IN THE UNITED STATES COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

CHRISTOPHER URQUHART, Individually, and as Widower of NANCY JUNE URQUHART, deceased, and AMY EHLERS, Individually, and as daughter of NANCY JUNE URQUHART, deceased,	)	
Plaintiffs,	)	Case No. 4:24-cv-01465-SRC
v.	)	
ABIOMED, INC.,	)	
Defendant.	)	

PLAINTIFF'S RENEWED MOTION FOR LEAVE TO AMEND COMPLAINT PURSUANT TO LOCAL RULE 4.07

NOW COMES Plaintiff, Amy Ehlers, by and through her attorneys, McGlynn & McGlynn and Michael L. McGlynn, and for "Plaintiff's Renewed Motion for Leave to Amend Complaint Pursuant to Local Rule 4.07" states as follows:

1. Plaintiff, Christopher Urquhart, the widower, has died. Plaintiff, Amy Ehlers, submits an amended complaint to reflect this unfortunate fact.

2. The Plaintiff sets out the claims with more specificity.

3. The proposed amended complaint is attached hereto as **Exhibit A**.

WHEREFORE, Plaintiff, Amy Ehlers, prays that the Court grant Plaintiff leave to file her Amended Complaint herein, and for any further relief this Court deems proper.

Respectfully submitted,

/s/ Michael L. McGlynn
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **"Plaintiff's Renewed Motion for Leave to Amend Complaint Pursuant to Local Rule 4.07"** has been electronically served on counsel via the PACER e-File system, or electronic mail, on this 31th day of January 2025. Under penalties of perjury as provided by law, I certify that the statements in this affidavit are true.

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IN THE CIRCUIT COURT OF THE CITY OF ST. LOUIS
STATE OF MISSOURI

CHRISTOPHER URQHART, Individually, and as Widower of NANCY JUNE URQHART, deceased, and AMY EHLERS, Individually, and as daughter of NANCY JUNE URQHART, deceased,	)	
Plaintiff,	)	Cause No. 2422-CC10841
v.	)	WRONGFUL DEATH
ABIOMED, INC.,	)	
Defendant.	)	

PETITION
(Wrongful Death)

NOW COMES Christopher Urqhart and Amy Ehlers, hereinafter referred to as Plaintiffs, by and through their attorneys, McGlynn and McGlynn, and Michael L. McGlynn, and for their general allegations against Defendant Abiomed, Inc. ("Abiomed"), states as follows:

1. Plaintiffs are residents of the State of Illinois.

2. Plaintiffs bring this action pursuant to the Missouri Wrongful Death Statue 537.080 et Seq.

3. Christopher Urqhart is the Widower Nancy June Urqhart, who died September 12, 2022.

4. Nancy June Urqhart is survived by her husband, Christopher Urqhart and her daughter, Amy Ehlers. Nancy Urqhart, hereinafter referred to as Plaintiff-Decedent, was had no other living children at the time of her death.

5. Plaintiffs are entitled to bring this wrongful death cause of action as the heirs at law who may sue pursuant to Mo. Rev. Stat. 537.080.

6. At all times relevant, Defendant, Abiomed, Inc., hereinafter referred to as Abiomed, is a foreign corporation in good standing doing business in the State of Missouri with the capacity to sue and be sued in its own name.

7. ~~—~~Plaintiff's claims arise from treatment resulting in ~~her~~ death on September 12, 2022.

8. The hereinafter acts complained of took place in the City of St. Louis and therefore venue is proper in the Circuit Court for the City of St. Louis.

9. On September 9, 2022, ~~Plaintiff-Decedent, Nancy June Urqhardt~~, presented to SSM St. Louis University Hospital in St. Louis, Missouri and underwent a "Mitral Valve Replacement" open heart surgical procedure.

10. Following ~~Plaintiff-Decedent's~~ open heart surgery Defendant's Impella, which had been used during the procedure, caused her to suffer from "intravascular hemolysis."

11. Defendant's Impella was designed and manufactured to be used as a pump during cardiac surgery.

12. The Impella utilized during Plaintiff's surgery, "Impella LDA Abiomed 5.5," had not been used before and was being used for the purpose for which it was manufactured.

13. At the time the Impella in question was manufactured, sold, distributed, or otherwise left the control of Defendant, it was unreasonably dangerous as the lead of the impella, which was supposed to release after the surgical procedure was completed, was improperly manufactured.

14. As a proximate result of the aforesaid unreasonable dangerous condition, the "Impella LDA Abiomed 5.5," presented an unreasonable danger of injury to intended users of the product.

15. As a result of the complications caused by the Impella, ~~Plaintiff-Decedent~~ died on September 12, 2024.

16. Defendant further breeched its implied warranty of merchantability which caused the ~~Plaintiff-Decedent's~~ death.

17. That as a direct and proximate result of one or more of the foregoing defects, and in consequences thereof, ~~Plaintiff-Decedent~~ suffered severe injuries, pain and suffering, and death.

18. By reason of the wrongful death of ~~Plaintiff-Decedent, Plaintiffs~~ have sustained damages including:

a. Great pecuniary losses suffered by reason of the death;

b. Funeral expenses;

c. Deprivation of services, companionship, comfort, instruction, guidance, counsel, training, and support;

d. Damages for great suffering by ~~Plaintiff-Decedent~~ before her death between the time of the open heart surgery until the time of her death;

e. The conduct of Defendant, Abiomed, created a high degree of probability of injury and death and showed complete disregard for the safety of others, including ~~Plaintiff-Decedent~~, justifying the award of exemplary damages in such amount to deter Defendant, Abiomed, from like conduct in the future.

~~WHEREFORE, Plaintiff prays judgment for an amount exceeding Seventy-Five Thousand ($75,000) as will fairly and adequately compensate the Plaintiffs for the damages sustained, exemplary damages and costs of this action and such other further relief the Court deems proper.~~

Respectfully submitted,

/s/ Michael L. McGlynn

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IN THE UNITED STATES COURT
FOR THE EASTERN DISTRICT OF MISSOURI
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AMY EHLERS, Individually, and as daughter of NANCY URQUHART, deceased,	)	
Plaintiff,	)	Case No. 4:24-cv-01465-SRC
v.	)	
ABIOMED, INC.,	)	
Defendant.	)	

PLAINTIFF'S FIRST AMENDED COMPLAINT

COMES NOW Amy Ehlers, hereinafter referred to as ("Plaintiff"), by and through her attorneys, McGlynn & McGlynn and Michael L. McGlynn, and for Plaintiff's First Amended Complaint against Abiomed, Inc., hereinafter referred to as ("Defendant"), states as follows:

PARTIES, JURISDICTION, AND VENUE

1. The Plaintiff, Amy Ehlers, is a citizen of the State of Illinois. Plaintiff, Amy Ehlers, is the daughter of her married parents, Nancy Urquhart, deceased, and Christopher Urquhart, deceased. Her parents were both citizens of the State of Illinois at the time of their deaths.

2. Defendant, Abiomed, Inc., was incorporated in the State of Delaware and has its principal place of business in the State of Massachusetts. The Defendant at all relevant times purposefully availed itself of the benefits, profits and privileges deriving from its business activities in this state.

3. The Defendant has at all times relevant been engaged in substantial business activities in the State of Missouri. At all relevant times the Defendant transacted, solicited, and conducted business in Missouri through its employees, agents, and/or sales representatives.

4. There is an affiliation between Missouri and the underlying controversy alleged in this Complaint, principally, activities and/or occurrences that took place in Missouri, and the Defendant is therefore subject to Missouri's regulation.

5. The Defendant also engaged in directed marketing and advertising efforts in St. Louis, Missouri, including direct to consumer and direct to physician marketing.

6. The Defendant has conducted continuous business and research activities that are sufficiently related to the Plaintiff' suit.

7. The Defendant and its agents placed the product into the stream of commerce resulting in the use of the Impella device that led to the untimely death of Nancy Urquhart.

8. Venue is proper in the City of St. Louis, Missouri in accordance with Section 508.010 (4) of the Missouri Revised Statutes because the conduct that gave rise to Plaintiff' cause of action occurred in the City of St. Louis, Missouri, and Nancy Urquhart was first injured by, and died as a consequence of, the wrongful acts and negligent conduct by the Defendant in the City of St. Louis, Missouri.

9. Defendant, Abiomed, Inc., is a for-profit corporation incorporated in the State Delaware. Defendant is authorized to and does business throughout the state of Missouri. Defendant's principal place of business is in the State of Massachusetts.

10. At all times herein mentioned, Defendant was engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing, and/or advertising for sale, and selling the Impella device. This product was utilized in Nancy Urquhart's surgery and was used by her physicians in

the same condition as when the Impella device left Defendant's control. As such, Defendant is liable to the Plaintiff for their damages.

11. Plaintiff, an Illinois resident, is entitled to bring this action as a Class I person who may sue under MO Rev. Stat. 537.080 (Wrongful Death Act) and (Survival Act) MO Rev. Stat 537.021. Plaintiff, Amy Ehlers, is the daughter of her married parents, Nancy Urquhart, deceased, and Christopher Urquhart, deceased. Plaintiff, Amy Ehlers, is a proper party to bring these claims which include theories of negligence, strict products liability, breach of express warranty, and breach of implied warranty for damages allowed under the Missouri (Wrongful Death Act) and (Survival Act).

COMPENDIUM / SUMMARY

12. Plaintiff's claims arise from treatment resulting in Nancy Urquhart's death on September 12, 2022.

13. The hereinafter acts complained of took place in the City of St. Louis and therefore venue is proper in the Circuit Court for the City of St. Louis, Missouri.

14. On September 9, 2022, Nancy June Urquhart presented to SSM St. Louis University Hospital in St. Louis, Missouri and underwent a "Mitral Valve Replacement, Triscuspid Valve Repair, CABG x 1, insertion of 5.5 Impella, left atrial appendage exclusion, LLE saphenous vein harvest, placement of temporary pacing wires and intra-operative TEE (N/A)" surgical procedure.

15. Following Nancy Urquhart's open heart surgery Defendant's Impella, which had been used during the procedure, caused her to suffer from "intravascular hemolysis."

16. Defendant's Impella was designed and manufactured to be used as a pump during cardiac surgery.

17. The Impella utilized during Plaintiff's surgery, “Impella LDA Abiomed 5.5,” had not been used before and was being used for the purpose for which it was manufactured.

18. At the time the Impella in question was manufactured, sold, distributed, or otherwise left the control of Defendant, it was unreasonably dangerous as the lead of the impella, which was supposed to release after the surgical procedure was completed, was improperly manufactured.

19. As a proximate result of the aforesaid unreasonable dangerous condition, the “Impella LDA Abiomed 5.5,” presented an unreasonable danger of injury to intended users of the product.

20. As a result of the complications caused by the Impella, Nancy Urquhart died on September 12, 2024.

21. Defendant further breeched its implied warranty of merchantability which caused the Nancy Urquhart’s death.

22. That as a direct and proximate result of one or more of the foregoing defects, and in consequences thereof, Nancy Urquhart suffered severe injuries, pain and suffering, and death.

23. By reason of the wrongful death of Nancy Urquhart, Plaintiff, Amy Ehlers, has sustained damages including:

a. Great pecuniary losses suffered by reason of the death;

b. Funeral expenses;

c. Deprivation of services, companionship, comfort, instruction, guidance, counsel, training, and support;

d. Damages for great suffering by Nancy Urquhart before her death between the time of the open heart surgery until the time of her death;

e. The conduct of Defendant, Abiomed, created a high degree of probability of injury and death and showed complete disregard for the safety of others, including Nancy Urquhart, justifying the award of exemplary damages in such amount to deter Defendant, Abiomed, from like conduct in the future.

INTRODUCTION

24. The primary responsibility for timely communicating complete, accurate and current safety and efficacy information related to a medical device rests with the manufacturer; the manufacturer has superior, and in many cases exclusive, access to the relevant safety and efficacy information, including post-market complaints and data.

25. To fulfill this essential responsibility, a manufacturer must vigilantly monitor all reasonably available information. The manufacturer must closely evaluate the post-market clinical experience with the device and its components and timely provide updated safety and efficacy information to the healthcare community and to consumers. The manufacturer also must carefully monitor its own manufacturing operations and quality controls to ensure that the device uniformly conforms to the manufacturer-approved design, as well as its representations and warranties and with specifications of approval.

26. When monitoring and reporting adverse events as required by both federal regulations and state law, including Missouri law, time is of the essence. The purpose of monitoring a product's post market experience is to detect potential safety signals that could indicate to the manufacturer and the medical community that a public safety problem exists. If a manufacturer waits to report post-market information, even for a few weeks or months, that bottleneck could cause researchers, regulatory bodies, and the medical community to be years behind in identifying a public safety issue associated with the device. In the meantime, more patients are harmed by using the product without understanding its true risks. This is why a manufacturer must not only completely and accurately monitor, investigate and report post-market experience, but it must also report the data as soon as it is received.

27. This action arises from Defendant's failures of their post-market responsibilities to monitor and warn about serious health risks that emerged after their device, Impella heart pump device began to be sold in the United States. The U.S. Food and Drug Administration ("FDA") approved the device for sale in the United States in 2008 based on limited clinical studies presented by the device manufacturer. When the FDA approved the device, the FDA was not aware that the device could cause serious health risks, such as hemolysis.

28. After the FDA approved the device for sale and it began to be utilized in patients in a real-world setting, Defendant became aware of serious adverse events that should have led the Defendant to: (a) directly inform healthcare providers and consumers of these risks by revising the warning label for the device; and (b) report the adverse events to the FDA. For example, Defendant failed to warn health care providers and consumers about complaints of serious injuries associated with the Impella after the device was approved for sale. Defendant also failed to timely report this new information to the FDA, which, upon evaluating the information, required actions by the manufacturer. If the Defendant had timely and adequately warned Nancy Urquhart's health care providers and Plaintiff of this new risk information, Nancy Urquhart's injuries and subsequent death would have been avoided.

29. Not only did Defendant fail to timely warn about Impella 's serious health risks, but Defendant also persisted in conducting a nationwide misleading marketing campaign. It represented that Impella was safer than other methods for short term support of the pumping chambers of the heart (ventricles) during high-risk catheter-based procedures called percutaneous coronary interventions ("PCI") or when a patient is suffering from ongoing cardiogenic shock.

30. The conduct of Defendant violated its obligations under relevant federal and state law, including Missouri law, governing the post-market conduct of medical device manufacturers.

DESCRIPTION OF THE IMPELLA

31. The Impella (Abiomed, Inc.) pump, ("Impella"), is a medical device that is used for short term hemodynamic support of the pumping chambers of the heart (ventricles) during high-risk catheter-based procedures called percutaneous coronary interventions ("PCI"). The Impella is also used for management of cardiogenic shock. Among mechanical circulatory support ("MCS") devices, micro axial pVADs such as the Impella (Abiomed) are commonly used.

32. The Impella (Abiomed) is a percutaneous micro axial, continuous flow, short-term ventricular assist device, that supports the left ventricle ("LV") and/or the right ventricle ("RV") by transferring blood across the aortic or tricuspid and pulmonary valves, on the basis of the principal of Archimedes' screw. It augments systemic and/or pulmonary forward flow, maintaining end-organ perfusion and also unloads the vertical, which results theoretically in a reduced area inside the ventricular pressure volume loop and consequently reduced myocardial oxygen demand.

33. The hemodynamic support of the Impella was compared with the intra-aortic balloon pump by retrospective registries in the United States. Their findings did not demonstrate a survival benefit of using pVAD compared with intra-aortic balloon pumps. This was attributed mainly to a higher rate of major bleeding complications.

34. Another explanation for the disappointing outcomes with micro axial pVAD support is the frequent occurrence of hemolysis, with a reported cumulative rate up to 62.5%.

35. The Impella (Abiomed) requires clear and safe manufacturer instructions setting out meticulous post-implantation management to avoid the two most frequent complications, namely bleeding and hemolysis, both of which affected Nancy Urquhart.

36. Clear and safe manufacturer instructions involving a standardized approach to the prevention, detection, and treatment of these complications by Defendant, Abiomed, Inc., are mandatory to improve outcomes.

37. Hemolysis is mostly present shortly after implantation and when there is suboptimal intracardiac device positioning which results in partial inlet or outlet obstruction and suction events. Hemolysis can perhaps be avoided by proper manufacturer instructions as to device positioning and management aided by the use of technical tools to assess dislocation of the pump.

38. Hemolysis is the release of hemoglobin into plasma from erythrocytes, which leads to a decline in efficient oxygen delivery and may be detected as an increase in plasma-free hemoglobin which occurs when capacity of protective hemoglobin-scavenging mechanisms, such as hapto-globin, becomes saturated.

39. Hemolysis results in increased vascular resistance, vasoconstriction, and platelet activation, aggregation, and arterial thrombosis, potentially resulting in ischemia in multiple organs. Furthermore, free hemoglobin can precipitate and induce pigment nephropathy, leading to acute renal failure. Additionally, ongoing hemoglobinuria leads to hemoglobin deficiency and reduces oxygen-carrying capacity of the blood. In an attempt to preserve end-organ oxygen delivery, cardiac output will increase. Initially this is achieved by increasing heart rate and later also by increasing stroke volume because of neuro-abnormal responses leading to fluid retention.

40. Bleeding complications typically occur in the first two to three (2-3) days after the device is implanted and rise in parallel with the duration of the micro axial pVAD support. Thrombotic complications also typically rise with the duration of support. In particular, the insertion sheath is slightly larger than the repositioning sheath, which might also contribute to the risk of access site bleeding.

41. Inherent function-related mechanisms of the micro axial pVAD might contribute to the occurrence of hemolysis. Increased shear stress during pVAD support is an important factor resulting in erythrocyte damage. When the erythrocyte membrane is mechanically stressed, the cell's capacity to deform and perform its normal functions starts to decline. This results in hemolysis or nonreversible sub hemolytic damage. The computational fluid dynamics of an Impella CP show higher shear stress at the tip of the impeller blade (between the rotor and the housing), which is in line with the established formula whereby linear pump speed and, consequently, shear stress are the highest at the outer tip of the impeller blades. Therefore, it is understandable that rotational speed in a micro axial pVAD effects the development of hemolysis.

42. When purge flow is obstructed, by thromboses or otherwise, hemolysis will occur immediately. In addition, reduced purge flow may be insufficient to attenuate motor heat resulting from attrition forces, resulting in increased local temperature and higher risk for clotting and hemolysis. Fifty percent (50%) obstruction of an Impella CP outlet leads to a detrimental increase in the exposure time of blood regions of high shear stress because of flow restriction and increase in turbulence near the impeller and the outlet windows.

43. Impella was manufactured, formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, marketed, advertised, promoted, distributed, and sold by the Defendant, Abiomed, Inc.

44. Since Impella 's market entry, the device has undergone several design and instruction/warning changes.

2024 MEDICAL JOURNAL FINDINGS

45. On April 7, 2024, the New England Journal of Medicine published an article entitled "Microaxial Flow Pump or Standard Care in Infarct-Related Cardiogenic Shock" N. England Med 2024: 390: 1382-1393.

46. While showing lower risk of death (excluding certain patient categories) the incidence of a composite of adverse events was higher with the use of the microaxial flow pump. Results, in part, included: Safety composite / safety end-point events (severe bleeding, limb ischemia, hemolysis, device failure, and worsening of the aortic regurgitation) occurred more often with the micro axial flow pump group than in the standard care group. Renal replacement therapy was administered almost twice as often with the microaxial flow pump as with standard care alone.

47. The study observed the incidence of complications was higher among patients who received microaxial flow pumps than among those who received standard care alone, a finding that was in agreement with registry data.

48. An unexpected finding was a considerably higher use of renal-replacement therapy in the microaxial flow pump group than in the standard care group. The study noted that 41.9% of the Impella group required renal replacement compared to 26.7% for the standard care group. Nancy Urquhart was a patient who used an Impella microaxial flow pump, and she sustained an acute kidney injury and acute renal failure.

49. The study observed: "the microaxial flow pump can also cause mechanical hemolysis. The subsequent increase in the level of plasma-free hemoglobin can induce nephropathy leading to acute kidney failure which may be further aggravated by bleeding and sepsis."

50. Just as related in the study released after her death, the Impella caused Nancy Urquhart to suffer from hemolysis subsequent to an increase in plasma-free hemoglobin leading to an acute

kidney injury aggravated by bleeding and ultimately acute renal failure and death on September 12, 2022.

PRE-MARKET APPROVAL OF IMPELLA

51. Premarket Approval ("PMA") Application to the FDA for the Impella was based upon data derived from limited studies conducted by Defendant to determine safety and effectiveness of the Impella device.

52. PMA is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of medical devices based on the information available at the time. See 21 U.S.C. § 360(e); 21 C.F.R. § 814.3(e).

53. Under 21 C.F.R. § 814.20, a PMA and/or PMA Supplement application must provide:

a. proposed indications for use;

b. device description including the manufacturing process;

c. any marketing history;

d. summary of studies (including non-clinical laboratory studies, clinical investigations involving human subjects, and conclusions from the study that address benefit and risk considerations);

e. each of the functional components or ingredients of the device;

f. methods used in manufacturing the device, including compliance with current good manufacturing practices; and

g. any other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should reasonably be known to the manufacturer from any source, foreign or domestic, including information derived

from investigations other than those proposed in the application and from commercial marketing experience.

54. Defendant, Abiomed, Inc., was required to summarize the studies conducted as part of the PMA application. Further, data from the Defendant which determined Impella safety and effectiveness was essential to the PMA. Thus, the data derived from Defendant was directly related to the regulatory approval of Impella and ultimately, the utilization of the Impella device during Nancy Urquhart's surgical procedure.

55. The FDA conditionally approved the Impella PMA application in 2008.

56. Because the FDA approval was based on limited studies of clinical trial patients for a short period of time, Defendant understood at that time that the nature of the human body's response to the Impella was limited or unknown.

57. The FDA's Conditional Premarket Approval ("CPMA") Order for Impella established several requirements for the manufacturer, and the approval made non-compliance with any of these requirements a violation of federal law. For example, the approval required that the manufacturer:

a. conduct a post-approval study in order to gather long-term safety and effectiveness data on Impella;

b. conduct a post-approval study in the U.S.;

c. annually report on the patients who participated in the post-approval studies;

d. ensure that any warranty statements are truthful, accurate, not misleading and are consistent with applicable federal and state laws;

e. submit a PMA supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling,

manufacturing, or device modification. In the case of a labeling modification under these circumstances, the type of mandatory PMA supplement to be submitted was a Special PMA Supplement – Changes Being Effected, which allowed the manufacturer to implement its label change without prior FDA approval;

f. submit annual post-approval reports to the FDA including reports of data from any clinical or nonclinical laboratory studies involving the device and reports in the scientific literature concerning the device;

g. submit a report to the FDA after Defendants receive or have knowledge or information of any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that has not been addressed by the device's labeling or has been addressed by the device's labeling but is occurring with unexpected severity or frequency. The express purpose of this requirement was to provide continued reasonable assurance of the safety and effectiveness of the device;

h. submit a report to the FDA after Defendants receive or have knowledge or information of any failure of the device to meet specifications established in the approved PMA that are not correctable by adjustments or procedures described in the approved labeling;

i. include in the Annual Report a bibliography and summary of information from unpublished reports of data from any clinical investigations or non-clinical laboratory studies involving Impella as well as reports in the scientific literature concerning Impella;

j. include in the Annual Report any failures of the device to meet the specifications established in the approved PMA that were correctable by procedures described in the approved labeling; and

k. "report to the FDA whenever it received information from any source that reasonably suggested that the device may have caused or contributed to a serious injury."

58. The CPMA Order for Impella further outlined reporting requirements that Defendant was required to follow under the Medical Device Reporting regulations ("MDR"). Under these requirements, Defendant was required to:

a. report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device may have caused or contributed to serious injury; and

b. report to the FDA within thirty (30) days whenever they receive or otherwise become aware of information, from any source, that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur.

59. The FDA made clear that a failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Act.

WARNINGS / RECALLS

60. In an FDA warning issued in May of 2019, the Agency highlighted an increased mortality rate with Abiomed Impella RP heart pumps. In clinical trials relied on to approve the device, 44 out of 60 patients, or 73.3 %, survived up to 30 days following use of the device. However, real-

world results from a 2019 post-approval study (PAS) showed only a 28% survival rate among Impella patients transitioning to long term therapy. The warning indicated that only 12 out of 42 patients enrolled in a Post-Approval Study (PAS) survived to the 30-day hospital discharge mark. The findings raised serious safety concerns.

61. In 2023, the FDA issued a Class I recall for Impella Left Sided Blood Pumps after reports of heart ventricle perforations.

62. On March 21, 2024, The FDA announced a Class 1 recall for the Impella following numerous reports of the pump catheter piercing the wall of the left ventricle. The recall included approximately 66,390 models of the device including the Impella 5.5 with SmartAssist.

63. In 2023, a recall for Impella 5.5 with SmartAssist pumps addressed purge fluid leaks that caused device failures, heart valve damage, and an increased risk of severe injuries.

64. On December 27, 2023, Defendant issued updated instructions for use of the Impella and added additional warnings to address the risks of the catheter causing a tear in the left ventricle. The reported reasoning for the recall was a potential risk that the Impella motor housing may come into contact with the distal stent of a transcatheter aortic valve replacement (TAVR). The contact may damage or destroy the motor's impeller blades. The damaged Impella system may have reduced blood flow or pump stop, which may delay therapy or fail to provide enough support to the patient. Systemic embolization of the fractured impeller material is a possibility. However, The FDA classified the actions as a Class 1 recall, indicating that the continued use of the Impella Heart Pumps poses a risk of serious injuries or death.

65. On August 17, 2023, the FDA issued an announcement indicating that the manufacturer /Defendant had become aware of at least 12 injuries reported in relation to the catheter system's instructions and labeling. That recall stated the instructions labels provided with the catheter

system do not provide proper safety precautions or actions health care providers should take if their patients anticoagulation clotting rate is below recommended levels. Officials indicated the Impella warning labels also fail to indicate the risk of developing blood clots or deposit formations associated with the use of the catheters, increasing the risk of formation of particle deposits, blood clots, and death.

66. The reported reasoning for recalling the Impella device was due to the pumps' Instructions for Use (IFU) not adequately addressing precautions to take when treating patients who have undergone transcatheter aortic valve replacement (TAVR). The IFU lacked guidance to clinicians on how to manage the use of Impella in patients with TAVR and failed to describe how the issue may present if an Impella interacts with TAVR.

ADVERTISING / FALSE CLAIMS ACT

67. The United States Attorney's Office, District of Boston released a statement on March 8, 2018, announcing "Abiomed, Inc. Agrees to Pay $31 Million to Resolve Kick Back Allegations." The press release stated Defendant, Abiomed, Inc., agreed to pay $31 million to resolve allegations that it violated the False Claims Act by purchasing lavish meals for physicians in order to induce them to use Abiomed's Impella line of heart pumps. See U.S. ex rel. Bennett v Abiomed, Inc., No 13-cv-12277-IT.

DEFENDANT BREACHED ITS OBLIGATION TO UPDATE WARNINGS AND REPORT ADVERSE EVENTS

68. Approval of a device through the PMA process signals the beginning, not the end, of a device manufacturer's duties to patients under both federal regulations and established state law, including Missouri law. The FDA's initial approval of a device label amounts to a finding by the FDA that the label is adequate for purposes of gaining initial approval to market the device. It does not represent a finding by the FDA that the label can never be deemed inadequate after approval

as new safety information from the real-world experience with the device becomes available to the manufacturer. Sound reasons support these principles: there are products, such as Impella, for which evidence of the device's defects comes to light only after the device is used in a real-world setting.

69. After Impella, received pre-market approval, Defendant was at all times responsible for maintaining the labeling of Impella in light of the most current risk information obtained from real-world clinical experience with the device. There is no federal requirement that a manufacturer maintain its original warning language in the face of new safety information. Nor does federal law give device manufacturers the right to market their device using the label originally approved by the FDA when new post-market information bearing on the safety of the device comes to light. To the contrary, the FDCA required Defendant not to sell a device that was accompanied by an inadequate warning or had a label that was false or misleading in any respect, 21 U.S.C. § 352(a), (f)(2), because such a deficient warning rendered the device "misbranded" under 21 U.S.C. § 331, as well as the Sherman Food, Drug, and Cosmetic Laws. West's Ann. Cal. Health & Safety Code § 111330.

70. Defendant had the ability under federal law, and the duty under state and federal law, to directly warn healthcare providers and consumers by unilaterally updating the labeling of Impella to reflect newly acquired safety information without advance approval by the FDA. 21 C.F.R. § 814.39(d) and CPMA Order, Conditions of Approval. The options available to the Defendant include:

a. labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction for which there is reasonable evidence of a causal association;

b. labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device;

c. labeling changes that ensure it is not misleading, false, or contains unsupported indications; and;

d. changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

71. Defendant breached its duties under federal law and state law, including Missouri law, to maintain labeling that: (a) added warnings about the adverse reactions alleged herein for which there was reasonable evidence of a causal association; (b) added instructions for use that would enhance the safe use of the device; and (c) added descriptions of adverse events to ensure that the labeling was not false or misleading.

72. Defendant's post-approval obligations under federal law also included duties to:

a. report to the FDA information suggesting that one of the Manufacturer's devices may have caused or contributed to a death or serious injury, or has malfunctioned and would be likely to cause death or serious injury if the malfunction were to recur, and conduct an investigation of each event and evaluate the cause of the event, 21 C.F.R. §§ 803.50, et seq.;

b. monitor the product after pre-market approval and discover and report to the FDA any complaints about the product's performance and any adverse health consequences of which it became aware and that are or may be attributable to the product, 21 C.F.R. §§ 814, et seq.;

c. submit a PMA Supplement for any change in Manufacturing Site, 21 C.F.R. §§ 814.39, et seq.; d. establish and maintain quality system requirements to ensure that quality requirements are met, 21 C.F.R. § 820.20, et seq.;

e. establish and maintain procedures for validating the device design, including testing of production units under actual or simulated use conditions, creation of a risk plan, and conducting risk analyses, 21 C.F.R. §§ 820.30, et seq.;

f. document all Corrective Action and Preventative Actions taken by the Manufacturer to address non-conformance and other internal quality control issues, 21 C.F.R. §§ 820.100, et seq.;

g. establish internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198 and §§ 820.100, et seq.;

h. establish Quality Management System ("QMS") procedures to assess potential causes of non-conforming products and other quality problems, 21 C.F.R. §§ 820.70, et seq. and 21 C.F.R. §§ 820.90, et seq.;

i. report on Post Approval Studies in a timely fashion, 21 C.F.R. §§ 814.80, et seq.; and,

j. advertise the device accurately and truthfully, 21 C.F.R. §§ 801, et seq.

73. Had the Defendant fulfilled these obligations in a timely fashion, which federal and state law required them to do, Nancy Urquhart's death would not have occurred. Defendant failed to do so.

74. The claims in this case concern Defendant's duties that arose after premarket approval of Impella, when the Defendant learned of new information bearing on the safety of its device.

Defendant breached its duties to take reasonable steps to prevent foreseeable and intended risks, including to Nancy Urquhart.

75. Under state law, including Missouri law, Defendant had a duty to exercise reasonable care in adequately warning Nancy Urquhart and/or her physicians about the dangers of the Impella, that were known or knowable to the Defendant at the time of distribution. Under both federal and state law, Defendant also has a post-market duty to monitor and report adverse events and risks associated with the device.

76. Despite having knowledge and possession of evidence that showed the use of Impella, was dangerous and likely to place users' health at serious risk, Defendant failed to disclose and warn of the health hazards and risks associated with Impella. Instead, Defendant marketed, advertised, and promoted Impella while failing to monitor, warn, or otherwise ensure the safety and efficacy of its users in violation of state law, including Missouri law, and FDA regulations.

77. The FDCA requires medical device manufacturers like the Defendant to maintain and submit information as required by FDA regulation, 21 U.S.C. § 360i, including submitting Adverse Reaction Reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports, 21 C.F.R. § 820.198(a). Specifically, 21 C.F.R. § 803.50 requires a manufacturer to report information no later than 30 days after it is received, from any source, if that information suggests that the device may have contributed to a serious injury or has malfunctioned and the malfunction would be likely to contribute to a serious injury if it were to recur.

78. The FDA publishes the adverse events and MDRs in a public, searchable database called MAUDE and updates the report monthly with "all reports received prior to the update." The general public, including physicians and patients, may use the MAUDE database to obtain safety

data on medical devices. See

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm

79. Defendant had a duty under state law, including Missouri law, to exercise reasonable care in warning Nancy Urquhart and/or her physicians about the dangers of Impella that were known or knowable to Defendant at the time of distribution. Defendant also had an obligation and the ability under federal regulations to maintain labeling that provided adequate warnings about risks and instructions for use; to conduct prompt, accurate and thorough post-market surveillance; to take action to ensure that the device can be used safely in accordance with the instructions; and to ensure that any labeling, warranties, or representations Defendant made were not false or misleading in any respect. Defendant's conduct here failed to meet these federal obligations and violated state law, including Missouri law.

80. Defendant failed to timely and/or effectively warn of the serious safety risks to the FDA and public.

81. The FDA's Office of Regulatory Affairs ("ORA") is the lead office for all field activities, including inspections and enforcement. During an inspection, if ORA investigators observe conditions they deem to be objectionable, these observations are required to be listed on an FDA Form 483 when they indicate that an FDA-regulated product may be in violation of FDA requirements.

82. FDA Form 483s typically are discussed with a company's management team at the conclusion of the inspection. The Form 483 is not an all-inclusive list of every possible deviation from law and regulation. There may be other objectionable conditions that exist that are not cited on the FDA Form 483. Companies must take corrective action to address the cited objectionable conditions and any related, non-cited objectionable conditions that exist.

83. Defendant was not timely and effectively reporting such instances as MDRs, and not analyzing them as failure modes in Design Controls, nor was it performing its post-market obligations to ensure that the Impella device was safe and effective as manufactured and in accordance with the requirements of the CPMA and FDA Regulations.

84. Defendant had reason to know of the frequency, severity, and permanence of the complications and risks associated with the Impella device. Despite this knowledge, Defendant failed to take necessary action—such as directing the filing of PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs - to advise users of Impella of the defects and risks described above, violating federal and state law, including Missouri law.

85. Because Defendant failed to timely, completely, or accurately report their knowledge of risks and complications associated with the Impella device, the public's knowledge of the risks associated with the Impella device were seriously hampered and delayed. This endangered patient safety, including Nancy Urquhart's safety.

86. Defendant delayed disclosure of the safety information regarding the Impella device in order to increase sales of the Impella, protect the Impella brand, and increase market share.

87. Defendant received direct financial benefit from their tortious conduct.

88. Defendant's actions violated the conditions of the Impella CPMA, parallel state laws governing the post-marketing conduct of the Defendant, and FDA Regulations.

89. Defendant had unique knowledge concerning the frequency, severity, and permanence of the complications and risks associated with the Impella device. Despite this unique knowledge, Defendant failed to take necessary action—such as filing PMA Supplements, unilaterally updating

its labeling through the CBE Process, or timely submitting MDRs—to advise users of Impella of the defects and risks described above, violating state law, including Missouri law.

90. Defendant's actions violated the conditions of the Impella CPMA and federal regulations and requirements governing the post-marketing conduct of Defendant, including, but not limited to, 21 C.F.R. § 814.39(d). The Defendant's actions also separately violated parallel duties under state law, including Missouri law, governing their post-marketing conduct.

91. Defendant also failed to timely submit Post-Approval Studies under the Impella CPMA. If Defendant had timely submitted accurate Post Approval Studies, Nancy Urquhart and her physicians would have received notice of these complaints.

92. Defendant's actions violated the conditions of the Impella CPMA, parallel state laws governing the post-marketing conduct of Defendant, and FDA Regulations, including, but not limited to, 21 C.F.R. §§ 814.80, et seq.

93. By failing to update its labeling as new post-marketing information became available to ensure that its labeling remained both accurate and adequate, Defendants also rendered Impella a "misbranded" device under the FDCA, which forbid this device from being marketed. These actions also violated parallel state laws governing Defendants' marketing representations and warnings. Despite this, Defendants continued to improperly market Impella for use in cardiac surgical procedures, including Nancy Urquhart's surgery, at a time it was prohibited from doing so under federal law. The Defendant's actions separately violated duties under state law, including Missouri law, governing their post-marketing conduct.

94. By failing to comply with several CPMA conditions and FDA post-marketing regulations prior to Nancy Urquhart's surgical procedure, Impella was also considered to be an "adulterated" device under § 501(f) of the FDCA and not allowed to be marketed. 21 U.S.C. § 351(h); 21 C.F.R.

§§ 814.80, et seq. Despite this, Defendants continued to improperly market Impella for use in cardiac surgical procedures, including Nancy Urquhart's surgery, at a time that it was prohibited from doing so under federal law. The Defendant's actions violated parallel duties under state law, including Missouri law, governing their post-marketing conduct.

95. Defendant's failure to timely file MDR's and to report to the FDA the complaints that were not addressed by the device's labeling and/or complaints that were occurring with an unexpected increase in severity and frequency, which it knew of from complaints that it received, violated the CPMA, FDA post-marketing regulations, and parallel state law. Defendant's violations prevented Nancy Urquhart, her physicians, and the public from understanding the true nature of Impella 's adverse events, risks, and ineffectiveness.

96. The Defendant's actions violated duties under state law, including Missouri law, governing its post-marketing conduct.

97. Prescribing and implanting physicians, healthcare providers, and patients, including Nancy Urquhart and her healthcare providers, neither knew, nor had reason to know at the time of their use of Impella, of the existence of the aforementioned adverse events and defects. Ordinary consumers would not have recognized the potential risks or side effects that Defendants concealed and misrepresented through their promotion of Impella as safe and effective.

QUALITY PROBLEMS AND MANUFACTURING DEFECTS

98. Defendant had a duty under state law, including Missouri law, to exercise reasonable care in the manufacture, development, marketing, labeling, distributing, and sale of Impella after it was approved for sale by the FDA. Defendant also had the obligation and ability under federal regulations to ensure that the product was manufactured utilizing Good Manufacturing Practices and to maintain quality controls to adequately address, investigate, and assess manufacturing

issues that arose from the device. Defendant's conduct failed to meet these federal obligations and violated parallel state law, including Missouri law.

99. Defendant did not have a quality control department. Instead, it contracted with an outside entity to periodically audit its manufacturing sites. During that time, the FDA inspected the Defendant's manufacturing facility and issued a Form 483 notice of violation reporting that: (1) design outputs identified as essential for the proper functioning of the device were not completely identified; (2) corrective and preventive action activities had not been documented, including implementation of corrective and preventive actions; (3) the procedures addressing verification or validation of corrective and preventive actions were not implemented; and (4) certain adverse events were not captured in the data submitted for Impella 's PMA.

100. Shortly after beginning to manufacture the devices, Defendant became aware post-market that the following manufacturing defects can occur with the device and lead to adverse consequences for Patients:

a. the Instructions for Use ("IFU") do not adequately address precautions to take when treating patients who have undergone transcatheter aortic valve replacement ("TAVR"). The IFU lacks guidance to clinicians on how to manage use of Impella in patients with TAVR and fails to describe how the issue may present if an Impella interacts with TAVR.

b. there is a potential risk for unintentional interaction of the Impella motor housing with the distal stent of a transcatheter aortic valve replacement (TAVR) resulting in destruction of the impeller blades. This has resulted in low flow from the damaged Impella system. Systemic embolization of the fractured impeller material is a possibility.

c. the damaged Impella system may have reduced blood flow or pump stop, which may delay therapy or fail to provide enough support to the patient. This could be life threatening in people who require high levels of support; and,

d. There is also a risk that pieces of the broken blades could enter the patient's bloodstream causing perforation, excessive bleeding, or hemolysis.

101. In 2022, in order to address the defects, Defendant added additional sensors to the Impella device called 'Smart Assist" modification. The Smart Assist modification that was incorporated into the Impella was utilized during Nancy Urquhart's surgery that resulted in her death.

DEFENDANT ENGAGED IN MISLEADING SALES AND MARKETING TACTICS

102. Defendant violated the Impella CPMA and §§ 502(q) and (r) of the FDCA and parallel state laws by engaging in misleading advertising of Impella.

103. Defendant continued to sell their product with misleading and false advertising in violation of the conditions of the Impella CPMA and state laws.

104. Defendant's advertising practices lead to litigation in Boston, Massachusetts.

105. Defendant knew or should have known Impella 's marketing campaign claims included misrepresentations and omissions of material safety information.

106. Defendant marketed the product as providing safer outcomes than other devices when studies concluded that the mortality rates were the same:

107. Defendant disseminated misleading information at a time when it knew or should have known there were no reasonable grounds for believing these claims to be true when considered in light of the post-market safety information in the possession of Defendant.

108. Despite the fact that evidence existed that the use of Impella was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose the health hazards and risks

associated with Impella to the FDA, physicians, and patients. Instead, Defendant marketed, advertised, and promoted Impella while failing to warn or otherwise ensure the safety of its users in violation of parallel state law, including Missouri law, the Impella CPMA, and FDA regulations.

109. Defendant advertised, promoted, and marketed on their websites, in print and/or video advertisements, brochures, and fact sheets stating the following about Impella , while failing to report the actual material facts: https://www.abiomed.com/en-us/products-and-services/impella/impella-55-with-smartassist

110. Doctors and patients, including Nancy Urquhart and her implanting physicians, relied on the misrepresentative marketing strategy developed by Defendants in Missouri.

111. Doctors and patients, including Nancy Urquhart and her implanting physicians, relied on these omissions and/or misrepresentations by Defendants.

112. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendant, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws."

113. Defendant's conduct not only violated its federal regulatory duties and its duties under state law, including Missouri law, but also failed to provide information that was necessary for the medical and scientific community to protect each patient's interest. Because the Defendant failed to timely, completely, or accurately report their knowledge of the risks and complications associated with the Impella device, the public's knowledge of the risks associated with the Impella device were seriously hampered and delayed. This delay of information endangered patient safety, including Nancy Urquhart's safety.

114. Only after the FDA forced Defendant to disclose the misleading information did the medical community become aware of this information, including data concerning the frequency, severity, and permanence of complications associated with the prescription and implementation of the Impella device.

115. This belated, untimely release of relevant information led to an increasing number of adverse events being reported to the FDA about Impella from patients and physicians.

116. Defendant's conduct violated the Impella CPMA, parallel state laws regarding post-marketing conduct, and the FDA post-marketing regulations, which ultimately prevented Plaintiff, physicians, and the public from understanding the true nature of Impella 's adverse events, risks, and ineffectiveness.

FDA REQUIRES WARNING FOR IMPELLA

117. Unfortunately, this new warning, labeling, and patient decision checklist came too late to warn Nancy Urquhart of the true risks of Impella. Had the Defendant complied with their federal regulatory duties and their duties under Missouri law by warning about and reporting the known risks and complications in a timely fashion, Nancy Urquhart and her physicians would have had this relevant, critical information available to them before the implantation of the Impella device.

118. At all relevant times, Defendant's Impella product was prescribed and used as intended by Defendant and in a manner reasonably foreseeable to Defendant.

PLAINTIFF-SPECIFIC ALLEGATIONS

119. On September 9, 2022, Nancy Urquhart, underwent a "Mitral Valve Replacement, Triscuspid Valve Repair, CABG x 1, insertion of 5.5 Impella, left atrial appendage exclusion, LLE saphenous vein harvest, placement of temporary pacing wires and intra-operativeTEE (N/A)" surgical procedure.

120. Lab Studies indicated the presence of hemolysis including but not limited to on the following dates and times; 09/09/2022 2207, 09/09/2022 2251, 09/10/2022 2121, 09/10/2022 2251, 09/11/2022 0104, 09/11/2022 1514, 09/11/2022 2110, 09/12/2022 0153, 09/12/2022 0339, and 09/12/2022 0935.

121. Nancy Urquhart was given multiple "fresh frozen plasma" / "open blood" transfusions due to persistent bleeding following the procedure including but not limited to on the following dates and times; 09/09/2022 1838, 09/10/2022 0051, 09/10/2022 0324, 09/10/2022 1745, 09/10/2022 1800, 09/11/2022 1141, 09/11/2022 1145, 09/11/2022 2112, 09/11/2022 2216, 09/12/2022 0431, 09/12/2022 0635, 09/12/2022 0921, 09/12/2022 0839, 09/12/2022 0930, and 09/12/2022 1158.

Nancy Urquhart's care givers noted:

"*…recovery complicated by bleeding….Multiple chemistry panels are unable to be completed due to hemolysis.*"

- **Luke Andrews, PA-C (09/10/2022)**

122. Nancy Urquhart, experienced a common sequela of hemolysis, which resulted in acute kidney injury and acute renal failure.

ORDER:
Consult to Nephrology
Reason for consult: "*Evaluation for acute renal failure*"

- **Luke Andrew Shoulders, PA-C (09/10/2022 1037)**

Cardiovascular:
"*…insertion of 5.5 Impella…this has been complicated by persistent shock and bleeding…*"

Renal:
"*Hyperkalemia…Potasium has been as high as 6.6…*"

- **Travis D. Homan, MD**
(09/11/2022 12:59 p.m.)

Nephrology: Progress Note:
"*Post op, patient arrived to ICU in cardiogenic shock, sedated intubated on pressors and Impella in place. Chest tubes in place. Fluid resuscitation give and blood products as well a reversal agents for coagulopathy, Patient required 4 pressors weaned on 9/12 to 2 pressors Epi and vasopressin. Cath done showed patent SVG to RCA and mild non obstructive CAD.*"

Review of Symptoms:
Hematologic: "*easy bruising / bleeding*"

Acute Kidney Injury: metabolite abnormalities (hypernatremia, hyperkalemia)

- **Dr. Nouthan Houjeji, MD**
(09/11/2022 2:02 p.m.)

123. On September 12, 2022, her physicians noted that hemolysis was caused by the Impella and explanted the device.

"Patient was seen and examined by me during CRRT today. Remains intubated, sedated, pressors, Impella is out due to intr vascular hemolysis and likely contributing to hyperkalmia. Severe hyperkalmia. Remains critically ill."

- **Mowaffaq R. Said, MD**
SSM Saint Louis University Hospital
(09/12/2022 at 3:06 p.m.)

124. Nancy Urquhart did not recover from her injuries, was comatose, and died on September 12, 2022.

Interval History:
"Overnight patient was hyperkalemic secondary intravascular hemolysis from Impella. Had to change prismasol to 2/0, and increased CRRT DFR to 3L/hr then to 5L/hr after potassium level went up to 7.2. CTS removed impella this morning 9/12. sedated intubated on 4 pressors with increase

in pressor requirement Code status changed to DNR, plan to withdraw care when rest of patient's family arrives"

- Dr. Nourhan Houjeij, MD
SSM Saint Louis University Hospital
(09/12/2022 at 4:22 p.m.)

125. Defendant is and was under a continuing duty to monitor and disclose the true character, quality, and nature of Impella. Because of Defendant's misconduct and fraudulent concealment of the true character, quality, and nature of its device, Defendant is estopped from relying on any statute of limitations defense.

CAUSES OF ACTION
FIRST CAUSE OF ACTION – NEGLIGENCE

126. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

127. Defendant formulated, tested, packaged, labeled, produced, created, made, constructed, assembled, advertised, manufactured, sold, distributed, marketed, and promoted Impella, including the Impella device that was utilized in Nancy Urquhart's surgery. The testing, development, marketing, promotion, and labeling conducted, in part, in Missouri was integral to Defendant's ability to distribute Impella to Nancy Urquhart and her physicians.

128. Defendant had a duty under parallel state law, including Missouri law, to exercise reasonable care to provide adequate warning about the risks and dangers of Impella that were known or knowable to Defendant at the time of distribution.

129. Defendant breached their duty in that they failed to warn Nancy Urquhart and her physicians by not reporting the risk of serious defects and life-altering complications described herein that Defendant knew or should have known were associated with Impella prior to the time

of Nancy Urquhart's surgery, including the actual level of risk and failure to communicate adverse events similar to the injuries suffered by Nancy Urquhart.

130. Specifically, Defendant breached its duties and violated federal and state law by, inter alia: receiving and failing to warn of or report many of the complaints about Impella to the FDA or the public; failing to warn of or report Impella 's failure to meet its performance specifications or perform as intended under the CPMA and FDA requirements; and receiving and failing to warn or report to the FDA and the medical community their knowledge and information regarding complaints about Impella , including but not limited to: instances of perforation, abnormal bleeding, and hemolysis.

131. Despite the fact that evidence existed that the use of Impella was dangerous and likely to place users at serious risk to their health, Defendant failed to disclose and warn of the health hazards and risks associated with Impella. Instead, Defendant marketed, advertised, and promoted Impella while failing to warn or otherwise ensure the safety of its users in violation of state law, including Missouri law, the Impella CPMA and FDA regulations.

132. In addition, the Impella CPMA set forth specific reporting requirements—as described above—that obligated Defendants to report:

a. knowledge or information of any adverse reactions, side effects, injuries, toxicity, or sensitivity reactions;
b. unanticipated adverse effects or increases in the frequency of anticipated adverse effects;
c. any knowledge or information of Impella 's failure to meet device specifications established in the approved CPMA;
d. any changes to the performance of the device;
e. changes to the facility or establishment to manufacture, process, or package the device;
f. whenever there is use of a different facility or establishment to manufacture, process, or package the device;

g. any information from any source that reasonably suggests a device has malfunctioned and would be likely to cause or contribute to serious injury if the malfunction were to recur; and,
h. any information from any source that reasonably suggests a device may have caused or contributed to serious injury.

133. Defendant negligently failed to comply with the above requirements and failed to take necessary actions—such as filing PMA Supplements, unilaterally updating its labeling through the CBE Process, or timely submitting MDRs—to advise users of Impella of the defects and risks described above.

134. The Defendant had the ability and the duty under state law to disclose its knowledge of adverse events to healthcare providers and the public to ensure its labeling and product were not misbranded.

135. Had Defendant timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Nancy Urquhart's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Nancy Urquhart and/or her physician, regarding the dangers of Impella that were known or knowable to Defendant at the time of distribution.

136. Defendant's delay in timely reporting their known complications prevented Nancy Urquhart and her physicians from having timely information concerning the real-life risks associated with the Impella device. Had Nancy Urquhart received timely and adequate information of these serious risks and adverse events, she would not have agreed to the use of the Impella device.

137. Defendant could have included this information in its labeling, physician use materials, and patient pamphlets, which Nancy Urquhart and her physician reviewed and relied upon, but

Defendant chose not to include it. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, physicians began to study Impella adverse events further and published articles in well-respected medical journals. This information would have been available for review by Nancy Urquhart and her physicians.

138. Indeed, if Nancy Urquhart and her physicians had been adequately warned of these serious risks and adverse events, they would not have agreed to or used the Impella. As a proximate and legal result of Defendant's failure to comply with its CPMA and FDA post-marketing regulations, Defendant breached their duty of care to Nancy Urquhart under parallel state law and caused Nancy Urquhart's death for which Plaintiff are entitled to compensatory and other damages in an amount to be proven at trial.

139. Defendant owed a duty in all of its several undertakings, including the communication of information concerning Impella, and to exercise reasonable care to ensure that they did not, in those undertakings, create unreasonable risks of personal injury to others

140. Defendant, in the course of its business and profession, knowingly and negligently disseminated inaccurate and misleading information through the Impella marketing strategy to physicians concerning the properties and effects of Impella with the intent and expectation that physicians would rely on that information in their decisions in recommending and prescribing Impella for their patients.

141. When Defendant disseminated information through the Impella marketing strategy to physicians and/or patients concerning the properties and effects of Impella , it knew or should have known that physicians and/or patients would reasonably rely on that information in their decisions concerning the use of Impella .

142. Defendant made these misleading representations at a time when Defendant knew, or should have known, that Impella had defects, dangers, and characteristics that were other than what Defendant had represented to consumers and the healthcare industry generally.

143. Defendant had reasonable grounds to avoid disseminating these misleading representations when they were made.

144. Defendant's breach of its duties under state law parallels its violations of federal law; the Impella CPMA specifically mandates, and state law independently requires, that any representations regarding the device must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

145. Defendant disseminated the misleading information through the Impella marketing strategy to prospective patients, physicians, the medical community, and the public with the intention to induce physicians to utilize the Impella during cardiac surgical procedures.

146. Defendant negligently failed to exercise reasonable care to ensure that the information disseminated to physicians and patients concerning the properties and effects of Impella was accurate and not misleading.

147. By failing to ensure representations regarding Impella were truthful, accurate, and not misleading, Defendant has violated the Impella CPMA, FDA regulations, and parallel state law.

148. Defendant expected or should have expected that patients, in reliance on misleading information, who underwent a cardiac surgical procedure wherein the Impella was utilized would be placed in unnecessary, avoidable, and unreasonable danger due to unwarranted exposure to Impella.

149. Nancy Urquhart and/or Nancy Urquhart's physicians did in fact reasonably rely on Defendant's negligent misrepresentations, as Defendant intended.

150. Specifically, Nancy Urquhart's physicians would have never recommended, and Nancy Urquhart would have never had Impella implanted, had they been aware of the complaints regarding Impella, or the Defendant's misrepresentations in the Impella marketing strategy.

151. As a proximate and foreseeable result of the foregoing misrepresentations by Defendant, Nancy Urquhart died causing Plaintiff to suffer and will continue to suffer severe emotional distress, mental anguish, economic loss, and other injuries.

152. Under federal law and regulations, Defendants were under a continuing duty to comply with the requirements listed in their CPMA and with the FDCA in the manufacture, development, promotion, marketing, labeling, distribution, and sale of Impella. See 21 U.S.C. ch. 9 §§ 301, et seq.

153. Violations of the following federal regulations also constitute violations of Defendants' parallel state law duties and give rise to negligence per se: 21 C.F.R. § 803.10; 21 C.F.R. § 803.50; 21 C.F.R. § 803.52; 21 C.F.R. §803.53; 21 C.F.R. § 803.56; 21, C.F.R. § 806; 21 C.F.R. § 814.1; 21 C.F.R. § 814.3; 21 C.F.R. § 814.9; 21 C.F.R. § 814.20; 21 C.F.R. § 814.37; 21 C.F.R. § 814.39; 21 C.F.R. § 814.80; 21 C.F.R. § 814.82; 21 C.F.R. § 814.84; 21 C.F.R. § 820.5; 21 C.F.R. § 820.20; 21 C.F.R. § 820.22; 21 C.F.R. § 820.25; 21 C.F.R. § 820.30; 21 § C.F.R. 820.70 and 21 C.F.R. § 820.160.

154. Nancy Urquhart was within the class of persons the statutes and regulations protect, and Nancy Urquhart's injuries and death is of the type of harm these statutes and regulations are designed to prevent.

155. Defendant's violations of these statutes and regulations proximately caused Nancy Urquhart's injuries and death alleged herein.

156. The conditions of the Impella CPMA incorporate these statutes and regulations. Failure to comply with the conditions of approval invalidates the CPMA. See 21 C.F.R. § 814.82(c).

157. The Defendant had a parallel duty under state law, including Missouri law, to exercise reasonable care in testing and inspecting their product, in performing continuing risk-analysis and risk assessments of Impella, and in marketing Impella to the public. The Defendant also undertook a duty to certify and train physicians on the proper implantation of the device.

158. The Defendant was negligent under state law, including Missouri law, in their development, promotion, marketing, distribution, and/or sale of Impella in one or more of the following particulars:

a. failing to conduct regular risk analysis of its Impella device, including a Design Failure Analysis, and failing to include and consider known complications from the device as part of its risk analysis processes;

b. in failing to properly meet the applicable standard of care by not complying with applicable federal regulations;

c. carelessly and negligently selling and distributing Impella in violation of the CPMA and federal law;

d. negligently incorporating components into Impella that could not stand up to normal usage;

e. failing to exercise reasonable care in its inspecting and testing of the product;

f. failing to exercise reasonable care to appropriately certify and train physicians on prescribing and implantation of the device.

159. The Defendant failed to exercise ordinary care in the manufacture, sale, testing, quality assurance, quality control, and/or distribution of Impella.

160. The Defendant failed to adequately inspect, test, and validate the materials and components used in the manufacture and assembly of Impella.

161. The Defendant failed to adequately inspect, test, and validate Impella after completion of assembly and immediately before delivery to Nancy Urquhart's physicians.

WHEREFORE, Plaintiff pray for judgment against Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) attorneys' fees and costs; (iv) punitive or exemplary damages according to proof; (v) injunctive relief; and (vi) such other and further relief as this Court may deem just and proper.

SECOND CAUSE OF ACTION - STRICT PRODUCTS LIABILITY

162. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

163. Defendant failed to warn Nancy Urquhart, and her physicians of the risk of serious defects and life altering complications described herein, rendering the device defective and unreasonably dangerous.

164. Specifically, Defendants failed to:

a. report Impella 's nonconformity with its performance specifications; and

b. update Impella 's labeling or report to the FDA and the medical community their postmarket information regarding complaints about Impella.

165. Defendant also failed to revise their labeling to warn of the accurate rate of occurrence of adverse events based upon the post-market adverse event information available to them.

166. Nancy Urquhart's Impella device was defective at the time of sale and distribution and at the time it left the possession of Defendant in that Defendant failed to adequately warn of the risks of perforation, penetration, blade breakage, abnormal bleeding, hemolysis, and pain, and other injuries involved in the use of Impella. The accurate rate of occurrence for these and other injuries associated with the use of Impella were not readily recognizable to the ordinary consumer, including Nancy Urquhart and/or her physicians

167. The Impella device was defective and unreasonably dangerous due to inadequate warnings and/or instruction because Defendant knew or should have known that the products created a serious risk of perforation, penetration, blade breakage, abnormal bleeding, hemolysis, and pain, and other harm to consumers, particularly with positioning, and Defendant failed to adequately warn consumers of said risks - including Nancy Urquhart and/or her healthcare physicians - in accordance with state law, including Missouri law.

168. The Impella device manufactured and sold by Defendant was defective and unreasonably dangerous due to inadequate warnings and instructions because Defendant knew or should have known that Impella created, among other things, a higher than expected risk for adverse events, and Defendant failed to adequately warn of those risks, to monitor those risks, report them, and update its labeling regarding such risks when the information became available.

169. At all relevant times, Nancy Urquhart's Impella device was prescribed and used as intended by Defendant and in a manner reasonably foreseeable to Defendant.

170. The Impella device manufactured, marketed, promoted, and sold by Defendant was expected to, and did, reach Nancy Urquhart without substantial change in the condition in which it was sold.

171. Despite the fact that Defendant knew or should have known that the use of Impella was unreasonably dangerous and likely to place users at serious risks to their health, Defendant failed to monitor and warn of the defects, health hazards, and risks associated with the Impella.

172. Nancy Urquhart's Impella device was also defective at the time of sale and distribution, and at the time the device left the possession of Defendant, in that the device differed from Defendant's intended result and design specifications and original approved device.

173. The Defendant violated state law, including Missouri law, by placing the Impella system into the stream of commerce in a defective and unreasonably dangerous condition.

174. The defects inherent in the Impella device were not readily recognizable to the ordinary consumer, including Nancy Urquhart and/or her physicians.

175. At all relevant times, Nancy Urquhart's Impella device was used as intended by Defendant and in a manner reasonably foreseeable to Defendant.

176. The Impella device manufactured, designed, promoted, marketed, and sold by Defendant was expected to, and did, reach Nancy Urquhart without substantial change in the condition in which it was sold and included unapproved modifications including the "Smart Assist" modification.

177. Defendant knew that the Impella device would be used by the ordinary purchaser or user without inspection for defects and without knowledge of the hazards involved in such use.

178. At all times relevant to this action, the dangerous propensities of Impella were known to Defendant or were reasonably and scientifically knowable to it, through appropriate research and testing by known methods, at the time they distributed, supplied, or sold the device, and not known to ordinary physicians who would be expected to utilize Impella during their patients' cardiac surgical procedures.

179. Defendant knew that physicians and other healthcare providers began prescribing this product as a safe and effective blood pump device despite its potential for serious, severe, and permanent side effects.

180. Defendant was required to provide adequate warnings to consumers and the medical community under federal and state law, including Missouri law, but failed to do so in a timely and responsible manner.

181. Had Defendant timely and adequately reported the adverse events to the FDA, there would have been effective warnings to physicians, including Nancy Urquhart's physician, of those adverse events both directly and through discussion of those events that would have followed in the literature and at meetings. Thus, additional information would have been available to the public, including Nancy Urquhart and/or her physicians, regarding the dangers of Impella that were known or knowable to Defendant at the time of distribution.

182. In this case, once the medical community and the FDA became aware of the undisclosed adverse events, the FDA held a public hearing discussing the risks and benefits of the device and then required a new warning that warns of many of the same injuries that Plaintiff have experienced due to Impella.

183. Defendant's delay in timely reporting their known complications prevented Nancy Urquhart and her physicians from having updated information concerning the real-life risks associated with the Impella device. Had Nancy Urquhart and her physicians received timely and adequate information of these serious risks and adverse events, she would not have agreed to the Impella implant, nor would her physicians have recommended use of this product.

184. Further, because Defendant failed to follow specifications, regulations, and required Good Manufacturing Practices, Nancy Urquhart's surgery was complicated by the Impella device which caused hemolysis resulting in her death.

185. Impella, which was manufactured, distributed, tested, sold, marketed, promoted, advertised, and represented defectively by Defendant, was a substantial contributing factor in bringing about Nancy Urquhart's injuries and death, which would not have occurred but for the use of the Impella device.

186. The defective warnings were a substantial contributing factor in bringing about Nancy Urquhart's injuries and death that would not have occurred but for the use of the Impella device.

187. As a proximate result and/or substantial factor of the Impella 's defective condition at the time it was sold, Nancy Urquhart died causing damages to her survivors.

188. By reason of the foregoing, Plaintiff have been damaged by Defendant's wrongful conduct. Defendant's conduct at the very least arose to the level of gross negligence so as to indicate a disregard of the rights and safety of others, justifying an award of punitive damages.

WHEREFORE, Plaintiff pray for judgment against Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) attorneys' fees and costs; (iv) punitive or exemplary damages according to proof; and (v) such other and further relief as this Court may deem just and proper.

THIRD CAUSE OF ACTION - BREACH OF EXPRESS WARRANTY

189. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

190. Defendant expressly warranted Impella to be safe for use by the general public, including Nancy Urquhart and/or her healthcare providers.

191. Defendant also expressly warranted that Impella was safer and more effective than other methods of short-term support of the pumping chambers of the heart (ventricles) during high-risk catheter-based procedures called percutaneous coronary interventions ("PCI") or when a patient is suffering from ongoing cardiogenic shock.

192. Defendant's express warranties disseminated through Defendant's marketing strategy were specifically and expressly communicated to Nancy Urquhart in such a manner that Nancy Urquhart understood and accepted them.

193. Defendant's affirmations of fact or promise and descriptions of Impella disseminated through Defendant's marketing strategy created a basis of the bargain for Nancy Urquhart and/or her physicians.

194. At the time of making of the express warranties, Defendant had knowledge of the purpose for which Impella was to be used and warranted the device to be in all respects fit, safe, effective, and proper for such purposes. Impella was unaccompanied by adequate warnings of its dangerous propensities and lack of effectiveness that were either known or knowable to the Defendant at the time of distribution and sale.

195. The Defendant's breaches of their express warranties under state law parallel their violations of federal law; the Impella CPMA specifically mandates, and state law, including Missouri law, independently requires that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws. The warranties developed through the Defendant's marketing strategy were misleading and not consistent with applicable federal and state laws.

196. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendant, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws."

197. Nancy Urquhart and/or her healthcare providers reasonably relied upon the skill and judgment of Defendant, and upon said express warranties, in using Impella . The warranties and representations developed through the marketing strategy Defendant were misleading in that Impella was unsafe and unsuited for the use for which it was intended.

198. As soon as the true nature of Impella and the fact that the warranties and representations were misleading was ascertained, Defendant was on notice of the breach of said warranties.

199. As a proximate result of Defendant's warranties and Nancy Urquhart and her physicians' reliance on same, Nancy Urquhart died causing damage to her survivors who have suffered and continue to suffer severe emotional distress, mental anguish, economic loss, and other injuries.

WHEREFORE, Plaintiff pray for judgment against Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) attorneys' fees and costs; (iv) punitive or exemplary damages according to proof; and (v) such other and further relief as this Court may deem just and proper.

FOURTH CAUSE OF ACTION BREACH OF IMPLIED WARRANTY

200. Plaintiff incorporates by reference all previous and subsequent paragraphs of this Petition as if fully set forth herein and further allege as follows:

201. At all relevant times, Defendant manufactured, compounded, packaged, distributed, recommended, merchandised, advertised, promoted, supplied, and sold Impella.

202. Prior to Nancy Urquhart's physicians' utilization of the Impella during Nancy Urquhart's cardiac surgery, Defendant's impliedly warranted to Nancy Urquhart and her health care providers that Impella was of merchantable quality, reasonably fit for its intended purpose, and safe for the use for which it was intended.

203. Defendant also warranted that Impella was safer and more effective than other methods for short term support of the pumping chambers of the heart (ventricles) during high-risk catheter-based procedures called percutaneous coronary interventions ("PCI") or when a patient is suffering from ongoing cardiogenic shock.

204. At all relevant times, Nancy Urquhart's physicians used the Impella device for the purpose and in the manner intended by Defendant.

205. At all relevant times, the Impella device was not reasonably safe for its expected purpose, nor reasonably fit for the ordinary purpose for which it was sold and/or used, and it did not meet the expectations for the performance of the product when used in a customary, usual and reasonably foreseeable manner.

206. Nancy Urquhart and/or her healthcare providers reasonably relied upon the skill and judgment of Defendant and upon said warranties in using Impella.

207. The Defendant's breaches of its implied warranties under state law parallel its violations of federal law; the Impella CPMA specifically mandates, and state law, including Missouri law, independently requires, that any warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws.

208. In its CPMA, the FDA explicitly declined to approve any warranties made by Defendant, such as those set forth herein, stating: "CDHR does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable federal and state laws."

209. As soon as the true nature of Impella and the fact that the warranties and representations were misleading was ascertained, Defendant was on notice of the breach of said warranties.

210. As a proximate and legal result of Defendant's breach of warranty, Nancy Urquhart died causing her survivors to suffer and will continue to suffer severe emotional distress, pain and suffering, mental anguish, loss of consortium, economic loss, medical expenses, funeral and burial expenses, and other injuries.

WHEREFORE, Plaintiff prays for judgment against Defendant in an amount in excess of Seventy Five Thousand Dollars ($75,000.00), awarding (i) economic and non-economic damages in an amount as provided by law and to be supported by evidence at trial; (ii) compensatory damages according to proof; (iii) attorneys' fees and costs; (iv) punitive or exemplary damages according to proof; and (v) such other and further relief as this Court may deem just and proper.

Respectfully submitted,

/s/ Michael L. McGlynn
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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **"Plaintiff' First Amended Complaint"** has been electronically served on counsel via the PACER e-File system, or electronic mail, on this 31st day of January 2025. Under penalties of perjury as provided by law, I certify that the statements in this affidavit are true.

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