

1 **BEFORE THE ARIZONA MEDICAL BOARD**

2 In the Matter of

3 **FRANK IORIO, M.D.**

4 Holder of License No **12233**  
5 For the Practice of Allopathic Medicine  
6 In the State of Arizona.

Board Case No. MD-04-1545A

**FINDINGS OF FACT,  
CONCLUSIONS OF LAW AND ORDER**

(Letter of Reprimand)

7 The Arizona Medical Board ("Board") considered this matter at its public meeting on June  
8 8, 2006. Frank Iorio, M.D., ("Respondent") appeared before the Board with legal counsel Michael  
9 R. Golder, for a formal interview pursuant to the authority vested in the Board by A.R.S. § 32-  
10 1451(H). The Board voted to issue the following Findings of Fact, Conclusions of Law and Order  
11 after due consideration of the facts and law applicable to this matter.

12 **FINDINGS OF FACT**

13 1. The Board is the duly constituted authority for the regulation and control of the  
14 practice of allopathic medicine in the State of Arizona.

15 2. Respondent is the holder of License No. 12233 for the practice of allopathic  
16 medicine in the State of Arizona.

17 3. The Board initiated case number MD-04-1545A after being notified of a medical  
18 malpractice settlement involving Respondent's care and treatment of a forty-nine year-old female  
19 patient ("CK"). On March 14, 2001 CK underwent an ultrasound of the thyroid that demonstrated  
20 bilateral thyromegaly with a 1.7 x 1.3 centimeter right thyroid mass. CK described some mild  
21 discomfort. CK presented to Respondent on March 28, 2001 for evaluation of a thyroid mass.  
22 Respondent's impression at the first visit was benign goiter with probable Hashimoto's thyroiditis  
23 with associated hypothyroidism. On April 25, 2001 CK presented for surgery. Respondent first  
24 removed the right thyroid lobe and sent it to pathology where a frozen section demonstrated  
25 "nodular thyroid lobe secondary to Hashimoto's thyroiditis. No neoplasm identified with tissue

1 sample." Respondent then performed a left thyroidectomy describing a shrunken left lobe with  
2 significant inflammatory changes. The remainder of CK's hospitalization was uneventful and she  
3 was discharged the following day with no breathing problems, no swallowing dysfunction, and her  
4 calcium was normal at 9.5. Review of the operative report reveals each procedure was performed  
5 in a proper manner. Over the next several months CK had episodes of dyspnea and raspiness to  
6 her voice appeared to wax and wane. On November 15, 2001 CK presented to the emergency  
7 room with severe dyspnea and subsequently underwent fiberoptic laryngoscopy that  
8 demonstrated limited cord motion. CK was then seen by an ear, nose, and throat ("ENT") surgeon  
9 who performed a tracheostomy.

10 4. Respondent testified regarding the two allegations against him. The first, that a  
11 fine needle aspiration biopsy should have been performed prior to the thyroidectomy and the  
12 second, that he should not have removed the left thyroid lobe after a frozen section of the right  
13 lobe demonstrated Hashimoto's thyroiditis, but no evidence of malignancy. Respondent testified  
14 he wholeheartedly agreed that fine needle aspiration biopsy is the appropriate recommendation  
15 and evaluation when evaluating dominant thyroid nodules. The range of false negative and false  
16 positive results is approximately identical at three to six percent and the incidence of a non-  
17 diagnostic fine needle aspiration biopsy ranges between ten to thirty percent. Respondent  
18 testified he thoroughly evaluated treatment and evaluation options with CK and he strongly  
19 encouraged and recommended aspiration biopsy, but CK remained adamant that she required a  
20 near 100 percent guarantee regarding the absence of thyroid cancer. Respondent noted CK was  
21 also legitimately concerned about her problems and symptoms related to presumed Hashimoto's  
22 thyroiditis; was experiencing intermittent episodes of neck pain and her neck was unresponsive to  
23 anti-inflammatory agents; her inflammatory thyroid condition resulted in both hypothyroid and  
24 hyperthyroid states requiring frequent adjustments in types and strengths of thyroid  
25 supplementation; and she remained adamant about not undergoing a fine needle aspiration

1 biopsy, even after a detailed discussion regarding the known potential surgical risks. Respondent  
2 testified he could not force her to undergo the recommended procedure, nor could he abandon  
3 her.

4         5.         Respondent testified he and CK agreed on the following approach as stated in his  
5 patient clinical data sheet "[n]eck exploration with right thyroid lobectomy with probable total  
6 thyroidectomy if a malignancy is identified at the time of the frozen section and/or additional  
7 nodules are identified in the left lobe that were not identified on ultrasound and/or total  
8 thyroidectomy if significant Hashimoto's thyroiditis is identified with or without an associated  
9 malignancy." Respondent noted he performed the procedure they mutually agreed would be  
10 accomplished based on the findings at surgery in conjunction with multiple considerations  
11 documented in the medical literature regarding thyroid disease. Respondent testified he has over  
12 twenty-five years of surgical experience and completes over 120 hours of continuing medical  
13 education annually. Respondent testified his decision to perform an opposite lobe (left) lobectomy  
14 was not based on just one fact, i.e., the failure of the pathologist to definitively identify a malignant  
15 process. Respondent noted his dictated operative report notes the pathologist stated the tissue  
16 examined revealed "severe Hashimotos's thyroiditis with a relatively benign-appearing nodule"  
17 and a definite diagnosis was "deferred until [the pathologist evaluated] a permanent section."  
18 Respondent noted therefore, he had to consider additional factors with regard to his decision to  
19 proceed with a total thyroidectomy. Respondent testified the literature substantiates that  
20 intraoperative frozen section evaluation is a difficult and unreliable method of analyzing in the  
21 background of severe inflammation as well as in patients with multinodular or micronodular  
22 disease. Respondent testified CK had both. Respondent also noted the literature states  
23 intraoperative frozen section diagnosis of benign disease is later changed to diagnosis of cancer  
24 in permanent section evaluation in a high as thirty percent of the cases.

25

1           6.       Respondent testified research suggests less than total thyroidectomy may be  
2 inadequate surgery when dealing with not only thyroid cancer patients, but also with patients who  
3 have multinodular disease and/or Hashimoto's thyroiditis. Respondent noted in many patients  
4 with benign multinodular goiter it is difficult to find an appreciable normal thyroid tissue during  
5 surgery and the potential for long-term recurrence is relatively high when abnormal thyroid tissue  
6 is left behind. Respondent testified even though CK had a shrunken left lobe of the thyroid when  
7 compared to the right, it was still involved in the same disease processes that were present in the  
8 right lobe and there was a risk of subsequent identification of a malignant process upon  
9 permanent section evaluation. Respondent testified when considering everything available to him  
10 and CK's wishes, he did what he thought was in CK's best interests.

11           7.       The Board asked Respondent what percentage of his practice involved thyroid  
12 surgery. Respondent testified he had modified his practice in the last five or six years and does  
13 mostly breast cancer, laparoscopic surgery, and a fair amount of thyroid surgery as well as other  
14 surgeries, but in 2001 he would say thyroid surgery represented ten to fifteen percent of his  
15 surgeries. Respondent testified he usually only does total thyroidectomies in patients with  
16 documented thyroid cancer unless there is a situation where intraoperatively he needs to make a  
17 decision regarding whether the second lobe is removed, in total probably twenty percent of his  
18 surgeries are total thyroidectomies. The Board noted this was a small percentage relative to the  
19 number of thyroid cases Respondent does in general.

20           8.       The Board asked how many of Respondent's thyroid patients present with what  
21 was described in CK's case as a raspy voice. Respondent testified not many and he evaluated  
22 CK's raspy voice by history that it would come and go and would coincide with neck swelling and  
23 erythema and tenderness suggestive of acute inflammation of her presumed Hashimoto's  
24 thyroiditis. Respondent noted if someone comes in with a persistent raspy voice he usually refers  
25 them to an ENT surgeon for a direct look. Respondent testified because CK's raspy voice

1 coincided fairly well with the up and down of her goiter, of her thyroid, he attributed it to  
2 inflammation from the thyroid itself and disease. The Board asked what was causing the  
3 raspiness – was it anatomic on the vocal cords or was it on the nerve. Respondent testified  
4 probably the nerve involved in the inflammatory tissue, the edematous tissue. The Board asked if  
5 Respondent felt the need at that time to evaluate that. Respondent testified he did not, but this is  
6 one of the things he has changed in his practice and he refers anyone who presents with any  
7 type of history of intermittent or constant voice change to an ENT surgeon.

8           9.       The Board asked Respondent to state the treatment options for Hashimoto's in  
9 general. Respondent testified the low thyroid state needs to be treated with thyroid  
10 supplementation and then some type of anti-inflammatory medication. Respondent noted CK was  
11 tried on various medications, including corticosteroids, but she could not tolerate them because  
12 she indicated they made her feel funny. The Board asked if it was correct that Respondent  
13 typically would not get a referral for surgery in a case of only Hashimoto's alone. Respondent  
14 agreed generally, unless it is unrelenting associated with a goiter or the patient is having  
15 compressive symptoms. Respondent agreed this would be in a small percentage of patients.  
16 Respondent testified CK was sent to him because her primary care physician could not control  
17 the symptoms related to Hashimoto's thyroid in conjunction with thyromegaly, multinodular goiter,  
18 and a dominant solid mass in the right lobe.

19           10.       Respondent testified it was, generally speaking, absolutely not his practice to offer  
20 total thyroidectomy to patients with Hashimoto's if they request it or have, as in CK's case, an  
21 apparent cancer phobia. The Board asked if it was Respondent's thought to do a total  
22 thyroidectomy in CK regardless of the intraoperative findings, especially since his note of the  
23 discussion of CK's options talks about a total thyroidectomy in the case of severe Hashimoto's  
24 and he already knew CK had severe Hashimoto's. Respondent testified that was not his thought  
25 and a lot of times you go in with some options in mind and then have to make a decision based

1 on what you see and feel. Respondent noted had he gone in and found severe Hashimoto's  
2 thyroiditis in conjunction with nodular disease or unanticipated findings then he probably would  
3 lean more toward total thyroidectomy. Respondent testified CK's was one of the most severe  
4 cases of inflammation he had ever seen and it was virtually impossible to grossly appreciate or  
5 feel a malignancy or suspicious area and virtually impossible for the pathologist to provide a  
6 reliable diagnosis – in fact he deferred until permanent section. Respondent testified he thought if  
7 he waited until he got the permanent section results from the pathologist and it was cancer there  
8 would be a mess going back in because of the inflammation.

9           11. The Board noted Respondent described the right lobe he sent to pathology as  
10 "very inflamed" and then described the left lobe as "shrunken." Respondent testified he described  
11 it as shrunken compared to the right, but it was involved with the same disease process as the  
12 right, micronodular disease, severe inflammation. It was smaller compared to the right lobe, but  
13 was still nasty looking and feeling. The Board noted Respondent's operative note not describing  
14 any nodules on the left lobe and only describing it as "shrunken" led to the natural question of  
15 why Respondent took the lobe out. Respondent testified it was his error in not putting in enough  
16 additional information and he was stressing that the left lobe appeared different in size compared  
17 to the right, but was still involved in the same disease process. Respondent noted even the  
18 pathologist mentioned both grossly and microscopically, that there was micronodular disease and  
19 severe inflammation. The Board asked if Respondent believed CK would have developed what  
20 seemed to be a bilateral recurrent laryngeal nerve paralysis of some sort ultimately requiring  
21 surgical tracheostomy if he had done only the right lobe. Respondent testified it was hard to say  
22 and if the nerve entrapment was secondary to a progressive process of severe inflammation and  
23 scarring it may have happened, but one could also argue that if you do not disturb that side  
24 theoretically there may be less inflammation induced from the surgical procedure.

25

1           12.     The Board asked if when Respondent saw CK preoperatively he was concerned  
2 that at the time of surgery by intervening he might indeed aggravate CK's raspiness that was due  
3 to enlarging and deep heat and would it have been better, even in retrospect, to have left at least  
4 one side and not risk doing something that could increase the risk of recurrent laryngeal nerve  
5 injury. Respondent testified it was unfair to look at this retrospectively because when he is in  
6 surgery and looking at an unreliable frozen section with a thirty percent chance the pathologist  
7 will later find cancer and he has to go back in he has to consider if he leaves the left lobe and it is  
8 involved in the same disease process it may enlarge in the post-op period and CK would still  
9 have Hashimoto's thyroiditis, pain, neck swelling and a thyroid level bouncing up and down. The  
10 Board asked if Respondent went into surgery knowing there was a thirty percent probability of  
11 cancer regardless of what the frozen section said what was the possibility that he was not going  
12 to remove the left lobe. Respondent testified if he had not found as severe Hashimoto's  
13 thyroiditis, or if it did not have a micronodular feel to it and if he went in and the left lobe looked  
14 different than the right then he would have removed the right and kept his fingers crossed that  
15 even though CK had some mild inflammatory changes the one surgery is all she would need.  
16 Respondent testified with the severe Hashimoto's thyroiditis, in conjunction with the way both  
17 sides looked and felt and the facts he presented, he felt removing both sides was the best option  
18 at the time. The Board asked if Respondent was saying it was surgically necessary to remove the  
19 left lobe during the first surgery. Respondent testified "yes and no" and noted he could have left it  
20 and if it came back cancerous or, if CK developed recurrent severe symptoms, he could have  
21 gone back in again with the likelihood of an increased complication rate.

22           13.     The Board asked if Respondent would be concerned about a high complication  
23 rate if he got the final pathology reading two days later and had to go back in. Respondent  
24 testified he would because CK had unbelievably severe inflammatory change and he knew that  
25 no one, including himself, would want to be back in CK's neck in two days, two months, or two

1 years. The Board asked what Respondent would do today if he had the same patient.  
2 Respondent testified he would do the same thing other than he would now involve an ENT  
3 surgeon preoperatively and then postoperatively if there were any problems.

4 14. The Board asked Respondent the standard of care for CK in terms of removing the  
5 second lobe in the first surgery and whether Respondent believed he met that standard.  
6 Respondent testified he absolutely met the standard of care and he researched this heavily and  
7 there are hundreds of articles advocating routine near or total thyroidectomy for even less severe  
8 cases of Hashimoto's thyroiditis, let alone multinodular goiter. Respondent testified it was a  
9 controversial area whether or not to do a total thyroidectomy and years ago it was more toward  
10 the conservative side and more recently it is more aggressive. The Board asked if it was correct  
11 that a majority of the literature Respondent submitted was from outside the United States.  
12 Respondent testified some of the literature he included specifically because it had statements he  
13 wanted highlighted, but there were several hundred articles, many from the United States. The  
14 Board asked if Respondent would agree that some of the literature were retrospective studies,  
15 some were just data collected studies that were non-controlled. Respondent testified he would  
16 and would not agree – Respondent indicated he did not know the percentage because he did  
17 research so many. The Board noted it was not saying foreign articles are not inadequate, but  
18 rather the peer review process may be different.

19 15. The Board asked if it was correct when Respondent saw CK in his office he could  
20 not palpate a dominant thyroid nodule in the right lobe. Respondent referred to his records and  
21 read his note from the record "[v]ague nodularity, superior aspect of the right lobe of the thyroid."  
22 The Board asked if Respondent could not feel a dominant nodule, whether or not CK was  
23 agreeable, he would have been unable to do a fine needle aspirate in his office. Respondent  
24 testified he could have done it under ultrasound guidance and he does this, but a lot of times he  
25 refers the patient to the X-ray department so the appropriate lab slides can be prepared right

1 there and dropped off at the lab right next door. The Board asked if in his office examination of  
2 CK he felt the thyroid gland was diffusely enlarged, clinically. Respondent testified he did. The  
3 Board asked Respondent's understanding of the normal weight of the thyroid gland. Respondent  
4 testified he would have to plead ignorance, but he knew it was extremely variable and dependent  
5 on whether it is inflamed, enlarged or normal size and on cystic components, among other things.  
6 The Board asked Respondent's understanding of the normal size of a thyroid gland on  
7 ultrasound. Respondent testified the size was variable. Respondent agreed there were a lot of  
8 people with thyroid antibodies that have had or presently have active Hashimoto's thyroiditis.  
9 Respondent also agreed the key for the surgeon is to try and determine which of these multiple  
10 people seen in the office will eventually require surgical intervention.

11           16. The Board noted the different modalities Respondent offered CK are not really  
12 equivalent – the morbidity that accompanies an open thyroid lobectomy is much greater than the  
13 morbidity that accompanies a fine needle aspirate that is done within five to six minutes in the  
14 office under local or no anesthesia. Respondent agreed. The Board asked the two entities in the  
15 face of Hashimoto's thyroiditis that he was concerned about as far as neoplasm. Respondent  
16 clarified the Board was asking as far as papillary carcinoma and as far as lymphoma. The Board  
17 asked the accuracy on frozen section, in the hands of a competent pathologist, of the diagnosis of  
18 papillary carcinoma. Respondent testified it depended on the amount of tissue presented for  
19 review, the technique of preparing the slide, and the cytopathologist. Respondent noted it was a  
20 difficult diagnosis to make in light of chronic inflammation and he would say it would approach 98  
21 per cent reliability, but in the face of chronic inflammation, it all changes. The Board asked if  
22 Respondent believed it changes significantly for papillary. Respondent testified he could not give  
23 an accurate percentage of how much it would change. Respondent agreed the pathologist had  
24 enough tissue to work with to make a diagnosis, depending on how many sections he made.

25

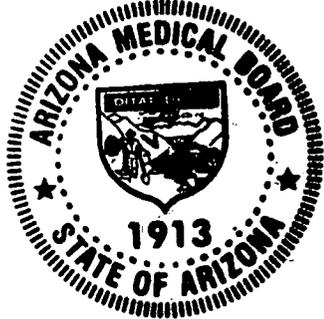
1           17.     The Board noted CK presented seven months after the surgery to the emergency  
2 room with significant inspiratory stridor and in severe respiratory distress requiring her to be  
3 scoped wherein they found minimal glottic opening, cord mobility severely limited, adduction and  
4 abduction virtually nonexistent with an impression of bilateral cord paralysis. The Board also  
5 noted in the interim and the period after the surgery Respondent performed, CK described her  
6 voice as having a high-pitched "Mickey Mouse" sound to it and in Respondent's written responses  
7 to the Board he appears to not be willing to acknowledge there was a bilateral nerve injury. The  
8 Board asked Respondent to explain the findings. Respondent testified the fact that it happened  
9 seven months later, he was not saying that something did not happen at the time of surgery in  
10 association with CK's severe inflammatory process and it does happen one to six percent of the  
11 time in the United States and it can be due to thermal injury, to traction, to inflammation and  
12 scarring, to direct trauma, and to transaction. Respondent noted CK also had chronic bronchitis,  
13 seasonal allergies, was a former smoker, and presented to the emergency room with acute onset  
14 of respiratory difficulty. Respondent testified he did not believe anyone could precisely ascertain  
15 what happened to CK, but obviously something developed over time in association with an acute  
16 episode and he was sure scarring and inflammation had to play a role. The Board asked if  
17 Respondent was saying he believed after everything that has transpired there was no injury  
18 during surgery to either the internal or external branch of the recurrent laryngeal nerve.  
19 Respondent testified he was not guaranteeing that did not happen and he was willing to say  
20 theoretically anything could make sense even though he identified the two nerves and he is  
21 willing to accept it as a possibility, but CK would not have responded the way she did in the  
22 immediate post-op period if there was bilateral nerve injury.

23           18.     The Board asked if perhaps identification of the nerves gave Respondent a false  
24 assurance they were safe and out of harm's way. The Board noted Respondent's operative report  
25 only indicates he identified the nerve, but nothing says he saw it again. Respondent testified he





1 DATED this 11<sup>th</sup> day of August, 2006.



THE ARIZONA MEDICAL BOARD

By *Timothy C. Miller*  
TIMOTHY C. MILLER, J.D.  
Executive Director

7 ORIGINAL of the foregoing filed this  
11<sup>th</sup> day of August, 2006 with:

8 Arizona Medical Board  
9 9545 East Doubletree Ranch Road  
Scottsdale, Arizona 85258

10 Executed copy of the foregoing  
11 mailed by U.S. Mail this  
11<sup>th</sup> day of August, 2006, to:

12 Michael R. Golder  
13 Shughart, Thompson & Kilroy, P.C.  
3636 North Central Avenue – Suite 1200  
14 Phoenix, Arizona 85012-0001

15 Frank Iorio, M.D.  
16 Address of Record

17 *Frank Iorio*  
18  
19  
20  
21  
22  
23  
24  
25