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October 8, [REDACTED]

[REDACTED]

Re: [REDACTED]

Dear Mr. [REDACTED],

This letter will confirm review of records sent regarding the above-named patient. After careful analysis, the reviewing physician, a board-certified general vascular surgeon, rendered the following summary and opinion.

Mr. [REDACTED] was a 63-year-old male who was evaluated by Dr. [REDACTED], general surgeon, on April 1, [REDACTED], and then referred to Dr. [REDACTED], general vascular surgeon, for a known abdominal aortic aneurysm. Diagnostic testing showed a 9 cm. (3.5 inches) long segment, in which the abdominal aorta was dilated, with a maximum diameter of 5.3 cm. (approximately 2 inches). The aneurysm was noted to have progressed since the previous diagnostic study.

On further study, the aneurysm appeared to have ulceration within the plaqued lining, and there was a circumferential mural thrombus throughout the aneurysm lumen that extended for several centimeters. Surgical repair of the “thick walled, inflammatory” abdominal aortic aneurysm was planned.

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James N. Saponaro, D.B.A. 1930-2003

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On July 14, ██████████, Mr. ██████████ was admitted to ██████████. It was described that the abdominal aortic aneurysm extended from “below the renal arteries to the bifurcation and was found to be approximately 4.6 cm in diameter by CT scan.” The surgical repair of the aneurysm involved use of a Dacron graft, and included hernia repair, as well. Postoperatively, Mr. ██████████ suffered a myocardial infarction and kidney failure.

In August of ██████████, Mr. ██████████ suffered a subdural hematoma, believed to be associated with the anti-platelet therapy necessary following the repair of his abdominal aortic aneurysm.

On January 5, ██████████, Mr. ██████████ reported to ██████████, C-FNP, of ██████████ ██████████ that he was suffering persistent left lower abdominal pain, noting that it “could be relieved with position changes.” That afternoon, Mr. ██████████ was examined by Dr. ██████████ for “sharp, burning pain...relieved by standing and by spreading his legs apart.” On January 10, ██████████, a CT scan revealed the presence of an abdominal aortic aneurysm, measuring 5 cm. x 5 cm., which originated from above the level of the renal arteries and extended to the aortic bifurcation to the right and left iliac arteries. It was documented that “along the anterior left lateral aspect of the abdominal aortic aneurysm, there was a rounded fluid attenuation focus that measured 2.0 x 2.4 cm. which caused mass effect upon the small bowel.”

An ultrasound examination was subsequently performed, and interpreted by Dr. ██████████, general surgeon, to show a repaired abdominal aortic aneurysm measuring 4.7 cm. x 5.4 cm. in diameter with a pseudoaneurysm.

An aneurysm describes a weakness of the arterial wall that with continued blood flow and blood pressure, allows a ballooning of a portion of the arterial wall. Small aneurysms are not repaired, and instead observed for changes and progression.

The term, pseudoaneurysm, describes a condition in which a hole, tear, or injury occurs in the interior walls of an artery, but not through to all layers of the blood vessel.

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Thus, as blood flows, it enters the abnormal opening but does not exit the blood vessel, becoming trapped beneath the outer layers. This causes enlargement and balloon dilation of the vessel, similar to an aneurysm, but from a different cause. It is a known, potential complication of an abdominal aortic aneurysm repair, and should be promptly recognized.

The following week, Mr. ██████ underwent a CT angiography study that was documented to reveal dilation of the abdominal aorta. An aneurysm was described to extend to the aortic bifurcation. The radiologist diagnosed a “stable 5.1 cm. infrarenal abdominal-aortic aneurysm,” and a cystic collection, that was possibly a diverticulum. Apparently, because the aneurysm was described as stable, nothing further was done.

Of importance, is that Mr. ██████ had undergone an aneurysm repair in June of ██████. Thus, if it was “fixed,” there should have been no aneurysm. An aneurysm of approximately the same size as prior to the repair, suggests a complication had occurred, and in this case, the aneurysm was actually somewhat larger than the one described at the time of surgery in June of ██████. Eight months later, Mr. ██████ complained of severe abdominal pain that radiated through his back, and around the area of his abdominal aortic aneurysm repair incision. His blood pressure was documented as 240/110.

A CT angiography was performed in September of ██████, and was reportedly compared to the previous studies done in May of ██████ and January of ██████. The radiologist documented that the study showed a “5.6 cm infrarenal abdominal aortic aneurysm that was unchanged in diameter compared to January 17, ██████.” Also noted was an abnormality which was suggested to represent a “small area of new ulceration.” Of note, is that the study was ostensibly assessed and evaluated by two radiologists, ██████████ and ██████████.

These findings were repeated by the treating and consulting physicians, and specifically, the consulting general vascular surgeon, ██████████, who documented that the CTA showed “no change in AAA diameter, possible ulcer,” and thus, Mr. ██████’s severe abdominal pain was “most likely due to muscle spasm/strain.” No acute surgical intervention was deemed necessary. Of importance, is that the report was signed by ██████████, as well.

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Again, if the aneurysm was repaired, the findings suggestive of an aneurysm on a CT angiography study could not have been stable. No aneurysm should have been present, at all. However, based upon the “stable” report of the aneurysm, Mr. ██████ was not taken to surgery; was not admitted to the Medical or Surgical Intensive Care Unit; and was, according to his wife, basically told that nothing was wrong.

On the morning of September 22, ██████, Mr. ██████ discharged himself, and then later that day, presented to ████████████████████. The visit to the previous hospital was reported, and it was merely repeated that CT angiography had shown a “stable infrarenal abdominal aortic aneurysm.” He was subsequently discharged from the Emergency Department, but readmitted after he felt something “pop” in his stomach; told his wife he “would meet her in heaven;” and then exhibited seizure activity. He subsequently passed away at 2:05 a.m., on September 23, ██████.

A CT scan of the abdomen before he died revealed an enlarged abdominal aortic aneurysm measuring 6.0 cm. x 5.5 cm., “now contrast within it,” which communicated with the adjacent small bowel.

That is, there was a pseudoaneurysm that had developed following the surgery. It had occurred at the proximal end of the graft, and it ultimately eroded through the wall of nearby small bowel. This abnormal passage between the aorta and the small bowel is known as an aorto-intestinal fistula. This occurred in the area that ██████████ described as having difficulty with during the April of ██████ surgery.

Following analysis of the CT angiography films, the reviewing physician clearly identifies that Mr. ██████ had a pseudoaneurysm of the vein graft. The graft actually separated from the aorta and the aneurysm. This pseudoaneurysm was correctly described by Dr. ██████████ on the ultrasound examination in January of ██████ but not addressed by the general vascular surgeon.

There is absolutely no question on the CTA scans that Mr. ██████ had undergone an aneurysm repair with a tube graft, and the study shows that the aneurysm is not only larger, but the portion of the aorta where the graft was placed was larger than the graft. This is not something to observe; this requires prompt surgical attention.

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The fact that Dr. ██████ decided not to immediately act, and to watch this with serial scans until it finally ruptured, represents an egregious deviation from the accepted standards of care. According to the reviewing physician, these conditions can be visualized on both CTA scans – in January of ██████ and September of ██████. It is obvious that something abnormal is present: the aneurysm is larger than prior to the repair; the graft is not attached to the aorta; and there is evidence suggestive of fistula formation.

Repair options include open surgery, of course, as well as fixing the complication within the aneurysm using a stent graft. The reviewing physician explains that although there are a variety of repair options, repair is definitively mandatory. To fail to act on these findings is gross negligence, both in January of ██████ and nine months later, when Mr. ██████ was clearly experiencing symptoms related to these complications.

It is the reviewing physician's opinion that the failure to recognize and act on these complications led to the rupture of the pseudoaneurysm, which caused Mr. ██████ demise on September 23, ██████. It is his opinion that surgical intervention, at any point between January of ██████ and Mr. ██████'s death, could have, more likely than not, prevented this tragic outcome.

As stated, this case involves gross negligence among multiple physicians which led to Mr. ██████'s death. The reviewing physician strongly recommends that this case be further pursued. It is also recommended that a radiology consultation be obtained regarding the care of Dr. ██████████ and Dr. ██████████.

Thank you for the opportunity to be of service to you. Please be advised that this letter is not submitted for use in trial, nor for presentation to the treating physicians or representatives. This letter is submitted to you in confidence at your request. Should you wish to proceed further with this case, or if you have any questions, please call me.

Sincerely,
SAPONARO, INC.

Guy R. Saponaro, President
sds