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**UNITED STATES DISTRICT COURT**  
**NORTHERN DISTRICT OF CALIFORNIA**

\_\_\_\_\_, Individually and on Behalf of  
All Others Similarly Situated,

Plaintiff,

vs.

PENUMBRA, INC., ADAM ELSESSER, and  
GITA BARRY,

Defendants.

Case No.:

**CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS**

**DEMAND FOR JURY TRIAL**

1 Plaintiff \_\_\_\_\_ (“Plaintiff”) alleges the following based upon personal  
2 knowledge as to allegations specifically pertaining to Plaintiff and, as to all other matters, upon  
3 the investigation of counsel, which included, without limitation: (a) review and analysis of  
4 public filings made by Penumbra, Inc. (“Penumbra” or the “Company”) with the United States  
5 Securities and Exchange Commission (“SEC”); (b) review and analysis of press releases  
6 and other publications disseminated by Defendants and other parties; (c) review of news articles,  
7 shareholder communications, conference calls and postings on Penumbra’s website concerning  
8 the Company’s public statements; and (d) review of other publicly available information  
9 concerning the Company.  
10

11 1. **NATURE OF THE ACTION**

12 This is a federal securities class action against Penumbra and certain of its  
13 officers (collectively, “Defendants”) for violations of the federal securities laws. Plaintiff brings  
14 this action on behalf of all persons or entities that purchased or otherwise acquired Penumbra  
15 common stock from August 3, 2020 through December 15, 2020, inclusive (the “Class Period”),  
16 seeking to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).  
17 The action alleges that Defendants engaged in a fraudulent scheme to artificially inflate the  
18 Company’s stock price in violation of Sections 10(b) and 20(a) of the Exchange Act.  
19

20 Penumbra is a global healthcare company that develops, manufactures and sells  
21 innovative medical devices for patients suffering from stroke and other vascular and neurovascular  
22 diseases. Penumbra was the first company to market aspiration catheters, a specialized  
23 catheter designed to remove blood clots from arteries and veins in stroke patients, in a surgical  
24 procedure known as a thrombectomy.  
25

26 Until recently, one of the Company’s flagship products was the “Jet 7 Xtra Flex,”  
27 an aspiration catheter designed to be inserted into an affected artery, navigated to a blood clot, and  
28 used to suck the clot out of the patient’s body. The Jet 7 Xtra Flex was introduced to the U.S.

1 market in July 2019 and quickly became a “growth driver” for the Company, a key source of new  
2 revenues.

3 4. In mid-2020, however, concerns about the Jet 7 Xtra Flex’s safety began to emerge.  
4 On June 22, 2020, for example, Penumbra’s distributor in Japan sent a letter to hospitals warning  
5 of issues with the new Jet 7 Xtra Flex, stating that “part of the catheter inflated into a balloon and  
6 damaged a patient’s blood vessel” when the product was used, causing injury and deaths. Shortly  
7 thereafter, the Company suspended sales of the Jet 7 Xtra Flex in Japan.

9 5. Approximately one month after that letter, on July 27, 2020, the Company issued a  
10 notice to its U.S. customers and practitioners acknowledging reported instances in which the distal  
11 tip of the catheter broke or expanded, carrying a risk of injury or death (the “July 2020 Notification”  
12 or “Notification”). The July 2020 Notification warned physicians to exercise caution with the  
13 Company’s Jet 7 Xtra Flex, and maintained that Penumbra was “committed to product safety and  
14 performance” and was “continuing to monitor and investigate these adverse event reports.”  
15 Despite these adverse reports, Defendants repeatedly assured investors during the Class Period  
16 that the Jet 7 Xtra Flex was “absolutely safe” and “not a product that has any possibility of needing  
17 to be recalled,” as the Company was taking all necessary steps to protect patients.

19 6. The Class Period begins on August 3, 2020, when the Company announced its  
20 financial results for the second quarter of 2020. On a conference call with analysts conducted the  
21 same day, Defendant Adam Elsesser, the Company’s CEO was asked about the Jet 7 Xtra Flex  
22 MAX, a delivery device that utilizes the Jet 7 Xtra Flex catheter, and responded that Penumbra  
23 was “doing some of the work we do with every new product that is cleared to evaluate and make  
24 sure it’s all good” and boasted that the device “is exactly what we hoped it would be.”

26 7. Throughout the Class Period, Defendants continued to make false and/or misleading  
27 statements and/or failed to disclose material adverse facts about the Jet 7 Xtra Flex’s safety, as  
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1 well as the Company's business, operations, and prospects. Specifically, Defendants failed to  
2 disclose to investors: (1) that the Jet 7 Xtra Flex had known design defects that made it unsafe for  
3 its normal use; (2) that Penumbra did not adequately address the risk of the Jet 7 Xtra Flex causing  
4 serious injury and deaths, which had in fact already occurred; (3) that the Jet 7 Xtra Flex was likely  
5 to be recalled due to its safety issues; and (4) as a result, Penumbra's public statements as set forth  
6 above were materially false and misleading at all relevant times.  
7

8         8. On September 14, 2020, the Foundation for Financial Journalism (the "FFJ"), an  
9 independent non-profit news outlet, published an article raising serious questions about the Jet 7  
10 Xtra Flex's safety profile. The FFJ noted that since being introduced in mid-2019, there were  
11 twelve deaths listed in an FDA database that occurred after a surgeon injected an iodine contrast  
12 dye into the Jet 7 Xtra Flex. The FFJ article described how Penumbra's warnings against using the  
13 product with contrast dye and non-Penumbra products did little to address the Jet 7 Xtra Flex's  
14 safety issues. In response, Penumbra's stock price fell by nearly 3%, from \$199.43 per share on  
15 September 13, 2020 to \$193.66 per share on September 14, 2020, a decline of \$5.77 per share.  
16

17         9. On November 9, 2020, the securities research firm Quintessential Capital  
18 Management ("QCM") released a presentation concerning Penumbra and the safety of the Jet 7  
19 Xtra Flex. Titled "Penumbra and Its Killer Catheter," QCM's report detailed injuries and deaths  
20 resulting from product malfunctions, and highlighted that Penumbra did not issue any notice to  
21 U.S. healthcare providers concerning the device's safety issues until more than a month after the  
22 Company's Japanese distributor sent out its warning, and more than nine months after the first  
23 patient died from the product's malfunction. QCM accused Penumbra of a "seemingly blatant  
24 disregard for patients' lives" and essentially "blaming doctors" for the devices' design defects.  
25 The Company, however, continued to insist that the Jet 7 Xtra Flex was "absolutely safe" and  
26 reassured investors that any claims to the contrary made "no sense" and there "isn't an issue."  
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1           10. On November 23, 2020, an article was published in the Journal of  
2 NeuroInterventional Surgery presenting the cases of three patients who suffered as a result of Jet  
3 7 Xtra Flex device malfunctions, including two fatalities. Although the journal article was not  
4 widely publicized on November 23 aside from a Twitter post just before market close from an  
5 account with a small following, over the next two days the article was more widely disseminated,  
6 particularly after it was shared by multiple reputed short sellers with hundreds of thousands of  
7 followers, including Marc Cohodes and Muddy Waters. As this report became more widely  
8 circulated, it caused Penumbra stock to fall from \$254.71 on November 23, 2020 to \$224.12 on  
9 November 25, 2020, a decline of about 12%.

11           11. On December 8, 2020, before the market opened, QCM issued another report  
12 reiterating its prior assertions and disclosing additional facts about the Jet 7 Xtra Flex's safety  
13 issues. Among other things, QCM's second report questioned the validity and independence of  
14 the scientific research supporting the Jet 7 Xtra Flex's safety, and accused the Company of using  
15 a fake author to publish studies regarding the purported safety and efficacy of its products. In  
16 response, Penumbra's stock price fell by 9%, from \$224.02 per share on December 7, 2020 to  
17 \$204.07 per share on December 8, 2020, a decline of \$19.95 per share.

19           12. Finally, on December 15, 2020, after the market closed, the Company issued a press  
20 release announcing that it was issuing an "urgent" recall of the Jet 7 Xtra Flex because the catheter  
21 "may become susceptible to distal tip damage during use" which could lead to injury or death. On  
22 a conference call held the same day, the Company's CEO acknowledged that the product's design  
23 "ma[de] the catheter susceptible to failure in certain scenarios" and that the Company's "steps to  
24 ensure the safe use of the product . . . were not able to fully address the risks." In response,  
25 Penumbra's stock price fell by 7%, from \$188.82 per share on December 15, 2020 to \$174.98 per  
26 share on December 16, 2020, a decline of \$13.84 per share.  
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1 13. As a result of Defendants' wrongful acts and omissions and the decline in the  
2 Company's share price, Plaintiff and other Class members have suffered significant damages.

3 **JURISDICTION AND VENUE**

4 14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act  
5 (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R.  
6 §240.10b-5).  
7

8 15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C.  
9 §1331, Section 27 of the Exchange Act (15 U.S.C. §78aa).

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

16 17. In connection with the acts, transactions, and conduct alleged herein, Defendants  
17 directly and indirectly used the means and instrumentalities of interstate commerce, including the  
18 United States mail, interstate telephone communications, and the facilities of a national securities  
19 exchange.  
20

21 **CLASS ACTION ALLEGATIONS**

22 18. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil  
23 Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased  
24 or otherwise acquired Penumbra common stock between August 3, 2020 and December 15, 2020,  
25 inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants,  
26 the officers and directors of the Company, at all relevant times, members of their immediate  
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1 families and their legal representatives, heirs, successors, or assigns, and any entity in which  
2 Defendants have or had a controlling interest.

3 19. The members of the Class are so numerous that joinder of all members is  
4 impracticable. Throughout the Class Period, Penumbra's common shares actively traded on the  
5 New York Stock Exchange ("NYSE"). While the exact number of Class members is unknown to  
6 Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes  
7 that there are at least hundreds or thousands of members in the proposed Class. Millions of shares  
8 of Penumbra common stock were traded publicly during the Class Period on the NYSE. Record  
9 owners and other members of the Class may be identified from records maintained by Penumbra  
10 or its transfer agent and may be notified of the pendency of this action by mail, using the form of  
11 notice similar to that customarily used in securities class actions.  
12

13  
14 20. Plaintiff's claims are typical of the claims of the members of the Class as all  
15 members of the Class are similarly affected by Defendants' wrongful conduct in violation of  
16 federal law that is complained of herein.

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

19 22. Common questions of law and fact exist as to all members of the Class and  
20 predominate over any questions solely affecting individual members of the Class. Among the  
21 questions of law and fact common to the Class are:  
22

- 23 a) whether the federal securities laws were violated by Defendants' acts and  
24 omissions as alleged herein;
- 25 b) whether Defendants participated in and pursued the common course of  
26 conduct complained of herein;
- 27 c) whether documents, press releases, and other statements disseminated to the  
28 investing public and the Company's shareholders during the Class Period  
misrepresented material facts about the business, finances, and prospects of  
Penumbra;

- 1
- 2 d) whether statements made by Defendants to the investing public during the
- 3 Class Period misrepresented and/or omitted to disclose material facts about
- 4 the business, finances, value, performance, and prospects of Penumbra;
- 5 e) whether the market price of Penumbra common stock during the Class
- 6 Period was artificially inflated due to the material misrepresentations and
- 7 failures to correct the material misrepresentations complained of herein; and
- 8 f) the extent to which the members of the Class have sustained damages and
- 9 the proper measure of damages.

10 23. A class action is superior to all other available methods for the fair and efficient

11 adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the

12 damages suffered by individual Class members may be relatively small, the expense and burden

13 of individual litigation makes it impossible for members of the Class to individually redress the

14 wrongs done to them. There will be no difficulty in the management of this action as a class action.

15 **PARTIES**

16 24. Plaintiff \_\_\_\_\_, as set forth in the accompanying certification,

17 incorporated by reference herein, purchased Penumbra common stock during the Class Period, and

18 suffered damages as a result of the federal securities law violations and false and/or

19 misleading statements and/or material omissions alleged herein.

20 25. Defendant Penumbra is incorporated under the laws of Delaware with its principal

21 executive offices located in Alameda, California. Penumbra's common stock trades on the NYSE

22 exchange under the symbol "PEN."

23 26. Defendant Adam Elsesser ("Elsesser") has served at all relevant times as the

24 Company's Chief Executive Officer ("CEO") and a member of its Board of Directors.

25 27. Defendant Gita Barry ("Barry") has served at all relevant times as the Company's

26 Executive Vice President, Global Marketing & Public Relations. Barry frequently serves as the

27 Company's spokesperson, issuing statements on behalf of the Company.

28



1           28. Defendants Elsesser and Barry (collectively the “Individual Defendants”), because  
2 of their positions with the Company, possessed the power and authority to control the contents of  
3 the Company’s reports to the SEC, press releases and presentations to securities analysts, money  
4 and portfolio managers and institutional investors, i.e., the market. The Individual Defendants  
5 were provided with copies of the Company’s reports and press releases alleged herein to be  
6 misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent  
7 their issuance or cause them to be corrected. Because of their positions and access to material non-  
8 public information available to them, the Individual Defendants knew that the adverse facts  
9 specified herein had not been disclosed to, and were being concealed from, the public, and that the  
10 positive representations which were being made were then materially false and/or misleading. The  
11 Individual Defendants are liable for the false statements pleaded herein.  
12

13           29. The Company and the Individual Defendants are collectively referred to as the  
14 “Defendants.”  
15

16                               **SUBSTANTIVE ALLEGATIONS**

17                                       **Background**

18           30. Penumbra is a global healthcare company that develops, manufactures and sells  
19 innovative medical devices for patients suffering from stroke and other vascular and neurovascular  
20 diseases. Penumbra was the first company to market aspiration catheters, a specialized catheter  
21 designed to remove blood clots from arteries and veins in stroke patients, in a surgical procedure  
22 known as a thrombectomy.  
23

24           31. Since their introduction in 2014, Penumbra’s aspiration catheters were rapidly  
25 adopted by healthcare providers and quickly became ubiquitous in operating rooms across the  
26 nation. This widespread adoption helped propel the Company’s stock price from roughly \$40 per  
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1 share following the Company's initial public offering on September 18, 2015, to over \$200 per  
2 share by the start of the Class Period in July 2020.

3           32. Until recently, one of the Company's flagship products was the "Jet 7 Xtra Flex,"  
4 an aspiration catheter designed to be inserted into an affected artery, navigated to a blood clot, and  
5 used to suck the clot out of the patient's body. The Jet 7 Xtra Flex was introduced to the U.S.  
6 market in July 2019 as a supposed improved version of the Company's groundbreaking Jet 7  
7 catheter, adding new technology that made the device far more flexible than the Company's prior  
8 aspiration catheters and those of its rivals. In announcing this innovative new line of catheters, the  
9 Company touted the Jet 7 Xtra Flex as offering "the highest thrombus removal force for  
10 revascularization of acute ischemic stroke patients with large vessel occlusions" of any available  
11 product.  
12

13           33. The Jet 7 Xtra Flex quickly became a star performer and key driver of the  
14 Company's revenue growth. Following its launch, Penumbra executives hailed the Jet 7 Xtra  
15 Flex's widespread adoption. For example, in November 2019, Defendant Elsesser told investors  
16 regarding the Jet 7 Xtra Flex that "physicians have been extremely favorable about its navigation,  
17 ease-of-use and the increase speed of the overall stroke procedure" which was "driv[ing] growth  
18 in our neuro business." Elsesser also stated that since the launch of the Jet 7 Xtra Flex, the  
19 Company "started to see signs that our team is beginning to take back share from those customers  
20 that we might have lost." The following month, the Company identified the new Jet 7 Xtra Flex  
21 in an investor presentation as a "near term growth driver."  
22

23           34. In mid-2020, concerns about the Jet 7 Xtra Flex's safety began to emerge. On June  
24 22, 2020, for example, Penumbra's distributor in Japan sent a letter to hospitals warning of issues  
25 with the new Jet 7 Xtra Flex, stating that "part of the catheter inflated into a balloon and damaged  
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1 a patient's blood vessel" when the product was used. Shortly thereafter, the Company suspended  
2 sales in Japan.

3 35. On July 27, 2020, Penumbra issued its Notification to physicians and other  
4 healthcare providers acknowledging reported instances in which the distal tip of the catheter broke  
5 or expanded, carrying a risk of injury or death, and warning physicians to exercise caution with  
6 the Company's Jet 7 Xtra Flex. In particular, the Notification warned against the practice of  
7 injecting contrast dye through the Jet 7 Xtra Flex to monitor blood flow, as well as using the Jet 7  
8 Xtra Flex in conjunction with non-Penumbra products. The Notification stated that:

9  
10 Penumbra has received reports of Penumbra JET 7 Reperfusion Catheter with Xtra  
11 Flex technology (JET 7 Xtra Flex) distal tip expansion or rupture when used during  
12 injection of contrast media. JET 7 Xtra Flex may become susceptible to expansion  
13 or rupture during contrast injection due to distal tip weakening from manipulation  
14 against resistance or use with other manufacturers' revascularization devices.  
Distal tip expansion or rupture may cause vessel damage and subsequent patient  
injury or death.

15 36. The Notification warned against (1) "[p]erforming contrast injections through JET  
16 7 Xtra Flex" because such use was purportedly "not consistent with the intended use of the  
17 product"; and (2) using the device with certain non-Penumbra products because the Jet 7 Xtra Flex  
18 "has not been tested for compatibility with other manufacturer's revascularization devices." The  
19 Notification further informed healthcare providers that Penumbra would issue a labeling update  
20 reflecting these warnings and that the Company was "committed to product safety and  
21 performance" and "continuing to monitor and investigate these adverse event reports." These  
22 issues continued into the Class Period as the Company assured investors and practitioners alike of  
23 Jet 7 Xtra Flex's safety.  
24

25 **Materially False and Misleading Statements**  
26 **Issued During the Class Period**

27 37. The Class Period begins on August 3, 2020, when the Company announced its  
28 financial results for the second quarter of 2020. On a conference call with analysts conducted the

1 same day, Elsesser was asked about the Jet 7 Xtra Flex MAX, a delivery device that utilizes the  
2 Jet 7 Xtra Flex catheter, and responded that Penumbra was “doing some of the work we do with  
3 every new product that is cleared to evaluate and make sure it’s all good” and stated that the device  
4 “is exactly what we hoped it would be.”

5  
6 38. On August 27, 2020, Capitol Forum, an investment research firm, published a report  
7 on Penumbra and the safety profile of the Jet 7 Xtra Flex based on interviews with doctors and an  
8 analysis of adverse incident reports contained in the FDA’s Manufacturer and User Facility Device  
9 Experience (“MAUDE”) database. Titled “Penumbra: Jet 7 Catheter Susceptible to Malfunction,  
10 Risking Injury or Patient,” the Capitol Forum report described how the Jet 7 Xtra Flex’s failures  
11 that caused injuries and death stemmed from doctors injecting contrast dye inside the catheter to  
12 monitor blood flow. The report further described that the MAUDE database logged 13 deaths  
13 involving a Jet 7 device following the introduction of the Jet 7 Xtra Flex, as opposed to two deaths  
14 prior to that.

15  
16 39. The Capitol Forum report included statements from the Company and Defendant  
17 Barry, a primary spokesperson for the Company concerning Jet 7 Xtra Flex-related issues,  
18 responding to Capitol Forum’s findings. First, Defendant Barry asserted that the catheter’s  
19 labeling “has always stated contrast injections should be made through a different catheter used to  
20 access the brain arteries, called a guide catheter.” Second, regarding the MAUDE reports, the  
21 Company asserted that it “actively discussed the reported adverse events and deaths with the FDA  
22 and published a voluntary Notification to Healthcare Providers with FDA’s support to notify  
23 physicians of labeling changes, intended to further remind physicians about the use of the catheter  
24 and contrast injection.” The Company further assured investors that it “continues to see strong  
25 demand for the Penumbra JET 7 Reperfusion Catheter with Xtra Flex technology and is not aware  
26 of any new reports of events that were the subject of the Notification.”  
27  
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1           40. On September 4, 2020, Capitol Forum published another report about the Jet 7 Xtra  
2 Flex in which Defendant Barry further assured investors that “Penumbra comprehensively files  
3 medical device reports with the FDA for all adverse events associated with its products, as reflected  
4 in the MAUDE database and in accordance with medical device reporting regulations applicable  
5 to medical device manufacturers . . . . Penumbra evaluates the medical device reports and takes  
6 all necessary and appropriate actions depending on the nature of the issue.”  
7

8           41. On September 9, 2020, at the Wells Fargo Securities 2020 Virtual Healthcare  
9 Conference, Defendant Elsesser again assured investors that the Jet 7 Xtra Flex was safe,  
10 minimized product failures as limited to “a rare number of cases,” and reiterated that the Company  
11 was taking all necessary actions in response to the deaths. Specifically, Elsesser stated that:

12           What we learned after tens of thousands of cases that, in some cases – again, not  
13 that any case you never want your product to ever not perform, and I don’t want to  
14 diminish this, it’s – we would love to have them be perfect. *When – in a rare  
15 number of cases when the catheter has injection of contrast put through it, the  
16 tip expands a little, and that expansion has hurt and caused the death of some  
17 patients.* As soon as we did our evaluation and went through all of the work that is  
18 sort of part of running a medical device company through your design control and  
19 quality system, *we made the determination that rather than rely on the IFU that  
20 existed that said do not do a contrast injection through the catheter, we wanted  
21 to make that even more strong, more aware so that physicians would be notified.  
22 And if they didn’t know what the IFU said, they would now know.*

23           So we worked with the FDA. We submitted a change to our IFU and had that  
24 cleared. They, of course, reviewed all of the data and all the incidents and  
25 everything to agree. *And we submitted that or sent that notification out to  
26 everyone who had purchased it through their – through the formal channels as  
27 well as giving it to the society so that there would be no possibility that people  
28 wouldn’t know about this.* It seemed like the right thing to do. It’s, without a doubt,  
being proactive in making sure people know about it.

29           *Now we certainly understand that some doctors need to or make the decision  
30 using their really great clinical judgment, that in certain cases, they may want to  
31 inject contrast. And then we just wanted to make sure that in those cases, they  
32 would not do it through our catheter, that they would use a different catheter,  
33 whether it’s a catheter that we sell or somebody else’s.* And they get to make that  
34 choice. That’s what a doctor does, and they have great judgment. So that’s sort of  
35 the fact pattern. (emphasis added).

1           42.    Additionally, in response to analyst concerns about the medical and market viability  
2 of the Jet 7 Xtra Flex, Elsesser staunchly denied “any possibility” of its recall, touted the success  
3 of the Company’s July 2020 Notification, and assured investors that the Company’s financial  
4 performance was not in question. Specifically, Elsesser stated that:

5                         Look, I don’t know where the conversation around recall started. That’s, I think, a  
6 competitive aspect. Again, I dare say that the company that just did a similar thing  
7 with their high-profile products, not planning on recalling that, the real recall is a  
8 different animal. ***This is not a product that has any possibility of needing to be  
9 recalled.*** If you – again, since our notification, this is really important, we have not  
10 had another incident that we’re aware of in which somebody did this and they had  
11 an issue. So it worked, and that was sort of the point of doing it and getting that  
warning out there. ***So I think you’re 100% accurate that recall is not something  
12 that seems – I’ve never heard that word being discussed again other than sort of  
13 in the shadows by competitors.***

14   \* \* \*

15                         ***So I have a lot of confidence that we’re not going to see share loss, and we don’t  
16 have to start measuring it by share loss. And I would actually be bold enough to  
17 say it’s not impossible when this is all done in the long run, maybe not in the  
18 short term, but in the long run, we might not see share gain from this. It’s – it  
19 sort of reeks a little of sort of desperation.*** (emphasis added).

20           43.    The above statements identified in ¶¶37-42 were materially false and/or misleading  
21 and failed to disclose material adverse facts about the Company’s business, operations, and  
22 prospects. Specifically, Defendants failed to disclose to investors: (1) that the Jet 7 Xtra Flex had  
23 known design defects that made it unsafe for its normal use; (2) that Penumbra did not adequately  
24 address the risk of Jet 7 Xtra Flex causing serious injury and deaths, which had in fact already  
25 occurred; (3) that the Jet 7 Xtra Flex was likely to be recalled due to its safety issues; and (4) as a  
26 result, Penumbra’s public statements as set forth above were materially false and misleading at all  
27 relevant times.  
28

1 **The Truth Gradually Emerges**  
2 **While Defendants Continue To Mislead Investors**

3 44. On September 14, 2020, the FFJ published an article raising serious questions about  
4 the Jet 7 Xtra Flex's safety profile. The article noted that since being introduced in mid-2019,  
5 there were twelve deaths listed in MAUDE that occurred after a surgeon injected an iodine contrast  
6 dye into the Jet 7 Xtra Flex. Like Capitol Forum, the FFJ underscored that Penumbra's warnings  
7 against using the product with contrast dye and non-Penumbra products did little to address the Jet  
8 7 Xtra Flex's safety issues.

9  
10 45. In reaction to the news, Penumbra's stock price fell by nearly 3%, from \$199.43 per  
11 share on September 13, 2020 to \$193.66 per share on September 14, 2020, a decline of \$5.77 per  
12 share.

13 46. On September 17, 2020, at the Morgan Stanley Healthcare Conference, an analyst  
14 highlighted the Company's approach to the Jet 7 Xtra Flex safety issues of "sharing the risk with  
15 clinicians" and questioned whether the product was safe. Elsesser responded unequivocally,  
16 stating that "Yes. There's – first of all, the answer is this product is absolutely safe. I mean there  
17 would be a massive uproar from physicians if somehow there's noise and sort of stuff pulled this  
18 – got people to say this product should go. I mean there would – that would just be absurd. I mean  
19 this product has enabled so many successful cases, that would not – I just think that's – that makes  
20 no sense to hear that. That isn't an issue." In addition to dismissing any safety issues with the Jet  
21 7 Xtra Flex, Elsesser essentially blamed doctors for the practice of injecting contrast through the  
22 catheter, stating, "I think a lot of folks who may have done that, this whole scenario gave them an  
23 opportunity to rethink it and go, why was I doing that? Maybe I should limit that."

24  
25  
26 47. On October 28, 2020, the Company announced its financial results for the third  
27 quarter of 2020. On a conference call with analysts conducted the same day, Elsesser reiterated  
28

1 the Jet 7 Xtra Flex’s safety, the success of the July 2020 Notification in ensuring its safe use, and  
2 the commercial success of the product, stating in relevant part:

3 Before getting to our neuro pipeline, let me talk about JET 7 XTRA FLEX. We  
4 have fielded a great number of questions from the investment community over the  
5 past few months regarding this product and the notification letter we sent to  
6 physicians at the end of July.

7 ***First, it is important to state the JET 7 XTRA FLEX is the most advanced***  
8 ***trackable reperfusion catheter we have ever launched. And its strong***  
9 ***contribution to our Q3 results, which I’ll touch on in a moment, supports this***  
10 ***statement. Second, we are proud of our physician customers, working together***  
11 ***with the Penumbra team, to take the time to refamiliarize and put into practice***  
12 ***the important instructions on how to use JET 7 XTRA FLEX to safely and***  
13 ***successfully treat their stroke patients.***

14 Given the questions this quarter, we think it's important to share more detail on 2  
15 fronts. ***First, JET 7 XTRA FLEX revenue in the U.S. in the third quarter was***  
16 ***within \$400,000 of the product’s highest sales quarter ever. Secondly and more***  
17 ***importantly, we are not aware of any new reports, either as reported to the***  
18 ***company or the MAUDE database, that were the subject of the notification and***  
19 ***were related to events that occurred after the date of their notification.*** It is  
20 important to remember, competition in the neurovascular space has always been  
21 and will likely continue to be significant and aggressive. (emphasis added).

22 48. On November 9, 2020, the securities research firm QCM released a report detailing  
23 its investigation into the Company and the Jet 7 Xtra Flex’s safety. Titled “Penumbra and Its Killer  
24 Catheter,” the QCM accused Penumbra of a “seemingly blatant disregard for patients’ lives” and  
25 essentially “blaming doctors” for the devices’ design defects. The QCM report highlighted that  
26 Penumbra did not issue any notice to U.S. healthcare providers until more than a month after its  
27 Japanese distributor sent out its warning in Japan, and more than nine months after the first patient  
28 died from the product’s malfunction.

49. On November 23, 2020, an article was published in the Journal of  
NeuroInterventional Surgery presenting the cases of three patients who suffered as a result of Jet  
7 Xtra Flex device malfunctions, including two fatalities. Although the journal article was not  
widely publicized on November 23 aside from a Twitter post just before market close from an



1 account with a small following, over the next two days the article was more widely disseminated,  
2 particularly after it was shared by multiple reputed short sellers with hundreds of thousands of  
3 followers, including Marc Cohodes and Muddy Waters. As this report became more widely  
4 circulated, it caused Penumbra stock to fall from \$254.71 on November 23, 2020 to \$224.12 on  
5 November 25, 2020, a decline of about 12%.

6  
7 50. On December 8, 2020, before the market opened, the Company held a conference  
8 call to discuss the status of the Jet 7 Xtra Flex. In response to an analyst request for an update on  
9 the product's availability outside of the United States, Elsesser stated that in Japan and Europe,  
10 the product was still not available pending regulatory approval of the same changes in its safety  
11 instructions that the Company had to submit to the FDA. However, Elsesser assured investors that  
12 once the Company received such regulatory approval, the product would be available in those  
13 markets.  
14

15 51. Also before market open on December 8, 2020, QCM issued another research report  
16 on Penumbra and the Jet 7 Xtra Flex. This second report reiterated QCM's findings regarding the  
17 Jet 7 Xtra Flex's safety, accused the Company of using a fake author for publishing studies that  
18 were foundational to the adoption of its products, and questioned the validity and independence of  
19 the Company's prior scientific research, including as to the Jet 7 Xtra Flex specifically. Later that  
20 day, QCM's managing partner and chief investment officer appeared on CNBC's "Halftime Report"  
21 and said that the Jet 7 Xtra Flex was still not available in Japan "to this day," and cited nonpublic  
22 sources stating that the device was also not on sale in the EU "because of the accidents." These  
23 disclosures contrasted with the Company's prior representations that the Jet 7 Xtra Flex's  
24 availability in the EU and Japanese markets was only a matter of obtaining regulatory approval for  
25 the Company's new instructions.  
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1           52. In reaction to the news, Penumbra’s stock price fell by 9%, from \$224.02 per share  
2 on December 7, 2020 to \$204.07 per share on December 8, 2020, a decline of \$19.95 per share.

3           53. In response to QCM’s research reports, Penumbra issued a press release on  
4 December 8, 2020 stating that it “stands by the record of the product” and that “Penumbra  
5 continues to follow all applicable Quality System Regulations and international standards that  
6 govern the design and quality of its products.” The release added that “Penumbra has helped  
7 thousands of sick patients and is unaware of a single patient death associated with the use of JET  
8 7 Xtra Flex when it is used in line with the instructions for use and the notice Penumbra has  
9 provided to physicians.”  
10

11           54. Finally, on December 15, 2020, after the market closed, the Company stunned  
12 investors by announcing that it was issuing an “urgent” and “voluntarily” recall of the Jet 7 Xtra  
13 Flex at the behest of the FDA. According to the Company’s press release, the recall was necessary  
14 “because the catheter may become susceptible to distal tip damage during use” which in  
15 conjunction with pressurization or contrast injection “may result in potential vessel damage, and  
16 subsequent patient injury or death.” Later that same day, the Company held a conference call with  
17 investors to discuss the recall. During the call, Defendant Elsesser admitted that while the Jet 7  
18 Xtra Flex’s “trackability” enabled physicians to treat more patients, “the design considerations  
19 necessary to achieve that trackability also make the catheter susceptible to failure in certain  
20 scenarios.” Elsesser conceded that the July 2020 Notification and “other steps to ensure the safe  
21 use of the product . . . were not able to fully address the risks.” Also on December 15, 2020,  
22 Penumbra filed with the SEC a Regulation FD Disclosure stating that as a result of the recall of  
23 the Jet 7 Xtra Flex, “the Company expects to record associated costs in the fourth quarter ending  
24 December 31, 2020, primarily as a one-time reduction to revenue of less than \$20 million to  
25 account for product returns.”  
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1           55. In reaction to the news, Penumbra’s stock price fell by 7%, from \$188.82 per share  
2 on December 15, 2020 to \$174.98 per share on December 16, 2020, a decline of \$13.84 per share.

3                                 **UNDISCLOSED ADVERSE FACTS**

4           56. The market for Penumbra’s common stock was open, well-developed, and efficient  
5 at all relevant times. As a result of these materially false and/or misleading statements, and/or  
6 failures to disclose, Penumbra’s common stock traded at artificially inflated prices during the Class  
7 Period. Plaintiff and other members of the Class purchased or otherwise acquired Penumbra’s  
8 common stock relying upon the integrity of the market price of the Company’s common stock and  
9 market information relating to Penumbra and have been damaged thereby.

10           57. During the Class Period, Defendants materially misled the investing public, thereby  
11 inflating the price of Penumbra’s common stock, by publicly issuing false and/or misleading  
12 statements and/or omitting to disclose material facts necessary to make Defendants’ statements, as  
13 set forth herein, not false and/or misleading. The statements and omissions were materially false  
14 and/or misleading because they failed to disclose material adverse information and/or  
15 misrepresented the truth about Penumbra’s business, operations, and prospects as alleged herein.

16           58. At all relevant times, the material misrepresentations and omissions particularized  
17 in this Complaint directly or proximately caused or were a substantial contributing cause of the  
18 damages sustained by Plaintiff and other members of the Class. As described herein, during the  
19 Class Period, Defendants made or caused to be made a series of materially false and/or misleading  
20 statements about Penumbra’s financial well-being and prospects.

21           59. These material misstatements and omissions had the cause and effect of creating in  
22 the market an unrealistically positive assessment of the Company and its financial well-being and  
23 prospects, thus causing the Company’s common stock to be overvalued and artificially inflated at  
24 all relevant times. Defendants’ materially false and misleading statements made during the Class  
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1 Period resulted in Plaintiff and the other members of the Class purchasing the Company's common  
2 stock at artificially inflated prices, thus causing the damages complained of herein.

### 3 LOSS CAUSATION

4 60. During the Class Period, as detailed herein, the Defendants engaged in a scheme to  
5 deceive the market and a course of conduct that artificially inflated the prices of Penumbra  
6 common stock and operated as a fraud or deceit on Class Period purchasers of Penumbra common  
7 stock. Defendants failed to disclose to investors that the Company's public statements concerning  
8 the Jet 7 Xtra Flex were materially misleading and misrepresented material information. When  
9 the Defendants' misrepresentations and fraudulent conduct were disclosed and became apparent  
10 to the market, the prices of Penumbra common stock fell precipitously as the prior inflation came  
11 out of the Company's stock price. As a result of their purchases of Penumbra common stock  
12 during the Class Period, Plaintiff and the other Class members suffered economic loss.

13 61. By failing to disclose the true state of the Company's business operations and  
14 financial prospects, investors were not aware of the true state of the Company's business  
15 operations and financial prospects. Instead of truthfully disclosing during the Class Period the true  
16 state of the Company's business, including with regard to the Jet 7 Xtra Flex, Defendants  
17 concealed the truth from investors and presented a misleading picture of Penumbra's business  
18 operations and financial prospects.

19 62. Defendants' false and misleading statements had the intended effect and caused  
20 Penumbra's common stock to trade at artificially inflated levels throughout the Class Period. The  
21 stock price drops discussed herein caused real economic loss to investors who purchased the  
22 Company's common stock during the Class Period.

23 63. The decline in the price of Penumbra's common stock after the truth emerged was a  
24 direct result of the nature and extent of the Defendants' fraud being revealed to investors and the  
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1 market. The timing and magnitude of Penumbra's common stock price decline negates any  
2 inference that the loss suffered by Plaintiff and the other Class members was caused by changed  
3 market conditions, macroeconomic or industry factors, or Company-specific facts unrelated to the  
4 Defendants' fraudulent conduct. The economic loss suffered by Plaintiff and the other Class  
5 members was a direct result of the Defendants' fraudulent scheme to artificially inflate the prices  
6 of Penumbra's common stock and the subsequent decline in the value of Penumbra's common  
7 stock when the Defendants' prior misrepresentations and other fraudulent conduct were revealed.

### 9 **SCIENTER ALLEGATIONS**

10 64. As alleged herein, Defendants acted with scienter since Defendants knew that the  
11 public documents and statements issued or disseminated in the name of the Company were  
12 materially false and/or misleading; knew that such statements or documents would be issued or  
13 disseminated to the investing public; and knowingly and substantially participated or acquiesced  
14 in the issuance or dissemination of such statements or documents as primary violations of the  
15 federal securities laws.

17 65. As alleged herein, the Individual Defendants, by virtue of their receipt of  
18 information reflecting the true facts regarding Penumbra, their control over, and/or receipt and/or  
19 modification of Penumbra's allegedly materially misleading misstatements and/or their  
20 associations with the Company which made them privy to confidential proprietary information  
21 concerning Penumbra, participated in the fraudulent scheme alleged herein.

### 23 **APPLICABILITY OF PRESUMPTION OF RELIANCE:** 24 **FRAUD-ON-THE-MARKET DOCTRINE**

25 66. At all relevant times, the market for Penumbra's common stock was an efficient  
26 market for the following reasons, among others:

- 27 a) Penumbra shares met the requirements for listing, and was listed and  
28 actively traded on the NYSE, a highly efficient and automated market;

- 1                   b)     As a regulated issuer, Penumbra filed periodic public reports with the SEC  
2   and/or the NYSE;
- 3                   c)     Penumbra regularly communicated with public investors via established  
4   market communication mechanisms, including through regular  
5   dissemination of press releases on the national circuits of major newswire  
6   services and through other wide-ranging public disclosures, such as  
7   communications with the financial press and other similar reporting  
8   services; and/or
- 9                   d)     Penumbra was followed by securities analysts employed by brokerage firms  
10   who wrote reports about the Company, and these reports were distributed  
11   to the sales force and certain customers of their respective brokerage firms.  
12   Each of these reports was publicly available and entered the public  
13   marketplace.

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

19                   68.    A Class-wide presumption of reliance is also appropriate in this action under the  
20   Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972),  
21   because the Class's claims are, in substantial part, grounded on Defendants' material omissions.

22   **NO SAFE HARBOR**

23                   69.    The federal statutory safe harbor provided for forward-looking statements under  
24   certain circumstances does not apply to any of the allegedly false statements pleaded in this  
25   Complaint. The statements alleged to be false and misleading herein all relate to then-existing  
26   facts and conditions. In addition, to the extent certain of the statements alleged to be false may be  
27   characterized as forward-looking, they were not identified as "forward-looking statements" when  
28   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.



1 participants in the wrongful and illegal conduct charged herein. The Individual Defendants are  
2 also sued herein as controlling persons of Penumbra, as alleged herein.

3           74. Penumbra and the Individual Defendants, individually and in concert, directly and  
4 indirectly, by the use of means or instrumentalities of interstate commerce and/or of the mails,  
5 engaged and participated in a continuous course of conduct to conceal adverse material  
6 information about the business, business practices, performance, operations and future prospects  
7 of Penumbra as specified herein. These Defendants employed devices, schemes and artifices to  
8 defraud, while in possession of material adverse non-public information and engaged in acts,  
9 practices, and a course of conduct as alleged herein in an effort to assure investors of Penumbra's  
10 value and performance and substantial growth, which included the making of, or the participation  
11 in the making of, untrue statements of material facts, and omitting to state material facts necessary  
12 in order to make the statements made about Penumbra and its business, operations and future  
13 prospects, in light of the circumstances under which they were made, not misleading, as set forth  
14 more particularly herein, and engaged in transactions, practices and a course of business which  
15 operated as a fraud and deceit upon the purchasers of Penumbra's common stock during the Class  
16 Period.  
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18  
19           75. Each of the Individual Defendants' primary liability, and controlling person liability,  
20 arises from the following facts: (i) each of the Individual Defendants was a high-level executive  
21 at the Company during the Class Period; (ii) each of the Individual Defendants, by virtue of his  
22 responsibilities and activities as a senior executive officer and/or director of the Company, was  
23 privy to and participated in the creation, development and reporting of the Company's operational  
24 and financial projections and/or reports; (iii) the Individual Defendants enjoyed significant  
25 personal contact and familiarity with each other, and were advised of and had access to other  
26 members of the Company's management team, internal reports, and other data and information  
27  
28



1 about the Company's business operations and financial performance at all relevant times; and (iv)  
2 the Individual Defendants were aware of the Company's dissemination of information to the  
3 investing public which they knew or recklessly disregarded was materially false and misleading.

4           76. These Defendants had actual knowledge of the misrepresentations and omissions of  
5 material facts set forth herein, or acted with reckless disregard for the truth in that they failed to  
6 ascertain and to disclose such facts, even though such facts were readily available to them. Such  
7 Defendants' material misrepresentations and/or omissions were done knowingly or recklessly, and  
8 for the purpose and effect of concealing Penumbra's operating condition, business practices and  
9 future business prospects from the investing public and supporting the artificially inflated price of  
10 its common stock. As demonstrated by their overstatements and misstatements of the Company's  
11 financial condition and performance throughout the Class Period, the Individual Defendants, if  
12 they did not have actual knowledge of the misrepresentations and omissions alleged, were severely  
13 reckless in failing to obtain such knowledge by deliberately refraining from taking those steps  
14 necessary to discover whether those statements were false or misleading.

15           77. As a result of the dissemination of the materially false and misleading information  
16 and failure to disclose material facts, as set forth above, the market price of Penumbra common  
17 stock was artificially inflated during the Class Period. In ignorance of the fact that the market  
18 price of Penumbra shares was artificially inflated, and relying directly or indirectly on the false  
19 and misleading statements made by Defendants, upon the integrity of the market in which the  
20 securities trade, and/or on the absence of material adverse information that was known to or  
21 recklessly disregarded by the Defendants but not disclosed in public statements by these  
22 Defendants during the Class Period, Plaintiff and the other members of the Class acquired  
23 Penumbra common stock during the Class Period at artificially inflated high prices and were  
24 damaged thereby.

1           78. At the time of said misrepresentations and omissions, Plaintiff and the other  
2 members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff  
3 and the other members of the Class and the marketplace known of the true performance, business  
4 practices, future prospects and intrinsic value of Penumbra, which were not disclosed by the  
5 Defendants, Plaintiff and the other members of the Class would not have purchased or otherwise  
6 acquired Penumbra common stock during the Class Period, or, if they had acquired such common  
7 stock during the Class Period, they would not have done so at the artificially inflated prices which  
8 they paid.  
9

10           79. By virtue of the foregoing, Penumbra and the Individual Defendants each violated  
11 §10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.  
12

13           80. As a direct and proximate result of the Defendants' wrongful conduct, Plaintiff and  
14 the other members of the Class suffered damages in connection with their purchases of the  
15 Company's common stock during the Class Period.  
16

## COUNT II

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

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18           81. Plaintiff repeats and realleges each and every allegation contained above as if fully  
19 set forth herein.  
20

21           82. The Individual Defendants were and acted as controlling persons of Penumbra  
22 within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their  
23 high-level positions with the Company, participation in and/or awareness of the Company's  
24 operations and/or intimate knowledge of the Company's actual performance, the Individual  
25 Defendants had the power to influence and control and did influence and control, directly or  
26 indirectly, the decision-making of the Company, including the content and dissemination of the  
27 various statements which Plaintiff contends are false and misleading. Each of the Individual  
28

1 Defendants was provided with or had unlimited access to copies of the Company's reports, press  
2 releases, public filings and other statements alleged by Plaintiff to be misleading prior to and/or  
3 shortly after these statements were issued, and had the ability to prevent the issuance of the  
4 statements or cause the statements to be corrected.

5  
6 83. In addition, each of the Individual Defendants had direct involvement in the day-to-  
7 day operations of the Company and, therefore, is presumed to have had the power to control or  
8 influence the particular transactions giving rise to the securities violations as alleged herein, and  
9 exercised the same.

10 84. As set forth above, Penumbra and the Individual Defendants each violated §10(b)  
11 and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their  
12 controlling positions, the Individual Defendants are liable pursuant to §20(a) of the Exchange Act.  
13 As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff and the other  
14 members of the Class suffered damages in connection with their purchases of the Company's  
15 common stock during the Class Period.  
16

17 **PRAYER FOR RELIEF**

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

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

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

24 (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in  
25 this action, including counsel fees and expert fees; and  
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27 (d) Such other and further relief as the Court may deem just and proper.  
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**JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

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