an inspection of the Company's bed manufacturing facility in Sanford, Florida. The warning letter takes issue with Invacare's compliance with the FDA's Quality System Regulation, specifically related to Invacare's ability to establish and maintain adequate procedures to analyze processes and operations and to document actions taken on product complaints.

"Invacare wants to assure users and the general public that we rigorously test our products and stand fully behind the safety of our products. ***The FDA warning letter does not state that our products are unsafe nor has it impacted our production. The letter is related to documentation procedures. We take all FDA matters very seriously, and we intend to address all of the FDA's concerns," said Gerald B. Blouch, president and chief executive officer.***

The Company has assembled a team including its internal quality and regulatory associates as well as outside experts to address the agency's concerns. A formal response including short term and long term actions will be submitted to the FDA as is required under the letter.

188. Revelation of the December 2010 Warning Letter caused Invacare stock to drop from $30.67 per share on January 3, 2011, to close at $29.29 per share on January 4, 2011, on usually heavy trading volume, representing a decline of 4.5% and a market capitalization loss of approximately $40 million.

189. Analysts with CL King & Associates ("CL King") were surprised by the unusual nature of the December 2010 Warning Letter and found Invacare's response "unsatisfactory." In a January 5, 2011 report, the CL King analyst, Robert Goldman, CFA, commented that "[w]hile warning letters are common in the medical device industry, the warning letter issued to Invacare strikes us as abnormal as the letter references patient deaths. Deaths occurred allegedly due to the bed (electronic) catching fire as well as to patients suffocating due to their heads being caught between the bed rail and mattress (entrapment) . . . death from a bed is atypical." The CL King analyst also called into question whether Invacare ever reported the incidents of bed fire to

the FDA as the Company was required to do. He noted that Invacare's bed fire incidents did not appear on the FDA's reporting mechanism called MAUDE (the manufacturer and user facility device experience), which is where adverse events are posted by the FDA after being reported by manufacturers like Invacare. The CL King analyst estimated that bed sales represent approximately 5% to 10% of Invacare's total sales, and, according to the Company, it commands a North America non-hospital patient care bed market share of greater than 25%.

190. On January 5, 2011, Defendant Blouch tried to further explain away the December 2010 Warning Letter as simply the consequence of enhanced enforcement efforts by the FDA generally.[8] On a page of the Company's website titled "Message from CEO Regarding FDA Letter," Blouch stated that "[i]n the past year, the FDA has increased its resources and enforcement actions have risen significantly." Blouch again tried to downplay the significance of the serious safety and compliance issues raised in the December 2010 Warning Letter by casting the issues as simply about "documentation and procedural processes" with no bearing on the safety or efficacy of Invacare products:

> ***It is also important to know that the FDA letter specifically focuses on internal documentation and procedural processes at the Sanford Facility. It does not call into question the safety or efficacy of Invacare products, and it has not impacted production.*** Of the complaints that are detailed in the letter, investigations to date show that no injuries or deaths were caused by a product defect.

191. The "Frequently Asked Questions" section of the Company website also included a page specifically addressed to the December 2010 Warning Letter that similarly mischaracterized the FDA inspections and results. The website stated, in part:

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[8] On information and belief, the statements by Defendants alleged in ¶¶190-93 were posted during the Class Period at www.invacare.com/cgi-bin/imhqprd/news/letterfromceo.jsp and www.invacare.com/cgi-bin/imhqprd/news/fda-Ietterfaqs, respectively, but have since been removed from the Company's website.

Why did Invacare receive a warning letter from the FDA?

After an Inspection of Invacare's Sanford, Florida facility, Invacare received a warning letter from the FDA related to internal process issues and documentation procedures. ***The letter did not call into question the safety or efficacy of Invacare products, and it has not impacted production. Invacare is taking the FDA's concerns very seriously and will address them appropriately.***

Will the FDA warning impact Invacare's operations?

To ensure that Invacare will continue to meet or exceed all regulatory requirements, the Company has assembled a team of internal quality and regulatory associates and outside experts to review the FDA's comments and recommend enhancements or improvements. This team will report directly to Gerry Blouch, president and CEO of Invacare and will ensure that the solutions we initiate are meaningful and permanent. In fact, as the team looks at possible enhancements or improvements at Sanford, these changes will be considered for all Invacare facilities.

It appears that Invacare has several complaints about its products. How do you know they are safe?

Invacare's products are used by millions of consumers worldwide, and we are proud of our more than 30-year legacy of helping patients live life better. Like any company with millions of products in service, Invacare sometimes receives questions or concerns from customers. All customer comments are taken very seriously.

Invacare respects the FDA's role in ensuring that all medical products companies achieve the agency's standards, and we look forward to addressing the FDA's concerns and making any enhancements or improvements necessary to ensure that we will meet or exceed all regulatory requirements.

192. The Invacare website also included a promise from the Company that it would address the FDA's concerns "quickly and completely."

193. The Company made similar comments to the press. For example, as reported in a January 5, 2011 article filed by the *Associated Press* (also published in the *Chronicle-Telegram*), Invacare spokesperson Mahoney stated that the December 2010 Warning Letter ***"involved procedures and documentation in the complaint process, not the actual issue of product safety."*** Spokesperson Mahoney added that "'[a]nytime we get any complaint we investigate it'"

and reassured that the Company was ***"working hard to address the issues involved."*** In addition to these representations by Invacare's spokesperson, the *Associated Press* also quoted Defendant Blouch's statements from the Company's January 4, 2011 press release.

194. **Reasons Why False**: The foregoing statements contained in Invacare's January 4, 2011 press release and posted on the Company website regarding the nature, extent and seriousness of the violations identified in the December 2010 Warning Letter, and purported corrective measures being undertaken at the Company to remediate those and other violations identified by the FDA were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in Section VI and ¶¶148-154 above. Additionally, the statements were false and misleading because the December 2010 Warning Letter was not related to simply "documentation procedures" but rather identified serial, repeat violations of federal laws, regulations, and cGMP the very purpose of which are ensuring the quality, safety, and effectiveness of a manufacturer's medical devices and safeguarding public health.

195. In addition, the statements that Invacare took the FDA's concerns "very seriously" and intended to "address them appropriately" – including, for example, by making "any enhancements or improvements necessary to ensure that [Invacare] will meet or exceed all regulatory requirements" – was false and misleading because, among other reasons, just two days after the FDA's December 15, 2010 Warning Letter, on December 17, 2010, the FDA issued two more Forms 483 listing numerous significant observations of quality control and manufacturing deficiencies at the Corporate Headquarters and the Taylor Street Facility following more than fifty inspections conducted by the FDA at those locations between August 11, 2010 and December 17, 2010, many of which were identical to those regulatory

violations described in the December 2010 Warning Letter. Tellingly, the Company did not immediately disclose receipt of the December 2010 Warning Letter to investors. Nor did the Company promptly disclose to investors the two new Forms 483 it had received regarding deficiencies at Corporate Headquarters and the Taylor Street Facility.

J. 2010 Annual Report

196. On February 3, 2011, Invacare issued a press release announcing "strong" fourth quarter and year-end results for 2010. The press release noted that net sales for the North American/HME segment increased 1.6% compared to the same period last year, "driven by increases in Standard and Rehab product lines," including "increased volumes in standard wheelchairs, beds and therapeutic support surfaces."

197. The February 3, 2011 press release continued to downplay the significance of the FDA's scrutiny of the Company by assuring investors that the issue was confined to the Sanford Facility, that the safety and efficacy of Invacare's products were not at issue, and that the Company was diligently working to address the FDA's concerns:

> In December 2010, the Company received a warning letter from the Food and Drug Administration (FDA) related to documentation and procedures at the Company's Sanford, Florida, facility. ***The letter does not call into question the safety or efficacy of Invacare products, and production has not been impacted.*** In fact, of the complaints that are detailed in the letter to illustrate the FDA's points on documentation, investigations to date show that no injuries or deaths were caused by a product defect. That said, the Company does have areas to improve and it is ***taking these issues very seriously. The Company has added resources to ensure it is addressing all of the FDA's concerns in a timely manner. The costs related to making the process improvements are not expected to be material*** and have been included in the Company's 2011 operating plan and guidance.

198. Invacare also held an earnings conference call on February 3, 2011 to discuss its earnings results. During the call, Defendant Blouch continued to reassure investors that the December 2010 Warning Letter was an isolated issue confined to the Sanford Facility, that it was

not a major cause for alarm, and that it would not impact production. Specifically, Blouch made the same or similar statements as those referenced above in the February 3, 2011 press release.

199. Analysts reacted favorably to these and other statements by Defendants on February 3, 2011. For example, analysts at WJB Capital Group ("WJB") highlighted that the Company beat Wall Street's "top- and bottom-line expectations" and issued "forecasts well above Street expectations." The WJB analysts remarked that "IVC's U.S. organic growth is accelerating, management is executing on cost-cutting measures, and the company is entering 2011 with a plan to launch the most new products in the U.S. in some time. This all adds up to a buying opportunity, in our view." Finally, the analysts noted that the December 2010 Warning Letter presented a risk of adding incremental costs to the Company, stating that "should IVC have to add processes, consultants, or pay for any other resource or fine, it could hurt operating income" and "should IVC continue to have quality control issues, the FDA could enforce stricter penalties." Indeed, WJB included this risk in several subsequent analyst reports issued on the Company during the Class Period.

200. On February 25, 2011, Invacare filed with the SEC its Form 10-K for the fourth quarter and fiscal year-end 2010 (the "2010 Annual Report"). The 2010 Annual Report, which was reviewed and authorized by Defendants Mixon and Blouch (among other Invacare directors and officers), confirmed the financial results previously announced by the Company in its February 3, 2011 press release. The 2010 Annual Report contained certifications by Blouch that attested to the purported accuracy and completeness of the report, using language identical to ¶160, *supra*.

201. Like the 2008 and 2009 Annual Reports, the Annual Report for 2010 disclosed that the Company was "subject to extensive government regulation," including by the FDA. The

report represented that, ***"[t]he company has established numerous policies and procedures that the company believes are sufficient to ensure that the company will operate in substantial compliance with these laws and regulations.***"

202. The 2010 Annual Report also briefly addressed the FDA's inspection of Invacare facilities, identifying by name only the purportedly "routine" inspection of the Sanford Facility. The 2010 Annual Report, however, continued the Company's practice of downplaying any concern related to the December 2010 Warning Letter. Specifically, the Annual Report reiterated that "[i]n December 2010, the company received a warning letter from the FDA related to documentation and procedures at the company's Sanford, Florida facility. ***The letter does not call into question the safety or efficacy of Invacare products, and production has not been impacted.***" The 2010 Annual Report also assured investors that, ***"The company is taking these issues very seriously and has added resources to ensure it is addressing all of the FDA's concerns in a timely manner."*** The Annual Report represented that, ***"The costs associated with making the process improvements indicated in the FDA's letter are currently not expected to be material."*** Finally, Invacare assured investors that the Company had ***"established numerous policies and procedures"*** that it believed were ***"sufficient to ensure that the company will operate in substantial compliance"*** with federal law and FDA regulations.

203. Invacare's 2010 Annual Report contained certifications by Defendant Mixon that were substantively the same as those identified in ¶160, above.

204. **Reasons Why False:** The foregoing statements contained in Invacare's 2010 Annual Report regarding Invacare's (1) regulatory compliance and compliance programs; (2) measures taken to strengthen its compliance programs and address the FDA's concerns and observed violations, and (3) the nature, extent and seriousness of the violations identified in the

December 2010 Warning Letter, and purported corrective measures being undertaken at the Company to remediate those and other violations identified by the FDA were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in Section VI and ¶¶148-154, above.

205. In addition, the statements that Invacare took the FDA's concerns "very seriously"; had "added resources to ensure it [was] addressing all of the FDA's concerns in a timely manner"; and was "continu[ing] to strengthen its programs to better ensure compliance with applicable regulations" were false and misleading because Defendants' falsely characterized the December 15, 2010 Warning Letter as though it merely "focuses on internal documentation and procedural processes . . . . [and] does not call into question the safety of efficacy of Invacare products." However, according to the FDA, the very purpose of the FDCA and related regulations is to serve the dual purpose of ensuring the quality, safety, and effectiveness of a manufacturer's medical devices and safeguarding public health. *See* A. Lowery, J. Strojny, and J. Puleo, Medical Device Quality Systems Manual: A Small Entity Compliance Guide, HHS Publication FDA 97-4179 (1st ed. 1996). In truth, as demonstrated by the Forms 483, Invacare's citations related to very grievous incidents of patients burning or suffocating – including fatalities of children – involving Invacare wheelchairs and beds. As a result, the FDA deemed Invacare wheelchairs and beds "adulterated" and "misbranded" under the FDCA and related regulations. Additionally, just two days after the FDA's December 15, 2010 Warning Letter, on December 17, 2010, the FDA issued two more Forms 483 listing numerous significant observations of quality control and manufacturing deficiencies at the Corporate Headquarters and the Taylor Street Facility following more than fifty inspections conducted by the FDA at those locations between August 11, 2010 and December 17, 2010, many of which were identical

to those regulatory violations described in the December 2010 Warning Letter. The Company did not immediately disclose receipt of the December 2010 Warning Letter to investors. Nor did the Company promptly disclose to investors the two new Forms 483 it had received regarding deficiencies at Corporate Headquarters and the Taylor Street Facility. Moreover, the Company made no concerted effort or meaningful commitment in dollars or resources to address the FDA's observed violations.

206. Additionally, these statements were false and misleading because, as multiple former Invacare employees have confirmed that the Company had a deeply-ingrained culture of non-compliance and contempt for the FDA, particularly as – in senior management's view – compliance was a "cost center" that did not increase revenue. For example, Invacare's manufacturing processes "frequently" resulted in parts that were "out of tolerance." According to CW7, despite the discrepancies in manufacturing tolerances, parts still went out the door because Invacare was more concerned about meeting sales goals. CW7 stated, "They always wanted to go beyond [Wall Street] expectations from the previous year. It was more about sales, not about safety."

207. Further, the statement that "the costs associated with making the process improvements indicated in the FDA's letter are currently not expected to be material" was false and misleading because, as Defendants knew, for over a decade the Company had not undertaken any serious effort to correct systemic deficiencies in its regulatory compliance processes, as set forth in the December 2010 Warning Letter and other Warning Letters, Forms 483, and written and oral correspondence previously issued to the Company. Since the end of the Class Period, Invacare has expended over $40 million and a far greater amount of internal resources to remediate compliance deficiencies and to ensure full QS Regulation compliance, which has

resulted in, among other things, delay of new product development, foregoing acquisitions and other business opportunities, and interruption of the Company's strategic Globalization initiative.

208. Shortly after the Company filed its 2010 Annual Report, on March 8, 2011, Invacare issued a Form 8-K revealing that its Board of Directors had caused the Company to enter into a share purchase agreement with Defendant Mixon. Pursuant to the agreement, Defendant Mixon sold 14%, or 350,000, of his personal holdings of Invacare stock back to the Company at a price of $29.94 per share, reaping proceeds of approximately $10.48 million. The sale of Defendant Mixon's shares was purportedly for "personal financial planning purposes." According to a March 8, 2011 report issued by analysts with CL King, "the share purchase agreement could justifiably be viewed by some investors as giving preferential treatment to Mr. Mixon."

K. First Quarter 2011

209. On April 28, 2011, Invacare issued a press release announcing its financial results for the first quarter of 2011. The press release, which was also filed with the SEC on Form 8-K, announced another "strong" quarter for the Company, including a 39% increase in year-over–year quarterly earnings, including 6.1% organic net sales growth with increases in all business segments, as well as a 6.1% increase in North America/HME net sales compared to the same period last year, "driven by increases in rehab, respiratory and standard product lines" including "custom power and custom manual wheelchairs and beds."

210. In addition to lauding the Company's financial performance, the press release assured investors of the Company's ongoing efforts to address the concerns raised by the FDA in the December 2010 Warning Letter. In that regard, the press release stated that, "The Company is providing updates to the Food & Drug Administration (FDA) regarding the improvements that it is making in response to the regulatory compliance concerns raised by the FDA in 2010. ***The***

Company is in the process of adding resources to its regulatory affairs and corporate compliance departments and engaging outside experts to accelerate implementation of its corrective actions."

211. On May 5, 2011, Invacare filed with the SEC its Form 10-Q for the first quarter of 2011, confirming the financial results previously announced by the Company in its April 28, 2011 press release. The Form 10-Q contained a certification by Defendant Blouch that attested to the purported accuracy and completeness of the report. The first quarter Form 10-Q also commented on Invacare's ongoing efforts to address the concerns raised in the December 2010 Warning Letter, assuring investors that compliance with FDA regulations was among its ***"highest priorities."***

212. In particular, Form 10-Q stated that, ***"The Company is providing updates to the FDA regarding the improvements that it is making in response to the regulatory compliance concerns raised by the FDA, including as a result of the FDA warning letter that was previously disclosed by the Company."*** Invacare reiterated that "***[a]t the time of this filing . . . the Company views its regulatory compliance actions to be among its highest priorities***."

213. ***The first quarter 2011 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2010, and directed investors to "carefully consider the risk factors disclosed."***

L. <u>Second Quarter 2011</u>

214. On July 28, 2011, Invacare issued a press release announcing its financial results for the second quarter 2011. The press release, which was also filed with the SEC on Form 8-K, announced Invacare's strong financial results, including a 15% increase in quarterly earnings compared to the second quarter of the prior year. The press release also announced that the Company was raising its 2011 guidance due to the positive quarterly financial results.

215. Invacare also hosted an earnings conference call with investors on July 28, 2011. During the call, an analyst with Great Lakes Review asked Invacare executives for a status update concerning the FDA Warning Letter relating to the Sanford Facility. In response, Defendant Blouch assured investors that Invacare was actively managing the situation and doing all it could to resolve the matter in a timely fashion. According to Blouch, the Company had "hit all of our follow-up deadlines with the FDA, so we have submitted all of our responses in terms of corrective actions. They are actively at this moment reviewing the implementation of those. ***We have had good, active dialogue with the FDA. So it is a work in process."***

216. On August 8, 2011, Invacare filed with the SEC its Form 10-Q for the second quarter of 2011, confirming the strong financial results previously announced by the Company in its July 28, 2011 press release. The Form 10-Q contained a certification by Defendant Blouch that attested to the purported accuracy and completeness of the report.

217. The second quarter Form 10-Q addressed Invacare's status in responding to the December 2010 Warning Letter, including by assuring investors that the Company was dedicating the necessary resources towards resolving the FDA's concerns and was implementing the necessary corrective actions. Specifically, the Form 10-Q stated that, ***"The Company continues to work on the improvements and corrective actions that it is making in response to regulatory compliance concerns raised by the FDA, including as a result of the FDA warning letter that was previously disclosed by the Company."*** The Form 10-Q continued to assure investors that Invacare was ***"in the process of adding resources to its regulatory affairs and corporate compliance departments and is engaging outside experts to accelerate implementation of various corrective actions."*** Finally, the Form 10-Q assured investors that ***"the Company continues to view its regulatory compliance actions as a high priority."***

218. ***The second quarter 2011 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2010, and directed investors to "carefully consider the risk factors disclosed."***

219. On August 18, 2011, in a further attempt to boost investor confidence in the Company, Invacare issued a press release announcing an extension of its share repurchase program, bringing its overall repurchase authorization up to 2.5 million common shares. The press release quotes Defendant Blouch stating that "[t]he Board's approval of this extension of Invacare's share repurchase program demonstrates its confidence in management's ability to maximize shareholder value through its ongoing globalization program."

220. **Reasons Why False:** The foregoing statements contained in Invacare's April 28, 2011 press release, first quarter 2011 Form 10-Q, July 28, 2011 press release, second quarter earnings conference call, and second quarter 2011 Form 10-Q regarding (1) purported corrective measures being undertaken to strengthen Invacare's compliance programs and remediate violations identified by the FDA, including in the December 2010 Warning Letter; and (2) statements in purported "risk factors" regarding Invacare's compliance with the FDCA and relevant regulations, and the programs maintained by the Company to ensure compliance were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in Section VI and ¶¶148-154, above.

221. The statements were also false and misleading because, on August 8, 2011, Invacare received two additional Forms 483 relating to objectionable conditions at its Corporate Headquarters and the Taylor Street Facility. Significantly, the Form 483 related to the Corporate Headquarters contained thirteen violations, ten of which were "repeat observations" of unremedied quality control deficiencies expressed in from the December 17, 2010 Form 483,

while the Form 483 related to the Taylor Street Facility set forth eight violations, five of which were repeats from the previously issued Form 483. Despite this clear message from the FDA concerning Invacare's continued and blatant noncompliance—especially in light of the significant number of repeat violations—the Company did not reveal its receipt of the August 8, 2011 Forms 483 to investors, but instead falsely led investors to believe that the Company had a "good, active dialogue with the FDA" and was making considerable progress in addressing the FDA's concerns.

M. **Third Quarter 2011**

222. On October 27, 2011, prior to the market opening, Invacare issued a press release announcing its third quarter 2011 financial results. The press release, which was also filed with the SEC on Form 8-K, reported yet another strong quarter, including a 5% increase in quarterly earnings compared to the third quarter of the prior year. The press release also reported on the Company's continued work with the FDA "related to the regulatory compliance concerns raised by the FDA over the past year." Significantly, the October 27, 2011 press release disclosed to investors for the first time that the Company was "actively making systemic improvements across its quality and regulatory systems" in response to the FDA's concerns.

223. In response to the October 27, 2011 press release, including the announcement that Invacare was making "systemic improvements across its quality and regulatory systems" in response to FDA's concerns, Invacare's stock price dropped from $23.81 per share on October 26, 2011 to close at $22.80 per share on October 27, 2011, a decline of 4.3% or $1.01 per share, on usually high trading volume.

224. Later that day on the Company's earnings conference call, an analyst from CL King, Robert Goldwin, noted that he found "curious" Invacare's added disclosure that it was continuing to work with the FDA regarding the purported improvements the Company was

making related to regulatory compliance concerns raised by the FDA over the past year. Goldwin then asked whether Defendants could "elaborate on what these concerns are, and what you're doing to correct them?" In response to the analyst's question, Defendant Blouch defensively responded that "[w]ell I think the 4[8]3s we've discussed in some details, so it's – so I would say we're pleased with what we're doing. We've met with the FDA twice and reviewed our progress with them. And – but there are – as we – I would assume you're surprised it's taking some time, but I don't know what the text of your question is. But we're pleased with what we're doing; we're confident with what we're doing. We're very pleased with the progress we're making."

225. Defendant Blouch added that ***"in a couple of cases"*** the Company ***"opted to go to some systemic enterprise technology solutions, just to be – so that we could have consistency across the whole Corporation. But I don't know – there's nothing on this side of the issue which is inconsistent with the plans we've laid out to the FDA and commitments we've made and we continue to report on."***

226. In his response to the analyst's question, Defendant Blouch also indicated for the first time that the issues set forth in the December 2010 Warning Letter were not exclusive to the Sanford Facility. Indeed, over the past 10 months, the Company had received four separate Forms 483 relating to its Corporate Headquarters and Taylor Street Facility, which had not been disclosed to investors. Blouch stated, rather cryptically, that ***"[t]he things that were cited in Florida were not just Florida issues. And we, rather than just taking them on as a Florida solution, we're dealing with enterprise solutions that will affect those improvements to be compliant across the whole Corporation."*** Blouch also assured investors that the Company's compliance issues were ***"eminently manageable, and we've got a lot of energy around it. We're***

happy with what we're doing. We're happy with our progress; and, again, I'm not a bash-FDA person. We got it. We always did get it. We've just got to clean some things up."

227. Defendant Blouch's defensive response prompted the analyst to ask a follow-up question about whether Invacare's most recent disclosure "suggest[ed] any increase in intensity by the FDA on this issue?" According to the Company's CFO, Gudbranson, the disclosure was not a cause for alarm. Gudbranson stated that "we're continuing to work the issue, and we felt if we didn't put a paragraph in, people would wonder what was going on. So, it's a pretty innocuous paragraph." Blouch further downplayed Invacare's disclosure by adding that ***"it was a non-issue . . . ."***

228. On November 8, 2011, Invacare filed with the SEC its Form 10-Q for the third quarter of 2011, confirming the financial results previously announced by the Company in its October 27 press release. The Form 10-Q contained a certification by Defendant Blouch that attested to the purported accuracy and completeness of the report. The third quarter Form 10-Q stated that the Sanford Facility was not the only major Invacare facility facing increased FDA scrutiny: "The Company also has received inspectional observations . . . in connection with inspections in 2010 and 2011 of its corporate facility and a manufacturing facility in Elyria, Ohio, as well as the Sanford, Florida facility." However, Invacare continued to assure investors that ***"the Company has been actively making systemic improvements in its reporting processes and enhancing its documentation and tools for capturing, investigating and assessing product complaints and quality data."*** The Form 10-Q also stated that, ***"The Company is working with the FDA to resolve the inspectional observations identified in the warning letter and in the FDA-483s."***

229. ***The third quarter 2011 Form 10-Q also contained a "Risk Factors" section, which adopted by reference the risk factors disclosed in Invacare's Annual Report on Form 10-K for 2010, and directed investors to "carefully consider the risk factors disclosed."***

230. **Reasons Why False:** The foregoing statements contained in Invacare's October 27, 2011 press release, third quarter earnings conference call, and Form 10-Q for the Third Quarter of 2011 regarding (1) purported corrective measures being undertaken to strengthen Invacare's compliance programs and remediate violations identified by the FDA, including in the December 2010 Warning Letter; and (2) statements in purported "risk factors" regarding Invacare's compliance with the FDCA and relevant regulations, and the programs maintained by the Company to ensure compliance were materially false and misleading, omitted material information, and lacked a reasonable basis when made for the reasons stated in Section VI and ¶¶148-154 above. Additionally, the statements were false and misleading because Invacare was not acting in earnest to "work with the FDA" to address the FDA's concerns, including those identified in the December 2010 Warning Letter, by "actively making systemic improvements" across its regulatory compliance processes. Indeed, just two days after the FDA's December 15, 2010 Warning Letter, on December 17, 2010, the FDA issued two more Forms 483 listing numerous significant observations of quality control and manufacturing deficiencies at the Corporate Headquarters and the Taylor Street Facility following more than fifty inspections conducted by the FDA at those locations between August 11, 2010 and December 17, 2010, many of which were identical to those regulatory violations described in the December 2010 Warning Letter. Nor did the Company promptly disclose to investors the two new Forms 483 it had received regarding deficiencies at Corporate Headquarters and the Taylor Street Facility. Moreover, on August 8, 2011, Invacare received two additional Forms 483

relating to objectionable conditions at its Corporate Headquarters and the Taylor Street Facility. Significantly, the Form 483 related to the Corporate Headquarters contained thirteen violations, ten of which were "repeat observations" of unremedied quality control deficiencies expressed in from the December 17, 2010 Form 483, while the Form 483 related to the Taylor Street facility set forth eight violations, five of which were repeats from the previously issued Form 483. Despite this clear message from the FDA concerning Invacare's continued and blatant noncompliance—especially in light of the significant number of repeat violations—the Company did not reveal its receipt of the August 8, 2011 Forms 483 to investors. Moreover, although defendants promised to the FDA to correct their violations in written responses to the August 2011 inspections, dated August 29, September 15, September 29, and October 28, 2011, none of these responses contained adequate evidence that Defendants had corrected their deviations. Further, representatives of Invacare also attended a regulatory meeting with FDA's Center for Devices and Radiological Health and Cincinnati District Office on October 24, 2011. At this meeting, the FDA made Defendants aware of the serious, uncured violations at their facilities.

231. Furthermore, contrary to Defendants Blouch's false assurances, the steps necessary to address the FDA's concerns and ensure full QSR compliance "across the whole corporation" were not "eminently manageable." As Defendants knew, for over a decade the Company had not undertaken any serious effort to correct systemic deficiencies in its regulatory compliance processes, as set forth in the December 2010 Warning Letter and other Warning Letters, Forms 483, and written and oral correspondence previously issued to the Company and its top executives, including Defendant Blouch himself. Consequently, the costs and resources necessary to remediate the numerous, serious, and pervasive deficiencies identified by the FDA and otherwise bring the Company into full regulatory compliance have been enormous and have

had a "ripple effect on the performance of the organization." For example, Invacare spent $2 million during the third quarter of 2011 and $4.1 million during the fourth quarter of 2011 purportedly to make "systemic improvements" in its regulatory processes. In contrast, since that time, Invacare has been force to expended over $40 million in additional incremental regulatory and compliance costs, including over $7 million in the first quarter of 2013 alone—*i.e.*, more than three and a half times the amount spent in the third quarter of 2011, and almost twice the amount spent in the fourth quarter of 2011. Moreover, the Company has been forced to devote substantial internal resources to address the FDA's compliance concerns, which has resulted in, among other things, delay of new product development, foregoing acquisitions and other business opportunities, and interruption of the Company's strategic Globalization initiative. "As recently as two weeks ago, Invacare reported to shareholders in its Form 10-Q for the third quarter of 2013 that "the limitations in the consent decree had, and likely will continue to have, a material adverse effect on the company's business, financial condition and results of operations."

VIII. LOSS CAUSATION

232. During the Class Period, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Invacare common stock. By misrepresenting Invacare's compliance with FDA regulations and cGMP, and failing to disclose systemic violations of federal law and FDA requirements concerning quality, safety, and recordkeeping related to the Company's regulated medical devices, among other adverse facts detailed herein, Defendants presented a misleading picture of Invacare's business and prospects.

233. Defendants' fraudulent scheme artificially inflated Invacare's stock price by failing to disclose: (1) the true scope and severity of the Company's regulatory compliance deficiencies at its Sanford Facility and Taylor Street Facility, as well as at its Corporate

Headquarters; (2) the actual investment in time and money needed to remediate those deficiencies; and (3) the resulting impact of the necessary remediation on Invacare's ongoing manufacturing and business operations. These false and misleading statements, individually and collectively, concealed Invacare's pervasive and systemic regulatory compliance deficiencies and true financial circumstances and future business prospects, resulting in the stock being artificially inflated until, as indicated herein, the relevant truth about Invacare was revealed. While each of these misrepresentations was independently fraudulent, they were all motivated by Defendants' desire to artificially inflate Invacare's stock price and the image of its future business prospects to give the market the false impression that Invacare's operations and business activities were sufficiently compliant with federal law and regulations. These false and misleading statements and omissions, among others, had the intended effect of preventing the market from learning the full truth and maintaining the artificial inflation in Invacare's stock price. As a result of Defendants' false and misleading statements and material omissions, Invacare's common stock traded at artificially inflated levels throughout the Class Period, reaching a Class Period high of $34.29 on July 7, 2011.

234. As Defendants' prior misrepresentations and omissions were disclosed and gradually became apparent to the market, the price of Invacare common stock fell significantly as the artificial inflation dissipated or was removed.

235. Investors began to learn the truth about the extent and severity of Invacare's quality, safety, and regulatory compliance deficiencies on January 4, 2011, when the FDA released a copy of its previously undisclosed December 15, 2010 Warning Letter to Invacare to the public. As discussed above, the December 15, 2010 Warning Letter detailed a host of significant quality, safety, recordkeeping and overall regulatory compliance deficiencies at the

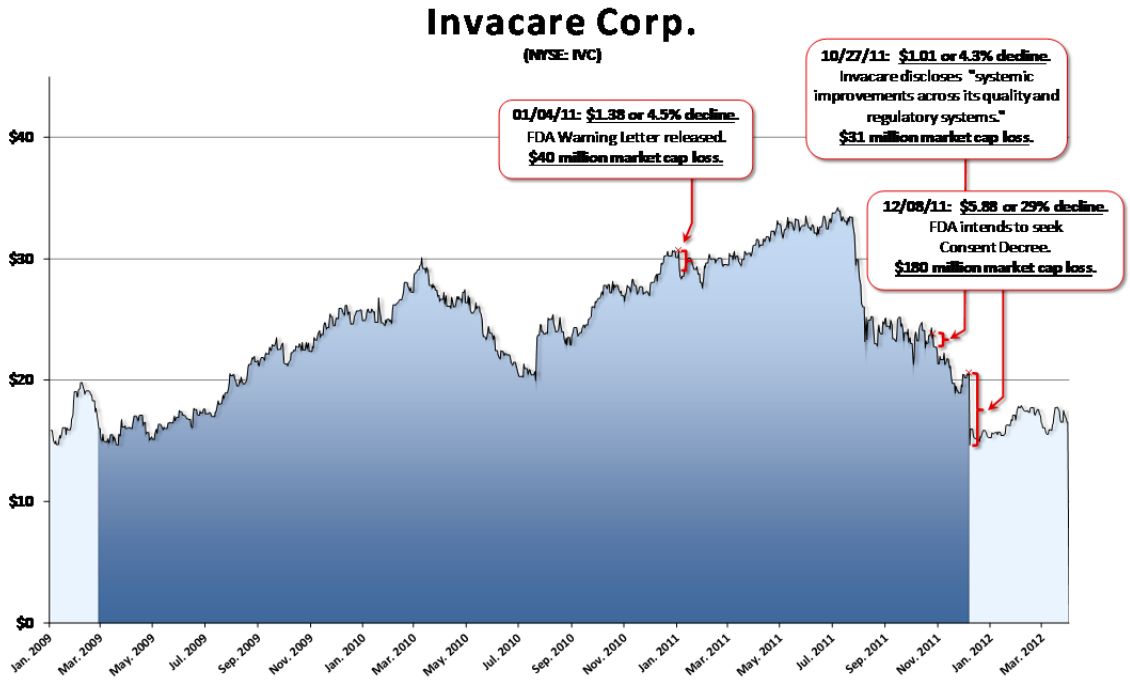
Company's Sanford Facility. In response to this news, Invacare common stock dropped from $30.67 per share on January 3, 2011, to close at $29.29 per share on January 4, 2011, a decline of 4.5% or $1.38 per share, on nearly three times the average daily trading volume during the Class Period. However, Defendants immediately reassured investors that though the Company took the FDA's concerns very seriously and intended to address all of them, the issues raised in the December 15, 2010 Warning Letter did not concern the safety of Invacare's products and did not have any impact on production, but rather were limited to mere "documentation procedures."

236. Then, on October 27, 2011, Invacare issued a press release announcing its third quarter financial results, which disclosed for the first time that the Company was "actively making systemic improvements across its quality and regulatory systems" in response to the deficiencies cited by the FDA over the course of the preceding year. In response to this announcement, Invacare's stock price dropped from $23.81 per share on October 26, 2011, to close at $22.80 per share on October 27, 2011, a decline of 4.3% or $1.01 per share, on over five times the average daily trading volume during the Class Period. However, Defendants reassured investors on an earnings conference call later that day that the new disclosure of "systemic improvements" being implemented by the Company was "pretty innocuous" and did not suggest an increase in intensity on the issue by the FDA.

237. Finally, on December 8, 2011, Invacare issued a press release revealing that the FDA intended to issue a consent decree of injunction that would suspend normal operations at Invacare's Taylor Street facility and Corporate Headquarters until the FDA determined that a variety of systemic and chronic regulatory compliance deficiencies had been adequately addressed by the Company. Specifically, Invacare's December 8, 2011 press release stated that "the U.S. Food and Drug administration (FDA) has requested that the Company negotiate and

agree to a consent decree of injunction relating to previously disclosed inspectional observations at the Company's corporate facility and its wheelchair manufacturing facility in Elyria, Ohio." In addition, the press release stated that "Invacare has confirmed that it intends to enter into discussions with the FDA regarding the terms of the consent decree." In response to this news, the price of Invacare stock plummeted nearly 29%, or $5.88 per share, from $20.58 per share on December 7, 2011, to close at $14.70 per share on December 8, 2011, on over seventeen times the average daily trading volume during the Class Period.

238. As illustrated on the stock price graph below, when the market was provided with these revelations on January 4, October 27, and December 8, 2011, it was an indication that Defendants' prior Class Period statements were false and misleading, and Invacare's stock price fell sharply as investors learned that Invacare's regulatory compliance deficiencies were far greater than they had realized and Defendants' had disclosed.



239. Analyst reaction to news that the FDA would be seeking a consent decree was predictably negative. For example, WJB Capital Group promptly issued a report on December 8, 2011, downgrading Invacare stock, finding that "[w]ith the FDA potentially asking for the suspension of key manufacturing capabilities as it relates to [Invacare]'s most profitable power wheelchair business, it is difficult to quantify the risk here." The WJB analyst, Joshua Zable, stated that although he had previously been bullish on Invacare stock, "today's news creates a level of uncertainty around the shares that makes it difficult to recommend buying them."

240. Similarly, analysts at Great Lakes Review, a division of Wellington Shields & Co., issued a report on December 8, 2011, that downgraded Invacare stock from "gradually accumulate" to "hold." The report, titled "FDA Consent Decree to Impact U.S. Production," noted that the "negotiation process with the FDA could take months, and the Company is in the process of forming a contingency plan should a significant amount of production at the Taylor Street Facility be suspended."

241. CL King also issued a report on December 8, 2011, lowering its rating on Invacare stock to "Sell" from "Neutral" based principally on the Company's revelation that the FDA asked it to enter into negotiations for a consent decree. The CL King analyst noted that both the Taylor Street Facility and Corporate Headquarters "have had a 483 pending, though no warning letter, suggesting to us that the FDA is quite disappointed in the company's progress in rectifying the problems."

242. Lead Plaintiff and the other members of the Class suffered damages as a direct result of Defendants' fraudulent conduct described in this Complaint. But for Defendants' misrepresentations and omissions, Lead Plaintiffs and the other members of the Class would not have purchased Invacare's stock, or would not have purchased it at artificially inflated prices. As

the reality of Defendants' conduct and a truer picture of Invacare's regulatory compliance, financial position, and business prospects were gradually revealed to the investing public, the price of Invacare common stock declined significantly in response to those revelations, as described above, causing damages to Lead Plaintiffs and other Class members.

243. The timing and magnitude of Invacare's stock price decline negates any inference that the loss suffered by Lead Plaintiff and other Class members was caused by changing market conditions, macroeconomic or industry factors or Company-specific facts unrelated to the Defendants' fraudulent conduct. The economic loss, *i.e.*, damages suffered by Lead Plaintiff and other members of the Class, was a direct result of Defendants' fraudulent scheme to artificially inflate Invacare's stock price and the subsequent decline in the value of Invacare's stock price when the truth was gradually revealed to the market. Lead Plaintiff and the other members of the Class suffered damages as a direct result of Defendants' fraudulent conduct described in this Complaint. But for Defendants' misrepresentations and omissions, Plaintiffs and the other members of the Class would not have purchased Invacare's stock, or would not have purchased it at artificially inflated prices. As the reality of Defendants' conduct and a truer picture of Invacare's regulatory compliance, financial position, and business prospects were gradually revealed to the investing public, the price of Invacare common stock declined significantly in response to those revelations, as described above, causing damages to Lead Plaintiffs and other Class members.

IX. ADDITIONAL SCIENTER ALLEGATIONS

244. As alleged herein, Defendants acted with scienter in that Defendants knew that the public documents and statements they issued or disseminated were materially false and

misleading when made. Defendants also knew and recklessly disregarded that such statements or documents would be issued or disseminated to the investing public.

245. Defendants knowingly and substantially participated in the issuance or dissemination of such statements or documents as primary violators of the federal securities laws. As set forth herein in detail, Defendants participated in the fraudulent scheme by virtue of (i) Defendants' receipt of information reflecting the true facts concerning Invacare's non-compliance with FDA regulations including cGMP; (ii) Defendants' control over and/or receipt and/or modification of the materially false and misleading statements and omissions alleged herein; and (iii) Defendants' position with the Company, which made them privy to confidential proprietary information concerning the true manufacturing practices and conditions at Invacare.

A. The FDA's Findings

246. Defendants' scienter is confirmed by the extensive record documenting repeated regulatory violations and demands by the FDA that Invacare take appropriate corrective action. In particular, as set forth above, and as alleged by the FDA Complaint, Defendants knew of the FDA violations, the continuous and repeated nature of the violations, the Forms 483, and had discussions with the FDA concerning those violations. As set forth in the FDA Complaint:

> **Defendants are well aware that their practices violate the Act**. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.
>
> * * * *
>
> At the conclusion of each of FDA's inspections of the firm, the FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act to a responsible individual at the firm, and discussed the documented observations with the recipient.

> Defendants made promises to correct their violations in written responses . . . . None of these responses contained adequate evidence that Defendants have corrected their deviations.
>
> Based on Defendants' conduct, [FDA] believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (k), and (q). (FDA Complaint at ¶¶24, 29, 30.

B. The Consent Decree

247. Scienter is also supported by the Consent Decree executed by Invacare and Defendant Blouch (Exhibit 1). In paragraph 5(H), Invacare and Blouch admit that they knew of the FDA violations since at least 2002. That provision of the Consent Decree prohibits Invacare from resuming operations unless and until "Defendants report to FDA in writing that actions have been taken to: (1) correct all violations brought to Defendants' attention by the Expert **and set forth in FDA's Inspectional Observations from all prior FDA inspections of the Corporate and Taylor Street Facility since 2002**; . . . ."

C. The Duration Of The Scheme

248. Defendants knew about and recklessly disregarded the materially false and misleading nature of their misstatements and omissions to the investing public. The ongoing fraudulent scheme could not have been perpetrated over the substantial two-year period of time, as has occurred here, without the knowledge, participation, and complicity of the executives at the highest level of the Company, including the Individual Defendants. Because Defendants Mixon and Blouch were the CEOs, President and Chairman of the Company at all times during the Class Period, their scienter is ascribed to the Company.

D. Hiring And Abrupt Resignation Of Colleen Craven

249. Incredibly, the Company did not have a Chief Compliance Officer prior to 2011. Moreover, the Company waited four months after receiving the FDA's December 15, 2010 Warning Letter to finally hire one. On April 4, 2011, Invacare issued a press release announcing

that the Company had hired Colleen Craven ("Craven") to serve as its new Chief Compliance Officer. The press release, titled "*Invacare Corporation Continues to Enhance Its Internal Regulatory & Corporate Compliance Functions with New Role of Chief Compliance Officer*," assured investors that Ms. Craven would be ***"responsible for overseeing the Company's initiatives to ensure it is in compliance with relevant laws and regulations regarding the design, manufacture and distribution of medical devices."*** The April 4, 2011 press release further assured investors that Ms. Craven was joining Invacare ***"as the Company looks to improve its corporate compliance procedures and documentation practices."***

250. Commenting on the hire, Defendant Blouch represented that: "As Invacare Corporation has grown into a $1.7 billion medical device manufacturer, it has realized that there is a lot of opportunity ***to make improvements to its corporate procedures and documentation practices***. We look forward to Colleen's contributions to the team. The Company will continue to look for opportunities to add talent and expertise to expand its regulatory affairs capabilities."

251. Ms. Craven was a highly-experienced and expert compliance professional and lawyer, having previously served as Chief Compliance Officer at Endo Pharmaceuticals for seven years and as a regulatory consultant to healthcare companies with PriceWaterhouseCoopers for six years. Craven also served as a member of the Advisory Board for the Pharmaceutical Compliance Congress, a compliance forum led by industry compliance professionals, and was a frequent panelist speaking on industry and FDA compliance matters. Ms. Craven earned a Juris Doctor Degree from The Catholic University of America Columbus School of Law and a Bachelor's Degree from Cleveland State University.

252. However, on April 22, 2010, ***less than three weeks*** after announcing Ms. Craven's hire, Invacare issued a press release announcing that the Company had made a change in the

leadership of its regulatory compliance function and that Ms. Craven was no longer with the Company. The April 22, 2010 press release represented that Ms. Craven had ***"resigned for personal reasons,"*** and that the Company's Senior Vice President of Global Engineering would "assume leadership of the company's regulatory team" in place of Craven. Commenting on the change in leadership of the regulatory compliance function, Defendant Blouch assured investors that Invacare was ***"actively recruiting for Colleen's replacement"*** and that ***"Invacare has many important initiatives underway to enhance its corporate compliance procedures, and we will continue to add resources and expertise to our regulatory affairs and compliance functions."***

253. According to CW9, Craven "stepped on toes" of people at Invacare. Invacare had brought Craven in hoping to use her to "sugarcoat" the problems and demonstrate to the FDA that they were actually working on the issues but Craven refused to sugarcoat it and management soon realized that they did not hire "a yes person" in Craven. So, Craven quickly left the Company.

E. Defendants Capitalized On The Fraud

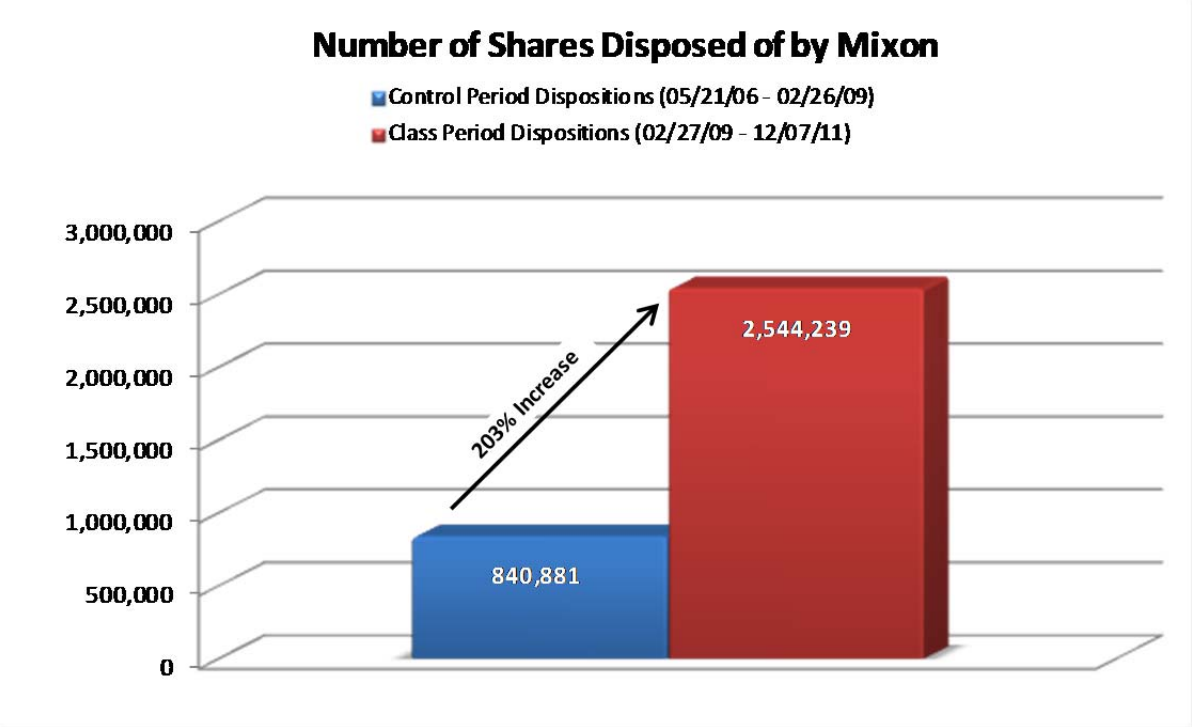
254. Defendants Mixon and Blouch were further motivated to engage in this fraudulent course of conduct in order to sell their personally-held Invacare common stock for gross proceeds of approximately $45.6 million during the Class Period. Indeed, Mixon and Blouch sold significant amounts of their personally-held Invacare stock during the Class Period while in possession of material, non-public information about the Company.

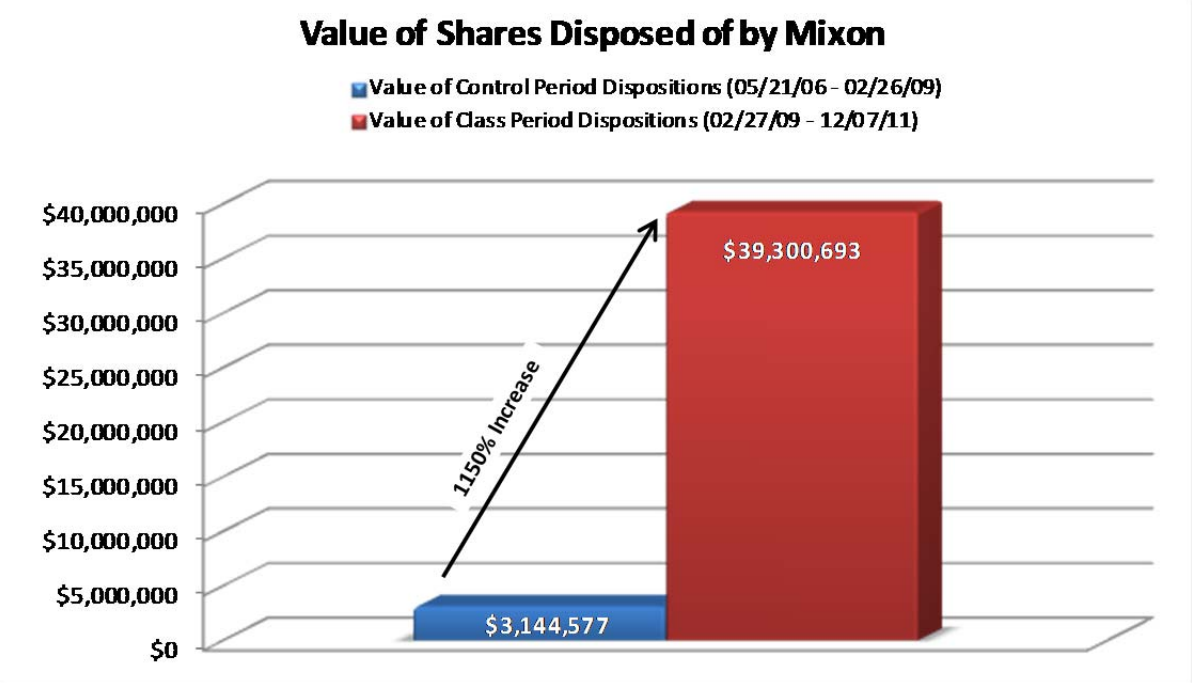
255. Defendants Mixon and Blouch's insider sales were suspicious in both timing and amount and provide additional indicia of scienter, particularly when compared to their trading during the "control period" of the same duration as the Class Period prior to the start of the Class Period. As set forth on the chart below, Mixon sold 2,544,239 shares for proceeds of approximately $39.3 million during the Class Period, and Blouch sold 191,261 shares for

proceeds of approximately $4.27 million during the Class Period all while Invacare's stock price was artificially inflated as a result of Defendants' false and misleading statements and material omissions. Notably, neither Mixon or Blouch purchased ***any*** Invacare common stock during the Class Period.

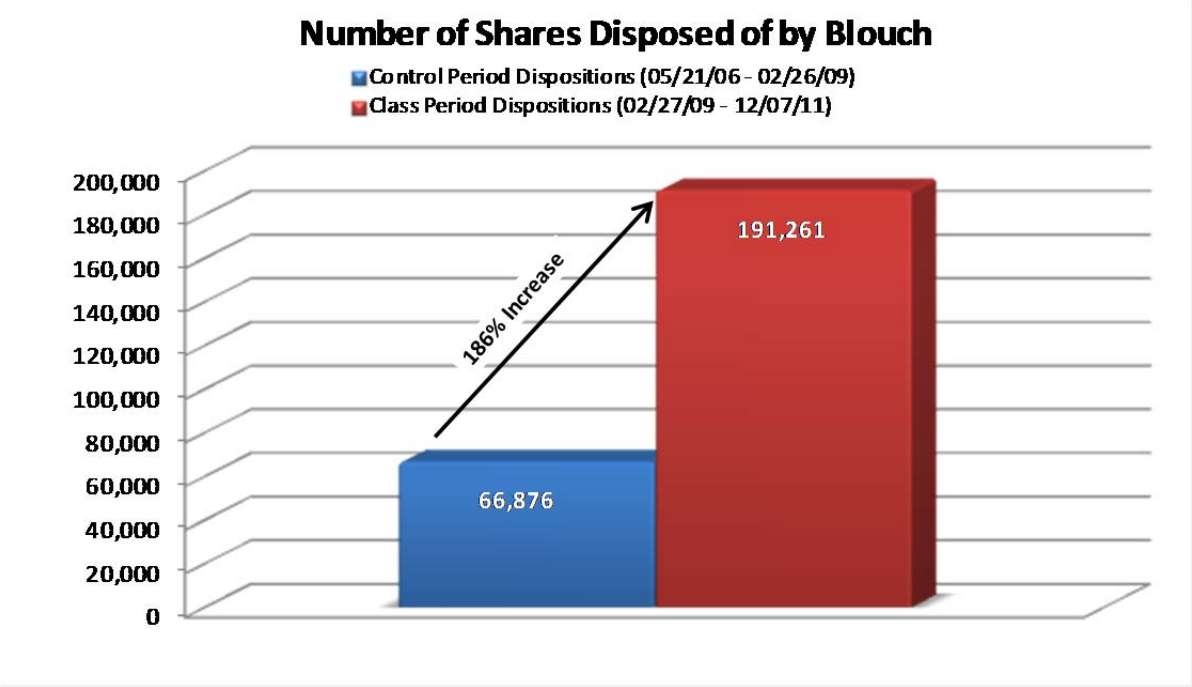
Defendant	Dates of Class Period Sales	Shares Disposed	Proceeds
Mixon	05/01/09-11/15/11	2,544,239	$39,300,693
Blouch	05/01/09-11/15/11	191,261	$4,277,353
TOTAL		**2,821,580**	**$45,660,259**

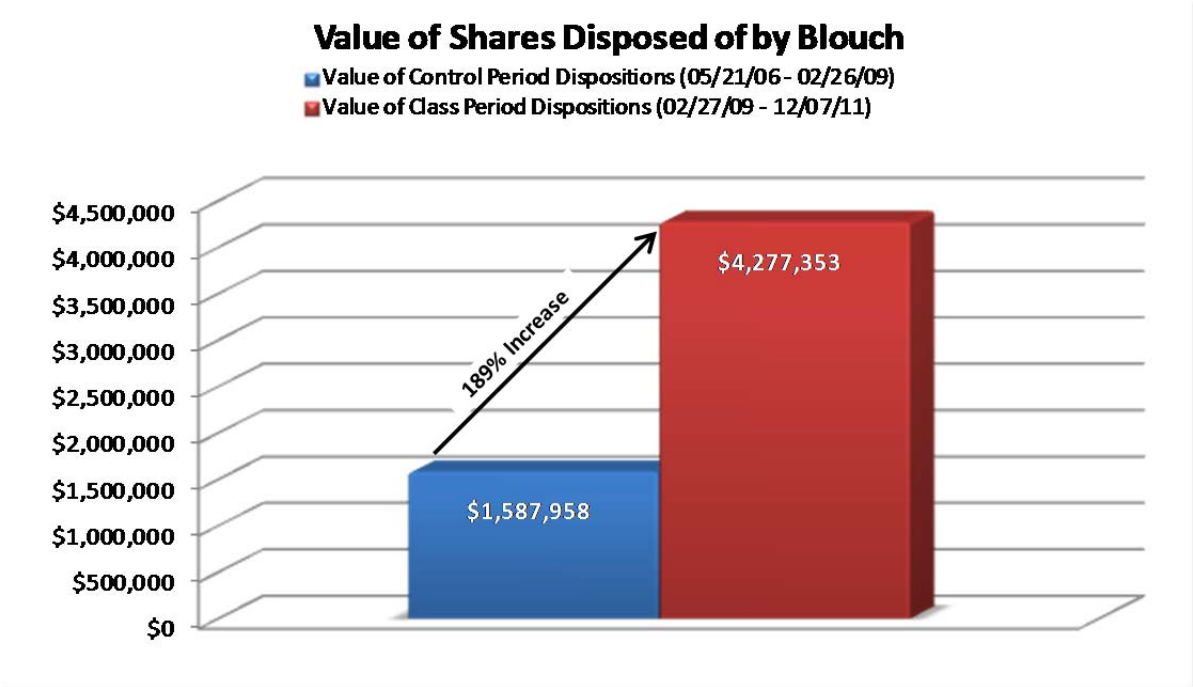
256. Defendants' Class Period stock sales are inconsistent with their trading during the control period prior to the Class Period (the "Control Period"). In particular, Mixon sold 840,881 shares for proceeds of approximately $3.1 million during the Control Period, and Blouch sold 66,876 shares for proceeds of approximately $1.58 million during the Control Period. As demonstrated below, Defendants' insider selling during the Class Period was extraordinary when compared to their prior selling activity during the Control Period. For example, Mixon's sales increased by over ***three times*** in number and over ***twelve times*** in value compared his selling during the Control Period.





257. Similarly, Blouch's sales increased by nearly ***three times*** in number and over ***two times*** in value when compared to his selling during the Control Period:





258. Scienter is further supported by the substantial stock sale between the Company and Defendant Mixon at the height of the scheme. On March 7, 2011, Invacare entered into a share purchase agreement with Mixon. Pursuant to the agreement, Mixon sold the Company 350,000 shares of Invacare common stock – or approximately 14% of Mixon's personal holdings

– for a total of $10,479,000. According to the Company's Form 8-K disclosing the private agreement between Invacare and its Chairman, the sale of Mixon's shares was for "personal financial planning purposes" and was funded by Invacare with borrowings under the Company's senior secured revolving credit facility.

F. Defendants' Culture Of Noncompliance And Contempt For The FDA

259. Defendants' inference of scienter is further supported by accounts of former Invacare employees who describe a longstanding culture of noncompliance, contempt for the FDA, and a campaign on misdirection and subterfuge to avoid FDA scrutiny.

260. CW4 was hired by Invacare as the General Manager for North America Business in October 2012. Prior to working at Invacare, CW4 had worked for 28 years at one of the world's largest consumer, pharmaceutical and medical device and diagnostics companies in the world. CW4 was hired to help the Company evolve from being a medical equipment company to a more stringently-regulated medical device company and to help develop a culture of compliance at Invacare. According to CW4, "I think when I started, it was evident that the way I defined compliance was not part of the culture at Invacare. I think it was very much an entrepreneurial environment where they did what needed to be done to make the customer happy and sell the product. I think that was generally how they did things. Invacare has been a medical equipment company for 30 years and needed to evolve to a medical device company, including changing its culture to focus on compliance, which was one of the primary reasons that CW4 was hired. Previously, there was a cost environment that resulted in negative business outcomes. Invacare was spending money buying companies, and had a sales environment of giving away in rebates and contracts, but they should have invested more in compliance. But, it was not necessarily because of the cost but was more because of principle – Invacare management felt they were doing what they needed to do and didn't need to do more."

261. Approximately ten years ago, the FDA started to look closer at medical device and equipment makers, which was largely driven by litigation out in the marketplace where patients had been injured, according to CW4. "If you go back to 2003, Invacare as a medical equipment manufacturer was probably the largest target out there in the U.S. market space. Invacare is probably the only company that remains out in the industry that is consolidated. They brought other companies – homecare companies, together so they were a bigger target."

262. According to CW4, Invacare's leadership [*i.e.*, Mixon, Blouch] decided that they knew better than the FDA. Invacare management believed that the Company was a medical ***equipment*** manufacturer – not a ***device*** manufacturer – and "[w]hat the government tells us is a negotiation. It's not an absolute. We'll do whatever we can to fly under the radar screen." According to CW4, ***Mixon "hates the FDA*** . . . . He's not a guy that wants organizations like the FDA in his backyard . . . or anything like that. He's going to fight against it. Again, he's a very, very powerful CEO – was CEO – now he's an executive chairman largely driven by the amount of stock he has in the company." Mixon did not want to spend more time, money and energy on "something that doesn't add value to the customer or the product."

263. Based on CW4's observations and interactions with Defendant Mixon, CW4 understood that Mixon has had in the past and probably continues to have influence over what happens at Invacare, primarily because of Mixon's position as Chairman and the amount of stock he holds in the business. "He started the business so it's his baby . . . . Were they really cavalier in what they did [as to compliance]? Absolutely."

264. Ultimately the FDA said "look, you have not done what we asked you to do. We've given you several warnings. Either stop doing business or negotiate a settlement with us." After the Consent Decree was entered, Invacare finally started implementing the necessary

measure to ensure compliance. For example, according to CW4, Invacare started putting in design control systems, looking at product complaints, and how they were handled. "The Company created a major awareness campaign amongst all associates around FDA compliance. Every day there were ten new procedures that had to be signed off on and literally brought the company to a standstill . . . . We were starting a culture where everyone could report issues without fear of retribution." Also, in December 2011, Invacare hired Uelmen as Senior Vice President for Quality Assurance and Regulatory Affairs. CW4 met with Uelmen to provide support for the new compliance efforts. The next thing was to do assessments – to figure out that they needed to hire numerous new employees – at least 80 to 100 people – who truly understood medical device systems. CW4's job included helping to create a new culture of compliance, commitment to requirements, training – in short, create a culture of compliance that had been absent from Invacare prior to 2012.

265. When asked why Invacare did not take sufficient steps to address compliance prior to the Consent Decree in 2012, CW4 commented that Defendants Blouch and Mixon "did not take it as serious as they should have." Mixon is a "sales guy" and "still thinks he can bypass things [with the FDA]." Mixon's personality is "to not necessarily follow regulations in general." "Mal [Mixon] wants to create the shortest distance from when a product is made, to when it gets into the hands of a customer. I think he prefers legislation that supports pure capitalism. He supports and lobbies through other bodies against regulations that he feels are not in the best interest of Invacare and the customer."

266. Rather than work to address the FDA citations, the Company's solution was to move product lines and manufacturing equipment out of the Taylor Street Facility in anticipation of the FDA Complaint. CW4 confirmed that the Company had been moving product lines and

manufacturing equipment out of the Taylor Street Facility in anticipation of the FDA Complaint. There were two prongs to the strategy. First, Invacare was trying to protect its business by moving manufacturing out to other plants before any U.S. operations were shut down by the FDA. Second, they also gained certain efficiencies and could start fresh. For example, moving production to Mexico they could start new lines and processes instead of trying to revamp things in Elyria. "Elyria was not the most efficient manufacturing environment." As CW4 noted, the Elyria manufacturing facility is an old facility. CW4 is certain that Invacare's Executive Committee devised the strategy.

267. CW4 quit Invacare after only approximately seven months. "I was hired to come and make changes and be an agent for change [in the compliance culture]. And when I got into the company, I found various challenges I had not been aware of, or leadership I was not aware of, and when putting a strategy in place to address the challenges there . . . the Chairman [Mixon] was not supportive of my strategy and I said, 'I'm not going to work 100 hours a week to be undermined at every step of the road.'" The challenges included the "'Mixon mindset' of doing things the same way for 40 years and not wanting [to change]."

268. CW3 stated that the sales management team had regular conference calls, which included discussions about the FDA inspections and Forms 483, with (among other people) CW3's immediate supervisor, Boeye, who, in turn, reported to Carl Will ("Will") (Senior Vice President, Global Commercial Operations), who reported to Defendant Blouch. Will was on approximately 80%-90% of the sales management conference calls. CW3 recalled one particular sales call in or around September 2011, with Invacare's entire sales management team, including Boeye and Will "because it was an important one." CW3 was concerned about the Forms 483 the Company already received. CW3 was concerned about the impact of any FDA action on the

sales team and how to set sales numbers because it [FDA action] directly affects income. "Invacare got in the habit of saying 'it's not gonna be that bad' . . . but ultimately it can cost the sales people lots of money and their jobs."

269. When CW3 raised his concerns about the Forms 483 on the call, Boeye stated, "You're thinking too much into this." Invacare did not want to go public with anything until they knew whether "***we were going to be able to duck this thing or not***." CW3 indicated that it seemed inevitable that Invacare would be shut down: "The question was not if it was going to happen – the question was when." On the call, CW3 said: "Guys – it looks like this is gonna happen.' But Rob [Boeye] said, 'We're gonna keep tight-lipped on this until we know what's going on.'" Until the consent decree actually came out, Invacare didn't want customers to have a knee-jerk reaction and start to pull their business away.

270. After the FDA Complaint was filed in December 2012, "Invacare tried everything to get around [the consent decree]." CW3, who retired in December 2011, received a phone call from a salesperson who had previously reported to CW3. CW3 was told that Invacare had come up with a "hokey" form, which was thought to exploit an FDA loophole. Invacare had salespeople going out to hospitals and VA facilities with the forms to certify that the patient absolutely had to have the Invacare product – meaning that there was no viable alternative wheelchair that the patient could have – and that was not true, so all Invacare ended up doing was "pissing off the FDA more." "That's what was going on at Invacare – instead of taking the punishment, they tried to get around it." CW3 explained that the loophole would not have prevented a shutdown. "They would always be shut down, but it's a loophole where they would still be able to sell that type of equipment – the prescription power wheelchair." While Invacare

could probably "pull the same crap" on a manual prescription wheelchair, Invacare had more interest in the prescription power chair because it was more profitable."

271. CW3 explained the way the Invacare power sales division works and used New York City as an example. The sales people would go out in the five boroughs (for example), and each borough would have at least one rehab-type hospital, or a hospital with a rehab wing. In that week, maybe five to ten high-end power wheelchairs are sold. The type of wheelchair that Christopher Reeves used, for example, is about a $30,000 power chair. Therefore, this type of sale would be very important to the company. The idea was go to into these facilities to pick up as many prescriptions as they could. If the government were to shut that division down, Invacare would still be allowed to sell to the customers who had prescriptions for the chairs, if it were documented that there was no other place that the patient could get that particular equipment. "The problem they ran into is that . . . the FDA saw a flood of these [suspicious prescriptions] and it made them more mad."

272. Former employees described a concerted program of secrecy and subterfuge in Invacare's dealings with the FDA during the Class Period. For example, CW5 stated that employees always knew when the FDA was there. Although the FDA does not have to announce when they are coming, as soon as they arrived, everyone knew. Employees on the floor are made aware by managers and were told not to say anything to the FDA. If the FDA asked employees questions, they were to direct the FDA to a manager or a supervisor. The workers on the floor were not allowed to have a conversation with the FDA inspectors.

273. Even after the FDA demanded the Company enter into a consent decree, Invacare took steps to avoid remediation and, instead, relocated production lines and manufacturing equipment to other facilities so that if the Taylor Street Facility was shut down, the Company

could continue to manufacture products. According to CW5, Invacare "did some serious shuffling" in 2012 before the Consent Decree, although plans were in the works throughout 2011. Certain production lines were moved to Invacare facilities in Mexico and Canada. CW5 recalled one instance in which the Company moved sewing machines from the wheelchair upholstery department to the Cleveland Street Facility during the night during the summer of 2012. The Company wanted to make sure they could keep producing if the Taylor Street Facility was shut down; "they sure knew how to scramble." The move was noteworthy because Invacare had previously planned to shut down the Cleveland Street Facility as a cost-cutting measure. However, with all of the problems with FDA hanging over the Taylor Street Facility, the Company decided to hang on to the Cleveland Street Facility building.

274. CW7 also described the Company's desperate last-ditch efforts to avoid the consequences of the impending Consent Decree. On Friday, December 21, 2012, the day after the FDA filed its complaint for permanent injunction, Invacare shut down production at the Taylor Street Facility. CW7 recalled attending a meeting at 2 p.m. where Invacare management told the employees "We're going to have to let everyone go." It was the Friday before Christmas. However, according to CW7, before midnight on Thursday, December 20, 2012, the Company directed that an entire assembly line be packed up to be transferred to Invacare's facility in Reynosa, Mexico so the Company could continue to produce wheelchairs after the FDA had shut down the Taylor Street Facility. CW7 reported that employees ten-hour shifts, often seven days a week, as Invacare was rushing through the manufacturing process to move everything to other facilities because the Company knew the consent decree was "going to come down" and close down the Taylor Street facility. In fact, Invacare had been transferring

production to its Mexico and Canada facilities to avoid FDA scrutiny "way before" the FDA complaint was filed – including throughout 2009.

275. CW9 said that the FDA issues started approximately ten years ago when the FDA began snooping around. Invacare had employees take "quality class" but then they would forget about it. There was no enforcement. If things were busy and they had to work overtime, they were expected to do whatever it took to get the product out. CW9 was told that the FDA issues concerned recordkeeping in Quality [Control]. According to CW9, Invacare had known about FDA concerns for ten to fifteen years but did nothing to correct issues except putting "Band-Aids" on it until the FDA said that they had to fix it. Between 2009 and 2012, Invacare started working to correct issues, "but not really hard." The Company brought in two outside consulting companies. Invacare failed so many audits that one of the consultants asked CW9 if they were trying to flunk the audits on purpose because they were not doing very well. According to CW9, it seemed that Invacare was trying to fail.

276. CW9 did not think that the Company was actually trying to fix anything. Invacare kept the FDA inspectors away from the workers because it did not want the floor employees talking to the FDA. Specifically, the Company did not want the FDA asking the workers questions like, "How long have you been doing this procedure?" when the answer was, "About a week." CW9 was told by a supervisor that he/she was only allowed to answer the questions the FDA asked and not to volunteer other information or otherwise interact with the FDA at all unless a foreman was there to monitor.

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR

277. The statutory safe harbor provided, under certain circumstances, for forward-looking statements does not apply to any of the allegedly false statements pleaded in this

Complaint. The statements alleged to be false or misleading herein relate to then-existing facts and conditions from which the truth or falsity of the statements could be determined at the time spoken, or were statements about the future that also function as communications of current expectations and were therefore not "forward-looking statements" when made. To the extent certain of the statements alleged to be false or misleading may be characterized as forward-looking, they were not identified by Defendants as forward-looking or accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Furthermore, at the time Defendants made any statement alleged herein to be false or misleading and that may be characterized as forward-looking, Defendants had actual knowledge that the particular forward-looking statement was false or misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of Invacare who knew that those statements were false or misleading when made.

XI. CLASS ACTION ALLEGATIONS

278. Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all those who purchased or otherwise acquired the common stock of Invacare between February 27, 2009, and December 7, 2011, inclusive, and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of the Company at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

279. The members of the Class are so numerous that joinder of all members is impracticable. As evidence of the start of the Class Period, Invacare had over 31 million shares

of common stock issued and outstanding, which actively traded on the NYSE throughout the Class Period. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Invacare or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class action.

280. Lead Plaintiff's 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 that is complained of herein.

281. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

282. 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 statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Invacare; and

(c) To what extent the members of the Class have sustained damages and the proper measurer of damages.

283. 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 action as a class action.

XII. LEAD PLAINTIFF RELIED UPON DEFENDANTS' FALSE AND MISLEADING STATEMENTS AND OMISSIONS

284. Lead Plaintiff is entitled to a presumption of reliance on Defendants' material misrepresentations and omissions pursuant to the fraud-on-the-market doctrine in that, among other things:

(a) The Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The misrepresentations and omissions were material;

(c) Invacare's common stock traded in an efficient market;

(d) The misrepresentations and omissions alleged would induce a reasonable investor to misjudge the value of Invacare's common stock; and

(e) Lead Plaintiff and other members of the Class purchased Invacare securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

285. At all relevant times, the market for Invacare's publicly traded common stock was an efficient market for the following reasons:

(a) Invacare's stock met the requirements for listing and was listed and actively traded on the NYSE, a presumptively efficient market;

(b) Invacare's securities volume was substantial. The Company had between approximately 30 million and 32 million shares outstanding and an average weekly trading volume of approximately 1 million shares, which represented turnover of more than 3.25% of the Company's highest shares outstanding amount;

(c) Institutional investors held the vast majority of Invacare common stock, in excess 85% of all outstanding shares;

(d) Invacare was eligible to file registration statements with the SEC on Form S-3. To be S-3 eligible, a company had to have $75 million in stock held by non-affiliates, and had to have filed financial reports with the SEC for at least one year. The value of the shares held by nonaffiliates of Invacare greatly exceeded the $75 million threshold. Moreover, as a regulated issuer, Invacare regularly filed annual, periodic, and interim public reports with the SEC;

(e) Invacare regularly communicated with public investors via other established market communication mechanisms, including through press releases that were carried by the media, newswires and on the internet, as well as through presentations to investors and analysts, and conference calls with analysts;

(f) At least six different firms followed Invacare, which collectively issued over fifty analyst reports concerning Invacare;

(g) The market reacted promptly to public information disseminated by Invacare;

(h) The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Invacare securities; and

(i) Without knowledge of the misrepresented or omitted material facts alleged herein, Lead Plaintiff purchased or acquired Invacare common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed.

286. As a result of the foregoing, the markets for Invacare common stock promptly reacted to current information regarding Invacare from publicly available sources and reflected such information in the trading price of Invacare common stock. Under these circumstances, a presumption of reliance applies.

287. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because plaintiffs' fraud claims are grounded in Defendants' material omissions. As this action involves Defendants' failure to disclose material adverse information regarding Invacare's regulatory compliance – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in the making investment decisions.

XIII. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF

For Violation Of Section 10(b) Of The Exchange Act And Rule 10(b)(5)
Against Invacare, Blouch, And Mixon

288. Lead Plaintiff repeats and re-alleges each and every allegation set forth in the foregoing paragraphs as if fully set forth herein.

289. This Count is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, on behalf of Lead Plaintiff and members of the Class against Defendants Invacare, Blouch, and Mixon.

290. Throughout the Class Period, Invacare and Defendants Mixon and Blouch, individually and in concert, directly and indirectly, by the use and means of instrumentalities of interstate commerce and/or of the United States mail, engaged and participated in a continuous course of conduct to conceal adverse material information about Invacare, its business operations and future prospects, as specified herein. This plan, scheme and course of conduct was intended to and, throughout the Class Period, did: (a) deceive the investing public, including Lead Plaintiff, as alleged herein; (b) artificially inflate the market price of Invacare securities; and (c) cause Lead Plaintiff and members of the Class to purchase Invacare securities at artificially inflated prices.

291. In furtherance of this unlawful scheme, plan and course of conduct, these Defendants, individually and jointly, took the actions set forth herein. While in possession of material, adverse non-public information, these Defendants (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading; (c) sold shares while in possession of material, adverse non-public information; and (d) engaged in acts, practices and a course of

conduct which operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to create and maintain artificially high market prices for Invacare's common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. Each of these Defendants was a direct, necessary and substantial participant in the common course of conduct alleged herein.

292. Defendants knew or, but for their deliberate recklessness, should have known, that their statements concerning the Company's business operations and future prospects, as disseminated to the investing public during the Class Period, were materially misstated. Further, Defendants knew of existing adverse facts which undermined their representations about Invacare's existing business operations and prospects during the Class Period.

293. In addition to the duties of full disclosure imposed on the Individual Defendants as a result of their responsibility for the Company's financial statements and making affirmative statements and reports to the investing public, the Individual Defendants had a duty to promptly disseminate truthful information that would be material to investors.

294. Invacare and the Individual Defendants, the top executive officers of the Company, are liable as direct participants in the wrongs complained of herein. Through their positions of control and authority as officers of the Company, each of these Individual Defendants was able to and did control the content of the public statements disseminated by Invacare. With knowledge of the falsity and/or misleading nature of the statements contained therein and in reckless disregard of the true business operations and future prospects of the Company, these Individual Defendants caused the heretofore complained of public statements to contain misstatements and omissions of material facts as alleged herein.

295. Invacare and the Individual Defendants acted with scienter throughout the Class Period in that they either had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein or acted with deliberate reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them. The Individual Defendants were among the senior management of the Company and were therefore directly responsible for the false and misleading statements and/or omissions disseminated to the public through press releases, news reports and filings with the SEC.

296. Invacare and the Individual Defendants' misrepresentations and/or omissions were intentional or deliberately reckless and in some instances done for the purpose of enriching themselves at the expense of the Company's investors, including Lead Plaintiff, and to conceal the Company's true operating condition from the investing public. Invacare and the Individual Defendants engaged in this scheme to inflate the Company's reported revenues and prospects in order to create the illusion that Invacare was a successful, strong and growing Company.

297. As a result of the dissemination of the materially false and misleading information and failure to disclose material facts, as set forth above, the market price of Invacare common stock was artificially inflated during the Class Period. In ignorance of the fact that market prices of Invacare's publicly traded common stock were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the common stock trade, and/or on the absence of material adverse information that was known to or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Lead Plaintiff and the other members of the Class acquired Invacare common stock during the Class Period at artificially high prices and were damaged thereby.

298. Had Lead Plaintiff and the other members of the Class and the marketplace known of the material adverse information not disclosed by Invacare and the Individual Defendants, or been aware of the truth behind these Defendants' material misstatements, they would not have purchased or otherwise acquired Invacare common stock at artificially inflated prices, or at all.

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

300. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff 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 CLAIM FOR RELIEF

For Violation Of Section 20(a) Of The Exchange Act Against The Individual Defendants

301. Lead Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

302. This Count is asserted against the Individual Defendants, *i.e.*, Defendants Blouch and Mixon.

303. The Individual Defendants acted as controlling persons of Invacare within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions within Invacare, their ownership and contractual rights, participation in and awareness of the Company's operations, and intimate knowledge of the Company's actual performance, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Lead Plaintiff contends are false and

misleading. The 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 Lead Plaintiff to be misleading prior to and shortly after these statements were issued and had the ability to prevent the issuance of the false statements and material omissions or cause such misleading statements and omissions to be corrected.

304. In addition, each of these Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same. For example, the Individual Defendants were able to and did control the content of various SEC filings, press releases, investor presentations, and other public statements pertaining to the Company during the Class Period. The Individual Defendants had access to the adverse undisclosed information about Invacare's business, operations, products, trends, financial statements, markets, and present and future business prospects via access to internal control documents; conversations and connections with other corporate officers, employees, and borrowers; participation at management and Board of Directors meetings and committees thereof, and reports and other information provided to them in connection therewith.

305. The Individual Defendants both participated in the drafting, preparation, and/or approval of the various public, shareholder, and investor reports and presentations, as well as other communications alleged herein.

306. As set forth above, Invacare and the Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of

the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

XIV. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff, on its own behalf and on behalf of the Class, prays for judgment as follows:

A. Declaring this action to be a class action pursuant to Rule 23;

B. Awarding compensatory damages, in favor of Lead Plaintiff and the Class against all Defendants, jointly and severally, in an amount to be proven at trial, involving interest thereon;

C. Awarding Lead Plaintiff its reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Awarding such other relief as the Court may deem just and proper.

XV. DEMAND FOR TRIAL BY JURY

Lead Plaintiff demands a trial by jury.

Dated: November 15, 2013

Respectfully submitted,

BERNSTEIN LITOWITZ BERGER
& GROSSMANN LLP

/s/ Blair A. Nicholas

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CERTIFICATE OF SERVICE

A copy of the foregoing was filed electronically this 15th day of November, 2013. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Blair A. Nicholas
Blair A. Nicholas