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CAUSE NO. 2018-45639

DR. O. HOWARD "BUD" FRAZIER,	§	IN THE DISTRICT COURT OF
PLAINTIFF	§	
	§	HARRIS COUNTY, TEXAS
v.	§	
	§	234TH JUDICIAL DISTRICT
	§	
PROPUBLICA, INCORPORATED;	§	
HEARST NEWSPAPERS, LLC d/b/a	§	
THE HOUSTON CHRONICLE,	§	
CHARLES ORNSTEIN,	§	
AND	§	
MICHAEL HIXENBAUGH,	§	
DEFENDANTS	§	

FIRST AMENDED PETITION

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TO THE HONORABLE JUDGE OF SAID COURT:

Dr. O. Howard "Bud" Frazier files this lawsuit for defamation against Defendants *ProPublica*, its reporter, Charles Ornstein, the *Houston Chronicle*, and its reporter Michael Hixenbaugh (collectively, Defendants). Defendants published an article about Dr. Frazier that ran with his picture—lifted from a previous, laudatory article about him—and a headline that ***unequivocally*** accuses Dr. Frazier of illegal and unethical medical practices: "***A Pioneering Heart Surgeon's Secret History of Research Violations, Conflicts of Interest and Poor Outcomes***."

Beginning with the defamatory headline and continuing throughout the article the Defendants printed a virtual cornucopia of allegations and accusations calculated to falsely portray Dr. Frazier as an inhumane physician who "put[] his quest to make medical history ahead of the needs of some patients."

In fact, Dr. Frazier, having transplanted 1,200 hearts, is widely regarded as the leading heart transplant surgeon in the world and as the medical researcher most responsible for the creation of the Left Ventricular Assist Device ("LVAD")—a lifesaving device implanted in the hearts of mortally ill patients that pumps blood through the heart when the heart can no longer pump blood on its own. LVADs have now received approval from governments around the world and have been implanted in tens of thousands of mortally ill patients—whose lives have been saved and extended in numbers far in excess of the predicted rate. As Defendants knew,

that is the true portrait of Dr. Frazier, but not the one that sells newspapers.

This petition demonstrates with example after example that the Defendants intended to mislead their readers and create a false impression of Dr. Frazier by printing accusations and allegations about him that Defendants (1) knew were false, (2) printed without regard to their truth or falsity, (3) printed with conscious disregard for the truth, and/or (4) printed with material facts omitted. Defendants did this despite having in their possession public records and other documents that put the lie to their portrayal of Bud Frazier and his alleged "secret history" of unspeakable, illegal acts, including that he implanted LVADs in patients who did not need them or left LVADs in patients who should have received a transplant instead.

As a result of their defamatory article, Defendants published a second article about Dr. Frazier in response to dozens of letters criticizing the Defendants' accuracy and praising Dr. Frazier, including letters from former patients or their family members, as well as letters from physicians, surgeons, and researchers who actually understand this complex field. In one of the letters, a distinguished cardiothoracic surgeon pointed out a significant flaw that rendered the Defendants' analysis of Dr. Frazier's mortality rate among Medicare implant patients meaningless. Despite acknowledging the flaw, the Defendants doubled down in the second article with this self-effacing conclusion: "We stand by our reporting and

have found no instances of errors."

No instances of errors? They were not looking. As this petition demonstrates, the first article is defamatory per se. The second article actually contains one absolutely false statement, one sleazy attempt to shade the truth and one deceitful attempt to dismiss as meaningless their admitted, irretrievably flawed "analysis" of Dr. Frazier's mortality rates in Medicare patients.

It is for these reasons that Dr. Frazier files this suit and shows as follows:

I. DISCOVERY-CONTROL PLAN

1. Discovery will be conducted pursuant to Level 3 of the Texas Rules of Civil Procedure 190.4.

II. PARTIES

A. Plaintiff

2. Plaintiff Dr. O. Howard "Bud" Frazier is a resident of Houston, Harris County, Texas.

B. Defendants

3. Defendant Hearst Newspapers, LLC d/b/a the *Houston Chronicle* is a Delaware Limited Liability Company duly authorized to conduct business in the State of Texas. The *Houston Chronicle* may be served with process through its registered agent, CT Corporation System, 1999 Bryan, Street, Suite 900, Dallas, Texas 75201.

4. Defendant ProPublica, Incorporated is a New York corporation with its principal place of business in the State of New York. *ProPublica* can be served at 155 Avenue of the Americas, 13th Floor, New York, New York 10013.

5. Defendant Charles Ornstein is Senior Editor of *ProPublica.* He can be served at his place of employment, 155 Avenue of the Americas, 13th Floor, New York, New York 10013.

6. Defendant Michael Hixenbaugh is an investigative reporter at the *Houston Chronicle.* He can be served at his place of employment 4747 Southwest Freeway, Houston, Texas 77027.

III. RESPONDEAT SUPERIOR

7. When Defendant Ornstein acted in the manner described in this Petition, he did so as an agent of *ProPublica* and within the scope of his authority from *ProPublica*. *ProPublica* is liable for the damages proximately caused by the conduct of its employees and agents, including Defendant Ornstein, pursuant to the doctrine of respondeat superior.

8. When Defendant Hixenbaugh acted in the manner described in this Petition, he did so as an agent of the *Houston Chronicle* and within the scope of his authority from the *Houston Chronicle*. The *Houston Chronicle* is liable for the damages proximately caused by the conduct of its employees and agents, including Defendant Hixenbaugh, pursuant to the doctrine of respondeat superior.

IV. VENUE

9. Venue for this suit is proper in Harris County, Texas, under Texas Civil Practice & Remedies Code Section 15.002(a)(1) because Harris County is the county in which all or a substantial part of the events giving rise to the claim occurred.

V. BACKGROUND

> "Bud Frazier had a different view of the world. If he had had the modern view, this field wouldn't exist, and tens of thousands of patients wouldn't be alive."
>
> —Dr. Billy Cohn, renowned Texas heart surgeon

A. Dr. Bud Frazier.

10. During his career, Dr. Frazier has performed more heart transplants than any other surgeon in the world and is widely acknowledged among his peers to be the world's leading heart transplant surgeon. However, heart transplants are difficult and the recovery rocky. For that reason, Dr. Frazier has dreamed since medical school of creating a fully mechanical heart that would take over the work of failing human hearts.

B. *Houston Chronicle* Reporter Michael Hixenbaugh's Reversal: In 2017, Hixenbaugh lauds Dr. Frazier and his work, but in 2018, Hixenbaugh claims Dr. Frazier is unethical and a fraud.

11. Just last year, Dr. Frazier's career and his lifelong goal were chronicled in a front-page story written by Defendant Michael Hixenbaugh—entitled "Five decades later, famed surgeon Bud Frazier continues quest for an artificial heart"

("2017 Article")—excerpted here:

> Fifty-one years ago—before he became Dr. Frazier, before he went to work developing a device to completely replace the human heart, before he set the record as the world's most prolific heart transplant surgeon—Bud Frazier was a 25-year-old medical student trying desperately to save a young man's life.
>
> . . .
>
> His weathered hands have held many devices over the years that promised to replicate the work of the human heart. He helped develop and test many of them here at the Texas Heart Institute. All have fallen short of the ultimate goal.
>
> . . .
>
> More success has come from the development of heart pumps, like the left ventricular assist device Frazier pioneered in the 1980s, which mimic the action of the left and right ventricles (sic), keeping patients alive long enough to receive heart transplants or giving a few extra years of life to those who aren't candidates for a donated organ.

Exhibit A.

12. By 2018, however, Hixenbaugh changed his mind. In concert with a reporter from *ProPublica*, Defendant Charles Ornstein, Hixenbaugh wrote a piece savaging Dr. Frazier's career as a heart surgeon and researcher ("2018 Article"). The 2018 Article is riddled with false statements, some made out of ignorance, some made knowingly, some made recklessly, but all of them calculated to support a malicious, defamatory headline: "A Pioneering Heart Surgeon's Secret History of Research Violations, Conflicts of Interest and Poor Outcomes." Exhibit B.

13. The 2018 Article ran first on Thursday, May 24, 2018, on *ProPublica*'s website, with both reporters' bylines and a credit to the *Houston Chronicle*. The

same day, the *Houston Chronicle* created a link to the story in its online edition. The next Sunday—the day of the week that the *Houston Chronicle* enjoys one of its two largest audiences—the story ran above the fold, with a picture of Dr. Frazier lifted from Hixenbaugh's previous, favorable article.

14. For reasons best known to him, Hixenbaugh failed to mention in the 2018 Article that, just the year before, he had written the 2017 Article, lionizing Dr. Frazier and his "weathered hands" in search of that "Holy Grail." Or, maybe the reason is not known just to Hixenbaugh. Perhaps he failed to mention the 2017 Article because it would call his credibility into question because he cannot credibly explain his 180-degree turn regarding Dr. Frazier's career and work or his reliance on "source material" that he knew to be dubious—including, as just one example, an accusation that would have been easily refuted by a simple Google search. The portrait Hixenbaugh and Ornstein painted of Dr. Frazier in 2018 is unrecognizable from the real man—and the person Hixenbaugh portrayed in the 2017 Article.

15. On June 29, 2018, approximately a month after the 2018 Article was published, *ProPublica* and the *Houston Chronicle* published another article, this one defending the defamatory statements in the 2018 Article—"Supporters of a Famed Houston Surgeon Have Alleged Inaccuracies in Our Investigation. Here's Our Response" (hereinafter, "Making Matters Worse Article"). Exhibit C. Instead of retracting their defamatory statements or correcting their inaccuracies, Hixenbaugh

and Ornstein doubled down:

> Several dozen people have authored letters defending Dr. O.H. "Bud" Frazier and criticizing an investigation by ProPublica and the Houston Chronicle. *We stand behind our story*.

Id. at 1 (emphasis added).

C. Dr. Frazier's lifelong journey to create an artificial heart.

16. To understand just how badly the 2018 Article defamed Dr. Frazier, it is necessary to digress a bit, first to 1991 and then to 2000, and to discuss just two of Dr. Frazier's many contributions to medical science and prolonging lives—tens of thousands of lives. These facts alone, publicly known, make it clear that Hixenbaugh and Ornstein could not have depicted Dr. Frazier as they did without defaming him and certainly make it clear that Dr. Frazier did not harbor some dark and secret history of ethical and research violations.

17. Dr. Frazier became Director of Cardiovascular Surgery Research, Cullen Cardiovascular Research Laboratories at the Texas Heart Institute (THI). THI was founded by world-renowned cardio vascular surgeon Dr. Denton A. Cooley in 1962. THI is a "nonprofit organization dedicated to reducing the devastating toll of cardiovascular disease through innovative and progressive programs in research, education and improved patient care."[1] The nonprofit is affiliated, housed, and supported by another nonprofit St. Luke's Episcopal Health System.

[1] https://www.texasheart.org/the-institute/about-us/

18. Until 1991, a patient with a LVAD was most often tethered via a long pneumatic tube to cumbersome equipment plugged into an electrical outlet, which was needed to supply power to the patient's air-driven LVAD. *See* Image 1. The United States Food and Drug Administration (FDA) regulations required these patients to stay in a hospital room until a suitable donor heart could be found for a transplant.

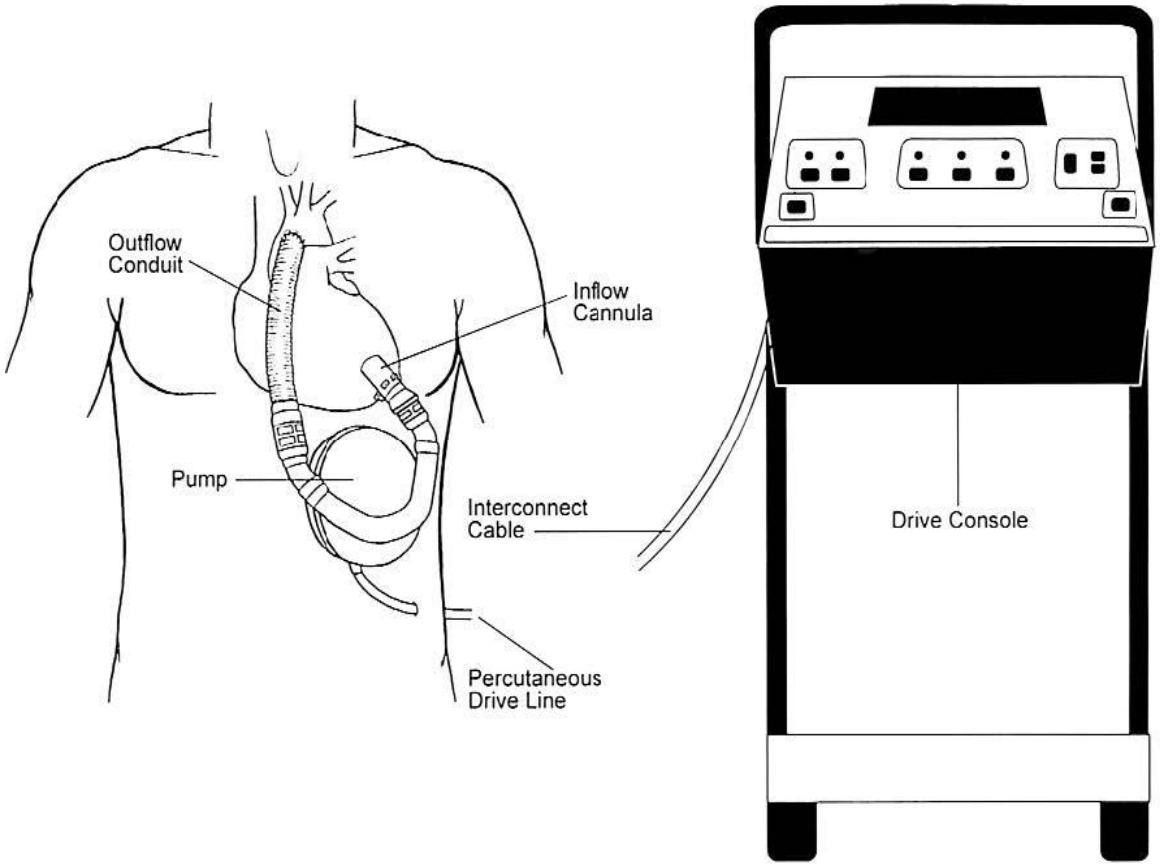

Image 1: External Ventricular Assist Device

19. In 1991, Dr. Frazier implanted the first electrical version of the LVAD, which he had helped to develop. *See* Image 2. FDA regulations also kept this patient

hospital bound for the first year after his implant, but he only wore a battery pack on his body, which allowed him to move freely about the hospital. Ultimately, the FDA deemed the device safe enough for the patient to leave the hospital—the first person in history to do so. All he needed to support the device was a battery pack.

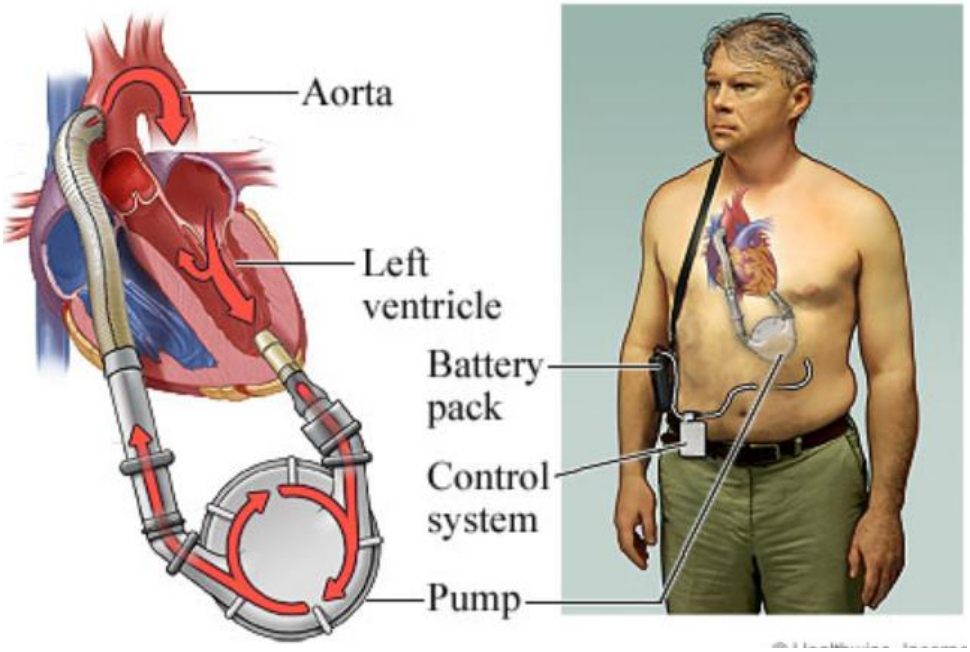

Image 2: Battery-Powered Left Ventricular Assist Device

20. Sixteen months following implantation of the LVAD, the patient died. The LVAD had functioned well, but was designed to keep the patient alive only until a matching heart could be found for what is called a bridge to transplant, meaning what it says—a device to keep the patient alive until a donor heart could be found. A donor heart that matched this patient's size and blood type was never located.

21. Despite the patient's death, the LVAD was considered a scientific success—a relative term in heart surgery—and LVAD studies slowly began to crop

up around the United States. The acknowledged leader in those experimental studies remained Dr. Frazier, who had championed assist devices since the 1980s, and THI, which he headed, and where most of the major breakthroughs occurred.

22. Subsequently, Dr. Frazier started to work with a different type of device that would be smaller, more efficient and deliver blood in what is called continuous flow—flow without a pulse. In 2000, Dr. Frazier and his team implanted a Jarvik 2000 continuous-flow pump with fully rechargeable batteries into the left ventricle. *See* Image 3. This device saved a woman who went on to have a heart transplant seventy-eight days after the implant of the Jarvik 2000.

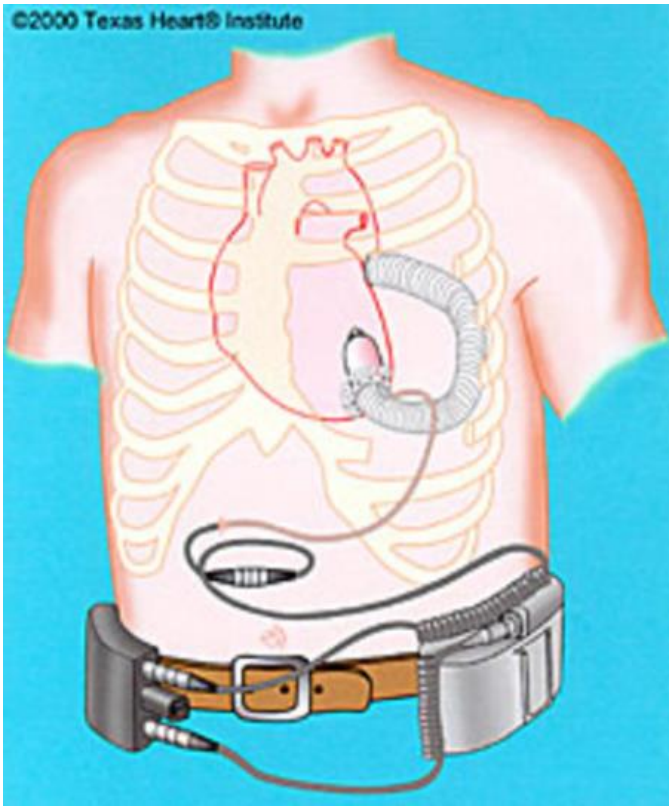

Image 3: Jarvik 2000

23. Next came another LVAD, this one from Thoratec, the HeartMate II—another continuous-flow (nonpulsatile) device. *See* Image 4. Dr. Frazier was also the first to implant this device.

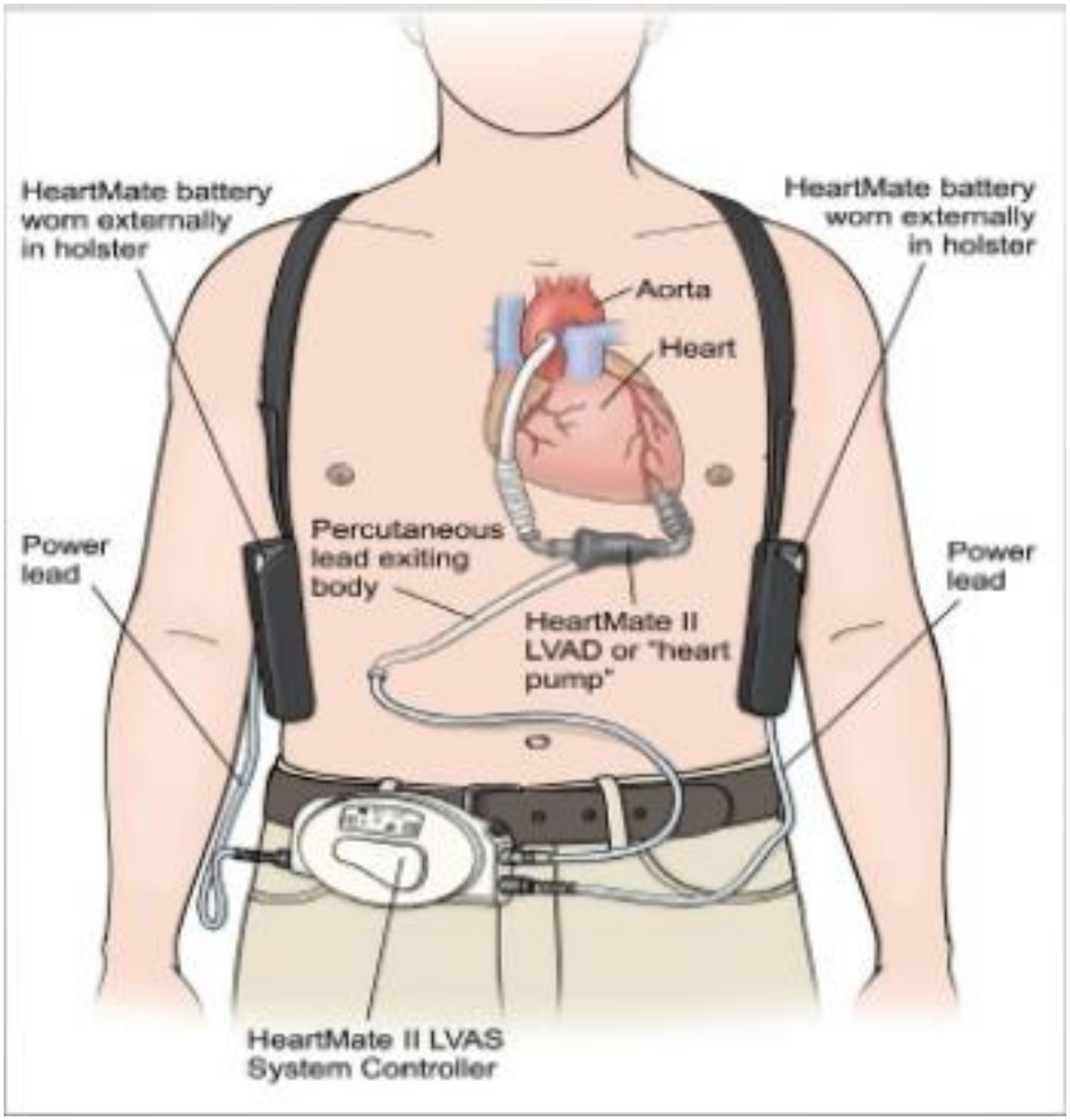

Image 4: HeartMate II

24. After the successful completion of the HeartMate II Clinical Study in

2008, the HeartMate II became the most widely used LVAD worldwide, and Dr. Frazier continued his efforts to develop a total artificial heart. Dr. Frazier's groundbreaking achievements, each a step toward more effective LVADs and a total heart replacement, along with his awards and decorations for his wartime service in Vietnam, can be found at https://en.wikipedia.org/wiki/O._H._Frazier.

D. HeartMate II Clinical Study.

25. Several companies developing LVADs sought approval from the FDA to market their devices. Many of them approached Dr. Frazier to learn what they could about the device's design and function. Dr. Frazier gave his advice freely. He never claimed what he knew was a trade secret or belonged only to him or THI (although his ideas surely were) and never sought to patent an LVAD (although he and THI surely would have received one). Either scenario would have made Dr. Frazier, as it soon did others, hundreds of millions of dollars.

26. Thoratec, one of the companies that sought Dr. Frazier's advice, sponsored a nationwide study—the HeartMate II Clinical Study. Patients were placed in one of two categories: Bridge to Transplant (BTT) and Destination Therapy (DT). As noted, the BTT meant that the LVAD would keep the patient alive until a donor heart could be found. DT meant that the patient would not have the LVAD removed for a transplant and would live as long as possible with his own heart supported by the LVAD. The BTT study was conducted at twenty-six

investigational sites. THI was selected to be one of the sites and enrolled nine of the 133 patients enrolled in the study—6.7%. The DT study was conducted at thirty-eight investigational sites. THI was selected to be one of the sites and enrolled thirteen of the 200 patients enrolled in the study—6.5%. It is important to note—because the 2018 Article did not—that FDA approval did not rise and fall based on the results at THI.

27. As discussed further below, before the HeartMate II Clinical Study could begin, the FDA required Thoratec to create and implement a stringent "Approval Protocol" for patients to be admitted into the study. There were also limited FDA-created exemptions for a patient to receive a HeartMate II outside of the sponsor's Approval Protocols. Further, the FDA required participating surgeons and clinical researchers to participate in rigorous training on the Approval Protocols before the HeartMate II Clinical Study could begin.

1. Rigorous "Approval Protocol" followed when selecting patients for the HeartMate II Clinical Study.

28. Patients were placed in one of two categories—BTT and DT. Those in the BTT category had Stage 4 heart failure—the deadliest category—and were eligible for heart transplantation. Those in the DT category exhibited advanced heart failure symptoms, but were ineligible for heart transplantation.

29. Patients for the HeartMate II Clinical Study had to be referred to Dr.

Frazier by the patient's cardiologist or to Dr. Frazier directly for an LVAD "work-up." If the patient had not been referred directly to Dr. Frazier, before any implantation, Dr. Frazier was required to obtain the agreement of the cardiologist admitting the patient. Even after the patient was referred to or came directly to Dr. Frazier, there were many criteria for inclusion and exclusion from the core study group.

30. Before Dr. Frazier or any heart surgeon in the study was allowed to implant a HeartMate II, the patient was screened through a rigorous Approval Protocol implemented by Thoratec and approved by the FDA. Compliance with the Approval Protocol also was monitored by the FDA.

31. In addition, a St. Luke's Medical Review Board, comprised of a surgeon, two cardiologists, a social worker, dietician, finance representative, and others depending on the patient's health condition (e.g., a nephrologist) had to approve the implant under criteria (the Approval Protocol) established by Thoratec.

32. Also, St. Luke's Internal Review Board (IRB) was responsible for overseeing the Study and was composed of at least five members (doctors, nurses, and at least one lay member) who primarily had experience with the subject of the review. Generally, many more individuals were included on the IRB, including psychologists, pharmacists, and personnel familiar with clinical monitoring.

33. Additionally, Dr. Frazier was required to obtain permission from

Thoratec, which had to be satisfied that the patient met the Approval Protocol or it would not provide the HeartMate II. The most important qualifying criteria were that the patient was near death, that the patient's heart condition was deteriorating, and that there was no other reasonable choice to save the patient's life.

2. Compassionate or Emergency Use Exemptions: FDA-created exceptions to the Approval Protocol.

34. Outside of the Approval Protocol used for patients in the HeartMate II Clinical Study, a patient could receive an LVAD through Compassionate or Emergency Use Exemptions—FDA-created exceptions to the Approval Protocol. In order to use the Exemptions, the LVAD could only be implanted if two doctors—other than the heart surgeon who would implant the device—agreed the patient was near death. In those cases, use of the LVAD still required the approval of the IRB, as well as Thoratec's approval. Thoratec, in turn, was required to and did notify the FDA of the facts and circumstances surrounding its approval.

3. FDA required participating surgeons and clinical researchers to train extensively on the Approval Protocol.

35. As indicated *supra*, the FDA required layer-after-layer of approvals and monitoring of each patient's records in the HeartMate II Clinical Study, as in all such studies, to ensure that the patients were treated with the utmost care and that the results were reported accurately. The device itself, in this case the HeartMate II, had to be proven for both safety and efficacy. Otherwise, the FDA will not approve a

device (or a food or a drug, etc.) for marketing.

36. Thus, before the HeartMate II Clinical Study—and the Jarvik 2000 Clinical Study—could begin, the FDA required all surgeons and clinical researchers participating in the Study receive training in the surgical procedures, protocols, and record keeping required by the Approval Protocol. For obvious reasons, Thoratec selected Dr. Frazier, Chief of the Center for Cardiac Support and Director of Cardiovascular Surgery Research at THI, and his team, to provide that training.

4. HeartMate II unanimously approved by the FDA for marketing to the public.

37. Following the successful conclusion of the HeartMate II Clinical Study, Thoratec filed a Premarket Approval application with the FDA, requesting approval to market the device for use as a Bridge to Transplant. For about a year, investigators at the FDA examined patient files from the BTT aspect of the HeartMate II Clinical Study, searching for non-compliance with the Approval Protocol or any other serious violations of FDA rules and regulations. In addition, the law requires the FDA to engage an independent body consisting of experts in the field, bioethicists, and other qualified professionals, along with citizen representatives, to study the records and results and provide a recommendation. The FDA's advisory panel concluded its review and unanimously recommended the BTT use of the HeartMate II for FDA approval on November 30, 2007. Exhibit D.

38. On April 21, 2008, the FDA approved the HeartMate II for the BTT indication. Two years later, on January 20, 2010, the device was approved for use as Destination Therapy. The FDA's European counterpart had already conducted its own studies and approved the device for a Conformité Européenne (CE) mark—approval for marketing—in November 2005. In addition to Germany, France, Greece, Spain, Italy, Netherlands, Denmark, Iceland, Switzerland, the United Kingdom, Belgium, Slovakia, Bulgaria, Sweden, Czech Republic, and other European countries, many other nations followed suit, following their own investigations, including Japan, Israel, and Kazakhstan. *See, e.g.,* Exhibit D at 13.

39. Presently, an estimated 40,000 LVADs have been implanted worldwide—all because one persistent doctor—Bud Frazier—continued to believe in the success of the device.

6. The success of the HeartMate II, according to Thoratec, which constantly follows up with patients who receive its implants, has exceeded those predicted by the results of the initial Clinical Study discussed above. In fact, one patient from the original study, thirteen years out, still has the LVAD supporting his heart. He has never wanted a transplant—which brings significant problems of its own from immune suppression and attendant medications—and continues to thrive at age 30. Here is Patient #2, an example of Dr. Frazier's "serious and repeated . . . research violations" according to Hixenbaugh and Ornstein:

Image 5: Patient #2

5. <u>FDA conducts onsite audits at THI in 2006 and 2009, each time inspecting the records of HeartMate II Clinical Study patients.</u>

40. In both 2006 and 2009, the FDA conducted on-site audits at THI to inspect patient records and related documents from the LVAD study. The first visit in August 2006 resulted in a clean bill of health, or, in FDA terms, an NAI—No Action Indicated—meaning that the investigator found no violations of FDA rules and regulations. Exhibit E at 1.

41. The second visit—called a "CDRH PMA-Based High Priority Directed, Clinical Investigator Data Validation Inspection"—occurred between June 2 and June 18, 2009. During that visit, the FDA investigator(s) spent nine work days

at THI examining the patient records related to the "The Evaluation of the HeartMate II left Ventricular Assist system – Destination Therapy Protocol." Exhibit E. In the 2018 Article, Hixenbaugh and Ornstein provided a link to the investigator's "Abbreviated Report," which found "*minor* discrepancies" in the THI study, but concluded: "The regulatory documents, patient records, and study files I reviewed indicated the study was well controlled and documented. I did not observe any *unreported adverse events* for any of the subjects enrolled." *Id.* at 4 (emphasis added).

42. There is no ethical way to harmonize the FDA's nine-day audit with the 2018 Article's vicious narrative about Dr. Frazier's "serious and repeated . . . research violations." Hixenbaugh and Ornstein found a way. They actually changed the FDA's finding of "minor discrepancies" in the study to "some deficiencies," elevating a matter of little moment to what is made to appear to be a series of bad acts. *Compare* Exhibit B at 9, *with* Exhibit E at 1. Taken by itself, that may have been an honest mistake. However, viewed in the context of the entire article, changing a word to manipulate a meaning is but one example of many showing Hixenbaugh and Ornstein's reckless disregard for the truth when stitching together the 2018 Article.

VI. THE 2018 ARTICLE: RECKLESS JOURNALISM & FALSEHOODS

43. Despite decades of monitoring, some of it required by law, some of it

required by medical ethics, but all of it very real; despite a *public record* that is testament to multiple layers of monitoring by St. Luke's, Thoratec (the sponsor), and the FDA; despite a massive paper trail demonstrating Dr. Frazier's assiduous observance of research protocol and his famous devotion to his patients; despite his pioneering, decades-long effort to develop a durable continuous heart-flow pump; despite the hard-won FDA approval of the HeartMate II and other LVADs, all of which started at Bud Frazier's desk; despite, most importantly, the tens and thousands of men and women brought back from the brink of death by the device that Dr. Frazier dreamed of and made a reality; despite all this, Hixenbaugh and Ornstein chose to savage Dr. Frazier's reputation and to accuse him of a "Secret History of Research Violations, Conflicts of Interests and Poor Results."

44. One might wonder: how is it that Dr. Frazier has ***never*** been sued for malpractice (which Hixenbaugh and Ornstein knew and failed to report), much less kept his medical license (given that St. Luke's, Thoratec, and the FDA scrupulously monitored his every decision, and that of his colleagues, to implant an LVAD, as well as the outcome of his surgeries)?

45. How is it that only these two dogged researchers—Hixenbaugh and Ornstein—were able to wrench Dr. Frazier's dark secrets of "serious and repeated research violations" from their sources and source materials when no one and no entity did? Did everyone involved at every level cover up Dr. Frazier's

malfeasance? Or, could it be that Hixenbaugh and Ornstein tortured what they learned into the vicious, false narrative about Dr. Frazier, resolving every question against him, ignoring the overwhelming evidence of oversight and monitoring, disregarding the well-documented warnings that their sources and source material were not reliable and Dr. Frazier's famous devotion to his patients—just to pursue a Pulitzer Prize at Bud Frazier's expense?

46. If one were searching for the truth, how did Hixenbaugh and Ornstein reach such vicious conclusions about Dr. Frazier's honesty and integrity? The answer is simple: ***garbage in, garbage out***. Using example after example of their reporting, this petition demonstrates just how far Hixenbaugh and Ornstein were willing to go to destroy Dr. Frazier's reputation, including Hixenbaugh and Ornstein's reliance on sources that they knew were deeply flawed, obviously untrue or wildly exaggerated. It was the *garbage in* that Hixenbaugh and Ornstein twisted into the *garbage out*, ***four specific accusations*** of Dr. Frazier's "secret history" that simply does not exist, but which they reported as true.

47. None too cleverly, the 2018 Article overwhelmed whatever good they reported about Dr. Frazier with accusations of hideous behavior, beginning with the headline and continuing in the article.

48. From the 2018 Article:

In the five decades since [an experience operating with Dr. DeBakey],

Dr. O.H. "Bud" Frazier has obsessively pursued that goal, contributing to many breakthroughs in the long and unfinished effort to develop a permanent mechanical replacement for the human heart. Today, devices he tested at Baylor St. Luke's Medical Center and its research partner, the Texas Heart Institute, are credited with extending the lives of thousands of people worldwide each year.

But out of public view, Frazier has been accused of violating federal research rules and skirting ethical guidelines, putting his quest to make medical history ahead of the needs of some patients, an investigation by ProPublica and the Houston Chronicle has found. *Reporters reviewed internal hospital reports, federal court filings, financial disclosures and government documents. The records and interviews with former St. Luke's physicians* ***show:***

FALSE ACCUSATION NO. 1: Dr. Frazier inhumanely experimented on patients and violated the law: "Frazier and his team implanted experimental heart pumps in patients who did not meet medical criteria to be included in clinical trials, according to a hospital investigation a decade ago. The findings, which have never been disclosed publicly, prompted St. Luke's to report serious research violations to the federal government and repay millions of dollars to Medicare." Exhibit B at 2.

TRUTH: Hixenbaugh and Ornstein published the 2018 Article knowing that its accusations of research violations omitted the unequivocal conclusion of one of the two studies regarding patient care, which explained that there was zero evidence of civil, criminal, or regulatory violations. *See discussion infra* at 44–49. In addition, Hixenbaugh and Ornstein's accusations were based on clearly unreliable sources—an inaccurate summary of reviews of THI and Dr. Frazier's work and that of Dr. Frank Smart, a cardiologist who never had and never will implant an LVAD or transplant a heart and who had never before been involved in a clinical study. *See discussion infra* at 34–39; 49–55; 55–59. Further, Hixenbaugh and Ornstein intentionally (and since, admittedly) omitted facts from the 2018 Article in order to create a false impression about Dr. Frazier's mortality rate and quality of care he provided patients. *See discussion infra* at 26–30. Hixenbaugh and Ornstein exacerbated their defamatory conduct and contacted the New England Journal of Medicine, triggering an investigation into Dr.

Frazier's publications about the HeartMate II Clinical Study. Hixenbaugh and Ornstein used the unwarranted investigation to create a false impression about Dr. Frazier and the legitimacy of the study. *See discussion infra* at 64–70.

FALSE ACCUSATION NO. 2: Dr. Frazier hid the harmful effects of the LVAD: "A former top St. Luke's cardiologist said he believes that Frazier favored experimental heart pumps over more proven treatments and that Frazier was reluctant to acknowledge when the devices led to serious complications. Two other doctors made similar observations. In one instance, one of them said Frazier discouraged publication of research that found a high rate of strokes in the first group of patients implanted with a pump he championed." Exhibit B at 2 (emphasis added).

TRUTH: Hixenbaugh and Ornstein purposefully avoided the truth—Dr. Frazier was a driving force in making public the high rate of strokes and resolving the problem. *See full discussion infra* at 30–34.

FALSE ACCUSATION NO. 3: Dr. Frazier was bought off and let money influence his medical decisions: "Frazier has often failed to publicly disclose consulting fees and research grants—and in one case, stock options he received and later transferred to his son—from companies that made the pumps he tested. Most medical journals require such disclosure so that other scientists and the public can judge whether personal interests may have influenced research findings." Exhibit B at 2 (emphasis added).

TRUTH: Hixenbaugh and Ornstein omitted material facts about the context in which Dr. Frazier received funding, consulting fees, and research grants. Hixenbaugh and Ornstein's clear intent when they omitted these facts was to create a false impression that Dr. Frazier could be "bought off" and valued money and medical history over saving lives. *See full discussion infra* at 39–44. Hixenbaugh and Ornstein also omitted a firsthand account from their most quoted source that Dr. Frazier "never did anything for money." *See full quote infra* at 40.

FALSE ACCUSATION NO. 4: Dr. Frazier allowed a researcher, who was an unlicensed doctor, to treat patients: "And a former St.

> Luke's nurse alleged that Frazier allowed a researcher who was not licensed to practice medicine in Texas to treat heart failure patients in his program. Her 1994 lawsuit, which was backed by patient records, testimony and secret recordings of hospital employees, revealed that Frazier's signature stamp was sometimes used to authorize the researcher's improper medical orders." Exhibit B at 2 (emphasis added).
>
> **TRUTH**: Hixenbaugh and Ornstein omitted facts and relied on unsubstantiated allegations to create the false impression that Dr. Frazier violated the law. *See full discussion infra* at 59–64. Notably, Hixenbaugh and Ornstein omitted the obvious fact that physician licensing is in the purview of the hospital, not Dr. Frazier, to maintain physician licensing in effect.

49. The deception did not stop with the 2018 Article. In the "Making Matters Worse Article," Hixenbaugh and Ornstein twist their own words into something they do not mean—that they merely reported someone else's accusations:

> The story, *which revealed that Frazier has been accused* of violating federal research rules and skirting ethical guidelines at St. Luke's Episcopal Hospital (now Baylor St. Luke's Medical Center) and its research arm, the Texas Heart Institute, was based on internal hospital records, court filings, official reports to federal regulators and interviews with medical professionals. Reporters posted several source documents with the online version of the story.

Exhibit B at 2 (emphasis added). That is a sleazy attempt to shade the truth. Hixenbaugh and Ornstein did not just *reveal* anything. In the headline alone, Hixenbaugh and Ornstein unequivocally *accused* Dr. Frazier of everything from unethical to illegal conduct. In the article, they reported that they confirmed the allegations in the four accusations above—and if they did not confirm them, why

print them?

50. What follows are specific examples of Hixenbaugh and Ornstein's most egregious reporting and the facts that make it so:

A. Hixenbaugh and Ornstein intentionally (and, only now, admittedly) failed to "risk-adjust" raw Medicare mortality data for the health risks of Dr. Frazier's mortally ill patients, a statistic identified by statistical analysis experts as "omitted-variable bias."

51. From *ProPublica*'s Code of Ethics:

> No story is fair if it omits facts of major importance or significance. Fairness includes completeness.

See https://www.propublica.org/code-of-ethics.

52. In previous, widely criticized articles, *ProPublica* has raised omitting significant facts to something of an art form. For example, in 2016, a Rand Corporation team of physicians and scientists—including the holder of the Rand Corporation Chair in Statistics—analyzed *ProPublica*'s 2015 "Surgeon Scorecard":

> [T]he first nationwide, multispecialty public reporting of individual surgeon outcomes. However, ProPublica's use of a previously undescribed outcome measure (composite of in-hospital mortality or 30-day related readmission) and inclusion of only inpatients have been questioned . . . ProPublica's outcome measure specifications exclude 82% of cases, miss 84% of postoperative complications, and correlate poorly with well-established postoperative outcomes. Thus, the validity of the ProPublica Surgeon Scorecard is questionable.

See A Methodological Critique of the ProPublica Surgeon Scorecard at https://www.rand.org/pubs/perspectives/PE170.html.

53. Hixenbaugh and Ornstein pulled the same stunt in the 2018 Article,

failing to adjust raw Medicare data showing one-year mortality rates for the outsized risks Dr. Frazier's mortally ill patients presented. Just like with the "Surgeon's Scorecard," Hixenbaugh and Ornstein failed to disclose the flaw in their methodology until forced to do so, in this case, by a distinguished cardiothoracic surgeon's critical response to the 2018 Article:

> I am not the least convinced by using the newspaper's quotes of Medicare mortality figures as a reliable tool to compare surgical outcomes since they are NOT risk-adjusted. Furthermore, these numbers do not take account of how many patients have died while waiting for a heart transplant that never became available. Indeed a surgeon who selects the better risk patients would obviously have better survival at one year, than somebody like yourself who will accept the neediest and sickest patients, without concern about how the publicly available statistics would look down the road.
>
> — Dr. Kamal G. Khalil, adjunct professor of cardiothoracic surgery at UTHealth's McGovern Medical School, in a letter to Frazier

Exhibit C at 6. The failure to "*risk-adjust*" results in what statistical analysis, as Hixenbaugh and Ornstein admittedly did not do, is defined by statistical analysis experts as "*omitted variable* ***bias***," a more scientific way of saying, "garbage-in, garbage-out."

54. On the same day *ProPublica* first published the 2018 Article, Hixenbaugh and Ornstein also published "How We Analyzed Bud Frazier's Outcome." Exhibit F. The words "risk-adjusted" do not appear anywhere in the article.

55. Hixenbaugh and Ornstein admitted the omission in the "Making Matters Worse Article"—an especially serious flaw in Dr. Frazier's case, as his patients were the sickest of the sick, often diagnosed with Stage 4 heart failure—the deadliest category. Quite often his patients were so close to death that no other surgeon was sufficiently experienced or willing to perform the surgery.

56. Instead of placing Dr. Frazier's high-risk practice in the proper context, Ornstein and Hixenbaugh simply invented one of their own: they portrayed Dr. Frazier as a doddering surgeon operating "well into his 70s," his diminished surgical skills proven by an abnormally high mortality rate:

57. From the 2018 Article:

> *Frazier continued to operate on patients well into his 70s, and during those latter years, his Medicare outcomes ranked among the worst in the country.* From 2010-15, about half of the traditional Medicare patients who received an implantable heart assist device from Frazier died within a year, *nearly double the national mortality rate* for such patients, according to a ProPublica analysis of federal data.
>
> . . .
>
> From 2010-15, Frazier implanted long-lasting left ventricular assist devices in 63 Medicare patients, according to a ProPublica review of federal data. Some 31 of those patients — *nearly half — did not survive a year*, one of the highest mortality rates in the nation.
>
> That was nearly double the 25 percent one-year mortality rate for Medicare patients who received LVADs from other St. Luke's surgeons during the same period; the national rate for Medicare was 28 percent. (See how we conducted our analysis.)

Exhibit B at 2, 11 (emphasis added).

58. In the "Making Matters Worse Article," Hixenbaugh and Ornstein admit their mistake about risk-adjustment and then, in the same journalistic breath, deny what they had just admitted: "We stand by our reporting and *have found no instances of errors*." Exhibit C at 3. That said, Hixenbaugh and Ornstein admit another error. This time Hixenbaugh and Ornstein ignored the very words that they wrote about their portrayal of a Dr. Frazier grown old and incompetent and, instead, whitewashed the accusation into a simple repetition of Medicare data:

> From 2010-15, about half of the traditional Medicare patients who received an implantable heart assist device from Frazier died within a year, nearly double the national mortality rate for such patients, according to a ProPublica analysis of federal data. We published an article explaining how we conducted the analysis.
>
> *It is correct that the mortality figures were not risk adjusted. That said, the differences between Frazier and other surgeons nationally and at his own hospital were profound. His Medicare outcomes ranked among the worst in the country.*

Exhibit C at 5 (emphasis added).

59. If Hixenbaugh and Ornstein wanted to publish the truth, there was a far more honest context for Dr. Frazier's skills, but not one that fits their vicious narrative. Dr. Denton Cooley, consistently had among the highest, if not the highest, mortality rates in the United States. That did not mean that he was a poor surgeon. He was, in fact, the best heart surgeon in the world. For Dr. Cooley, that meant—as it did for Dr. Frazier—heart surgeons nationwide sent their hardest cases to Dr.

Cooley and Dr. Frazier.

B. Hixenbaugh and Ornstein falsely claimed that Dr. Frazier hid research that found a high rate of strokes.

60. One of the 2018 Article's defamatory narratives was clear from the headline alone that the erstwhile "pioneer" in the business of saving lives actually put his patients at risk. He allegedly left in LVADs when a heart transplant was called for and harmed the wider medical world by refusing to publicize the high rate of strokes in LVAD recipients at the start of the HeartMate II Clinical Study. Dr. Frazier allegedly did all of this in search of his place in medical history, which (ironically) was already secured decades ago.

61. From the 2018 Article:

> A former top St. Luke's cardiologist said he believes that Frazier favored experimental heart pumps over more proven treatments and that Frazier was reluctant to acknowledge when the devices led to serious complications. Two other doctors made similar observations. In one instance, one of them said Frazier discouraged publication of research that found a high rate of strokes in the first group of patients implanted with a pump he championed.
>
> . . .
>
> Two physicians familiar with the research told reporters that they believed those findings should have been published in a medical journal, but they were not. One of the doctors said Frazier argued against it because doing so would "kill the field" of mechanical heart pumps.
>
> [Billy] Cohn, the surgeon who worked closely with Frazier after joining the program in 2004, recalled the disagreement. He said doctors had already figured out a way to more accurately measure patients' blood pressure and, as a result, better manage the pump settings to reduce the

> risk of brain bleeding.
>
> Frazier didn't want to needlessly "freak people out" with research showing a high rate of serious complications, Cohn said. "That would just pour water on the smoking ember of this new important field," Cohn said, adding that, in hindsight, the team "probably should have" published the stroke findings alongside their solution. Dr. Biswajit Kar, the former St. Luke's cardiologist who led the effort documenting the high rate of strokes, declined to comment.
>
> In a written response, Frazier said he did not recall any effort to turn the stroke research into a paper and "never opposed [Kar] publishing anything."
>
> Frazier said he was the first to diagnose hemorrhagic strokes in patients who had received HeartMate II devices, years earlier in 2006, and he recalls organizing a meeting in Chicago with leading cardiologists from other hospitals and the device's maker to discuss the issue. "I recommended to the company that they require that blood pressure be controlled and that all new implanting centers be required to do the same."
>
> ***Nevertheless, the initial stroke findings were never published.***
>
> Kar presented a summary of the report at a 2009 cardiology conference, with Frazier listed among the authors of the presentation. But other than a ***short abstract*** included in the conference program — which is not available online — there is ***no public record*** of the research.

Exhibit B at 2, 9–10 (emphasis added).

62. "No public record" of the initial stroke findings? A Google search proved otherwise. The research abstract about the high rate of strokes and LVADs, referenced in the 2018 Article, includes Dr. Frazier as a co-author and was reproduced in at least two journals, including the Journal of the American College of Cardiology and the Journal of Heart and Lung Transplantation:

https://www.documentcloud.org/documents/4482042-2009-Stroke-Abstract.html

and

https://www.jhltonline.org/article/S1053-2498(08)01335-1/abstract?code=healun-site.

There are also other articles online about the danger of strokes and LVADs, each of which includes Dr. Frazier as an author, including:

https://www.ncbi.nlm.nih.gov/pubmed/24316083;

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1995046/pdf/20070900s00003p275.pdf;

and

https://www.jhltonline.org/article/S1053-2498(11)00187-2/abstract.

63. Notably, the following quote is from the Texas Heart Institute Journal, published in 2007, where Dr. Frazier is the first-named author and Dr. Biswajit Kar—"the former St. Luke's cardiologist who led the effort documenting the high rate of strokes"—is one of the other authors.

> We pay particular attention to the proper level of anticoagulation and to the measurement and control of blood pressure in patients without a detectable pulse. ***To date, experience with these pumps in a limited patient population has suggested an increased incidence of hemorrhagic stroke***. This may be related to the difficulty of properly monitoring blood pressure due to the absent or dampened pulse imparted by this technology. If hypertension is present but not easily measurable, inadequate pharmacologic control of blood pressure may result, in turn subjecting these patients to an increased risk of hypertensive hemorrhagic stroke. An additional concern is that the altered stress on the aortic valve may result in valve leaflet fusion and aortic insufficiency and stenosis.

See https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1995046 (emphasis added). The article also includes an insert that describes anti-coagulation instructions to help prevent strokes.

64. Moreover, "short abstracts" are universally employed to inform members of all manner of professions in the clinical and research communities of important developments in their field. That is precisely what Drs. Kar and Frazier were doing. The "short abstract" is entitled "*Ventricular Assist Devices: The Good, the Bad and the Ugly*" and includes the stark warning, "*A relatively large percentage of patients on HeartMate II developed stroke.*" It should also be noted that Dr. Kar delivered a presentation about the danger of strokes to the organizations most critically involved in and dependent on the results of LVAD implants, the American College of Cardiology and the International Society of Heart and Lung Transplantation.

65. Most important, Dr. Frazier did not just organize a meeting in Chicago that included "the device maker." He organized a meeting that included Thoratec's then Vice President of Research and Scientific Affairs, David Farrar, Ph.D., the one man who could implement Dr. Frazier's fix for the stroke problem. The other attendees at the March 24, 2006 meeting were the Principal Investigators of two leading research centers enrolled in the study, Duke and Johns Hopkins Universities, to disclose and discuss the stroke issue and Dr. Frazier's remedy. Exhibit G. Based

on Dr. Frazier's recommendation, Thoratec's Farrar modified its procedures and protocol, requiring all participants to maintain blood pressure at the levels Dr. Frazier concluded were safe, and soon thereafter, the rate of strokes among LVAD recipients dropped to the predicted rate.

C. Hixenbaugh and Ornstein relied on an unreliable source and purposefully avoid the truth to make implausible accusations—Dr. Smart's disagreement with Dr. Frazier about patient diagnoses.

66. From the 2018 Article:

> Dr. Frank Smart, Texas Heart's top transplant cardiologist between 2003 and 2006 . . . said he admired Frazier's commitment to developing lifesaving heart pumps, but he believed it led him to surgically *implant the devices into some patients who were not yet sick enough to justify what was, at the time, an experimental treatment*.
>
> Frazier's drive likely moved the field forward, Smart said, but he and others worried that it sometimes came at the expense of individual patients.
>
> "In the old days of medicine … that's the way these guys did things," said Smart, now the chief of cardiology at Louisiana State University School of Medicine. "It was, 'Well, I have an idea, and I'm the one that knows best, and by golly, I'm going to do it.' And did that advance the field? Maybe. Is it the right thing to do? Absolutely not."

Exhibit B at 3 (emphasis added). Hixenbaugh and Ornstein's statements were yet another example of their purposeful avoidance of the truth to make incredible accusations.

67. Why might Frazier implant pumps in patients who "were not yet sick enough to justify . . . an experimental treatment?" With all due apologies to

Hixenbaugh and Ornstein's truly unreliable source—a cardiologist who had not devoted his life to surgery, who never had and never will implant an LVAD or transplant a heart, who had never before been involved in a clinical study—there were various patients who did better having the LVAD pumps for a time before receiving heart transplants. Those outcomes, in turn, were better than those of other patients who had transplants immediately, which—also omitted by Hixenbaugh and Ornstein—could create an entirely different set of medical problems and shortened life span. In fact, many patients have chosen to keep such pumps for the rest of their lives rather than risk their health and life with transplants.

68. The larger point is this: Dr. Frazier was dealing every day with the sickest of the sick, whose outcomes from the beginning were never assured, whose death, to the attending physicians and surgeons, seemed assured. Heart surgery is a risky business; experimental heart surgery is even riskier. Hixenbaugh and Ornstein damn Frazier for making judgment calls that in one doctor's opinion was incorrect; perhaps they should have done a little more research on the ages-old disagreements between cardiologists and surgeons, who can obviously have very different opinions about what should be done for a patient.

69. Following publication of the 2018 Article, Dr. Smart responded to an email from Dr. Frazier's wife, Rachel, and accused Hixenbaugh and Ornstein of taking his comments "out of context," which may or may not be true. However, he

did offer this opinion, unlike anything he was quoted as saying in the 2018 Article:

> Bud always thought he was doing the right thing by keeping VADs in people listed for transplant who were doing well. I didn't agree, and in the end it is one of the reasons I decided to leave. As for putting VADs in early, yes there were patients that I thought got a VAD before they had been given an adequate chance on heart failure medications. He and I frequently discussed this as well. I will say I thought the influence of one of the cardiologists had more to do with premature implants than Bud.

Exhibit H.

70. It should be noted that, from 2003-2006, Dr. Smart practiced as Medical Director of Heart Failure, Cardiac Transplant and Mechanical Circulatory Support at THI during the HeartMate II Clinical Study—and that he was actively involved in the study, as noted, his first. Hixenbaugh and Ornstein knew and failed to report that the FDA audited patient records enrolled in the LVAD implant study for any evidence of noncompliance and concluded "NAI"—there was no violations of FDA regulations.

71. One of Smart's harshest criticisms of Dr. Frazier was the decision to implant an LVAD into a patient referred to as "Patient #1," which was discussed in a May 9, 2018 email from Dr. Frazier's counsel, David Berg, to Hixenbaugh and Ornstein ("May 9 Email"). Exhibit I. To put this years-old disagreement into context, Dr. Frazier was out of town, but agreed wholeheartedly with his THI colleague, Dr. Igor Gregoric's decision to implant an LVAD to support the thirteen-

year-old's obviously failing heart. Dr. Smart disagreed, strongly, and confronted Dr. Frazier when he returned, insisting that the boy should never have received an LVAD, that he was too sick to survive, and that he did not meet the Approval Protocol. In retrospect, it seems pretty clear who was right. Had anyone listened to the perpetually angry cardiologist, that boy would be dead. Instead, he is 27 and thriving, just as "Patient #2. *See* Image 5 ("Patient #2").

72. From the 2018 Article (more from Dr. Smart):

> As the medical director of the program, Smart said, he felt powerless. He recalled growing so frustrated that, on a few occasions, he yelled at Frazier. Sometimes, Smart and other *cardiologists resorted to "hiding patients" — moving them to other parts of the hospital to prevent Frazier from recommending experimental LVADs*, buying the patients time to recover with less invasive treatments or receive a transplant instead. Two other former St. Luke's staffers confirmed the highly unusual practice.

Exhibit B at 6 (emphasis added).

73. So, how could a patient be hidden at St. Luke's Hospital? This is another farfetched statement in the 2018 Article that does not make sense. Patients are admitted to a hospital under the care of a specific physician; so if a patient were admitted to Dr. Smart, there is absolutely nothing Dr. Frazier could do for that patient unless Dr. Smart referred the patient to him or the HeartMate II Clinical Study. If a patient were admitted to Dr. Frazier, he could recommend an LVAD (and he would have added a heart failure cardiologist to the team as consultant). However, Dr.

Frazier could not unilaterally decide to implant a device without following the Approval Protocol, including approval by the Medical Review Board. Therefore, if a patient were referred to Dr. Smart, there would be no reason for him to move the patient anywhere, and he would treat the patient as he saw fit. Dr. Frazier could not change the treatment of the admitting physician.

74. Further, it is a matter of *public record* that before an LVAD can be implanted, all of Dr. Frazier's patients (and Dr. Smart's) required multiple levels of approval to ensure compliance with FDA-approved clinical study protocols:

> **How Are Participants Protected . . . Institutional review boards**. Each federally supported or conducted clinical study and each study of a drug, biological product, or medical device regulated by FDA must be reviewed, approved, and monitored by an institutional review board (IRB). An IRB is made up of doctors, researchers, and members of the community. Its role is to make sure that the study is ethical and that the rights and welfare of participants are protected. This includes making sure that research risks are minimized and are reasonable in relation to any potential benefits, among other responsibilities.
>
> In addition to being monitored by an IRB, some clinical studies are also monitored by data monitoring committees (also called data safety and monitoring boards).[2]

The HeartMate II Clinical Study was not only monitored by an IRB but also by a data safety and monitoring board. Implantation of an LVAD was never a unilateral decision by any physician, including Dr. Frazier. In addition, all patients are seen

[2] *Learn About Clinical Studies*, U.S. National Library of Medicine (June 25, 2018), clinicaltrials.gov/ct2/about-studies/learn.

daily on hospital "rounds" by the heart failure team, which includes nurse coordinators. So, a patient could not just "disappear" (i.e., be moved around without notice).

D. <u>Hixenbaugh and Ornstein omitted material facts to create a false impression that Dr. Frazier could be "bought off" and valued money and medical history over saving lives.</u>

75. From the 2018 Article:

> Frazier has often failed to publicly disclose consulting fees and research grants — and in one case, stock options he received and later transferred to his son — from companies that made the pumps he tested. *Most medical journals require such disclosure* so that other scientists and the public can judge whether personal interests may have influenced research findings.

Exhibit B at 2 (emphasis added).

76. This was perhaps the unkindest cut of all—the implication that Dr. Frazier concealed financial interests in companies whose LVADs he was testing. Their implication was clear: Dr. Frazier failed to disclose his financial interests for fear of raising suspicion about the accuracy of his reported results—of boosting LVADs that may not deserve his endorsement, so he could make a buck. In other words, Hixenbaugh and Ornstein were saying that Dr. Frazier could be bought off. If they were saying something else, it is difficult to imagine what it was.

77. Anyone who knows Bud Frazier understands that he would not compromise his medical ethics for money. Oddly, although Hixenbaugh and

Ornstein interviewed some of those people who know Dr. Frazier well, they did not quote anyone rebutting these charges, other than Dr. Frazier. If, however, they had such information, they owed it to Dr. Frazier and his family to include it in the 2018 Article and if not to them, to the journalism profession and balanced reporting.

78. Of course they did have such a defense, which they left out of the 2018 Article, from their source, Dr. Frank Smart. As noted *supra*, following the publication of the 2018 Article, Dr. Smart responded to an email from Dr. Frazier's wife, Rachel, stating, "I specifically said [to the reporter] Bud was not doing anything for money, ever." Exhibit H. In an email to Dr. Frazier, also following publication, Dr. Smart added, "you (sic) never did anything for money, [I] even said [to the reporter] I was not sure you sent a bill. The pay for talks and travel was a ridiculous assessment." Exhibit J. Apparently not content with that conclusion, Hixenbaugh and Ornstein tried to change Dr. Smart's mind. "He told me about the fact there were stock options, and I said I was 100% certain Bud was never financially motivated." *Id*. Dr. Smart also wrote, "I had/have no idea about options, but I think that was an underhanded statement as well." *Id.* Dr. Smart got it right. Hixenbaugh and Ornstein intentionally left it out.

79. From the 2018 Article:

> A 2008 Securities and Exchange Commission filing shows that HeartWare awarded Frazier options to purchase the equivalent of 7,142 shares in its newly formed U.S. company at a pre-set price. Frazier said

> he held the options until March 2009, when he transferred them to his son, Todd, a musician. Todd Frazier exercised the options between 2010 and 2011, collecting proceeds totaling $130,813, according to financial documents provided by Berg.
>
> HeartWare's stock more than doubled in value between early 2009 and the end of 2011 as physicians tested the device in a pair of key clinical trials. The elder Frazier played a leading role in the research, implanting the pumps in numerous St. Luke's patients in those years and speaking glowingly of them in HeartWare's corporate press releases. But when those studies were published in 2012 and 2013, Frazier disclosed no conflicts, even as some of his fellow authors did.

Exhibit B at 10 (emphasis added); *see also* Exhibit C at 4–5.

80. HeartWare (as distinguished from HeartMate, the product of an entirely different company and the device used in the Clinical Study described at length *supra*), another LVAD manufacturer, close to bankruptcy, had enlisted Dr. Frazier's help in developing its device. In 2008, for the first and only time in his career, Dr. Frazier accepted stock options and then transferred them to his son, Todd, a "musician."[3] Instead of an exception, Hixenbaugh and Ornstein reported the stock options as if they were the rule, linking them to other "windfalls," such as reimbursements Dr. Frazier received for travel costs associated with lectures he gave—knowledge he shared—with implant and transplant surgeons around the world. Hixenbaugh and Ornstein intentionally omitted these facts in order to create

[3] For the record, Todd Frazier is not a struggling drummer in a garage band. He is a composer and Juilliard graduate identified by the school as one of its 100 distinguished alumnus, who now runs a nonprofit that provides music therapy for hospitalized patients and their families.

a substantially false impression about the only time Dr. Frazier received stock options in his decades-long career.

81. From the 2018 Article:

> ProPublica and the Chronicle reviewed the past 100 papers on which Frazier was listed as an author, dating to 2010. Frazier disclosed conflicts of interest in less than 10 percent, and those disclosures often were inconsistent and incomplete.

Exhibit B at 10.

82. What Hixenbaugh and Ornstein either knew, or failed to research, is that industry standards for reporting conflicts of interest in medical journals vary; some journals do not even publish conflict of interest statements—especially during the time period Hixenbaugh and Ornstein mention. Other medical journals report only conflicts of $10,000 or more: "In the US, the level above which a financial relationship is considered to be COI is 10,000 US dollars (USD) and in case of ownership of a company, at 5%."[4]

83. In the last one hundred papers of which Dr. Frazier was an author, which date back to 2011 and are the group described by Hixenbaugh and Ornstein, he was the first author on only five—meaning that he actually wrote those five papers. The rest were drafted by other authors who were responsible for obtaining conflicts of interest from the coauthors. Four of the five first-authored papers were

[4] 42 CFR 50.604 ("Responsibilities of Institutions regarding Investigator financial conflicts of interest").

general reviews; none were specific to the HeartWare LVAD. The only article first-authored by Dr. Frazier that was specifically about the HeartWare LVAD was published in 2011, more than two years after Dr. Frazier transferred the HeartWare stock options. Dr. Frazier disclosed his relationship as an unpaid medical advisor to HeartWare. These facts were purposefully omitted to distort the truth. Also, of the one hundred articles mentioned by Hixenbaugh and Ornstein, many were about general heart surgery, devices and complications of devices other than the HeartWare (including total artificial hearts), transplants, and so on—none of which would even require a statement of conflict of interest.

84. From the 2018 Article:

> In the years that followed, from mid-2013 through 2016 — the only period for which federal data is available — device makers paid Frazier more than $44,000 for travel, meals and work on their behalf. He was listed as the primary investigator on research grants that brought in another $56,000 to St. Luke's and Texas Heart in 2015 and 2016, according to payment data compiled by the Centers for Medicare and Medicaid Services.
>
> But more often than not, Frazier did not disclose those payments in related research papers.

Exhibit B at 11 (emphasis added).

85. That is very true: Dr. Frazier was reimbursed for expenses incurred while attending dozens of conferences and demonstrating his techniques around the world in places like Kazakhstan. However, again, Hixenbaugh and Ornstein

intentionally left out facts in order to create a substantially false impression.

86. Of the $44,000, nearly all of the dollars were for travel, food, and lodging. Only $500 was for consulting and $7,400 for speaking at meetings. This amount was paid over a several-year period and would not have caused Dr. Frazier to have any conflicts of interest, as generally defined as "a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest."[5]

87. As far as the claim that: "He was listed as the primary investigator on research grants that brought in another $56,000 payments to THI," Dr. Frazier received no money from any payment given to THI for company-funded research. The money received went directly towards supporting the research study.

E. Hixenbaugh and Ornstein omitted facts known to them that put the lie to their allegation that Dr. Frazier violated the law and hid those violations—the mischaracterization of Dr. James Young's report.

88. From the 2018 Article:

> In one of the reviews commissioned by the hospital, a prominent Cleveland Clinic cardiologist, Dr. James Young, *concluded* that St. Luke's heart failure program *pushes the limits*, according to the summary document. Dr. Young found the *documentation to be poor* and *noted that Dr. Frazier was not up-front*."

[5] CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 45–46 (Bernard Lo & Marilyn J Field eds., The National Academies Press 2009).

Exhibit B at 7 (emphasis added).

89. As an initial matter, Hixenbaugh and Ornstein were not quoting Dr. James Young's Report ("Young Report," Exhibit K) or even quoting an executive summary that was prepared by a medical professional. They were quoting, as Hixenbaugh and Ornstein knew, but did not report, a *summary* of the Young Report that was prepared by a law firm ("Law Firm Summary," Exhibit L) and provided for a subcommittee of the St. Luke's Board of Directors. Before publication, before they quoted the Law Firm Summary, as if it were Gospel, Hixenbaugh and Ornstein had every reason to doubt its accuracy.

90. In a May 13, 2018 email ("May 13 Email"), Dr. Frazier's counsel, David Berg, responded on Dr. Frazier's behalf to Hixenbaugh and Ornstein's question about the statements attributed to Dr. Young in the Law Firm Summary, by quoting Dr. Young himself, verbatim, from the Young Report:

> *Of importance* is the fact that during my review I found *no evidence of a violation of criminal, civil or administrative law* to the extent I am familiar with those statutes.

Exhibit M at 5 (emphasis added) (quoting Exhibit K at 3).

91. Here is the falsehood in the "Making Matters Worse Article," in which Hixenbaugh and Ornstein actually claimed:

> Frazier had an opportunity to respond to every finding from our reporting before the story was published. We sent extensive and detailed questions to Frazier and a lawyer representing him and repeatedly extended the deadline

> for them to respond. *We took their responses seriously and included them in our story.*

Exhibit C at 3 (emphasis added).

92. Took our responses seriously and included them in their story? Hixenbaugh and Ornstein did not include one word of Dr. Young's unequivocal conclusion that the HeartMate II Clinical Study—directed at THI by Dr. Frazier as Principal Investigator—disclosed no research violations of any kind. Nonetheless, undeterred by the truth, Hixenbaugh and Ornstein accused Dr. Frazier of *the very research violations Dr. Young concluded never happened*.

93. From the 2018 Article:

> [O]ut of public view, Frazier has been accused of violating federal research rules and skirting ethical guidelines, *putting his quest to make medical history ahead of the needs of some patients*, an investigation by *ProPublica* and the *Houston Chronicle* has found.

Exhibit B at 1 (emphasis added).

94. "Put medical history ahead of his patient's needs"? Whom did these reporters interview? There is no one in the article quoted as saying those words and certainly not Dr. Young who included fulsome praise of Dr. Frazier and the THI team in the Young Report, describing them as "dedicated and committed to the highest standards regarding patient care for an extraordinarily challenging group—those facing imminent death."

95. Hixenbaugh and Ornstein also knew that the Young Report contained

high praise of Dr. Frazier's "Multiple seminal contributions to the field." Exhibit M at 5 (emphasis added) (quoting Exhibit K at 2). Berg included both of those statements from the Young Report in the May 13 email to Hixenbaugh and Ornstein. Not a word of those statements was included, either. In fact, neither Hixenbaugh nor Ornstein had even read the Young Report, or at least that is what they implied in response to the May 13 Email, when they requested Berg send them the Young Report because they did not "have it." Nonetheless, knowing Dr. Young's actual conclusions, Hixenbaugh and Ornstein plunged ahead, recklessly publishing the 2018 Article, knowing that their documentary resource, the Law Firm Summary, failed to tell the complete story of what Dr. Young thought of the HeartMate II Clinical Study, Dr. Frazier, and THI.

96. To understand why it was so utterly inexcusable for Hixenbaugh and Ornstein to attribute those statements about Dr. Frazier to Dr. Young, two facts must be explained.

97. ***First***, Dr. Young was hired by a law firm retained by St. Luke's—Baker, Donelson, Bearman, Caldwell, & Berkowitz PC ("Baker Donelson") of Memphis, Tennessee—"to review the Heart Transplant and Mechanical Circulatory Support Program at St. Luke's." Exhibit K. Dr. Young reported his findings to Baker Donelson in November 2007—"Young Report"—and not to the firm that purported to quote Dr. Young's conclusions in the Law Firm Summary, Epstein

Becker & Green, P.C., ("Epstein").

98. ***Second***, Epstein did not retain Dr. Young. Epstein retained the Anson Group to complete an "assessment of the St. Luke's Episcopal Hospital's mechanical circulatory support program." Exhibit N. The Anson Group reported its findings to Epstein in February 2008. ("Anson Report"). *Id.* Importantly, a lawyer at Epstein, not even the Anson Group or Dr. Young, drafted the conclusions attributed to them in the Law Firm Summary, which was prepared for a subcommittee of the St. Luke's Board of Directors. Exhibit L. In the Law Firm Summary, Epstein summarized the six-page Young Report in just a few sentences:

> James Young, MD (a cardiologist with previous links to Baylor College of Medicine and The Methodist Hospital), a Cleveland Clinic physician, conducted an assessment of St. Luke's heart failure program. He described it as an *aggressive program that pushes the limits*. Dr. Young found the documentation to be poor and noted that *Dr. Frazier was not up-front*.

Id. at 3 (emphasis added).

99. Bottom line: Dr. Young did not state or conclude in the Young Report that "St. Luke's heart failure program *pushes the limits*" or that "Dr. Frazier *was not up-front*." Nowhere in the Young Report will you find the phrases "pushes the limits" or "was not up-front." As noted, the statements in the Law Firm Summary were written by a lawyer, not Dr. Young. Hixenbaugh and Ornstein's reliance on a second-hand quote in a lawyer's summary was reckless, to say nothing of being

false.

100. One of the ways the law identifies fraud is fraud by omission—when a speaker or in this case, when reporters, leave out that which makes what was written false. The law labels that kind of action the "secret lie"—precisely what Hixenbaugh and Ornstein did when they omitted Dr. Young's conclusion that put the lie to their reckless accusations and purposefully avoided the truth.

F. Hixenbaugh and Ornstein's accusations were based on a clearly unreliable source, the Law Firm Summary.

101. From the 2018 Article:

> Based on *multiple reviews* summarized in the report to hospital board members, St. Luke's executives concluded that Frazier and his team had implanted the experimental HeartMate II and another LVAD, the Jarvik 2000, in 30 patients who were enrolled in government health plans and for whom the *medical need for the devices and compliance with trial parameters "could not be documented by the patient's medical record."* The patients had been enrolled in the trials "without justification," the summary said.
>
> . . .
>
> Top officials at St. Luke's and Texas Heart reported the research violations to the federal Office for Human Research Protections in July 2008, and they pledged a host of reforms, according to a letter obtained by ProPublica and the Chronicle through the Freedom of Information Act.
>
> St. Luke's and Texas Heart said they would audit every ongoing study for which Frazier was the lead researcher, to find and report any additional research deviations. And, according to the report to St. Luke's board, *the hospital planned to give back between $3.4 million and $5.4 million in payments that Medicare had made on behalf of patients who received unjustified surgical treatments.*

Exhibit B at 7, 8 (emphasis added). Hixenbaugh and Ornstein's false accusations are based, in large part, on the Law Firm Summary. Prior to publication of the 2018 Article, Hixenbaugh and Ornstein were presented with several reasons to doubt the accuracy of the Law Firm Summary, but they pressed ahead despite the warning.

102. The most obvious indication that the Law Firm Summary is unreliable is its conclusion that Dr. Frazier failed to comply with the Approval Protocol, which is completely at odds with the many layers of monitoring and oversight by the IRB, MRB, and Thoratec (now, Abbott), as well as the FDA's 2006 and 2009 audits giving THI a clean bill of health. *See discussion supra* at 19–20. This alone should have caused Hixenbaugh and Ornstein to doubt the truth of what they were writing and the reliability of the Law Firm Summary. However, Hixenbaugh and Ornstein remained undaunted by the truth.

103. Counsel for Dr. Frazier also warned Hixenbaugh and Ornstein about the unreliability of the Anson Report, the document underlying the Law Firm Summary. Hixenbaugh and Ornstein ignored the warning.

104. In a May 9, 2018 email to Hixenbaugh and Ornstein ("May 9 Email), Dr. Frazier's counsel quoted verbatim the Anson Report and the Anson Group's own *extensive* catalogue of reasons to doubt its conclusion that Dr. Frazier was noncompliant with the Approval Protocol:

Let me start with the Anson group's admission that their conclusions

could have been different had they not been so limited in their investigation, which was conducted over two days, November 5-7, with insufficient Anson personnel, covered a decade of complex scientific data, *and failed to include a single interview with any participant in the program(s)—notably, not even Dr. Frazier.* Here is what they say at page 2, fn. 1:

> We understand that our engagement was intended to be limited. Due to the limitation of our engagement, the results described in this report encompass only the conclusions we were able to reach based on the [REDACTION IN ORIGINAL] documents provided. *A full assessment of a heart transplant and mechanic support program would entail conducting interviews of all essential personnel and a review of the documentation and records that could provide a more complete review and/or greater insight into the reasons behind observed instances of noncompliance. We also would like to point out that given the size of the program a full assessment would require significantly more time and human resources than were dedicated to this initial assessment.*

Exhibit I (emphasis added).

105. Hixenbaugh and Ornstein's response? *They asked Dr. Frazier's counsel to provide them with a copy of the Anson Report, another primary source document, which they apparently had not read.* Indeed, when counsel for Dr. Frazier asked in a May 23, 2018 email if Hixenbaugh and Ornstein had read the report, neither Hixenbaugh nor Ornstein responded. Exhibit O.

106. In the May 13 Email, sent prior to publication of the 2018 Article, Berg emailed Hixenbaugh and Ornstein ***again*** about the Anson Report, St. Luke's self-

reporting to the FDA, and reimbursement of Medicare dollars. The email speaks for itself:

> Gentlemen:
>
> Thank you for your response and for providing us with your source material, five documents in all, three of which relate to "research misconduct." However, each of those three documents either summarized or were in response to the Anson Group report—a ten-year-old (February 2008) internal investigation of Left Ventricular Assist Device implementation (LVAD) and heart transplant studies at the Texas Heart Institute (THI). To understand why it is unwise to rely on that report, and the documents it generated in response, one need only read the warnings in the Anson report itself. As we pointed out, Anson admits that it had conducted its "audit" [covering complex scientific data collected from years of implant surgeries with two different and evolving devices] (1) over a two-day period (November 5-7, 2007), (2) while understaffed, (3) reviewed only the documents provided to them [the nature of which were whited out], and finally, (4) failed to interview to interview the "key personnel in the Program, including Dr. Frazier, the Principal Investigator."
>
> The Anson Group's caveats did not stop it from confidently reaching an incredibly defamatory, false conclusion—that "bridge to transplant patients" (BTT) who "failed to meet entry criteria . . . for entry into the protocol" were implanted and transplanted nonetheless. To demonstrate for you how wrong Anson was, Dr. Frazier discussed two of the patients the study used as prime examples of noncompliance. Neither patient qualified for the core study protocol because they had already received temporary LVAD implants from which they could not be weaned (slowly removed) and therefore would die without more permanent support. The sponsor's core protocol allowed more permanent, long- term LVAD implants. Such patients were always reported to the FDA, as were these two, but they were excluded from the core study protocol due to their high perceived mortality. In addition, one of the patients was also underage and too young to be included in the age range of the core study protocol. The other patient,

around nineteen years old[6], was deemed psychologically unfit for implant eligibility at the time. Both of these boys faced imminent death (Subject #1 actually arrested on his way from Texas Children's Hospital to St. Luke's), and both received long-term LVADS, but, as stated, were ineligible for inclusion in the core study group due to the perceived, at the time, high risk of death—and both were, in fact, mortally ill. As mentioned, both operations were reported to the FDA and both were performed under the Humanitarian Device Exemption or Emergency Device Implantation long recognized and accepted by the FDA in such cases. (One of the reasons for these exclusions was the early experience of high mortality in LVAD-supported patients. In this high-risk patient group, mortality was unavoidable in spite of effective LVAD support. To effectively test the LVAD it had to be implanted in patients who were perceived to have a hope of survival. Otherwise, it would be like operating on a cancer patient after the cancer had already spread and was incurable.)

Two years post-implant, Dr. Frazier removed the fourteen -year-old patient's pump. The patient, who sees Dr. Frazier annually, is now twenty-eight and thriving. The nineteen year old still has the permanent LVAD, and his cardiologist recently reported to Dr. Frazier that the patient, now thirty, is also alive and thriving. That is not noncompliance. That is miraculous.

Nonetheless, for reasons best known to the Anson report's authors, there is no mention of the exemptions, the fact that the FDA conducted unannounced audits of the program, and that the sponsor and the FDA were fully informed about these cases. Nor, contrary to the report's warning that the FDA, should it discover what the Anson investigators learned of the study's noncompliance, would "likely" issue an FDA Form 483 (a first step toward such serious action as shutting down the research altogether), did the FDA ever issue a 483. In fact, neither the sponsor nor the FDA ever informed Dr. Frazier of any so-called noncompliance.

Anson did not stop there: it concluded that the noncompliance resulted in improper Medicare reimbursements in the amount of $3.4

[6] The patient was 17 years old when the operation took place.

million—a serious allegation that can be traced into the July 8 St. Luke's letter. It should be obvious that ill-founded allegations such as this are not just wrong but also defamatory.

In your response, you not only provided us with your source material, but also candidly stated that you do not have the Anson study, which explains why we are not, as you correctly state, "on the same page." The two examples above, alone, should undermine your faith in the report and your source documents, which were generated as a direct result of the Anson report. You ask me to provide a copy of the Anson report. I have to ask why you would be interested in using a report that is so deeply flawed—or any document created in response to it.

Your response did lead me to contact Dr. James Kirklin to obtain his assessment of Dr. Frazier's responses. Dr. Kirklin is, himself, a renowned heart transplant pioneer and the principal Investigator of the $15 million NIH-sponsored national Registry for Mechanically Assisted Circulatory Support (INTERMACS). As you probably know, INTERMACS is a North American registry for the clinical outcomes of patients who receive an FDA-approved mechanical circulatory support device to treat advanced heart failure. Dr. Kirklin also verified what I presume you know: that it is the hospital and not the surgeon who is responsible for all reporting of transplants and LVADs. I invite you to investigate his qualifications. Here is what he had to say after I forwarded the answers to your questions 2-5, 10 and 6.

> Dear David,
>
> I have read the responses, and they are excellent—and completely consistent with what I know of Dr. Frazier. Not only is he a major pioneer in this field, he is also a compassionate and caring physician and person. Given the complexity of the field, the near death state of most patients who need this therapy, and the number of years that have elapsed since this trial, I believe the reporter would be unfair and mean-spirited to proceed with an article without a prolonged, serious look at more data.

Let me know if I can provide further help.

Best,
Jim

James K. Kirklin
Professor of Surgery
Division of Cardiothoracic Surgery
Director, Kirklin Institute for Research in Surgical Outcomes (KIRSO)
University of Alabama at Birmingham (UAB)

In the law we have a concept known as the "fruit of the poisonous tree." When a search is illegal, whatever evidence recovered as a result is inadmissible in a court of law. I understand that journalistic practices are different, but accuracy and nuance are still important. I would hope you recognize that the Anson report is the poisonous tree and that the accuracy of all that follows is questionable.

. . .

I learned from your email that you have tried to get answers since January and neither doubt your word nor gainsay your frustration. The delay aside, however, you are dealing with Dr. Frazier's reputation, which he has built over fifty years of saving lives, not only with the continuous flow pump he perfected but also with the labor of his hands and days. Dr. Frazier has spent his life in operating room and the lab, advancing surgical techniques and processes that have saved thousands of lives. It should be of some significance that he has never been sued for malpractice. His seminal work—the continuous-flow pump—has been implanted in 40,000 patients worldwide. He is now at work on a total artificial heart, the Holy Grail of heart medical innovation. I am not suggesting that you are indifferent to his contributions and his reputation. I raise these points, however, in an attempt to stop a runaway train that would unjustifiably tarnish his career.

Exhibit M.

G. <u>Hixenbaugh and Ornstein intentionally misstated the number of reviews of the HeartMate II Clinical Study, exaggerating to create a false impression that there were "multiple reviews" in agreement about Dr.</u>

Frazier's alleged "noncompliance" with the Approval Protocol and "serious and repeated . . . research violations."

107. Hixenbaugh and Ornstein wrote that, according to the Law Firm Summary, there were "multiple reviews" of the HeartMate II and Jarvik Clinical Studies that led St. Luke's executives to reimburse Medicare. Exhibit B at 7. That is false. There were two reviews of the study—one conducted by Dr. Young and the other conducted by the Anson Group. Hixenbaugh and Ornstein knew that there were only two such reviews because they relied on the Law Firm Study, made clear the number of reviews. "Multiple" is a gross exaggeration, especially when one of the two studies, Dr. Young's, put the lie to their conclusions about Dr. Frazier's "serious and repeated . . . research violations." This is yet another indication that Hixenbaugh and Ornstein intended to mislead readers of the 2018 Article about Dr. Frazier and his work.

H. St. Luke's decision to reimburse Medicare was based on the deeply flawed Law Firm Summary.

108. It is worth noting why the St. Luke's Board members—like the readers of the 2018 Article—were misled by the unreliable Law Firm Summary. As a result, St. Luke's made an ill-advised decision when it reimbursed Medicare.

109. The Law Firm Summary summarized the findings of the Anson Report and *supposedly* the findings of the Young Report. The summary was then provided to the St. Luke's Board members. As noted *supra*, the Law Firm Summary—like

the 2018 Article—failed to provide full, fair, accurate, and complete information about Dr. Young's review and the contents of his report. For example, the summary did not include the conclusion in the Young Report about Dr. Frazier and THI: "*Of importance is the fact that during my review I found no evidence of a violation of criminal, civil or administrative law* to the extent I am familiar with those statutes." Exhibit K at 2 (emphasis added). Also, the Board, like Hixenbaugh and Ornstein should have found the Law Firm Summary unreliable, given the significant Government oversight and monitoring that were part of the THI implant and transplant programs.

110. St. Luke's decision to reimburse Medicare, based on the Law Firm Summary, was unnecessary and ill advised. The Board read what the reader of the 2018 Article read—and was also misled by the incomplete and misleading Law Firm Summary.

I. Hixenbaugh and Ornstein omitted material facts that are fatal to their conclusions drawn from the Law Firm Summary, the Anson Report, and Dr. Smart's accusations, of research violations regarding the LVAD.

111. The Anson Report was not unreliable simply because of its own admitted shortcomings. It was also unreliable because the very month the Anson Group conducted its two-day "review" of the HeartMate II and Jarvik Clinical Studies at THI and concluded that seventeen BTT patients failed to meet the Approval Protocol (citing sixteen HeartMate II BTT patient records) was the very

month—November 30, 2007 to be exact—that the FDA panel considering the HeartMate II for the BTT indication unanimously approved the device for that use. A few months later, in April 2008, the FDA approved the HeartMate II for the BTT indication.

112. The Anson Report not only accused the THI study of noncompliance and predicted that the FDA would likely impose the harsh sanction of a Form 483, which could lead to shutting down THI's implant study, but also held the Principal Investigator, "Dr. OHF" responsible. Exhibit N at 1–3. The Anson Report conclusions were based on seventeen BTT implants that its investigator(s) concluded did not meet the entry requirements of the implant core study protocol.[7] Had either the FDA panel or the FDA itself found any evidence in their review of BTT patient records to support such a conclusion neither would have endorsed the HeartMate II for BTT implantation.

113. Hixenbaugh and Ornstein intentionally omitted these facts about the FDA panel's recommendation in 2007 or the FDA approval in 2008 of the HeartMate II for BTT use—investigations of BT patients files that overlapped in time and substance with the Law Firm Summary and the documents and actions it generated. It should have been apparent, as the May 13 Email pointed out, that any

[7] The Law Firm Summary of the Anson Report—Hixenbaugh and Ornstein's main source material for the allegations of "serious and repeated . . . research violation" in the article, cites thirty such cases, but concludes thirteen of those are "arguable'; hence, the remaining seventeen.

document or action that the Law Firm Summary precipitated was no more or less than the fruit of the poisonous tree.

114. It is not as if three entities of equal stature, the FDA panel, the FDA itself, and the Anson Group, arrived at two equally credible conclusions. ***On one hand you have***, the Anson Group—a law-firm retained entity of "experts"—that concluded Dr. Frazier had engaged in "serious and repeated . . . research violations." Just possibly, these "experts" arrived at these conclusions (that were false), as a result of its admittedly hamstrung "investigation" ***or***, in the vicious world of academics, because of the store-bought result dictated by an unknown enemy of Dr. Frazier. ***On the other hand you have***, the FDA panel—which included relevant medical professionals, among others—***and*** the FDA—an established government agency, whose *sine qua non* is approving a device for marketing only after scrupulous due diligence, in this case a review of patient records. The FDA concluded there were no research violations, unlike those described in the for-profit Anson Report.

115. Not much more need be said, except that Dr. Smart participated in the very study the FDA reviewed. Surely it occurred to the intrepid researchers that his vicious accusations might be just a touch exaggerated, or just maybe, proven absolutely wrong by the contemporaneous assessment of the FDA.

J. Hixenbaugh and Ornstein omitted facts and relied on unsubstantiated allegations to create the false impression that Dr. Frazier violated the law—Dr. Branislav "Brano" Radovancevic and allegations of unlicensed practice of medicine.

116. From the 2018 Article:

> And a former St. Luke's nurse alleged that Frazier allowed a researcher who was not licensed to practice medicine in Texas to treat heart failure patients in his program. Her 1994 lawsuit, which was backed by patient records, testimony and secret recordings of hospital employees, revealed that Frazier's signature stamp was sometimes used to authorize the researcher's improper medical orders.

Exhibit B at 2.

117. Hixenbaugh and Ornstein's claims about Dr. Radovancevic are replete with errors and false impressions. He was not exactly "an unlicensed physician," which suggests a quack with less than honest motives. He was a brilliant physician who emigrated from Yugoslavia and was much loved and admired by his colleagues at THI, who affectionately called him "Dr. Brano." He had excellent patient skills and did a great deal of follow-up in an understaffed St. Luke's hospital. Dr. Radovancevic was the Director of the Center for Cardiac Support as part of THI, a research position.

118. As for Dr. Radovancevic's licensing, it was in the purview of the hospital, not Dr. Frazier, to maintain physician licensing in effect. This fact was omitted from the 2018 Article. To claim that "Frazier allowed" any unlicensed physician to practice medicine is false.

119. After Dr. Radovancevic died, he was honored in 2006 by an international society founded in his name, which exists today: the Brano Radovancevic Heart Failure Forum.[8] Every year, peer-reviewed presentations are given on the latest updates in the field of heart failure. Last year, more than five hundred participants and ninety faculty attended. How and why would leading physicians and researchers worldwide honor a quack physician dishonestly practicing medicine?

120. From the 2018 Article:

> But even then, his program was accused of crossing serious ethical lines: An unlicensed physician had been illegally treating heart failure patients, according to a 1994 federal lawsuit filed by former St. Luke's nurse Joyce Riley. The hospital and Frazier "participated in a scheme" to unnecessarily admit patients in order to move them higher on the national heart transplant waiting list, the lawsuit alleged.

Exhibit B at 3.

121. The lawsuit filed by the late Joyce Riley? Perhaps Hixenbaugh and Ornstein intentionally omitted the law and certain facts underlying the case to create a substantially false impression that there was any credence to Riley's claims.

122. In 1994, Riley filed a suit on behalf of the United States Government under the False Claims Act, a federal statute that allows an individual to sue on behalf of the Government when the individual believes that taxpayer dollars have

[8] https://www.brano-hff.org/

been fraudulently taken from the Government. Riley's suit claimed that Dr. Radovancevic, Dr. Frazier, Surgical Associates of Texas, P.A., the University of Texas Houston Health Science Center, Baylor College of Medicine, Texas Heart Institute, and Dr. Edward K. Massin engaged in a scheme to charge Medicare for medical services performed by Radovancevic, as if he were a licensed physician, and thus, the defendants should pay back all Medicare reimbursements.

123. In 2006, St. Luke's retained Joel Androphy, of Berg & Androphy, to defend the suit. Berg & Androphy is also lead counsel representing Dr. Frazier in this case.

124. As Hixenbaugh and Ornstein correctly wrote of Riley's suit—the "litigation dragged on for more than a decade, with little publicity." In fact, the lawsuit lasted for more than fifteen years.

125. After investigating the case for almost two years, the Government declined to intervene in the case—a matter of public record that was unreported in the 2018 Article. Why does that matter? The Government's failure to intervene can mean many things, including that the allegations lacked merit. In fact, at one point, the case was dismissed by the federal court, only to be revived by the United States Fifth Circuit Court of Appeals.

126. In 2009, as the case "dragged" on and legal expenses mounted into the millions, St. Luke's, THI, Dr. Frazier, and other defendants settled the case with the

Government. If Riley's case was so strong and the defendants' conduct so widespread and egregious, why would the Government settle for $500,000—as Hixenbaugh and Ornstein reported (*see infra*)—after ***fifteen years*** of litigation? Of course, this is not the type of question one explores or mentions when one is trying to create a false impression that something nefarious has occurred.

127. From the 2018 Article:

> Two years later, in 2009, St. Luke's, Texas Heart, Frazier and other defendants agreed to settle the case, attracting no media attention. The terms — including the total payment and whether the defendants acknowledged any wrongdoing — ***remain secret***.
>
> A spokeswoman for the U.S. Justice Department said the ***federal government's share was $500,000, but that does not include the amount paid to Riley — between 15 and 30 percent of the total settlement*** — as a reward for bringing the case forward, or the significant legal fees repaid to her lawyers.

Exhibit B at 4 (emphasis added).

128. Hixenbaugh and Ornstein's claim that the terms of settlement "remain secret" was clearly their purposeful avoidance of the truth. If Hixenbaugh and Ornstein wanted the terms of settlement and the Department of Justice refused, they could have filed a Freedom of Information Act request, commonly done by journalists seeking undisclosed Government information. But why wait for information that would make the 2018 Article fair, balanced, and accurate? Instead, Hixenbaugh and Ornstein claimed that the settlement terms "remain secret." That is

simply not true.

129. Also, Hixenbaugh and Ornstein's claim that the $500,000 paid to the Government "does not include the amount paid to Riley—between 15 and 30 percent of the total settlement" is not accurate and is *again* another example of their feckless journalism. Even a cursory review of the False Claims Act statutory language, particularly 31 U.S.C. 3730(d) ["Award to Qui Tam Plaintiff"] would establish two inaccuracies in the statement quoted above: (1) a relator receives a percentage of what the Government is paid, not some separate amount and (2) if the Government does not intervene, like in Riley's case, the percentage is between 25 and 30 percent, not "between 15 and 30 percent."

130. As noted *supra*, the "Making Matters Worse Article" confirms that in the 2018 Article Hixenbaugh and Ornstein verified and vouched for ". . . ***allegations*** of serious research violations and ethical breaches by famed Houston heart surgeon O.H. "Bud" Frazier." Exhibit C at 1. The problem is that allegations are, just that, allegations. But Hixenbaugh and Ornstein present the allegations made in the Riley lawsuit (pre-1994 conduct) and myriad other allegations recounted in the 2018 Article as though they are true when they knew, or had reason to know, that the allegations were false. Not only were many of the allegations discussed in the 2018 Article false, but also were never determined to be true by a court or any governmental entity.

K. Hixenbaugh and Ornstein contacted the New England Journal of Medicine and triggered an investigation into Dr. Frazier's publications about the HeartMate II Clinical Study, creating a false and humiliating impression about Dr. Frazier and the legitimacy of the study results he published.

131. From the 2018 Article, discussing the results of the Young Report and Anson Report:

> *None of this* was disclosed when the results of the HeartMate II trial were published in the prestigious *New England Journal of Medicine [NEJM]* in 2009, with Frazier listed as an author. A spokeswoman for the journal said editors were not aware of the issues until reporters asked in April and are now seeking more information.
>
> Abbott, which now owns the company that makes HeartMate II, said the "study was conducted in accordance with the highest research standards, all patients were enrolled and followed per study protocol, and all data was fully audited and vetted prior to publication and submission to the FDA."

Exhibit B at 8 (emphasis added).

132. The meaning of Hixenbaugh and Ornstein's comments is unmistakable: had Dr. Frazier not kept secret his "noncompliance" with the Approval Protocol, NEJM would never have run the 2009 article. In other words, they allege that Dr. Frazier managed to put one over on the NEJM and his colleagues who read the article.

133. One would think, because Hixenbaugh and Ornstein triggered an investigation by NEJM and raised significant doubts about Dr. Frazier's honesty and the legitimacy of the results he reported, that Hixenbaugh and Ornstein would have

waited for the results of the investigation and NEJM's response to it before printing their article. They did not. The reason seems obvious. Just from the public record available to them, Hixenbaugh and Ornstein, their editors and publishers—all of them—would have known that the FDA would never have included THI's results from the HeartMate II Clinical Study, indeed, might not have approved the HeartMate II for marketing, if Hixenbaugh and Ornstein's accusations were true. Thus, it merited Hixenbaugh and Ornstein nothing to wait for the results of the investigation and NEJM's response.

134. As a result of Hixenbaugh and Ornstein's accusations, NEMJ, which does not conduct its own research, but relies instead on the honesty of the researchers who report results to it, required that Abbott Laboratories, which bought Thoratec and now owns the HeartMate II, answer the accusations of Dr. Frazier's undisclosed noncompliance with the Approval Protocol. The result, if Hixenbaugh and Ornstein were telling the truth, would have forced NEJM to retract the story.

135. As Hixenbaugh and Ornstein knew, the stakes were high. Retraction by such a credible source like NEJM would have substantiated the reporters' allegations about Dr. Frazier's research violations. However, if the opposite were true, if Dr. Frazier's reported results (he was the first-listed author) were affirmed, if no research violations were found, and if NEJM did not retract the 2009 article, Hixenbaugh and Ornstein's story (refuted at its core) may well have been killed.

136. Abbott did exactly as the NEJM required, retrieving the ten-year-old patient records (thousands of pages), not only about the core study group results reported in the NEJM article, but also about those "noncompliant" patients who received an implant outside the Approval Protocol, under Compassionate or Emergency Use Exemptions. In addition, the Abbott investigators reviewed a 2007 NEJM article with Dr. Frazier as first-listed author, documenting the early results of the HeartMate II Clinical Study, which Hixenbaugh and Ornstein had not mentioned.

137. Just ***eighteen*** days following publication of the *ProPublica* and *Houston Chronicle* Article, on June 11, 2018, Abbott sent a letter, signed by David J. Farrar, Ph.D., Abbott's Director of Research and Scientific Affairs (and, previously, Thoratec's Vice President of Regulatory and Scientific Affairs during the HeartMate II Clinical Study) and Donald Middlebrook, Abbott's Regulatory and Clinical Consultant, reporting its findings to Dr. John Jacho, NEJM Deputy Editor, and detailing Abbott's prodigious efforts to review the HeartMate II Clinical Study that Hixenbaugh and Ornstein called into question. This was Abbott's conclusion:

> We have reviewed the HeartMate II (HMII) clinical trial documents from a decade ago and are responding to your e-mail of May 2 regarding alleged non-compliance to study protocols at St Luke's Hospital - Houston/Texas Heart Institute. Our review below confirms that the HMII results as published in the NEJM for BTT (Miller L Wet al NEJM 2007;357(9):885-96) and DT (Slaughter et al NEJM 2009;361 (23):2241-51) have been validated and are undisputable beyond reproach. *We had no breaches of research ethics and our records show good research practice was adhered to throughout the study.*

Exhibit P (emphasis added).

138. The NEJM is not going to retract ***a single word*** of the 2007 and 2009 articles with Dr. Frazier as first-listed author, in which he and other researchers accurately reported the results of the HeartMate II Clinical Study at THI. Small wonder that Dr. Jacho wrote in a June 12 email to Dr. Frazier's assistant:

> The fact that the Journal published these two articles at the time is our certification that, to the best of our knowledge, the reports appeared accurate and free of any indication of misconduct. The fact that *we have not retracted these papers or issued corrections, and have no plan to do so*, is our only affirmation that we continue to have confidence in the articles as published.

Exhibit Q (emphasis added).

139. In short, Hixenbaugh and Ornstein, in their haste, slandered Dr. Frazier in their calls to the NEJM, libeled him in their emails, and humiliated him with the employees and executives of that highly regarded publication. What is worse is that, even without the results of NEJM's investigation, Hixenbaugh and Ornstein had more than sufficient evidence just from the public record to doubt the integrity and accuracy of their own primary sources.

140. At some point following publication, NEJM also informed Hixenbaugh and Ornstein that the publication was not going to take any further action, which they published in the "Making Matters Worse Article," with no hint of a retraction or the common courtesy of an apology for their egregious blunder in failing to wait

those eighteen days.

141. From the "Making Matters Worse Article":

> The New England Journal of Medicine, which published studies based in part on Frazier's research, initially told reporters that it was not aware of any concerns prior to our reporting. In an email this month, a journal spokeswoman wrote that editors subsequently received information about patients enrolled in the trial.
>
> > "Based on this information, which is confidential, we are satisfied that the published data are accurate and that the trial is appropriately described. For these reasons, we do not consider it necessary to take further action. *The internal Texas Heart Institute review you provided* to us focused on the clinical trials of two different devices: the HeartMate II device and the Jarvik 2000 device. NEJM did not publish any data from the Jarvik 2000 study, so we cannot evaluate the veracity of reports from that trial."

Exhibit C at 5 (emphasis added).

142. NEJM's statement raises two questions: 1) Just what does it take for Hixenbaugh and Ornstein to admit a mistake? and 2) Just what "review" did Hixenbaugh and Ornstein provide NEMJ? Was it the Anson Report, the one Hixenbaugh and Ornstein claimed they did not have? Or did Hixenbaugh and Ornstein provide the Law Firm Summary? Either way, Hixenbaugh and Ornstein created a false impression of Dr. Frazier among his colleagues at NEJM, with whom he had worked for decades, and potentially, a career-ending allegation that the HeartMate II results he authored were false, itself pretty bizarre, given that the HeartMate II and other LVADs are not only saving and prolonging lives

worldwide—but also producing results far better than the study predicted.

143. Dr. Frazier has dedicated his life to saving the lives of others. Ornstein and Hixenbaugh have, in this instance, dedicated their lives to destroying someone else's.

VII. CAUSES OF ACTION

A. DEFAMATION

144. Plaintiff realleges and incorporates by reference every allegation contained in all paragraphs of this Petition, as though they were fully set forth herein.

145. Defendants made numerous false and misleading statements in the 2018 Article and accused Dr. Frazier of inhumanely experimenting on patients; hiding the harmful effects of the LVAD; letting "pay offs" influence his medical decisions; and allowing a researcher, who was an unlicensed doctor, to treat patients ("Defendants' statements").

146. Defendants' statements and publications as a whole and each of their statements explicitly and through their implications and impressions are false and defamatory.

147. Defendants' statements and publications as a whole and each of their statements explicitly and through their implications and impressions were made in a grossly irresponsible manner and negligently, with want of reasonable, due care and without appropriate and reasonable fact checking, investigation and regard for

accuracy.

148. Defendants' statements and publications as a whole and each of their statements explicitly and through their implications and impressions were made with knowledge of their falsity or with reckless disregard for their truth or falsity.

149. Defendants' conduct and statements were knowing, committed and made with actual malice, willful and wanton, entitling Dr. Frazier to an award of punitive damages.

150. The false and defamatory statements published by Defendants caused grievous and irreparable injury and harm to the person, character, and career of Dr. Frazier, caused him to suffer loss of income, caused him extreme emotional pain and mental anguish, altered his life and that of his family, and caused injury to his earning capacity, reputation, and goodwill.

B. INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS

151. Plaintiff realleges and incorporates by reference every allegation contained in all paragraphs of this Petition, as though they were fully set forth herein.

152. Defendants knew or should have known that their publication of false and misleading statements in the 2018 Article would cause Dr. Frazier to suffer severe emotional distress.

153. Defendants' publication of false and misleading statements in the 2018 Article—Dr. Frazier inhumanely experimented on patients, hid the harmful effects

of the LVAD, was bought off and let money influence his medical decisions, allowed a researcher, who was an unlicensed doctor, to treat patients—and decision to publish the article in the first instance, is conduct that is undeniably extreme and outrageous, going beyond all possible bounds of decency.

154. Defendants were warned prior to publication that they had misconstrued data and misinterpreted facts. Therefore, Defendants' conduct was intentional or reckless.

VIII. DAMAGES

155. Plaintiff incorporates all the foregoing paragraphs by reference as though fully set forth herein.

156. As a direct result of Defendants' acts and omissions alleged herein, Dr. Frazier has suffered general and special damages, including a severe degree of mental stress and anguish.

157. Dr. Frazier has also suffered damage to his reputation and image, both up to the present and into the future.

158. Defendants' conduct amounts to defamation per se. Thus, Dr. Frazier is entitled to an award of presumed damages.

159. Dr. Frazier is entitled to an award of nominal damages and a judgment clearing his names.

160. Dr. Frazier is entitled to exemplary damages because the Defendants

acted with knowledge that their statements were false or with reckless disregard for their truth or falsity.

161. Dr. Frazier is also entitled to pre-judgment and post-judgment interest, costs of court, and attorneys' fees.

162. Pursuant to Rule 47 of the Texas Rules of Civil Procedure, Dr. Frazier is seeking relief in excess of $1,000,000.

IX. JURY DEMAND

163. Plaintiff demands a trial by jury and pays the requisite fee.

X. PRAYER

164. Plaintiff Dr. Bud Frazier prays that Defendants *ProPublica*, the *Houston Chronicle*, reporter Charles Ornstein, and reporter Michael Hixenbaugh be cited to appear and answer herein, and that Plaintiff recover the following:

a. Actual damages within the jurisdictional limits of the Court;

b. Special damages;

c. Exemplary Damages;

d. Prejudgment and post judgment interest;

e. Costs of suit; and

f. All other relief to which Plaintiff is justly entitled.

Dated: July 23, 2018.

Respectfully submitted,

BERG & ANDROPHY

/s/ David H. Berg

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