12-Person Jury

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

DAVID CHODAK, Independent Executor of the Estate of RUTH COLBY, Deceased, Plaintiff,	)	
v.	)	No.
THE UNIVERSITY OF CHICAGO HOSPITALS AND HEALTH SYSTEM, and HUSAM H. BALKHY, M.D., Defendants.	)	***PLAINTIFF DEMANDS TRIAL BY JURY***

COMPLAINT AT LAW

Plaintiff, DAVID CHODAK, Independent Executor of the Estate of RUTH COLBY, Deceased, by his attorneys, CLIFFORD LAW OFFICES, P.C., complaining of Defendants, THE UNIVERSITY OF CHICAGO HOSPITALS AND HEALTH SYSTEM (hereinafter "UCHICAGO"), and HUSAM H. BALKHY, M.D. (hereinafter "BALKHY"), states as follows:

COUNT I – WRONGFUL DEATH

1. On September 25, 2023, and at all relevant times mentioned herein, Defendant, UCHICAGO, was a health care facility employing physicians.

2. On September 25, 2023, and at all relevant times mentioned herein, Defendant, BALKHY, was a physician specializing in cardiovascular surgery.

3. On September 25, 2023, and at all relevant times mentioned herein, Defendant, BALKHY, was a duly authorized agent and employee of Defendant, UCHICAGO, acting within the scope of his agency and employment.

4. On July 11, 2023, RUTH COLBY underwent a transthoracic echocardiogram (TTE).

5. Shortly after July 11, 2023, RUTH COLBY was referred to the Defendant UCHICAGO for evaluation for possible robotic assisted minimally invasive mitral valve repair.

6. On August 2, 2023, Defendant, BALKHY, evaluated RUTH COLBY, at Defendant, UCHICAGO MEDICINE, for possible robotic minimally invasive valve repair.

7. On August 2, 2023, Defendant, BALKHY, recommended a robotic assisted minimally invasive mitral valve repair procedure.

8. RUTH COLBY presented to Defendant, UCHICAGO, and underwent preoperative cardiac catheterization which revealed normal artery anatomy, clean coronaries in the absence of any gradient from the left ventricular cavity through the subaortic region, aortic valve, and the aortic root on pull back.

9. On September 24, 2023, RUTH COLBY presented to Defendant, UCHICAGO, for scheduled robotic mitral valve repair with Defendant, BALKHY.

10. On September 25, 2023, Defendant, BALKHY, performed a mitral valve annuloplasty and septal shaving.

11. On September 25, 2023, after completion of a mitral valve annuloplasty and shaving of the septum, RUTH COLBY was unable to be transitioned off conventual cardiopulmonary bypass and suffered severe systolic anterior motion (SAM) and severely reduced right ventricular performance.

12. On September 25, 2023, RUTH COLBY's right ventricular performance improved with inotropic support, but the SAM remained, and RUTH COLBY was not able to be transitioned off cardiopulmonary bypass.

13. On September 25, 2023, Defendant, BALKHY, reinstituted cardiopulmonary bypass and performed additional septal shaving with the addition of an Alfieri stitch and extra

Neonchords.

14. On September 25, 2023, Defendant, BALKHY, made several repeated attempts to transition RUTH COLBY off conventual cardiopulmonary bypass without success.

15. On September 25, 2023, Defendant, BALKHY, placed RUTH COLBY on veno-arterial extracorporeal membrane oxygenation (ECMO).

16. On September 25, 2023, RUTH COLBY was transferred from the operating room and transported to the cardiothoracic intensive care unit in critical condition.

17. On September 25, 2023, and thereafter, RUTH COLBY, suffered severe right heart failure.

18. On September 28, 2023, and thereafter, repeat TEEs in the ICU revealed overall poor right-sided heart performance with tricuspid regurgitation.

19. On September 28, 2023, and thereafter, RUTH COLBY developed hepatic and renal failure.

20. On October 1, 2023, and thereafter, RUTH COLBY developed atrial fibrillation and ventricular arrythmias.

21. On October 15, 2023, RUTH COLBY died as the result of prolonged cardiogenic shock, organ malperfusion and worsening multi-system organ failure.

22. On September 25, 2023, and at all times mentioned herein, Defendant, BALKHY, had a duty to possess and use the knowledge, skill, and care ordinarily used by a reasonable careful physician under the same or similar circumstances.

23. On and before September 25, 2023, and at all times mentioned herein, Defendant, BALKHY, was professionally negligent in the following ways:

a) did not document the presence of SAM and presumed LVOTO before the surgical procedure;

b) did not provide adequate and acceptable myocardial protection during the performance of the surgical procedure;
c) did not convert to an open procedure;
d) did not replace the mitral valve with a bioprosthetic valve;
e) did not preserve left and right ventricle function;
f) did not return RUTH COLBY to the operating room immediately after the initial surgery to perform mitral valve replacement.

24. As a direct and proximate result of the aforesaid negligent acts and/or omissions, RUTH COLBY sustained injuries which resulted in her death on October 15, 2023.

25. Plaintiff's Decedent, RUTH COLBY, is survived by her husband, Donald DeFrank, and son, David Chodak, both of whom have sustained personal and pecuniary loss as a result of her death, including, but not limited to, loss of society, love, companionship, affection, consortium and guidance.

26. Plaintiff, DAVID CHODAK, is the Independent Executor of the Estate of RUTH COLBY, Deceased, and brings this action on behalf of the Estate of RUTH COLBY, deceased, pursuant to the Wrongful Death Act of the State of Illinois, 740 ILCS 180/1 *et seq.*

27. Attached to this Complaint at Law is the affidavit of one of Plaintiff's attorneys and the physician's report required by 735 ILCS 5/2-622.

WHEREFORE, Plaintiff, DAVID CHODAK Independent Executor of the Estate of RUTH COLBY, Deceased, demands judgment against Defendants, THE UNIVERSITY OF CHICAGO HOSPITALS AND HEALTH SYSTEM, and HUSAM H. BALKHY, M.D., and each of them, in an amount in excess of FIFTY THOUSAND DOLLARS ($50,000.00).

COUNT II – SURVIVAL ACTION

1-23. Plaintiff, DAVID CHODAK, Independent Executor of the Estate of RUTH COLBY, Deceased, and DAVID CHODAK, individually, by his attorneys, CLIFFORD LAW OFFICES, P.C., hereby reasserts and re-alleges Paragraphs **1 through 23** of this Complaint at

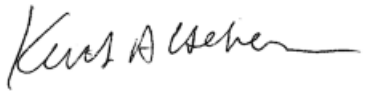
Law, as if fully set forth herein.

24. As a direct and proximate result of the aforesaid negligent acts or omissions, RUTH COLBY sustained injuries of a personal and pecuniary nature before her death, including but not limited to conscious pain and suffering, and had she survived she would have been entitled to bring an action for those injuries and this action survives her.

25. Plaintiff, DAVID CHODAK, is the Independent Executor of the Estate of RUTH COLBY, Deceased, and brings this action pursuant to 755 ILCS 5/27-6, otherwise known as the Survival Act of the State of Illinois.

26. Attached to this Complaint at Law is the affidavit of one of Plaintiff's attorneys and the physician's report required by 735 ILCS 5/2-622.

WHEREFORE, Plaintiff, DAVID CHODAK, Independent Executor of the Estate of RUTH COLBY, Deceased, demands judgment against Defendants, THE UNIVERSITY OF CHICAGO HOSPITALS AND HEALTH SYSTEM, and HUSAM H. BALKHY, M.D., and each of them, in an amount in excess of FIFTY THOUSAND DOLLARS ($50,000.00).



Attorneys for Plaintiff

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Plaintiff,	)	
v.	)	No.
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Defendants.	)	

PLAINTIFF'S ATTORNEY AFFIDAVIT PURSUANT TO 735 ILCS 5/2-622(a)(1)

KEITH A. HEBEISEN states as follows:

1. I am one of the attorneys with responsibility for this matter on behalf of the Plaintiff.

2. I have consulted and reviewed the facts of this case with a health professional whom I reasonably believe: (i) is knowledgeable in the relevant issues involved in this particular action; (ii) practices or has practiced within the last six (6) years or teaches or has taught within the last six (6) years in the same area of health care or medicine that is at issue in this particular action; and (iii) is qualified by experience or demonstrated competence in the subject of this case.

3. The reviewing health professional has determined in a written report after review of the medical records and other relevant material involved in this particular action that there is a reasonable and meritorious cause for the filing of this action against THE UNIVERSITY OF CHICAGO HOSPITALS AND HEALTH SYSTEM and HUSAM H. BALKHY, M.D.

4. I have concluded on the basis of the reviewing health professional's review and consultation that there is a reasonable and meritorious cause for filing of this action against THE

UNIVERSITY OF CHICAGO HOSPITALS AND HEALTH SYSTEM and HUSAM H. BALKHY, M.D.

5. A copy of the written report is attached.

FURTHER AFFIANT SAYETH NOT.

Attorney for Plaintiff

[X] Under penalties as provided by law pursuant to 735 ILCS 5/1-109 of the Code of Civil Procedure, I certify that the statements set forth in this instrument are true and correct, except as to matters therein stated to be on information and belief and as to such matters the undersigned certifies as aforesaid that I verily believe the same to be true.

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February 12, 2024

VIA EMAIL TO: kah@cliffordlaw.com
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RE: *Colby, Ruth deceased*

Dear Mr. Hebeisen:

At your request I have completed my review of the medical records of Ruth Colby from Silver Cross Hospital and her admission to the University of Chicago Medicine hospital from 24 September 2023 thru her death on 15 October 2023 after undergoing what was to be a routine mitral valve replacement for mitral regurgitation by cardiovascular surgeon Dr. Husam H. Balkhy. My review includes all imaging, including echocardiograms and the cardiac catheterization in July 2023. It is my understanding from the voluminous medical records (>8000 pages) that at the time of Ms. Colby's death she was a 69-year-old female health executive with a history of sick-sinus syndrome (SSS) which required a DDD pacemaker in 2006 with medical comorbidities of hypertension, hypercholesterolemia, Raynaud's disease, and the recent onset of symptoms of shortness of breath, dyspnea on exertion, and easy fatigueability. She was an established patient of Dr. Kathleen J. Drinan and cardiologist Dr. Jia Goo (who was managing her pacemaker and did a battery exchange) and was referred to the University of Chicago for evaluation of symptoms consistent with mitral regurgitation. I have reviewed all of the medical records of the admission to the University of Chicago Medicine hospital and records of prior treatment dating back to the late 1990's. What is important in those records is the relative absence of any mention of mitral valve disease until Ms. Colby presented with signs of Sick Sinus Syndrome and underwent evaluation by Dr. Goo. Although the records indicate Ms. Colby was functional, she developed signs of worsening mitral regurgitation in the early spring of 2023, noted after light exercise, swimming, and bicycling. The referral to cardiology by her PCP was appropriate as was the cardiology workup to include CTA, PET-MUGA, TTE, TEE, and cardiac catheterization.

A transthoracic echo (TTE) was performed in June 2023 which demonstrated a preserved ejection fraction of 63%, normal left and right ventricular size, normal atrial size, apparent myxomatous degeneration of both the anterior and posterior mitral valve leaflets with moderate to severe mitral regurgitation, and suggestion of SAM (systolic anterior movement of the mitral valve leaflet). Additional mention is made of LVOTO (left ventricular outlet obstruction). With these findings she was referred to Dr. Balkhy for evaluation for possible robotic assisted minimally invasive mitral valve replacement on 2 August 2023. From the record authored by the physician assistant, it is clear that surgery was to be offered and preoperative cardiac catheterization, PET-Cardiac CT-A and clearance from Dr. Goo would be required. Cardiac catheterization was performed in July 2023 in anticipation of surgery.

The TEE of 7/21/23 was well done with excellent images, is elucidating and consistent with the operative description of the mitral apparatus. There is an elongated anterior mitral valve (MV) leaflet that is longer than the posterior MV leaflet which is somewhat unusual but can occur with her disease of mitral valve prolapse. The challenging aspect of the interpretation is that the chordae are thickened and elongated. It is difficult to interpret where the MV leaflet ends and the chordae begin. My interpretation is that there is predominantly late systolic chordal SAM and there is outflow tract turbulence by color doppler with what appears to be an outflow gradient of at most 7 mm. Importantly there also is a 7 mm gradient on the cardiac cath. A single end hole catheter was used for the entire cath procedure and there's no notation that it had a side hole. Although the report incorrectly says no gradient, the fact that there is a small gradient without hemodynamic consequence should not require intervention. DDD pacing alone would have substantially diminished the SAM and likely resolved the small gradient. There is mild to at most moderate left ventricular hypertrophy (LVH) of 1.4-1.5 cm which is not asymmetric and with, at most, a minimal amount of basal septal prominence. There is moderate to moderately severe MV regurgitation pre-operatively.

A CT of the chest was also performed, which did not reveal any anatomical pathology. With this information Dr. Balkhy, in my opinion "sold" Ms. Colby on a robotic minimally invasive mitral valve surgical procedure. What was required was a mitral valve replacement with a bioprosthetic. This would have addressed her diseased myxomatous valve resulting in her regurgitation and corrected any possibility or question of SAM with LVOTO. There was no evidence of LVOTO or hypertrophied septum on any preoperative study which justified the subsequent "shaving" of the septum multiple times by Dr. Balkhy during surgery.

According to the records of both the anesthesiologist and Dr. Balkhy, after completion of a mitral valve annuloplasty and "shaving" of the septum, Ms. Colby was unable to be transitioned off conventual cardiopulmonary bypass. The intraoperative records reflect that with increase in volume to the heart the "SAM got worse" as did her right ventricular performance, which in my opinion was due to poor myocardial protection. With the addition of inotropic support her pressures were acceptable, but the SAM remained, and she was not able to be transitioned off cardiopulmonary bypass. Dr. Balkhy reinstituted cardiopulmonary bypass and, according to the records, performed more "shaving" of the septum with the addition of an "Alfieri" stitch, the "bow-tie stitch" or "edge to edge stitch" which is a bail-out procedure to bring the two leaflets into apposition after mitral valve repair. It is my opinion that after this failed attempt to salvage a degenerated myxomatous valve, mitral valve replacement with a bioprosthetic should have been performed. Ms. Colby again failed to be able to be weaned from cardiopulmonary bypass. ECMO via a femoral-femoral route was instituted and Ms. Colby was transported to the cardiac intensive care unit.

In the ICU Ms. Colby had several postoperative complications associated with her prolonged bypass run, right ventricular failure, and low cardiac output. It was decided to wean and separate her from ECMO. However, as she had suffered severe right heart failure, she required oxy-RVA-J (via internal jugular cannulation). In addition to requiring oxy-RVA-J, after decannulation it was observed that her right leg had become ischemic. Vascular surgery was consulted, and Ms. Colby was returned for femoral artery and femoral vein exploration. The records indicate the artery was partially occluded, this was repaired, and flow restored to her lower extremity. Repeat TEE in the ICU revealed overall poor right sided heart performance with tricuspid regurgitation. There was a little mitral regurgitation, more probable than not a result of poor volume to the left side of heart in the presence of continued low cardiac output, or mitral valve stenosis. To say Ms. Colby had a rocky postoperative course would be an understatement. With continued low cardiac output and right ventricular failure she developed hepatic and renal failure, both as a result of prolonged cardiac assist and primarily right sided congestive heart failure. Both hepatology and nephrology were consulted, and Ms. Colby was started on CVVH then dialysis.

With continued heart failure it was requested that she be evaluated by the heart failure team and then by the transplant service for the possibility of transplant. Further complicating her course was the development of atrial fibrillation and ventricular arrythmias. This responded to changing her pacemaker thresholds and pacing with the addition of chemical cardioversion. Unfortunately, with prolonged cardiogenic shock and organ malperfusion, Ms. Colby suffered worsening multi-system organ failure which culminated in her death on 15 October 2023. The certificate of death lists the cause of death as right ventricular heart failure with underlying contributing factor of mitral valve regurgitation.

As a practicing board-certified cardiovascular surgeon and a board-certified trauma general surgeon, with additional prior board certification in surgical critical care, with over four (4) decades of surgical experience, I am routinely consulted to offer surgical treatment to patients with valvular disease, and I am familiar with the available surgical techniques available and the contraindications, complications, and indications for mitral valve replacement or repair. Therefore, I am able to provide you with this medical opinion with regard to the care and treatment provided to Ms. Colby by the cardiovascular surgeon Dr. Husam H. Balkhy. I attach a recent curriculum vitae which outlines my education, training, and over four (4) decades of surgical experience.

At issue is the over-all substandard care provided to the deceased by cardiovascular surgeon Dr. Husam H. Balkhy which resulted in an unacceptable patient outcome. Per Dr. Balkhy's own STS risk score assessment, Ms. Colby should have had a predicted mortality of less than 1.3%-1.7%. However, as Dr. Balkhy failed to conform to the standard of care, Ms. Colby had a mortality of 100%. Dr. Balkhy departed from the accepted standards of care and breached those standards which resulted in this unacceptable patient outcome, specifically:

1. There was a lack of documentation of the presence of SAM and presumed LVOTO prior to the surgical procedure. Although a single TTE suggested SAM and LVOTO, certainly the cardiac catheterization did not show a gradient from the left ventricle thru the subaortic, annular, and aortic root during pull back pressures, so this was not a case of septal hypertrophy. Although one of the etiologies of LVOTO is SAM where there is displacement of the anterior mitral valve leaflet (AMVL) towards the left ventricle, the cure

is mitral valve replacement with a bioprosthetic and tucking the AMVL under the annulus, which preserves LV and RV function.

2. Dr. Balkhy failed to provide adequate and acceptable myocardial protection during the performance of his minimally invasive surgical procedure which resulted in right ventricular failure. All preoperative studies document preserved LV and RV function without evidence of pulmonary hypertension or RVOTO. Given normal right and left coronary artery anatomy, there is no other logical explanation for the right ventricle becoming ischemic due to poor myocardial protection. There is also no evidence of excessive pulmonary artery pressures (PHTN), which can occur with chronic mitral valve stenosis or incompetence. This is a failure to conform to acceptable standards of care with regard to myocardial protection.

3. Although robotic minimally invasive mitral valve repair (MVr) or replacement (MVR) may be a selling point to patients, when intraoperative complications arise, the standard of care is to convert to an open procedure which provides exposure and the ability to access regional wall motion, and replace the valve with a bioprosthetic with confidence. From the intraoperative records, repair of a myxomatous valve, which by definition is already diseased, in the presence of presumed SAM, would mandate replacement rather than repair without septal "shaving". There is no evidence that her SAM was a result of LVOTO and Ms. Colby's clinical presentation was neither suggestive of or clinically confirmed to be isolated SAM or LVOTO.

4. Lastly, it is my professional medical opinion that since he failed to do so in the operating room, Dr. Balkhy was required by the standard of care to return Ms. Colby to the operating room immediately after the initial surgery to perform mitral valve replacement. Although the post-procedural TEE's reflect "minimal" mitral valve regurgitation, it is my opinion that Ms. Colby remained in a low cardiac output state and with worsening right ventricular failure due to functional mitral stenosis. Although the 'Alfieri" stitch brings the leaflets together, in patients that have undergone an annuloplasty and have myxomatous valve disease (the leaflets are stiff) a major concern is functional mitral valve stenosis. I do not see that was considered as a cause of Ms. Colby's worsening right sided heart failure in conjunction with poor myocardial protection.

In summary, it is my professional medical opinion that Ruth Colby's death at age 69 was preventable. Surgeons, for a variety of reasons use "minimally invasive", "Robotic MIS", and "minimal invasive port-access surgery" among other catch phrases to "sell surgery" and to imply that patients will have an easier recovery and better outcomes. This may be true in some cases, but in the case of Ms. Colby it is my professional medical opinion, based upon by education, training, and over four (4) decades of surgical experience that Dr. Husam Balkhy departed from and breached the standard of care for the reasons previously mentioned. Ruth Colby should have had the predicted STS score of a mortality of less than 1.3%-1.7%. Unfortunately as Dr. Balkhy did not conform with and breached the standard of care in several respects, Ms. Colby died from what should have been a straightforward mitral valve replacement with a bioprosthetic. This would have corrected her mitral regurgitation from myxomatous mitral valve disease and resolved any issues with the presence of SAM or LVOTO from the AMVL.

I reserve the right to change or modify these medical opinions if new or undisclosed information becomes available for my review.

If you have any questions after your review of this medical opinion, please do not hesitate to contact me.

Sincerely yours,