**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF OHIO**
**EASTERN DIVISION**

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| CAMBRIDGE RETIREMENT SYSTEM, on behalf of itself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>INVACARE CORPORATION, GERALD B. BLOUCH, A. MALACHI MIXON, III, and ROBERT K. GUDBRANSON,<br><br>Defendants. | Case No.<br><br>CLASS ACTION<br><br>**COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS**<br><br>JURY TRIAL DEMANDED |

Plaintiff Cambridge Retirement System ("Plaintiff"), by and through its counsel, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, *inter alia*, counsel's investigation, which includes review and analysis of: (a) regulatory filings made by Invacare Corporation ("Invacare" or the "Company") with the United States Securities and Exchange Commission ("SEC"); (b) press releases and media reports issued by and disseminated by Invacare; and (c) other publicly available information concerning Invacare.

## INTRODUCTION

1. This is a federal securities class action brought on behalf of purchasers of Invacare's publicly traded common stock between July 22, 2010 and December 7, 2011, inclusive (the "Class Period"). The claims asserted herein are alleged against Invacare and certain of the Company's senior executives (collectively, "Defendants"), and seek to pursue

remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Invacare is a global manufacturer and distributor of medical supplies and equipment for the home medical and long-term care product markets. The Company, which is headquartered in Elyria, Ohio ("Headquarters"), operates two major manufacturing facilities in the United States: one on Taylor Street in Elyria, Ohio (the "Taylor Street Facility") and another in Sanford, Florida (the "Sanford Facility"). At these factories, the Company produces, among other things, powered mobility and custom manual wheelchairs and seating products, homecare and institutional care beds, and a variety of standard manual wheelchairs.

3. As a manufacturer of medical devices in the United States, Invacare is regulated by the U.S. Food and Drug Administration ("FDA"), which subjects the Company to comply with certain labeling and record keeping requirements, product design, and manufacturing controls. Throughout the Class period, Defendants materially misrepresented Invacare's compliance with FDA guidelines and Current Good Manufacturing Practices ("CGMP") to investors, and masked the fact that the Company suffered from widespread operational, quality, and regulatory deficiencies. Defendants' concealment of these known problems, which impacted Invacare's key corporate and manufacturing facilities, deceived investors and rendered Defendants' statements about Invacare's regulatory compliance and business prospects materially false and misleading.

4. Invacare has a checkered history relating to its compliance with FDA guidelines and CGMP. In April 2010, prior to the start of the Class Period, however, the Company assured investors that although it had received past warnings from the FDA, the problems that triggered those warnings had been fully addressed. Indeed, on July 22, 2010, the start of the Class Period,

Invacare issued a press release reporting strong financial results for the second quarter of 2010, including earnings growth of about 30 percent year-over-year. As a result of Invacare's stronger than expected earnings results, Defendants reported that the Company would raise its full year earnings guidance.

5. On August 18, 2010, following a two week investigation of the Sanford Facility by the FDA, the Company received a Form 483—a list of deficiencies observed by FDA personnel during its investigation—setting forth serious concerns discovered during the investigation. Instead of disclosing the Form 483 to investors, the Company concealed it and the deficiencies set forth therein, and continued to disclose growing revenues and increasing earnings guidance.

6. On December 15, 2010, the FDA sent a Warning Letter to Invacare concerning the August 2010 inspection of the Sanford Facility. The Warning Letter identified a litany of CGMP violations and "recurring" consumer complaints concerning the safety of Invacare's beds, including grisly incidents of death caused by entrapment and fire. In the Warning Letter, the FDA chastised Invacare for failing to take preventative action, document and evaluate serious complaints, and complete risk assessments to ensure the safety of its products. According to the FDA, a September 8, 2010 letter sent by Invacare following receipt of the August 18, 2010 Form 483, which purported to address the FDA's concerns, was "not adequate," and the failure to promptly remediate these issues could result in regulatory action.

7. Two days later, on December 17, 2010, the Company received two additional Forms 483 relating to compliance concerns at its Headquarters and the Taylor Street Facility. These new Forms 483 memorialized more than fifty FDA inspections of these facilities

conducted between August 11, 2010 and December 17, 2010. The Company did not disclose the Warning Letter or the two new Forms 483 to investors.

8. Investors did not learn of the rampant CGMP violations at the Company until January 4, 2011, when the FDA released the letter to the public. That disclosure caused Invacare stock to drop over 4 percent from $30.67 per share on January 3, 2011 to close at $29.29 per share on January 4, 2011, representing a market capitalization loss of about $40 million.

9. Defendants downplayed the significance of the Warning Letter by falsely assuring investors that the FDA's concerns did not impact production or relate to the safety of Invacare's products. According to Defendants, the Warning Letter merely concerned "documentation procedures" at the Sanford Facility. Defendants further reassured investors that Invacare was dedicating increased resources to bolster its quality assurance program systemically and was working with the FDA to ensure compliance with applicable rules and regulations.

10. Then, on August 8, 2011, the Company received two additional Forms 483, which set forth several violations at the Headquarters and the Taylor Street Facility. Notably, the vast majority of the "observations" listed in these new Forms 483 were repeat observations of CGMP violations identified in the December 17, 2010 Forms 483, and which had not been resolved by the Company.

11. 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 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."

12. One month later, on December 8, 2011, Invacare shocked investors by issuing a press release announcing that the FDA intended to enter a consent decree relating to its Headquarters and the Taylor Street Facility. The consent decree would require the suspension of certain operations until those facilities became compliant with FDA regulations. News of Invacare's systemic quality and regulatory deficiencies, which could take many months to remediate and impact Invacare's revenue and growth, caused the Company stock to plummet nearly 29 percent from $20.58 per share on December 7, 2011 to close at $14.70 per share on December 8, 2011, wiping out over $180 million in market capitalization.

## JURISDICTION AND VENUE

13. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.P.R. §240.10b-5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. §78aa.

14. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Invacare maintains its executive offices in this District and many of the acts and conduct that constitute the violations of law complained of herein, including dissemination to the public of materially false and misleading information to the investing public, occurred in and/or were issued from this District. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

## PARTIES

15. Plaintiff Cambridge Retirement System represents approximately 5,400 active and retired public employees from Cambridge, Massachusetts, and manages more than $850 million in assets to provide for them in retirement. Cambridge Retirement System purchased the publicly-traded common stock of Invacare at artificially inflated prices during the Class Period, as set forth in the accompanying Certification and incorporated by reference herein, and has been damaged thereby.

16. Defendant Invacare is an Ohio corporation whose subsidiaries and affiliates design, manufacture, and distribute a line of health care products for the non-acute care environment, including the home health care and extended care markets. Invacare maintains its principal executive offices at One Invacare Way, Elyria, Ohio. Invacare also maintains additional warehouses, offices, and manufacturing facilities in, among other places, Elyria, Ohio, Akron, Ohio, and North Ridgeville, Ohio. Invacare's common stock trades under the symbol IVC on the New York Stock Exchange, which is an efficient market.

17. Defendant Gerald B. Blouch is Invacare's current President and CEO. Blouch has been President and a director of Invacare since November 1996. Blouch also served as interim CEO of the Company from April 2010 through December 2010.

18. Defendant A. Malachi Mixon, III has served as Invacare's Chairman of the Board since 1983. Mixon previously served as Invacare's President and CEO. Mixon's tenure as President of Invacare lasted from 1979 through 1996 and his tenure as CEO of the Company lasted from 1979 through 2010.

19. Defendant Robert K. Gudbranson has served as Invacare's Senior Vice President and Chief Financial Officer since April 2008.

20. Defendants Blouch, Mixon, and Gudbranson are collectively referred to hereinafter as the "Individual Defendants." The Individual Defendants, because of their positions with Invacare, possessed the power and authority to control the contents of Invacare's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Individual Defendants was provided with copies of the Company's reports and press releases 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 and access to material non-public information available to them, each of 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 which were being made were then materially false and/or misleading.

## BACKGROUND

21. Invacare designs, manufactures, and distributes health care products for the non-acute care environment, including the home health care and extended care markets. According to its 2009 Annual Report to Shareholders—which was filed with the SEC on April 7, 2010—Invacare "is committed to design and deliver the best value in medical products, which promote recovery and active lifestyles for people requiring home and other non-acute health care." Among the principles it follows in pursuit of its commitment, the Company lists "continually striving for total quality throughout the organization."

22. Invacare operates the following segments in North America: North America/Home Medical Equipment ("NA/HME"), Invacare Supply Group and Institutional Products Group. The Company operates four major North American factories, which include the Taylor Street Facility, the Sanford Facility, and two other 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, accounting for over 40 percent of the Company's annual revenues in 2009, 2010, and 2011.

23. As a manufacturer of medical devices in the United States, Invacare is regulated by the FDA, which subjects the Company to certain labeling and record keeping requirements, product design regulations, and manufacturing controls. During 2008 and 2009, the FDA inspected Invacare's Taylor Street Facility and its Sanford Facility. At the conclusion of each inspection, the FDA issued its inspectional observations on FDA Form 483, which, according to Invacare, were adequately "addressed" by the Company. On April 7, 2010, in its 2009 Annual Report, the Company assured investors that it "continues to strengthen its programs to better ensure compliance with applicable regulations and actively keeps abreast of proposed regulations, particularly those which could have a material adverse effect on the company."

## DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

24. On July 22, 2010, the first day of the Class Period, Invacare issued a press release announcing its second quarter 2010 financial results. The press release was also filed with the SEC on Form 8-K, which was signed by Defendant Gudbranson. In the press release, the Company reported strong financial results for the second quarter of 2010, including earnings growth of about 30 percent year-over-year. As a result of Invacare's stronger than expected earnings results, Defendants reported that the Company would raise its full year earnings guidance.

25. During Invacare's earnings conference call that same day, Defendant Blouch further boasted that "I think we're really well positioned to be the manufacturer of choice for the whole industry. So we feel good about where we are."

26. Invacare's positive earnings announcement and outlook caused the price of Invacare common stock to jump from $20.00 per share on July 21, 2010 to close at $23.48 per share on July 22, 2010. The Company's announcement also prompted analysts at Natixis Bleichroeder Equity Research to remark in their July 22 report that "the company is gaining sales momentum, executing, and could deliver potential upside in 2010 . . . [Accordingly,] [w]e are raising our 2010 EPS and revenue estimates to account for 2Q's stronger than expected results and improvements in the company's fundamentals."

27. On August 6, 2010, Invacare filed with the SEC its Form 10-Q for the second quarter of 2010 (the "2Q2010 10-Q"), confirming the financial results and increased earnings guidance previously announced by the Company in its July 22 press release. The 2Q2010 10-Q was signed by Defendant Gudbranson and contained certifications by Defendants Blouch and Gudbranson that attested to the purported accuracy and completeness of the Company's 2Q2010 10-Q.

28. In August 2010, the FDA conducted an inspection of Invacare's Sanford Facility, one of the Company's four major manufacturing facilities. As a result of that inspection, which lasted over two weeks, the FDA issued a Form 483 on August 18, 2010, which set forth significant safety, recordkeeping, and compliance issues, including among others: (a) Improper responses to "recurring complaints relating to potential sparks/fires associated with the beds;" (b) Reports of control systems shooting sparks, beds catching fire, and patients getting trapped between the mattress and the rail, some of which reportedly resulted in death; (c) A finding that

the Company's beds were "adulterated" because the methods or facilities used to manufacture them were "not in conformity with the Current Good Manufacturing Practice;" (d) A failure to establish and maintain adequate procedures to analyze processes to identify products that do not conform to FDA regulations and guidelines; (e) A finding that Invacare beds were "misbranded" under federal law, in that Invacare had failed or refused to furnish material or information respecting the beds as required by federal law and regulations; and (f) A failure to submit complaints concerning entrapment of patients in Invacare beds, as required to the FDA.

29. Invacare did not disclose to investors that it had received the August 18, 2010 Form 483, nor did it disclose the significant compliance issues the Company faced at the Sanford Facility.

30. On October 28, 2010, Invacare issued a press release announcing its third quarter 2010 financial results. The press release was also filed with the SEC on Form 8-K, which was signed by Defendant Gudbranson. For the third quarter, Invacare recorded another strong quarter, beating analysts' earnings estimates and reporting 8 percent quarterly earnings growth year-over-year. Again, Invacare omitted any mention of the August 18, 2010 Form 483 or any of the significant compliance issues raised by the FDA therein.

31. Analysts with WJB Capital were impressed by Invacare's earnings results and commented 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."

32. On November 5, 2010, Invacare filed with the SEC its Form 10-Q for the third quarter of 2010 (the "3Q2010 10-Q"), confirming the financial results previously announced by the Company in its October 28 press release. The 3Q2010 10-Q was signed by Defendant

Gudbranson and contained certifications by Defendants Blouch and Gudbranson that attested to the purported accuracy and completeness of the Company's 3Q2010 10-Q. The 3Q2010 10-Q did not mention the August 18, 2010 Form 483 or any of the significant compliance issues raised by the FDA therein.

33. On December 15, 2010, the FDA issued a Warning Letter to Invacare, which chastised the Company for not adequately responding to the compliance deficiencies previously identified in the FDA's August 18, 2010 Form 483. Two days later, on December 17, 2010, the FDA issued two additional Forms 483 relating to deficiencies at the Headquarters and the Taylor Street Facility. These new Forms 483 memorialized more than fifty inspections at these facilities between August 11, 2010 and December 17, 2010. The Company did not immediately disclose receipt of the Warning Letter or the two new Forms 483 to investors.

**THE FDA RELEASES THE WARNING LETTER TO THE PUBLIC**

34. On January 4, 2011, the FDA released a copy of the December 15, 2010 Warning Letter to the public. Remarkably, the issues raised in the Warning Letter were the same issues raised several months earlier in the August 18, 2010 Form 483, which the Company had failed to address. Specifically, the Warning Letter stated that certain of Invacare's medical devices manufactured at the Sanford Facility "are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation."

35. Among other deficiencies, the Warning Letter also cited the Company's "[f]ailure to establish and maintain adequate procedures to identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems." Specifically, the Warning Letter discussed "recurring complaints relating to potential sparks/fires associated with

the beds" and "complaints relating to entrapment with the use of your firm's bed rails," including several incidents that resulted in death.

36. That same day, the Company issued a press release relating to the Warning Letter. The press release states that 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." The press release also quotes Defendant Blouch assuring investors that "[t]he FDA warning letter does not state that our products are unsafe nor has it impacted our production," which directly contradicts the Warning Letter's statements that Invacare products caused fire and entrapment related deaths. Blouch added that Invacare "take[s] all FDA matters very seriously, and we intend to address all of the FDA's concerns." Furthermore, the press release explained that the "Company has assembled a team including its internal quality and regulatory associates as well as outside experts to address the agency's concerns." In addition to Invacare's press release, a Company spokeswoman stressed that the consumer complaints detailed in the Warning Letter were simply "allegations."

37. News of Invacare's receipt of the FDA Warning Letter caused the Company stock to drop over 4 percent from $30.67 per share on January 3, 2011 to close at $29.29 per share on January 4, 2011, representing a market capitalization loss of about $40 million.

38. Analysts with CL King & Associates were surprised by the unusual nature of the Warning Letter and found Invacare's response "unsatisfactory." In a January 5, 2011 report, they 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 analysts also called into question whether Invacare ever reported the incidents of bed fire to the FDA as the Company was required to do. After all, Invacare's bed fire incidents do not appear on 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 analysts estimated that bed sales represent approximately 5 percent to 10 percent 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 percent.

39. In a follow-up report dated January 7, 2011, CL King analysts reported that Invacare had informed them that "Invacare's internal investigation to date suggests none of the patient deaths or injuries are related to product defects." Nevertheless, based on the analysts' further analysis of MAUDE, "Invacare beds accounted for about 50 percent of all the adverse events among the four competitors that have an event code of death . . . [O]ur MAUDE analysis could call into question the safety of Invacare beds."

**INVACARE DOWNPLAYS ITS COMPLIANCE DEFICIENCIES**

40. On February 3, 2011, Invacare issued a press release announcing strong fourth quarter and year-end results for 2010. The press release was also filed with the SEC on Form 8-K, which was signed by Defendant Gudbranson. In its press release, Invacare continued to downplay the significance of the FDA's scrutiny into the Company by assuring investors that the issue was confined to the Sanford Facility, that the safety and efficacy of the Company's products were not at issue, and that the Company was diligently working to address the FDA's concerns. Specifically, the press release reiterated that the Warning Letter "does not call into question the safety or efficacy of Invacare products, and production has not been impacted." The

press release also stated that "the Company does have areas to improve and it is taking these issues very seriously" and that "[t]he Company has added resources to ensure it is addressing all of the FDA's concerns in a timely manner."

41. Invacare also held an earnings conference call on February 3 to discuss its earnings results. During the call, Defendant Blouch continued to reassure investors that the Warning Letter was an isolated issue related to the Sanford Facility, that it was not a major cause for alarm, and that it would not impact production. Defendant Blouch also told investors that Invacare would dedicate increased resources to address the FDA's concerns in a timely manner.

42. In particular, Defendant Blouch stated that "Invacare received a warning letter, as most of you know, from the Food and Drug Administration, the FDA, related to documentation and procedures of the Company's Sanford, Florida facility." Blouch reiterated that "[t]he letter does not call into question the safety or efficacy of Invacare's product, and it does not impact production" and that the "investigation shows to-date that no injuries or deaths were caused by product defect." Blouch also assured investors that "the Company does have areas of improvement and is taking these issues very seriously. Invacare has redeployed internal resources and is adding external resources to ensure that it is addressing all of the FDA's concerns in a timely manner and an effective manner."

43. On February 25, 2011, Invacare filed with the SEC its Form 10-K for the fourth quarter and fiscal year 2010 (the "2010 10-K"), confirming the financial results previously announced by the Company in its February 3 press release. The 2010 10-K was signed by Defendants Mixon, Blouch, and Gudbranson and contained certifications by Defendants Blouch and Gudbranson that attested to the purported accuracy and completeness of the Company's 2010 10-K.

44. Significantly, the 2010 10-K attributed Invacare's purported success in part to the Company's focus on quality. According to the 2010 10-K, "Invacare is committed to design 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." The 2010 10-K also briefly addressed the FDA's inspection of Invacare facilities, identifying by name only the purportedly "routine" inspection of the Sanford Facility.

45. The 2010 10-K also continued to downplay any concern related to the Warning Letter. Specifically, the 2010 10-K 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 10-K also assured investors that "[t]he 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." Finally, the 2010 10-K stated that "[t]he costs associated with making the process improvements indicated in the FDA's letter are currently not expected to be material."

46. Shortly thereafter, on March 8, 2011, Invacare issued a Form 8-K revealing that the Company's Board of Directors entered a share purchase agreement with Defendant Mixon. Pursuant to the agreement, Defendant Mixon sold 14 percent, or 350,000, of his personally owned shares of Invacare stock back to the Company at $29.94 per share, reaping proceeds of approximately $10.48 million. The sale of Defendant Mixon's shares was apparently for "personal financial planning purposes." According to a March 8 report issued by analysts with

CL King, "we believe the share purchase agreement could justifiably be viewed by some investors as giving preferential treatment to Mr. Mixon."

47. Invacare continued to bolster investors' belief that the Company was taking the Warning Letter seriously by issuing a press release on April 4, 2011, announcing the recent hiring of Colleen Craven to serve as Invacare's Chief Compliance Officer. According to the press release, "Craven will 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. Craven joins Invacare as the Company looks to improve its corporate compliance procedures and documentation practices."

48. A few weeks into her new role at Invacare, however, Colleen Craven mysteriously stepped down as the Company's Chief Compliance Officer, purportedly for "personal reasons." In a press release about Craven's departure issued on April 22, 2011, Invacare announced the appointment of Doug Newlin, Senior Vice President of Global Engineering, to assume leadership of Invacare's regulatory team pending the recruitment of a permanent replacement for Craven. According to Defendant Blouch, "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."

49. One week later, on April 28, 2011, Invacare issued a press release announcing its financial results for the first quarter 2011. The press release was also filed with the SEC on Form 8-K, which was signed by Defendant Gudbranson. For the first quarter, Invacare announced another solid quarter, reporting a 39 percent increase in quarterly earnings year-over–year. The press release also quotes Defendant Blouch touting that "Invacare is confident that the

momentum from this quarter will continue to deliver positive results for its shareholders in 2011."

50. 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 Warning Letter. In that regard, the press release stated that "[t]he 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."

51. On May 5, 2011, Invacare filed with the SEC its Form 10-Q for the first quarter of 2011 (the "1Q2011 10-Q"), confirming the financial results previously announced by the Company in its April 28 press release. The 1Q2011 10-Q was signed by Defendant Gudbranson and contained certifications by Defendants Blouch and Gudbranson that attested to the purported accuracy and completeness of the Company's 1Q2011 10-Q. The 1Q2011 10-Q also commented on Invacare's ongoing efforts to address the concerns raised in the Warning Letter, assuring investors that compliance with FDA regulations was among its "highest priorities."

52. The 1Q2011 10-Q stated that "[t]he 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." The Company also continued to assure investors that it "is 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." Invacare also

reiterated that "the Company views its regulatory compliance actions to be among its highest priorities."

53. On July 28, 2011, Invacare issued a press release announcing its financial results for the second quarter 2011. The press release was also filed with the SEC on Form 8-K, which was signed by Defendant Gudbranson. For the second quarter, Invacare reported strong financial results, including a 15 percent 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. In addition, the press release quotes Defendant Blouch assuring investors of the Company's continued success, stating that "[t]he Company is encouraged by the sales growth in the first half of the year" and announcing that the Company was "raising its guidance on organic net sales growth." Conspicuously absent from the July 28 press release, however, was any mention of the Warning Letter or purported progress made towards addressing the concerns raised therein.

54. During Invacare's July 28 earnings conference 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 to this query, 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 Defendant 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."

55. On August 8, 2011, Invacare filed with the SEC its Form 10-Q for the second quarter of 2011 (the "2Q2011 10-Q"), confirming the strong financial results previously

announced by the Company in its July 28 press release. The 2Q2011 10-Q was signed by Defendant Gudbranson and contained certifications by Defendants Blouch and Gudbranson that attested to the purported accuracy and completeness of the Company's 2Q2011 10-Q.

56. The 2Q2011 10-Q addressed Invacare's purported status in addressing the Warning Letter, including by assuring investors that Invacare was dedicating the necessary resources towards resolving the FDA's concerns. Specifically, the 2Q2011 10-Q stated that "[t]he 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 2Q2011 10-Q also reiterated that Invacare "is 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." In addition, the 2Q2011 10-Q continued to assure investors that "the Company continues to view its regulatory compliance actions as a high priority."

57. That same day, however, Invacare received two additional Forms 483 relating to deficiencies at its Headquarters and the Taylor Street Facility. Significantly, the Form 483 related to the Headquarters contained thirteen violations, ten of which were "repeat observations" 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 a 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.

58. 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."

59. On October 27, 2011, Invacare issued a press release announcing its third quarter 2011 financial results. The press release was also filed with the SEC on Form 8-K, which was signed by Defendant Gudbranson. The press release reported yet another strong quarter, announcing a 5 percent increase in quarterly earnings compared to the third quarter of the prior year. Invacare also indicated in the October 27 press release that it continued to work with the FDA to become compliant with applicable regulations, including by "actively making systemic improvements across its quality and regulatory systems."

60. During Invacare's October 27 earnings conference call, an analyst who found Invacare's added disclosure about the Company's "systemic improvements" to be "curious" asked the Defendants for further detail regarding the concerns raised by the FDA over the past year and the efforts taken by the Company to correct those concerns. 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."

61. Defendant Blouch added that 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."

62. In his response to the analyst's question, Defendant Blouch also indicated for the first time that the issues set forth in the Warning Letter were not exclusive to the Sanford Facility. Indeed, the Company had previously received several Forms 483 relating to its Headquarters and Taylor Street Facilities, which had not been disclosed to investors. Defendant 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."

63. 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 Defendant 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." Defendant Blouch further downplayed Invacare's disclosure by adding that "[w]e didn't want to let people think we weren't – it was a non-issue. As the CEO of the Company, I'm pleased with what we're doing, pleased with the progress we're making, pleased with the

researches we've applied against it. And it's – we were just trying to anticipate things that you folks would be asking; that as why it is in there."

64. On November 8, 2011, Invacare filed with the SEC its Form 10-Q for the third quarter of 2011 (the "3Q2011 10-Q"), confirming the financial results previously announced by the Company in its October 27 press release. The 3Q2011 10-Q was signed by Defendant Gudbranson and contained certifications by Defendants Blouch and Gudbranson that attested to the purported accuracy and completeness of the Company's 3Q2011 10-Q.

65. In the 3Q2011 10-Q, the Company, for the first time, revealed that the Sanford Facility was not the only major Invacare facility facing increased FDA scrutiny. According to the 3Q2011 10-Q "[t]he 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."

66. In the 3Q2011 10-Q, 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 3Q2011 10-Q also stated that "[t]he Company also has engaged outside experts with proven quality systems and regulatory experience in the medical device industry in order to accelerate these improvements" and that "[t]he Company is working with the FDA to resolve the inspectional observations identified in the warning letter and in the FDA-483s."

**THE TRUE EXTENT OF INVACARE'S NONCOMPLIANCE IS DISCLOSED**

67. On December 8, 2011, prior to the market opening, Invacare shocked investors by revealing that the FDA intended to issue a consent decree of injunction related to the Company's Headquarters and the Taylor Street Facility. The consent decree proposed by the FDA would

suspend certain operations at the Headquarters and the Taylor Street Facility pending a determination by the FDA that Invacare was compliant with the applicable regulations.

68. Specifically, the 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." The press release also disclosed that the consent decree "would require suspension of certain operations at the facilities until they are determined by the FDA to be in compliance." 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."

69. Following the disclosure of the looming consent decree of injunction, an analyst with WJB Capital Group 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." WJB Capital downgraded the Company's common 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."

70. Following this disclosure, Invacare stock plummeted nearly 29 percent, 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 unusually high trading volume, wiping out over $180 million in market capitalization.

71. The aforementioned statements, which were made by Defendants during the Class Period, were false and misleading because Invacare: (a) continued to flout FDA regulations; (b)

concealed that the FDA raised concerns about other key Invacare facilities; and (c) gave the false impression that quality improvements were being proactively applied across the Company, when, in fact, this was done in an effort to stave off broader regulatory action by the FDA.

72. As a result of Defendants' false statements, Invacare common stock traded at artificially inflated levels during the Class Period. When Defendants revealed Invacare's true compliance issues and their impact on its business prospects, the price of Invacare common stock fell over 55 percent from its Class Period high.

## LOSS CAUSATION

73. During the Class Period, as detailed herein, Defendants made false and misleading statements and engaged in a scheme to deceive the market. This artificially inflated the price of Invacare common stock and operated as a fraud or deceit on the Class. Later, when Defendants' prior misrepresentations and fraudulent conduct were disclosed to the market on January 4, 2011 and December 8, 2011, the price of Invacare common stock fell precipitously, as the prior artificial inflation came out of the price over time. As a result of their purchases of Invacare common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

## CLASS ACTION ALLEGATIONS

74. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased the common stock of Invacare during the Class Period (the "Class"). Excluded from the Class are Defendants and their families, directors, and officers of Invacare and their families and affiliates.

75. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits

to the parties and the Court. Invacare has more than 31 million shares of common stock outstanding, owned by hundreds or thousands of persons.

76. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

(a) Whether Defendants violated the Exchange Act;

(b) Whether Defendants omitted and/or misrepresented material facts;

(c) Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

(e) Whether the price of Invacare common stock was artificially inflated; and

(f) The extent of damage sustained by Class members and the appropriate measure of damages.

77. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct.

78. Plaintiff will adequately protect the interests of the Class and has retained counsel experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

79. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

**INAPPLICABILITY OF STATUTORY SAFE HARBOR**

80. Invacare's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

81. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Invacare who knew that the FLS was false. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

**PRESUMPTION OF RELIANCE**

82. At all relevant times, the market for Invacare's common stock was an efficient market for the following reasons, among others:

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

(b) As a regulated issuer, Invacare filed periodic public reports with the SEC and the NYSE;

(c) Invacare regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Invacare was followed by several securities analysts employed by major brokerage firm(s) who wrote reports which were distributed to the sales force and certain customers of their respective brokerage firm(s). Each of these reports was publicly available and entered the public marketplace.

83. As a result of the foregoing, the market for Invacare securities promptly digested current information regarding Invacare from all publicly available sources and reflected such information in Invacare's stock price. Under these circumstances, all purchasers of Invacare common stock during the Class Period suffered similar injury through their purchase of Invacare common stock at artificially inflated prices and the presumption of reliance applies.

## COUNT I

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

84. Plaintiff repeats, incorporates, and realleges each and every allegation set forth above as if fully set forth herein.

85. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

86. Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 in that they made untrue statements of material facts or omitted to state material facts necessary in order

to make the statements made, in light of the circumstances under which they were made, not misleading.

87. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Invacare common stock. Plaintiff and the Class would not have purchased Invacare common stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

88. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Invacare common stock during the Class Period.

## COUNT II

**For Violation of Section 20(a) of the Exchange Act Against the Individual Defendants**

89. Plaintiff repeats, incorporates, and realleges each and every allegation set forth above as if fully set forth herein.

90. The Individual Defendants acted as controlling persons of Invacare within the meaning of Section 20(a) of the Exchange Act. By virtue of their positions and their power to control public statements about Invacare, the Individual Defendants had the power and ability to control the actions of Invacare and its employees. By reason of such conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Determining that this action is a proper class action, designating Plaintiff as Lead Plaintiff and certifying Plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and Plaintiff's counsel as Lead Counsel;

B. Awarding Plaintiff and the members of the Class damages and interest;

C. Awarding Plaintiff's reasonable costs, including attorneys' fees; and

D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiff demands a trial by jury.

Dated: May 24, 2013

Respectfully submitted,

s/ *Scott D. Simpkins*

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