UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. MIMEDX GROUP, INC., JOSEPH H. CAPPER, TODD NEWTON, TIMOTHY R. WRIGHT, DOUG RICE, and PETE CARLSON , Defendants.	Case No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

Plaintiff _____ ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, 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, among other things, his counsel's investigation, which includes without limitation: (a) review and analysis of regulatory filings made by MiMedx Group, Inc. ("MiMedx" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by MiMedx; and (c) review of other publicly available information concerning MiMedx.

NATURE OF THE ACTION AND OVERVIEW

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired MiMedx securities between November 2, 2022 and December 29, 2023, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. MiMedx is a biomedical company. On September 20, 2022, MiMedx announced the launch of a new product, Axiofill. Axiofill is an extracellular matrix particulate product derived from human placental tissue. Axiofill and other particulate products are used as a collagen scaffold to support healing, often as a part of grafting matrix for surgical recovery from traumatic wounds or tissue deficit repair. At the time of launch Axiofill was the first and only human placental-derived particulate product available for surgical recovery procedures.

3. Generally, the United States Food and Drug Administration ("FDA") regulates human cells, tissues and cellular and tissue-based products ("HCT/Ps"), under Section 361 of the Public Health Service Act ("Section 361"). Section 361 products do not require pre-market clearance or approval by the FDA and are regulated solely under Section 361. However, human

cells, tissues and cellular and tissue-based products considered to be drugs, devices, and/or biological products are regulated under the significantly stricter Section 351 of the Public Health Service Act ("Section 351"). Biological products regulated under Section 351 require pre-market clearance or approval by the FDA, licensure and are subject to additional, related regulations.

4. On December 29, 2023, after the market closed, MiMedx issued a press release announcing that it had received a warning letter from the FDA concerning Axiofill, headlined "*Receipt of FDA Warning Letter for AXIOFILL Classification; Not Related to Safety"* (the "Press Release"). The Press Release disclosed that the FDA had performed a "routine inspection earlier in the year" after which the FDA "took the position" that Axiofill does not meet the requirements as a Section 361 product and is therefore subject to enforcement as a Section 351 product, which the warning letter "reitterat[ed]" (the "Warning Letter"). The Press Release disclosed the Company "has been actively engaged with the agency through its "Request For Designation" ("RFD") process." The Press Release also emphasized the Warning Letter did not "assert any product safety claims or adverse events related to Axiofill."

5. On this news, MiMedx's stock price fell $0.90 per share, or 10.26%, to close at $7.87 per share on January 2, 2024 on unusually heavy trading volume.

6. Then, on January 9, 2023, at approximately 12:00 PM EST the FDA publicly published the Warning Letter. The Warning Letter stated Axiofill "is a biological product as defined in section 351," "is not regulated solely under section 361" and "[b]ased upon this information" the FDA "determined that your [MiMedx] actions have violated the [Federal Food, Drug, and Cosmetic Act] and the PHS Act." The Warning Letter further identified "significant deviations from good manufacturing practice" applicable to Axiofill and revealed that the Company had received a Form FDA-483 after inspections between February 22, 2023 and March

2, 2023, indicating these deviations but that the Company failed to adequately address those deviations in correspondence dated March 23, 2023 and October 23, 2023. These significant deviations included that the Company failed to put in place written procedures for production and process control and lacked sound lab controls to ensure product identity, strength, quality and purity.

7. On this news, MiMedx's stock price fell $0.19 per share, or 2.3%, to close at $8.03 per share on January 9, 2024 on unusually heavy trading volume.

8. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Axiofill was not sufficiently developed and manufactured to comply with the requirements of Section 361; (2) that MiMedx was engaged with the FDA regarding the classification of Axiofill; (3) there was a significant risk Axiofill would be identified by the FDA as a biological product regulated under Section 351 and subject to premarket review; (4) that MiMedx engaged in significant deviations from current good manufacturing practice requirements in the production of Axiofill; (5) that the MiMedx was notified of the deficiencies applicable to the manufacturing of Axiofill but failed to take sufficient measures to remediate them; and (6) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

9. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

10. 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.F.R. § 240.10b-5).

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

12. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District.

13. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

14. Plaintiff ____, as set forth in the accompanying certification, incorporated by reference herein, purchased MiMedx securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

15. Defendant MiMedx is incorporated under the laws of Florida with its principal executive offices located in Marietta, Georgia. MiMedx's common stock trades on the NASDAQ exchange under the symbol "MDXG."

16. Defendant Joseph H. Capper ("Capper") has been the Company's Chief Executive Officer ("CEO") since January 30, 2023.

17. Defendant Todd Newton ("Newton") was the Company's Interim CEO from September 6, 2022 until January 30, 2023.

18. Defendant Timothy R. Wright ("Wright") was the Company's CEO from May 2019 until September 6, 2022.

19. Defendant Doug Rice ("Rice") has been the Company's Chief Financial Officer ("CFO") since July 5, 2023.

20. Defendant Pete Carlson ("Carlson") was the Company's CFO from March 2020 until July 5, 2023.

21. Defendants Capper, Newton, Wright, Rice, and Carlson (together, the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, i.e., the market. The Individual Defendants were 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, 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. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

22. MiMedx is a biomedical company. On September 20, 2022, MiMedx announced the launch of a new product, Axiofill. Axiofill is an extracellular matrix particulate product derived from human placental tissue. Axiofill and other particulate products are used as a collagen scaffold to support healing, often as a part of grafting matrix for surgical recovery from traumatic wounds or tissue deficit repair. At the time of launch Axiofill was the first and only human placental-derived particulate product available for surgical recovery procedures.

23. Generally, the FDA regulates human cells, tissues and cellular and tissue-based products under Section 361. Section 361 products do not require pre-market clearance or approval by the FDA and are regulated solely under Section 361. However, human cells, tissues and cellular and tissue-based products considered to be drugs, devices, and/or biological products are regulated under the significantly stricter Section 351. Biological products regulated under Section 351 require pre-market clearance or approval by the FDA, licensure and are subject to additional, related regulations.

Materially False and Misleading

Statements Issued During the Class Period

24. The Class Period begins on November 2, 2022. On that day, MiMedx submitted its quarterly fiscal report for the period ended September 30, 2022 on a Form 10-Q with the SEC (the "3Q22 10-Q").[1] The 3Q22 10-Q stated in relevant part the following concerning the classification of the Company's products:

> We have two classes of products: (1) ***Advanced Wound Care products, or Section 361 products***, consisting of our tissue and cord sheet allograft products, as well as

[1] Unless otherwise stated, all emphasis in bold and italics hereinafter is added, and all footnotes are omitted.

certain particulate products regulated under Section 361, and (2) ***Section 351 products, consisting of our micronized and certain other particulate products***, which, prior to May 31, 2021, the date the FDA's period of enforcement discretion ended (as described below), were used to treat a variety of clinical conditions, including both advanced wound care and musculoskeletal applications. Our Advanced Wound Care products includes two product categories: Tissue/Other and Cord products. We sell product through two distribution channels: (1) direct to customers (healthcare professionals and/or facilities); and (2) sales through distributors.

* * *

As of May 31, 2021, the Company stopped marketing its Section 351 products in the United States and is precluded from marketing such products until a Biologics License Application ("BLA") is granted. If and when the FDA approves a BLA, the Company expects to be allowed to market its Section 351 products in the United States again, but only for specific indications as permitted by the FDA.

* * *

The Company currently markets EPICORD® and AMNIOCORD® tissue products derived from human umbilical cord as providing a protective environment or as a barrier. ***If the FDA were to determine that EPICORD and AMNIOCORD do not meet the requirements for regulation solely under Section 361, then pre-market clearance or approval would be required for these products.*** The loss of the Company's ability to market and sell its umbilical cord-derived products could have an adverse effect on the Company's revenue, business, financial condition, and results of operations. Net sales of the Company's umbilical cord-derived products were $5.7 million and $6.2 million for the three months ended September 30, 2022 and 2021 and $17.2 million and $17.1 million for the nine months ended September 30, 2022 and 2021, respectively. The Company's cord inventory, which would be at risk for write-down in the case of such a determination by the FDA, was $1.8 million and $1.9 million as of September 30, 2022 and December 31, 2021, respectively.

25. The 3Q22 10-Q stated in relevant part the following concerning the Company's product classes and net sales by class of product (amounts in thousands):

MIMEDX has two primary classes of products: (1) Advanced Wound Care, or Section 361, products, consisting of its tissue and cord sheet allograft products as well as certain particulate products regulated under Section 361, and (2) Section 351 products, consisting of the Company's micronized and certain other particulate products. Advanced Wound Care is further disaggregated between the Company's Tissue/Other and Cord products.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Advanced Wound Care				
Tissue/Other	$ 61,131	$ 56,035	$ 174,256	$ 156,012
Cord	5,678	6,247	17,165	17,093
Total Advanced Wound Care	66,809	62,282	191,421	173,105
Section 351	796	489	1,815	17,187
Other[1]	84	303	230	914
Total	$ 67,689	$ 63,074	$ 193,466	$ 191,206

(1) "Other" represents revenue transactions in the indicated period relating to performance obligations settled prior to October 1, 2019, the date at which the Company changed its pattern of revenue recognition. For all practical purposes, the Company is not able to allocate these revenue transactions to different product groups. This revenue is reflected as part of the Wound & Surgical segment.

26. The 3Q22 10-Q stated in relevant part the following concerning the Company's manufacturing practices:

> ***The Company applies Current Good Tissue Practices, Current Good Manufacturing Practices, and terminal sterilization to produce its allografts***. MIMEDX provides products primarily in the wound care, burn, and surgical recovery sectors of healthcare. All of its products are regulated by the U.S. Food & Drug Administration ("FDA").
>
> * * *
>
> ***We apply Current Good Tissue Practice ("CGTP") and Current Good Manufacturing Practice ("CGMP") standards in addition to terminal sterilization to produce our allografts***. MIMEDX provides products primarily in the wound care, burn, and surgical recovery sectors of healthcare.

27. On February 28, 2023 the Company submitted its annual report for the fiscal year ended December 31, 2022 on a Form 10-K with the SEC (the "FY2022 10-K"). The FY2022 10-K stated the following, in relevant part, concerning the FDA's classification of Axiofill:

> *2017 FDA Guidance*. The products we sell are regulated by the FDA. ***Generally, our products are regulated as Human Cells, Tissues and Cellular and Tissue – Based Products ("HCT/Ps"), which do not require pre-market clearance or approval by the FDA and are subject solely to Section 361 of the Public Health Service Act ("Section 361") and related regulations***. However, in November 2017 the FDA published a series of related guidance documents, including one entitled

"Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue–Based Products: Minimal Manipulation and Homologous Use – Guidance for Industry and Food and Drug Administration Staff" (collectively, the "Guidance"), which established an updated framework for the FDA's regulation of cellular and tissue-based products. Among other things, the Guidance clarified the FDA's views about the criteria that differentiate those products subject to regulation solely under Section 361 ("Section 361 HCT/Ps") from those cellular and tissue-based products considered to be drugs, devices, and/or biological products ("Section 351 HCT/Ps") subject to licensure under Section 351 of the Public Health Service Act ("Section 351") and related regulations.

* * *

Effect of Guidance on Our Products. Under the Guidance***, we expect that the FDA will continue to regulate certain of our placental tissue products (EPIFIX, AMNIOFIX, EPICORD, AMNIOCORD, AMNIOBURN, AXIOFILL and AMNIOEFFECT) as Section 361 HCT/Ps so long as the claims we make for them are consistent with the Section 361 framework***.

* * *

The products manufactured and processed by the Company are derived from human tissue. As discussed below, our Section 361 HCT/Ps are tissue-based products that are regulated solely under Section 361 and do not require pre-market clearance or approval by the FDA. Our Section 351 HCT/Ps are also tissue products, but are regulated as biological products, and, in order to be lawfully marketed in the United States, require FDA pre-market approval.

28. The FY2022 10-K purported to warn of the risks related to regulatory approval of its products and other government regulations:

The products we manufacture and process are derived from human tissue. ***Amniotic and other birth tissue have in the past generally been regulated as HCT/P and were therefore eligible to be subject to regulation solely under Section 361 ("Section 361 HCT/P") depending on whether the specific product at issue and the claims made for it were consistent with the applicable criteria***. HCT/Ps that do not meet these criteria are subject to more extensive regulation as drugs, medical devices, biological products, or combination products. These HCT/Ps must comply with both the FDA's requirements for HCT/Ps and the requirements applicable to biologics, devices or drugs, including pre-market clearance or approval from the FDA. Obtaining FDA pre-market clearance or approval involves significant time and investment by the Company.

* * *

> Also, the Company currently markets EPICORD and AMNIOCORD, tissue products derived from the protective covering and extracellular matrix cushioning layers of the human umbilical cord, as providing a protective environment or as a barrier. ***In warning letters to several companies marketing human umbilical cord derived products for a variety of uses, the FDA has stated that those products fail to meet one or more of the Section 361 criteria***, including the minimal manipulation criterion, the dependence on the metabolic activity of living cells for their primary function criterion, and the homologous use criterion, as "the product is not intended to perform the same basic function or functions of umbilical cord in the recipient as in the donor, such as serving as a conduit." ***We are engaged with the FDA regarding the classification of our umbilical cord-derived products. If the FDA makes a final determination that our umbilical cord products do not meet the requirements for regulation solely under Section 361, in order to continue to market the products, we would be required to obtain the appropriate FDA approval or clearance.***

29. The FY2022 10-K stated the following in relevant part, concerning the Company's manufacturing practices:

> ***We employ Current Good Tissue Practices ("CGTP"), Current Good Manufacturing Practices ("CGMP"), and terminal sterilization to produce our allografts***.
>
> * * *
>
> ***We maintain strict quality controls designed in accordance with CGTP to ensure the safe procurement and processing of our tissue***, including terminal sterilization of our products. These controls are intended to prevent the transmission of communicable disease. However, risks exist with any human tissue implantation.

30. On May 1, 2023 the Company submitted its amended annual report for the fiscal year ended December 31, 2022 on a Form 10-K/A with the SEC, which reiterated the above statements and was modified only to include information required by Part III of Form 10- specifically adding new certifications of the CEO and CFO as exhibits and deleting the reference on the cover page to the incorporation by reference of portions of the Company's definitive proxy statement.

31. On May 2, 2023 the Company submitted its quarterly report for the fiscal period ended March 31, 2023 on Form 10-Q filed with the SEC which stated in relevant part the following

concerning the Company's product classes, net sale by product class (amounts in thousands) and manufacturing practices:

> MIMEDX has two primary classes of products: (1) Advanced Wound Care, or ***Section 361, products, consisting of its tissue and cord sheet allograft products as well as certain particulate products regulated under Section 361,*** and (2) ***Section 351 products, consisting of the Company's micronized and certain other particulate products.*** Advanced Wound Care is further disaggregated between the Company's Tissue/Other and Cord products. ***We apply Current Good Tissue Practices ("CGTP") and Current Good Manufacturing Practice ("CGMP") standards in addition to terminal sterilization to produce our allografts***.

	Three Months Ended March 31,	
	2023	2022
Advanced Wound Care		
Tissue/Other	$ 65,771	$ 52,852
Cord	5,439	5,597
Total Advanced Wound Care	71,210	58,449
Section 351[(1)]	466	445
Total	$ 71,676	$ 58,894

(1) Revenue recognized from collections relating to revenue transactions for which performance obligations were fulfilled prior to October 1, 2019, the date at which the Company changed its pattern of revenue recognition, for the three months ended March 31, 2022 of $0.1 million, which were separately presented in previously-issued financial statements, are presented as part of Section 351 in the table above.

32. On August 1, 2023, the Company submitted its quarterly report for the fiscal period ended June 30, 2023, on Form 10-Q filed with the SEC which stated in relevant part the following concerning the Company's product classes, net sale by product class (amounts in thousands) and manufacturing practices:

> We have two classes of products: (1) ***Advanced Wound Care products, or Section 361 products, consisting of our tissue and cord sheet allograft products, as well as certain particulate products regulated under Section 361***, and (2) ***Section 351 products, consisting of our micronized and certain other particulate products,*** which, prior to May 31, 2021, the date the FDA's period of enforcement discretion ended, were used to treat a variety of clinical conditions, including both advanced wound care and musculoskeletal applications. Our Advanced Wound Care products includes two product categories: Tissue/Other and Cord products. ***We apply Current Good Tissue Practices ("CGTP") and Current Good Manufacturing***

Practice ("CGMP") standards in addition to terminal sterilization to produce our allografts.

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Advanced Wound Care				
Tissue/Other	$ 75,490	$ 60,274	$ 141,261	$ 113,126
Cord	5,748	5,889	11,187	11,486
Total Advanced Wound Care	81,238	66,163	152,448	124,612
Section 351[1]	19	720	485	1,165
Total	$ 81,257	$ 66,883	$ 152,933	$ 125,777

(1) Revenue recognized from collections relating to revenue transactions for which performance obligations were fulfilled prior to October 1, 2019, the date at which the Company changed its pattern of revenue recognition, for the three and six months ended June 30, 2022 of $0.1 million, which were separately presented in previously-issued financial statements, are presented as part of Section 351 in the table above.

33. On October 30, 2023 the Company submitted its quarterly report for the fiscal period ended September 30, 2023, on Form 10-Q filed with the SEC which stated in relevant part the following concerning the Company's product classes, net sale by product class (amounts in thousands) and manufacturing practices:

> The Company has two primary classes of products: (***1) Advanced Wound Care, or Section 361, products, consisting of its tissue and cord sheet allograft products as well as certain particulate products subject to regulation under Section 361 of the Public Health Service Act and related regulations ("Section 361"), and (2) Section 351 products,*** consisting of the Company's micronized and certain other particulate products subject to regulation under Section 351 of the Public Health Service Act and related regulations ("Section 351"). Advanced Wound Care is further disaggregated between the Company's Tissue/Other and Cord products.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Advanced Wound Care				
Tissue/Other	$ 75,570	$ 61,131	$ 216,825	$ 174,256
Cord	6,066	5,678	17,259	17,165
Total Advanced Wound Care	81,636	66,809	234,084	191,421
Section 351[1]	76	880	561	2,045
Total	$ 81,712	$ 67,689	$ 234,645	$ 193,466

(1) Revenue recognized from collections relating to revenue transactions for which performance obligations were fulfilled prior to October 1, 2019, the date at which the Company changed its pattern of revenue recognition, for the three and nine months ended September 30, 2022 of $0.1 million and $0.2 million, respectively, which were separately presented in previously-issued financial statements, are presented as part of Section 351 in the table above.

* * *

MIMEDX is a pioneer and leader in placental biologics focused on delivering innovative solutions to patients and the healthcare professionals who treat them. With more than a decade of experience helping clinicians manage acute and chronic wounds, MIMEDX has been dedicated to providing a leading portfolio of products for applications in the wound care, burn, and surgical sectors of healthcare. All of our products sold in the United States are regulated by the U.S. Food & Drug Administration ("FDA"). ***We apply Current Good Tissue Practices ("CGTP") standards in addition to terminal sterilization to produce our allografts***.

34. The above statements identified in ¶¶ 24-33 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Axiofill was not sufficiently developed and manufactured to comply with the requirements of Section 361; (2) that MiMedx was engaged with the FDA regarding the classification of Axiofill; (3) there was a significant risk Axiofill would be identified by the FDA as a biological product regulated under Section 351 and subject to premarket review; (4) that MiMedx engaged in significant deviations from current good manufacturing practice requirements in the production of Axiofill; (5) that the MiMedx was notified of the deficiencies applicable to the manufacturing of Axiofill but failed to take sufficient measures to remediate them; and (6) that, as a result of the foregoing, Defendants'

positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

Disclosures at the End of the Class Period

35. On December 29, 2023, after the market closed MiMedx issued a press release announcing that it had received a warning letter from the FDA concerning Axiofill, headlined "*Receipt of FDA Warning Letter for AXIOFILL Classification; Not Related to Safety"*. The Press Release disclosed that the FDA had performed a "routine inspection earlier in the year" after which the FDA "took the position" that Axiofill does not meet the requirements as a Section 361 product and is therefore subject to enforcement as a Section 351 product, which the Warning Letter "reitterat[ed]." The Press Release disclosed the Company "has been actively engaged with the agency through its "Request For Designation" ("RFD") process." The Press Release also emphasized the Warning Letter did not "assert any product safety claims or adverse events related to Axiofill."

36. On this news, MiMedx's stock price fell $0.90 per share, or 10.26%, to close at $7.87 per share on January 2, 2024 on unusually heavy trading volume.

37. Then, on January 9, 2023, at approximately 12:00 PM EST, the FDA publicly published the Warning Letter. The Warning Letter stated the Axiofill "is a biological product as defined in section 351" and "is not regulated solely under section 361" and "[b]ased upon this information, we have determined that your actions have violated the [Federal Food, Drug, and Cosmetic Act] and the PHS Act." The Warning Letter also identified "significant deviations from good manufacturing practice" applicable to Axiofill's manufacturing. The Warning Letter revealed that the Company had received a Form FDA-483 after inspections between February 22, 2023 and March 2, 2023, and that the Company failed to adequately address those deviations in correspondence dated March 23, 2023 and October 23, 2023.

38. The FDA's Warning letter outlined the Company's significant deviations from current good manufacturing practice including that the Company: failed to establish adequate written procedures for production and process control designed to assure that the drug product has the identity, strength, purity, and quality it purports or is represented to possess; failed to establish laboratory controls that include scientifically sound and appropriate specifications designed to assure that drug products conform to appropriate standards of identity, strength, quality, and purity; had deficient in-process control procedures; had drug product samples which were not representative; failed to conduct at least one test to verify the identity of each component of a drug product using specific identity tests; failed to withhold each lot of components from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit; failed to take representative samples of each shipment of each lot of components for testing or examination; and did not provide a disinfectant efficacy study used in the processing facility and on production equipment during the inspection, although it was requested.

39. The Warning Letter concluded:

> We have reviewed your responses and have determined that your responses are inadequate to address the deficiencies noted above. We note that "MIMEDX does not agree that the CGMP requirements are legally applicable to AXIOFILL" and that your responses contain no corrective actions directly related to the FDA-483 observations.

40. On this news, MiMedx's stock price fell $0.19 per share, or 2.3%, to close at $8.03 per share on January 9, 2024 on unusually heavy trading volume.

CLASS ACTION ALLEGATIONS

41. 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 persons and entities that purchased or otherwise acquired MiMedx securities between November 2, 2022 and December 29, 2023 inclusive , and who were damaged thereby (the "Class"). 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.

42. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, MiMedx's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of MiMedx shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by MiMedx 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 actions.

43. 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.

44. 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.

45. 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 omitted and/or misrepresented material facts about the business, operations, and prospects of MiMedx; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

46. 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 makes 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.

UNDISCLOSED ADVERSE FACTS

47. The market for MiMedx's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, MiMedx's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired MiMedx's securities relying upon the integrity of the market price of the Company's securities and market information relating to MiMedx, and have been damaged thereby.

48. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of MiMedx's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about MiMedx's business, operations, and prospects as alleged herein.

49. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about MiMedx's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

50. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

51. During the Class Period, Plaintiff and the Class purchased MiMedx's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

52. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced

in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding MiMedx, their control over, and/or receipt and/or modification of MiMedx's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning MiMedx, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE

(FRAUD-ON-THE-MARKET DOCTRINE)

53. The market for MiMedx's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, MiMedx's securities traded at artificially inflated prices during the Class Period. On December 19, 2023, the Company's stock price closed at a Class Period high of $9.14 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of MiMedx's securities and market information relating to MiMedx, and have been damaged thereby.

54. During the Class Period, the artificial inflation of MiMedx's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about MiMedx's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of MiMedx and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company shares. Defendants' materially false and/or misleading statements during the Class Period resulted

in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

55. At all relevant times, the market for MiMedx's securities was an efficient market for the following reasons, among others:

(a) MiMedx shares met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, MiMedx filed periodic public reports with the SEC and/or the NASDAQ;

(c) MiMedx regularly communicated with public investors via established market communication mechanisms, including through regular dissemination 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/or

(d) MiMedx was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

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

57. 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. United States*, 406 U.S. 128 (1972),

because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—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 making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

58. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of MiMedx who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of The Exchange Act and

Rule 10b-5 Promulgated Thereunder

Against All Defendants

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

60. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase MiMedx's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

61. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for MiMedx's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

62. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about MiMedx's financial well-being and prospects, as specified herein.

63. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of MiMedx's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about MiMedx and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

64. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

65. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing MiMedx's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

66. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of MiMedx's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities 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 securities trades, and/or in 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, Plaintiff and the other members of the Class acquired MiMedx's securities during the Class Period at artificially high prices and were damaged thereby.

67. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that MiMedx was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their MiMedx securities,

or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

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

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

SECOND CLAIM

Violation of Section 20(a) of The Exchange Act

Against the Individual Defendants

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

71. Individual Defendants acted as controlling persons of MiMedx within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, 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 Plaintiff contends are false and misleading. 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 Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

72. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

73. As set forth above, MiMedx and 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 position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

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

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: _____, 2024

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