

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
STATE BOARD OF MEDICAL EXAMINERS

EFFECTIVE DATE: July 10, 2015

In the matter of:

DIONE WILLIAMS, M.D.

FINAL ORDER ADOPTING INITIAL
DECISION AND SUSPENDING
LICENSURE

This matter was reopened before the New Jersey State Board of Medical Examiners (the "Board") on or about April 17, 2015, upon the Board's receipt of an Initial Decision ("ID") filed by Administrative Law Judge ("ALJ") Jesse H. Strauss. Within the ID, ALJ Strauss summarized testimony and evidence presented during a three day trial held in November, 2014, and based thereon, concluded that respondent Dione Williams, M.D. engaged in gross negligence and gross malpractice, when, on September 1, 2009, she prescribed a Fentanyl patch (Duragesic) to a nineteen year old girl, A.Q., after performing a tonsillectomy. A.Q. died the following morning from Fentanyl toxicity. ALJ Strauss concluded that Dr. Williams acted with reckless disregard for A.Q.'s safety, as it had then been established that prescribing Fentanyl patches

CERTIFIED TRUE COPY

for post-surgical pain was inappropriate, and that Fentanyl patches were only to be prescribed for use by opioid tolerant patients with chronic pain not well controlled with other pain medicines.

ALJ Strauss also concluded that Dr. Williams engaged in repeated acts of negligence when she prescribed Duragesic to fourteen additional patients between January 2008 and June 2009. While none of those patients suffered fatal consequences like A.Q., ALJ Strauss concluded that Dr. Williams' prescribing -- in each case -- was not an appropriate exercise of her medical judgment.

Finally, ALJ Strauss found that, on February 17, 2012, Dr. Williams falsely testified under oath before the Medical Practitioner Review Panel. Specifically, ALJ Strauss found that Dr. Williams lied when she testified that she had used Duragesic "maybe once" after 2004, and in so doing specifically rejected Dr. Williams' claim that her testimony was merely a "mistake."

Based on the constellation of findings made, ALJ Strauss recommended that the Board suspend Dr. Williams' license for a period of five years with three years active, assess a civil penalty of \$50,000 and require Dr. Williams to pay costs. Neither party filed any written exceptions to ALJ Strauss' Initial Decision. We therefore scheduled this matter solely for a hearing

limited to the issue of penalty to be assessed.¹ On June 11, 2015, DAsG David Puteska and Jillian Sauchelli appeared on behalf of Complainant John Hoffman, Attorney General of New Jersey. Respondent appeared, represented by Michael J. Keating, Esq., Dughi, Hewit & Domalewski.²

Prior to commencing the penalty phase hearing on June 11, we conducted an independent review of the record below in order to first determine whether to adopt, reject or modify the proposed findings of fact and conclusions of law within ALJ Strauss' opinion. Upon review, we concluded that good cause existed to adopt, in their entirety, all of the recommended findings of fact and conclusions of law made by ALJ Strauss.³

¹ The OAL Rules require parties to file exceptions not only to proposed findings of fact or conclusions of law, but also upon the proposed disposition of a case. See N.J.A.C. 1:1-18.4(b) (requiring parties to specify dispositions to which exception is taken and to set out dispositions proposed in lieu of or in addition to those reached by the judge). Given that respondent did not file any exceptions at all, we could have simply reviewed this matter on the papers, and not scheduled any penalty phase hearing. Nonetheless, as the Board's customary practice has been to afford licensees an opportunity to present mitigation evidence directly before the Board, prior to finalizing any penalty decision in cases returned from OAL, we elected to provide Dr. Williams that opportunity notwithstanding the absence of filed exceptions.

² The 45 day period for issuing a final decision was extended from June 1, 2015 through July 16, 2015, pursuant to an Order of Extension entered by Chief Administrative Law Judge Sanders.

³ We specifically read ALJ Strauss' decision to have found that Dr. Williams engaged in gross negligence in the A.Q. case, and in "repeated acts of negligence" (i.e., negligence not rising to the level of "gross" negligence) in the fourteen cases which were the predicate for Count 2 of the Complaint. See ID, "Analysis and Legal Conclusions", at p. 18-19.

We thereafter proceeded to conduct a hearing on penalty. The Attorney General offered three documents in evidence during the penalty hearing, all of which were admitted without objection:

P-1 Consent Order IMO Dione Williams, filed March 16, 2005 (also entered in the OAL hearing record as Exhibit P-23).

P-2 Consent Order IMO Dione Williams, filed June 14, 2011 (also entered in the OAL hearing record as Exhibit P-24).

P-3 Certification of Deputy Attorney General David M. Puteska, dated May 27, 2015 (cost certification).

Prior to voting to adopt all of the findings of fact and conclusions of law in the ID, we independently considered whether to *sua sponte* modify ALJ Strauss' determinations upon the degree of Dr. Williams' negligence in some or all of the fourteen additional cases (that is, we considered whether cause existed to specifically find that Dr. Williams' engaged in gross negligence in any or all of those fourteen cases). We concluded that the record below adequately supported the distinction which ALJ Strauss made, and thus specifically decided not to modify the referenced findings.

It later became apparent (during DAG Puteska's closing statement in the penalty phase of the hearing) that the Attorney General interpreted the ID differently, and had read the opinion to have included findings that Dr. Williams engaged in gross negligence in all fifteen cases, as that specific finding was made at page 14 of the Opinion ("I FIND that Williams' administration of Duragesic in each of the above cases to be a gross deviation from the standard of care.").

We pointed out at the hearing, and reiterate now, that notwithstanding the apparent inconsistency between the findings set out at page 14 of the ID and the conclusions stated at page 19, we specifically read and interpreted the conclusions of law made to have been that Dr. Williams: (1) engaged in gross negligence in the A.Q. case, providing grounds for disciplinary sanction pursuant to N.J.S.A. 45:1-21(c), and (2) engaged in repeated acts of negligence in the fourteen "Count 2" cases, providing an independent basis for disciplinary sanction pursuant to N.J.S.A. 45:1-21 (d). Our determinations upon penalty assessment were all predicated on the delineated reading and understanding of the ID.

Dr. Williams addressed the Board during the mitigation hearing. She stated that she accepted the conclusions of ALJ Strauss, even though she disagreed with those findings. Dr. Williams pointed out that she has always accepted responsibility for her actions, and did so in this case. She asked the Board to consider that she had devoted her entire career to patients, many of whom were economically distressed. Dr. Williams' expressed concern for the ongoing care of her patients, and implored the Board to be lenient and to allow her a reasonable chance to return to practice.

In closing arguments, Mr. Keating pointed out that Dr. Williams practiced as an ENT specialist in a community at high risk for head and neck cancers, and was willing to take care of anyone. Like Dr. Williams, he stated that he accepted the findings made by ALJ Strauss, and implored the Board to approach penalty assessment with a sense of reasonableness and fairness.

In his closing statement, Deputy Attorney General Puteska suggested that a particularly strong sanction was appropriate in this case, given the findings below not only that Dr. Williams had engaged in grossly negligent medical practice, but also had purposefully sought to mislead the Panel when testifying before that body. DAG Puteska argued that the Board should weigh the fact

that this was not the first instance where Dr. Williams was found to have caused a patient death through grossly negligent medical care when conducting penalty deliberations. Finally, D.A.G. Puteska urged the Board to consider the devastating impact of Dr. Williams' actions on the family of A.Q., which he conveyed by reading a statement that A.Q.'s mother had offered (in another legal proceeding) expressing the anguish and the depth of loss which she experienced following A.Q.'s passing.

Upon independent review of the entire record and consideration of the presentations made by the parties during the penalty phase hearing, we conclude that good cause exists to follow and adopt the framework suggested by ALJ Strauss in his recommendations as to penalty. We point out that a lengthy period of license suspension is fully warranted and supported by the findings and conclusions made in this matter. A.Q.'s death was not only unfortunate but also entirely preventable, and should not have occurred but for Dr. Williams' failure to have appreciated the gravity and severity of the risk of harm occasioned when she prescribed A.Q. a Fentanyl patch. Dr. Williams knew, or certainly should have known, the magnitude of the risk in September 2009, as those risks had by then been the subject of prominent PDR, manufacturer and FDA warnings and advisories. That further deaths, or substantial harm, did not occur in any of the fourteen

additional cases where Dr. Williams negligently prescribed fentanyl patches is fortuitous, but those patients were all clearly exposed to heightened and unnecessary risks by Dr. Williams' prescribing in contraindicated circumstances. Dr. Williams' dishonesty - specifically, her provision of false testimony before the Medical Practitioner Review Panel - provides yet further support for the adoption of the penalty recommendations which were made below.

Further, we find that the imposition of a lengthy suspension is fully supported upon consideration of Dr. Williams' prior disciplinary history. Dr. Williams was found, in two prior matters resolved by Consent Orders, to have provided negligent and/or grossly negligent care to her patients. This case thus marks the third instance where Dr. Williams has been found to have failed to adhere to basic standards of good medical practice and, of particular import, the second instance where her gross negligence has resulted in a patient death.⁴

Our paramount obligation and responsibility is to protect the public health, safety and welfare. While we have considered and sought to weigh the mitigation testimony offered by Dr. Williams, we conclude on balance that the imposition of any penalty

⁴ See P-2, Consent Order filed June 14, 2011. Dr. Williams was found therein to have provided grossly negligent care to patient G.M., to include performing surgery which led to a subarachnoid hemorrhage, coma and brain death.

less than that recommended by ALJ Strauss would compromise our paramount obligation to protect the public.

We add only that we perceive a clear need for Dr. Williams to address issues necessarily raised by the findings made herein - concerning both her medical competency and her ethics - prior to any reinstatement of license. We thus herein modify ALJ Strauss' recommendations upon penalty by the addition of requirements that, during the period of active license suspension, Dr. Williams is to complete courses acceptable to the Board both in the prescribing of Controlled Dangerous Substances and in medical ethics. Additionally, prior to any reinstatement, we will require Dr. Williams to submit to and complete a focused assessment of her general medical knowledge, as a safeguard to ensure that her fund of knowledge is in fact sufficient to allow her to return to medical practice.

Finally, on the issue of costs, we point out that we have independently reviewed the certification of costs and accompanying documentation submitted by the Attorney General, and find that good cause exists to award all sought costs. We are fully satisfied that the documentation supporting the attorneys' fee submission adequately delineates the legal work which was performed, and we specifically find the aggregate number of hours billed in this case to be reasonable and fully supported by the substantial public

import of this matter. Likewise, we conclude (as we have uniformly done in prior matters) that the billing rates for legal work by assigned Deputy Attorneys General is reasonable, and we thus award all sought attorneys' fees (totaling \$35,170.00). Lastly, we find that additional cost items (expert witness, transcript and investigative costs) to be adequately documented and reasonable, and we thus award all of those sought costs as well.⁵

WHEREFORE, it is on this 8th day of July, 2015

ORDERED:

1. The Board hereby adopts, in their entirety, all findings of fact and conclusions of law set forth within the Initial Decision of ALJ Jesse H. Strauss dated April 17, 2015, copy of which is appended hereto and incorporated herein by reference.

2. The Board hereby modifies ALJ Strauss' recommendations as to penalty, and assesses the following penalties in this matter:

a) Dr. Williams license to practice medicine and surgery in the State of New Jersey shall be suspended for a period of five years, three years of which shall be served as an active period of suspension and the remainder of which shall be stayed and served as

⁵ Respondent did not offer any specific objections to the cost application made by the Attorney General, nor did she submit any documentation or evidence to the Board to seek to demonstrate financial hardship.

a period of probation. The suspension ordered herein shall be effective at the close of business on July 10, 2015. Dr. Williams is ordered to make all appropriate arrangements for the transfer of care and transfer of medical records of all present patients prior to the effective date of the suspension. Upon the suspension of her license, Dr. Williams shall comply with the attached "Directives," which are incorporated herein by reference.

b) Prior to any resumption of medical practice in New Jersey (either during the period of probation or thereafter), Dr. Williams shall be required to successfully complete courses acceptable to the Board in ethics and in the prescribing of Controlled Dangerous Substances. Additionally, prior to resumption of practice, Dr. Williams shall be required to submit to a practice assessment, to be completed by a Board approved assessment entity (to include the Colorado Personalized Education Program, the Albany Medical College in New York or any other entity which conducts assessment programs of comparable rigor) of her general foundation of knowledge to competently re-enter practice in Dr. Williams' medical specialty. Dr. Williams shall be required to secure written approval from the Medical Director of the Board approving any proposed assessment entity prior to commencing the assessment ordered herein, and shall provide any consent(s) necessary to allow the assessment entity to provide a written report detailing all findings made upon

assessment, along with any recommendations for necessary remediation, to be made directly to the Board. Finally, Dr. Williams shall be required, prior to reinstatement, to appear before a Committee of the Board and demonstrate that she has complied with all terms and conditions of this Order, complied with any recommendations for remediation which may be made by the approved assessment entity (to the extent she is able to do so without holding a medical license) and that she is fit to resume medical practice. The Board expressly reserves all rights to impose any conditions or limitations on Dr. Williams resumed practice of medicine that it may, in its discretion, deem necessary and appropriate, based on review of the assessment report required herein.

c) Dr. Williams is assessed a civil penalty of \$50,000.

d) Dr. Williams is assessed costs as follows - attorneys' fees of \$35,137.00; expert witness costs of \$5525, transcript costs of 2553.95, and Enforcement Bureau costs of \$496.16, for a total cost assessment of \$43,685.11.

e) Dr. Williams is to pay all assessed civil penalties and costs (\$93,685.11) within 30 days of the date of entry of this Order, or pursuant to an installment plan subject to express approval by the Board, which installment plan may allow for payment of the assessed penalties and costs over a period of time not to

exceed two years. In the event Dr. Williams seeks an installment plan, she must apply for such a payment plan not later than thirty days from the date of entry of this Order.

NEW JERSEY STATE BOARD
OF MEDICAL EXAMINERS

By:

A handwritten signature in blue ink, appearing to read "Stewart A. Berkowitz", is written over a horizontal line.

Stewart A. Berkowitz, M.D.

Board President



State of New Jersey
OFFICE OF ADMINISTRATIVE LAW

FILED
APRIL 17, 2015
NEW JERSEY STATE BOARD
OF MEDICAL EXAMINERS

INITIAL DECISION

OAL DKT. NO. BDS 02904-14

**IN THE MATTER OF THE SUSPENSION
OR REVOCATION OF THE LICENSE OF
DIONE M. WILLIAMS, M.D., LICENSE NO. 25MA04572300,
TO PRACTICE MEDICINE AND SURGERY
IN THE STATE OF NEW JERSEY.**

**David M. Puteska, Deputy Attorney General, for complainant (John J. Hoffman,
Acting Attorney General of New Jersey, attorney)**

**Michael J. Keating, Esq., for respondent Dione M. Williams, M.D. (Dughi, Hewit
& Domalewski, attorneys)**

Record Closed: March 6, 2015

Decided: April 17, 2015

BEFORE JESSE H. STRAUSS, ALJ:

STATEMENT OF THE CASE

The Attorney General of the State of New Jersey (complainant) initiated administrative disciplinary proceedings against respondent Dione M. Williams, M.D., a person licensed by the State Board of Medical Examiners (Board). Complainant contends that Williams: committed gross negligence by (a) prescribing a Fentanyl patch for the post-surgical pain of patient A.Q. following a tonsillectomy, where such use was

CERTIFIED TRUE COPY

contraindicated; (b) prescribing a Fentanyl patch for post-surgical pain in a patient with a known severe morphine allergy; (c) discharging of A.Q. from the hospital before the potentially deadly side effects of the Fentanyl Patch could be monitored and corrected; and/or (d) refusing to see A.Q. in her medical office after her discharge from the hospital. Complainant further contends that Williams committed fourteen separate acts of gross negligence, gross malpractice, or incompetence by prescribing of Duragesic¹ for post-surgical pain despite such actions being contraindicated. Additionally, complainant contends that Williams's February 17, 2014, testimony before the Medical Practitioner Review Panel (Panel) of the Board was misleading, deceptive, and/or outright false when she testified that after 2004 she used Duragesic maybe once when, in fact she used it in fourteen cases and that she was not aware of the June 2009 absolute ban on using Duragesic for post-surgical patients.

Accordingly, complainant seeks relief including the suspension or revocation of the license issued to Williams to practice medicine and surgery in the State of New Jersey; the imposition of penalties; and the imposition of costs related to the investigation and hearing.

PROCEDURAL HISTORY

On September 3, 2013, complainant filed a Complaint with the Board with notice to Williams to file an Answer. Williams filed an Answer on February 25, 2014. Thereafter, the Board transmitted the matter to the Office of Administrative Law (OAL) pursuant to N.J.S.A. 52:14B-1 to -15 and N.J.S.A. 52:14F-1 to -13, where, on March 12, 2014, it was filed for hearing and determination as a contested case.

I heard the matter on November 17, 19, and 20, 2014, and closed the hearing record on March 6, 2014, upon receipt of briefs.

In 2005 the Board reprimanded Williams and directed remedial coursework after she admitted that she had engaged in repeated acts of negligence by failing to send

¹ Duragesic is a preparation of the medication Fentanyl, and the two terms are used interchangeably.

pathological tissue for testing in a timely manner. (P-23.) In 2011 pursuant to a Consent Order, she received a stayed suspension, a \$5000 civil penalty, and was required to complete remedial coursework after agreeing with the Board that her grossly negligent actions led to the death of a patient. (P-24.) The Attorney General's Office subsequently moved to vacate the terms of the Consent Order after receiving information regarding the treatment of fourteen patients with a Fentanyl patch as mentioned above. The instant Complaint ensued.

FACTUAL DISCUSSION

Background

I **FIND** the following background **FACTS** in this proceeding.

Williams is a board-certified specialist in otolaryngology and head and neck surgery. She received both her undergraduate and medical degrees from Northwestern University in 1982. Williams completed a five-year residency program in otolaryngology and head and neck surgery at the former University of Medicine and Dentistry in Newark. For the past thirty years, she has been providing specialty care to patients in Newark and East Orange, New Jersey. She had performed surgeries at both Newark Beth Israel Medical Center and East Orange General Hospital and, currently, exclusively at East Orange General Hospital. Since 1987 Williams's private practice has consisted of general otolaryngology, which includes tonsillectomies, ear surgeries, nasal surgeries, the treatment of sinus infections, trauma surgery, and head and neck cancer surgery.

Duragesic is a brandname preparation of the narcotic medication Fentanyl, administered in a patch form for pain relief, with each patch being effective for approximately seventy-two hours as the medication is time-released. In 2006, the Physician's Desk Reference (PDR) included a "black box" warning for Duragesic, wherein it was indicated that Duragesic should only be used in the treatment of opioid-dependent patients, and that Duragesic was contraindicated for the management of postoperative pain, specifically citing tonsillectomies as an example where it should not

be used. (P-3).² It was also indicated that the patch should only be used for moderate to severe chronic pain. In addition, Duragesic poses a “risk of fatal overdose, due to respiratory depression.” (P-3.)

The PDR warning was a codification of a July 2005 Food and Drug Administration (FDA) warning on the use of a Fentanyl transdermal patch, alerting health care providers that Duragesic “should not be used to treat short-term pain, pain that is not constant, or pain after an operation. Fentanyl transdermal patches should only be used by opioid tolerant patients who are already taking other narcotic analgesics, and who have chronic pain that is not well controlled with shorter-acting analgesics.” The warning also advised that the directions for the use of Fentanyl must be followed exactly to prevent death or other severe side effects from overdosing with Fentanyl. (P-5.) The FDA warning followed a black box warning issued in June 2005 by Janssen, the manufacturer of Duragesic. (P-4.) The Janssen warning directed that Duragesic should be used only in patients who are opioid tolerant. It specifically advised that Duragesic is contraindicated in patients who are not opioid tolerant and in the management of postoperative pain “including use after out-patient or day surgeries (e.g., tonsillectomies).”

In a June 2009 physician advisory (R-1), the FDA noted:

Despite issuing an advisory in July 2005 that emphasized the safe use of the Fentanyl patch, FDA continues to receive reports of death and life-threatening side effects in patients who use the Fentanyl patch. The reports indicate that doctors have **inappropriately prescribed** the Fentanyl patch to patients for **acute pain following surgery**, for headaches, occasional or mild pain, and other indications for which a Fentanyl patch should not be prescribed It is **only intended** for treating persistent, moderate to severe **pain in patients who are opioid tolerant**, meaning those patients who take a regular, daily, around-the-clock narcotic pain medicine. This is extremely important because patients who are opioid tolerant are more resistant to the dangerous side effects of narcotic pain medicines than patients who

² A black box warning is placed to get everyone's attention because of a serious risk of complication associated with a drug.

only occasionally take these medicines. **For patients who are not opioid tolerant, the amount of Fentanyl in one Fentanyl patch of the lowest strength is large enough to cause dangerous side effects such as respiratory depression (severe trouble breathing or very slow or shallow breathing) and death The Fentanyl patch should only be used by patients who are opioid-tolerant and have chronic pain that is not well controlled with other pain medicines. They are not to be used to treat sudden, occasional, or mild pain or pain after surgery.**

[Emphasis supplied.]

Counts One and Two

Williams testified that she learned how to perform tonsillectomies as part of her training. Tonsils are balls of white blood cells surrounded by a capsule and embedded inside of soft tissues at the back of the mouth. At the start of Williams's career, tonsillectomies were performed usually when there was infection that did not respond to antibiotics. Later they were performed to address airway obstruction that can present itself in the first eight to ten hours after surgery during the post-anesthetic period. Early on, the procedure was performed under general anesthesia where narcotics were used to relax the patient and to offer some postoperative relief. During her training the practice of keeping a tonsillectomy patient overnight gave way to same-day surgery due to pressure from insurance companies. In Williams's experience postoperative pain from tonsillectomies is severe and can last for several days. Swallowing is often difficult.

In order to become board certified after her residency, Williams took oral and written exams in Chicago in 1987 and 1988. During the course of her private practice, Williams performed several hundred tonsillectomies. Most of her adult tonsillectomy patients have pain when swallowing on the second or third day following surgery, more so than with children. During her residency a typical postoperative order included a needle-administered opiate, usually morphine, to relieve pain in the controlled setting of the recovery room or Post Anesthesia Care Unit (PACU). Once the patient could swallow, he or she would be given a liquid pain reliever such as Tylenol and codeine. If

swallowing was difficult, the patient would be kept in the hospital and continue to receive a needle-administered opiate.

In the 1990's, Williams attended a conference where Dr. Josef Krespi, whom she had met as a medical student at Northwestern, introduced her to the use of a Fentanyl patch for post-surgical pain relief for same-day sleep apnea surgery. It was a new procedure that he was recommending as an adjunct to pain management in the post-operative setting after both office-based laser-assisted uvulopalatopharyngoplasty (UPP) and laser-assisted tonsillectomy surgeries. In this environment, the patient would be sent home after the surgery without any PACU period. Other than this conference, Williams has had no other training on the use of Fentanyl. Williams testified that she became aware that other surgeons were using the Fentanyl patch for postoperative pain without problems. She began prescribing it regularly for tonsillectomy post-surgical pain for adults in the 1990's and for other post-surgical procedures where the patient was having trouble swallowing. Williams described Fentanyl as being more potent than Morphine. She explained that Morphine is a plant-based opioid while Fentanyl is a synthetic opioid.

Williams testified that, in the 2000's, she became aware, through the PDR, of reports of misuse of the Fentanyl patch thereby requiring more monitoring of its use in the postoperative setting because some patients were experiencing breathing problems. She then tried to prescribe it less and monitor patients where she did. Between 2005 and 2009, she made medical judgment decisions on a case-by-case basis depending on each patient's pain threshold and any background information contained in the patient's medical chart. Williams received notices in the mail from drug companies, and there is also online access to FDA advisories. She tended to review what she could but not regarding medications she was using unless there was a change. She recalled learning of the information set forth in the 2005 FDA advisory regarding the Fentanyl patch. (P-5.) Although the advisory did not use the term "contraindicated," she was aware that Fentanyl transdermal patches should not be used to treat short-term pain or pain after an operation and should not be used on patients who are not opioid tolerant. She also recalled seeing the information in the June 18, 2009 FDA advisory (R-1). Although the term "contraindicated" is again not used, Williams understood the advisory

to have the same effect with its use of “the reports indicate that doctors have inappropriately prescribed the Fentanyl patch to patients for acute pain following surgery” She, however, denied that she knew of a black box warning for Fentanyl until 2009. She used the PDR but did not rely on it as she would a communication from the FDA. She repeated in her testimony that, in 2006, she was aware that there were certain risks or side effects from Duragesic but not that there was an absolute contraindication despite the language in the 2006 PDR. This was her knowledge despite her admission that the 2006 PDR had a black box contraindication. However, she thought she had seen something like the PDR information around 2006. Despite what she learned in 2005, 2006, and in 2009, Williams, nevertheless, continued to prescribe Fentanyl because she did not consider the contraindications to be absolute, despite the lack of any qualifiers in the literature.

Dr. Paul Carniol testified on behalf of complainant after qualifying as an expert in otolaryngology, head and neck surgery, as well as prescribing related to those procedures. He is licensed to practice in New Jersey and New York. He holds hospital privileges at University Hospital in Newark and Overlook Hospital in Summit. He prepared a report after reviewing fifteen patient records and consulting with Dr. Huma Quaraishi, Director of Pediatric Otolaryngology at Rutgers Medical School and Dr. Andrew Kaufman, Director of pain management at Rutgers Medical School. Carniol testified as to certain information derived from various patient files including that of patient A.Q. There is no dispute as to the following descriptions of the various procedures and the accuracy of the information in the records. I therefore **FIND** them to be **FACTS** in this matter. Opinions derived therefrom will be discussed below.

Carniol testified as to certain information derived from the patient file of A.Q. maintained by Williams and East Orange General Hospital. Williams began treating patient A.Q., a nineteen-year-old girl, in June of 2009. After an examination and subsequent diagnosis of tonsillitis, serious otitis media, and asthma, a tonsillectomy was recommended by Williams. A.Q. had previously suffered from a reaction to Morphine. Specifically, her chart included the following notation: “Morphine→ respiratory depression.” (P-6, Bate 40.) Carniol explained that this represents a drug reaction to

the narcotic Morphine and suggests that the patient is sensitive to narcotics in general, including Duragesic, in terms of ventilation.

Williams performed a tonsillectomy on A.Q. on September 1, 2009, and prescribed a Duragesic patch, twenty-five micrograms, for post-operative pain. (P-6, Bate 43 and 63.) The record does not indicate that A.Q. was opioid tolerant. Subsequently, A.Q. died in her own home on September 2, 2009, the morning after her tonsillitis surgery, of Fentanyl toxicity. (P-6, Bate 81.) Carniol determined that Williams's use of Duragesic postoperatively was a gross deviation from the standard of care, due to the fact that A.Q. was not opioid tolerant and given her history of sensitivity to narcotics. In addition, Carniol testified that it was a gross deviation from the standard of care to administer to A.Q. a Duragesic patch and subsequently fail to monitor her overnight in the hospital.

Williams testified that she admitted A.Q. to East Orange General Hospital on September 1, 2009, for a tonsillectomy because, after almost three months from her first office visit, A.Q. still had significantly enlarged tonsils indicating infection with airway obstruction. Williams recorded in the history she took from A.Q. and on other hospital records that she was allergic to Morphine. Her original plan was to do the surgery and put A.Q. on Tylenol and Codeine and perhaps some Morphine in the PACU and see how she did. However, upon learning that A.Q. was allergic to plant-based opioids, thereby eliminating Codeine and Morphine as options, Williams decided to prescribe Fentanyl, because it was a synthetic opioid, and Tylenol. She made this decision based on learning of the Morphine allergy without delaying the surgery or consulting with a pain-management specialist. Her decision nevertheless ignored the fact that Williams was opioid intolerant, regardless of whether Duragesic was plant-based or synthetic and ignored the warnings against postoperative use. She acknowledged in her testimony that A.Q. was not opioid tolerant when she made her decision to prescribe Fentanyl. It is noted that this plan about which Williams testified is from her memory rather than recorded in any of the preoperative medical records. She prescribed the Fentanyl to A.Q. in September 2009, despite the warnings of 2005, 2006 and June 2009. Also, Williams testified that she was unaware of any other physicians using the Fentanyl patch for postoperative pain after 2005.

Williams acknowledged that, although she has taken some internet courses on pain management, she is not board certified in pain management or anesthesia. She knows that Fentanyl is several more times powerful than Morphine and must be monitored ideally in a hospital ICU setting.

Williams performed a UPP and a bilateral nasal endoscopy on February 24, 2009, on patient R.A.A. (P-7.) For post-surgical pain control, Williams prescribed the Duragesic patch, twenty-five micrograms. Carniol found that this use of Duragesic by Williams was a gross deviation from the standard of care due to the fact that this patient had no history of opioid dependency, and Duragesic was administered for postoperative pain. Williams testified that she had the patient in the Intensive Care Unit overnight after the surgery because she had put him on Duragesic, and he had a history of airway obstruction. Her records do not reflect why she prescribed Duragesic. She agreed that the patient was not opioid tolerant. She discharged the patient and noted that he was tolerating pain with Duragesic.

On patient Ro.A., Williams performed a subtotal thyroidectomy on January 17, 2008, under general anesthesia. (P-8). Among medications prescribed post-operatively for this patient, Williams administered a Duragesic patch, twenty-five micrograms. Notably, Ro.A. was discharged on the same day as the surgery was performed. Carniol found the administration of the Duragesic patch to be a gross deviation from the standard of care. Williams testified that the anesthesia records disclosed that this patient had a high tolerance for pain medications and had to receive multiple doses before induction. Because of the perceived increased pain tolerance intraoperatively, she prescribed Duragesic, but did not record her reason for this prescription.

Williams performed a Parotidectomy on patient Ar.B. on January 8, 2009. (P-9.) The Duragesic patch was prescribed postoperatively for pain at twenty-five micrograms. In light of this, Carniol found there to be a gross deviation from the standard of care. Williams testified that Ar.B. had significant postoperative pain due to exposed nerves after the removal of a tumor, which was the reason for prescribing Duragesic. She did

not record her reason.³ The patient was on the Duragesic during a three-day hospital stay, during which time she was monitored, and was discharged with the patch still on.

Patient Ad.B. underwent a UPP, tonsillectomy, and a direct laryngoscopy with biopsy bronchoscopy on January 6, 2009. He had sleep apnea. (P-10.) After performing the surgery, Williams prescribed a Duragesic patch for postoperative pain—twenty-five micrograms for three days. She had him admitted to the ICU for monitoring because of her concern regarding the Duragesic. There were no problems, and he was discharged without receiving a new patch. Carniol again found this to be a gross deviation from the standard of care.

Williams performed a tonsillectomy on patient V.C. on April 29, 2008. (P-11.) After surgery, V.C. was given a Duragesic patch, fifty micrograms. At the time the Duragesic patch was prescribed for V.C., she had a pain score of zero, or in other words, was reporting no pain. (P-11, Bate 555.) Carniol thus found the prescribing of Duragesic for this patient to be a gross deviation from the standard of care. Williams testified that she ordered the Duragesic because the patient was large and still had considerable pain after being on an extensive amount of Morphine. She had had him admitted to the ICU for monitoring for respiratory suppression. He was discharged with the patch still on. She was concerned about liver damage if he had to take too much Tylenol with Codeine instead of Duragesic.

On February 19, 2008, Williams performed a subtotal thyroidectomy on patient L.C. (P-12.) The patient was obese and had sleep apnea. Post-operatively, L.C. was administered a Duragesic patch on Williams's orders, fifty micrograms, for pain. At the time the Duragesic patch was given to L.C., she was reporting no pain. Upon discharge, L.C. was again given a Duragesic patch, this time at twenty-five micrograms. (1T 82:7-9.) Carniol found the administration of Duragesic in this case to be a gross deviation from the standard of care due to a lack of opioid dependency, and the patient's transient pain post-surgery. Williams testified that the patient received

³ Williams acknowledged that she did not make entries in the records of any of the patients who are the subject of this Complaint as to why she decided to prescribe Duragesic.

Fentanyl intravenously during the surgery to sedate her. In the PACU a combination of the Duragesic patch and a total of ten milligrams of I.V. Morphine managed the pain. She was unsuccessful in having the patient admitted to the ICU, so she discharged her the next day after decreasing the Duragesic from fifty to twenty five micrograms. She gave her a Duragesic because of her large size, and the surgery had entailed an extensive dissection. Williams wanted her to be comfortable enough to swallow her medications.

Williams performed a tonsillectomy on patient D.F. on February 14, 2008. (P-13.) Postoperatively, a Duragesic patch, fifty micrograms, was ordered for D.F. by Williams. (1T 83:13). Once again, the patch was applied post-operatively when D.F. was experiencing no pain. Carniol found this to be a gross deviation from the standard of care. Williams testified that D.F. was on Percocet, an opioid, at the time of the surgery. Her high pain level just after the surgery, despite having received a lot of I.V. Fentanyl during the surgery, indicated to Williams that the patient was an opioid-tolerant patient. She was concerned that the patient would have difficulty swallowing. This testimony is perplexing. If her decision here, as she testified, was to use Duragesic because the patient was opioid tolerant, then she was aware of the warnings not to use it where a patient was not opioid tolerant. Yet, she did so multiple times.

Williams performed a UPP and a laryngoscopy on patient B.H. on February 19, 2008. (P-14.) After the surgery, Williams prescribed the Duragesic patch, twenty-five micrograms for three days. B.H. was reporting no pain at the time the Duragesic patch was administered by Williams. Carniol once again found the administration of Duragesic to be a gross deviation from the standard of care. Williams testified that her plan had been to have B.H. admitted to the ICU for monitoring after the surgery because there was an airway blockage associated with severe heart disease. She prescribed Duragesic to give the patient enough pain relief to allow her to swallow while anticipating ICU admission. The Hospital instead admitted her to the telemetry floor rather than the ICU because of a hospital rule reserving the ICU for heart disease patients. Due to swallowing problems, Williams prescribed three successive Duragesic patches, which the patient tolerated.

On November 13, 2008, Williams performed an endoscopy and biopsy on patient L.M. (P-15.) Post-procedure she prescribed Duragesic, twenty-five micrograms for pain. (1T 88:24.) Carniol again found this administration of Duragesic to be a gross deviation from the standard of care due to the fact that L.M. had no history of opioid use, and the transient nature of postoperative pain. Williams testified that she prescribed the Duragesic patch because the patient had had extensive surgery, and she anticipated a swallowing problem but had not yet confirmed a swallowing problem. However, the medical charts indicate that she prescribed Duragesic to L.M. before the patient was even admitted to the PACU and thus before she would have been able to determine whether L.M. could swallow.

Williams performed a tonsillectomy on patient A.M. on February 17, 2009. (P-16.) Post-surgically, Williams prescribed the Duragesic patch, twenty-five micrograms. At the time Duragesic was administered, A.M. was experiencing no pain according to the pain flow sheet post-surgery. In terms of the prescribing of Duragesic, Carniol found this to be a gross deviation from the standard of care. Williams testified that she had wanted to admit the patient to the ICU in order to monitor the effects of Duragesic on the surgery and the patient's airway. She explained that the patient's pain level was zero when she arrived at the PACU because she was still benefiting from the intra-operative I.V. Fentanyl. Her pain level increased later in the PACU. She therefore prescribed the Duragesic patch so that the patient could have pain relief without having the ability to swallow. Yet, Williams admitted that she prescribed the patch before and without ever assessing the patient in the PACU in anticipation of her comfort.

Williams performed a right ethmoid, and maxillary and frontal sinusotomy on patient M.O. on September 25, 2008. (P-17.) Post-surgery, Williams prescribed the Duragesic patch, twenty-five micrograms. Duragesic was prescribed again to M.O. upon discharge. Carniol found this to be a gross deviation from the standard of care. Williams testified that she prescribed the Duragesic patch here because the patient had been plagued with common chronic pain and muscle spasms, even though she had not been on any opiates. She expected the patient to have a high degree of pain because of the nerve endings exposed from the removal of bones inside her head. Williams admitted, however, that the patient was not opiate tolerant. There is nothing in the

record to indicate the chronic pain history. This opinion of Williams does not support the notion of an appropriate exercise of medical judgment where a drug many times more potent than heroin is prescribed for a non-opiate-tolerant patient.

On October 8, 2008, Williams performed a UPP, suspension laryngoscopy, and biopsy on patient E.R. (P-18.) Post-surgically, Williams prescribed the Duragesic patch, twenty-five micrograms. Carniol again found the prescribing of Duragesic to be a gross deviation from the standard of care because E.R. had no prior opioid dependence, and there was an increased risk of sensitivity due to E.R.'s age. Williams, however, showed from the record that E.R. had been taking the opioid Roxicet before he came to the hospital due to cancer and was opioid tolerant. She gave him the Duragesic patch upon discharge because she wanted to give the patient significant pain relief while monitoring him regarding his airway. However, the hospital again thwarted her intention to have the patient monitored in the ICU.

Patient S.S. underwent a right tonsillectomy on April 15, 2008. (P-19.) Williams performed the surgery and prescribed the Duragesic patch, twenty-five micrograms, postoperatively for pain. Carniol once again found this to be a gross deviation from the standard of care. Williams again testified that she prescribed the Duragesic patch because she anticipated a significant amount of pain and that S.S. would not be able to swallow medications.

Williams performed a tonsillectomy, septoplasty, and UPP on patient G.T. on March 31, 2009. (P-20.) Postoperatively, Williams prescribed the Duragesic patch, fifty micrograms, for pain. G.T. was discharged on April 1, 2009, the day following surgery. Carniol found the administration of Duragesic in this case to be a gross deviation from the standard of care. Williams testified that G.T. was on the opioid Methadone making her opioid tolerant. She prescribed the Duragesic patch because the Morphine had not taken away the pain sufficiently, and she anticipated a high pain tolerance.

Of additional relevance, Dr. Carniol testified that, in the entirety of his career, he has never had a patient who could not swallow following a tonsillectomy. He has had

patients that had pain on swallowing, but never anyone who absolutely could not swallow post-surgery.

Dr. Carniol further noted that in the Post Anesthesia Care Unit, of primary concern is a patient's airway and ability to breathe on their own so that the patient can be safely moved to a hospital floor or discharged.

In addition, although Dr. Carniol stated that when a drug is contraindicated, it may still be used for that contraindicated purpose in extreme circumstances; however, none of the postoperative circumstances with respect to these fifteen patients could be characterized as "extreme." He agreed that even where there is a black box warning of a risk of an adverse outcome, some physicians use their judgment to weigh the balance of risk versus value of benefit. He is not aware of a physician prescribing when a black box has contraindication, unless there is a dire need for that specific medication. Carniol also acknowledged that FDA advisories are just that, advisories, rather than a mandate.

I reject the argument of Williams that the publications did not create a standard of care because the 2005 FDA advisory merely suggested that the Fentanyl patch "should not be used" but did not use the word "contraindicated." She argues that the need for the 2009 update suggests that the 2005 physician advisory had potentially misled physicians regarding the safety and efficacy of the use of the Fentanyl patch. She neglects to acknowledge the 2005 Janssen and the PDR warnings that used the word "contraindicated." Instead, despite Carniol's recognition that FDA advisories are not mandates, I **FIND** that Williams's administration of Duragesic in each of the above cases to be a gross deviation from the standard of care. The multiple pieces of literature from the manufacturer, the FDA, and the PDR with regard to the use of Duragesic from June 2005 to June 2009 could not have been clearer, more specific, more compelling, or more consistent to support the existence of a standard of care. I **FIND** that the standard of care as of 2005 contraindicated the use of Duragesic or Fentanyl for non-opioid-tolerant patients or for postoperative pain relief. Williams may very well have received guidance in the 1990's from pre-eminent physicians promoting the use of Fentanyl for postoperative pain relief. However, experiences in the ensuing

years led to the multiple warnings that earlier expectations of safe and effective use were not realized. Williams not only acknowledged that she was aware of the multiple warnings, importantly, she admitted that she knew of no other doctors who used Duragesic in postoperative situations after the warnings began to issue. She produced no witness, expert or otherwise, to refute the overwhelming evidence that a standard of care had been established that Duragesic not be used for patients who were not opioid tolerant or who were in a postoperative setting.

Yet, in each of the above fifteen cases, she prescribed this drug for postoperative pain relief to patients, the records for whom, with one possible exception, were devoid of information that they were opioid tolerant. It is compelling that the literature set forth two independent bases for not using Duragesic. That is, not being opioid tolerant and for postoperative pain relief—both of which Williams ignored. Even though Carniol acknowledged that, when a drug is contraindicated, it may still be used for that contraindicated purpose in extreme circumstances, there is no persuasive evidence that extreme circumstances existed in any of these cases to justify an exercise of judgment to use Duragesic. The conduct by Williams resulted in the tragic death of A.Q. but three months after yet another emphatic FDA warning. Even if Williams prescribed for A.Q. as she did because of a known Morphine sensitivity and prior respiratory depression and Duragesic, unlike Morphine, is synthetic, Williams was nevertheless grossly negligent because A.Q. was still opioid intolerant and thereby still a candidate for respiratory depression.

It is further disturbing that, although Williams testified from her recollection as to the reasons she prescribed Duragesic for the fifteen patients, there is no entry in any of the medical charts memorializing why she prescribed Duragesic over any other pain medication postoperatively, or, in other words, why she exercised her medical judgment in this manner. If Williams truly believed in each case that there was an extraordinary circumstance that warranted her to supersede the contraindications, it is incredible that she would not have recorded in the patient charts why she was so acting. Her claim of extraordinary circumstances or the exercise of her judgment is further eroded by her actions in the case of A.M. where Williams prescribed Duragesic before A.M. was assessed in the PACU. Additionally, why would she prescribe Duragesic for, of all

patients, those with sleep apnea, when the published concerns were for respiratory depression when Duragesic was used?

Count Three

Williams sat before the Medical Practitioner Review Panel of the Board on February 17, 2012, where she testified under oath as follows in response to a question of whether the Fentanyl patch was something that she frequently used in her course of discharge:

I had some experience using Fentanyl patches before 2004 when the physician advisory came out that this was not always appropriate in a post-operative setting. Then after 2004, I used it maybe once. And then I really stopped using it really for post-operative care and kind of preserved it for my patients who had cancer and who had some long-term opiate use.

[P-21, Bate 129.]

In contrast to the story given by Williams during this investigative panel, she continued to prescribe the Duragesic patch for postoperative pain well after 2004, as evidenced by A.Q. and the fourteen other patients that she prescribed Duragesic to in 2008 and 2009. (P-6 thru P-20.)

In defense of this contradiction, Williams claims that she meant 2009, instead of 2004 (which she mentioned twice), and stopped her use of Duragesic after the June 18, 2009, FDA alert. Yet, even if this assertion is to be believed, it still fails to explain why Williams would prescribe Duragesic to A.Q. nearly three months after that 2009 FDA advisory was disseminated. Moreover, Williams's current contention that she meant 2009 rather than 2004 in her earlier testimony is not credible in light of her admission that she knew as early as 2005 from the FDA notice of concerns about the use of Duragesic. The 2009 advisory was much stronger than her characterization to the Panel that she then first learned that Duragesic "was not always appropriate in a postoperative setting." But so were the earlier warnings of which she was aware. Use of the phrases "contraindicated," "should not be used to treat . . . pain after an

operation,” and “contraindicated . . . in the management of postoperative pain . . .” (P-3, P-4, and P-5) educated Williams long before 2009 that Duragesic was not always appropriate in a postoperative setting. Consequently, it is again incredible that she inadvertently misspoke before the Committee when she said 2004 when she meant 2009. Accordingly, I **FIND** that Williams gave false testimony before the Medical Practitioner Review Panel of the Board regarding her use of Duragesic after 2004.

ANALYSIS AND LEGAL CONCLUSIONS

The Attorney General has charged that Williams’s conduct constituted gross negligence, gross malpractice or gross incompetence and/or repeated acts of negligence in violation of N.J.S.A. 45:1-21(c) and (d). It has also charged her with professional misconduct in violation of N.J.S.A. 45:1-21(e).

In addition to safeguarding the public from harmful medical practices, the Board protects the reputation of the medical profession by punishing conduct that “lowers the standing of the medical profession in the public’s eyes.” In re Fanelli, 174 N.J. 165, 179 (2002) (citation omitted). In this regard, the Board may suspend or revoke the license of a physician where she has engaged in gross negligence, gross malpractice or gross incompetence which damaged or endangered the life, health, welfare, or safety of any person or has engaged in repeated acts of negligence. N.J.S.A. 45:1-21(c) and (d). At an administrative hearing to address allegations of such conduct, the Attorney General must prove the elements of his case by a preponderance of the substantial credible evidence, meaning more likely than not that the charges are true. In re Polk, 90 N.J. 550 (1982).

Physicians are expected to exercise the degree of care, knowledge and skill ordinarily possessed and exercised in similar situations by the average member of the profession practicing in the same field. In re Quinlan, 70 N.J. 10, 45 (1975) (citing, Schueler v. Strelinger, 43 N.J. 330, 344 (1964)). Failure to exercise a degree of care constitutes negligence. Ibid. A physician must not depart from the requirement of accepted medical practice, whether by act or omission. Schueler, supra, 43 N.J. at 345.

Establishing a standard of care is a pivotal aspect of a case such as this. See Ward v. Scott, 11 N.J. 117, 123 (1952).

“Gross malpractice” as that term is used in the licensing statute, requires something much greater than ordinary malpractice in a civil suit for personal injury. In an ordinary malpractice case, the plaintiff must demonstrate that the physician deviated from an accepted standard and that such deviation caused harm to the patient. Germann v. Matriss, 55 N.J. 193 (1970). The Supreme Court in Polk, supra, 90 N.J. at 565-566 explained the burden of establishing that gross malpractice or misconduct has occurred:

The Legislature has also recognized the importance of a medical license and the interest of the physician in retaining his license. The regulatory statute requires, in most instances, that a physician not be found guilty of professional misconduct unless his acts are so particularly egregious as to constitute misconduct in the magnitude of gross malpractice See In re Kerlin, 151 N.J. Super. 179, 185-186 (App. Div. 1977) (a greater degree of misconduct than applicable in ordinary tort cases is required for discipline). By requiring a showing of flagrant misconduct, the Legislature has significantly increased the substantive burden which the State must bear in proving that professional dereliction warrants sanction.

“Gross neglect” has also been equated with “wanton or reckless disregard of the safety of others” or willful misconduct amounting to “heedlessness or reckless[ness].” Kerlin, supra, 151 N.J. Super. at 186. As noted by the Kerlin court,

It is obvious that the terms “neglect” and “malpractice,” standing alone, import a deviation from normal standards of conduct. “Gross neglect” or “gross malpractice” suggest conduct beyond such wrongful action -- how far beyond has been left to the judgment of the Board, subject, of course, to judicial review.

[Ibid.]

I **CONCLUDE** that Williams has engaged in both gross negligence and malpractice and repeated acts of negligence. She stresses the evolution of the

Fentanyl patch whereby she started to use it less frequently after 2000 when reports began to appear that some patients were experiencing life-threatening complications such as respiratory depression. She describes the 2005 FDA advisory as non-binding without a contraindication despite the 2006 PDR black box warning of contraindication. She argues that it was not until the July 2009 FDA update that ambiguity was resolved as to the use of Duragesic for non-opioid-tolerant patients or for postoperative pain when the FDA called its use "inappropriate." Williams, nevertheless prescribed Duragesic for A.Q. with fatal consequences after what she contends was the definitive word on the use of Duragesic. Without conceding (which I do not, as discussed in the above findings) that Williams appropriately exercised her medical judgment to prescribe the Duragesic patch before July 2009, her having done so in September 2009 demonstrates a reckless disregard for the safety of A.Q., knowing that she was opioid intolerant and knowing that the Duragesic prescription for A.Q. was to address her post-surgical pain. This is gross negligence and gross malpractice and not ordinary negligence.

Moreover, as found above, her prescribing of Duragesic for the other fourteen patients, despite not leading to the terrible consequences that befell A.Q., was not an appropriate exercise of her medical judgment. As such, those cases collectively establish that there were repeated acts of negligence.

The Board may suspend or revoke the license of a physician who has engaged in professional or occupational misconduct. N.J.S.A. 45:1-21(e). N.J.A.C. 13:45C-1.1 et seq., imposes upon all Board licensees a duty to cooperate in Board investigations and inquiries into a licensee's conduct, fitness or capacity to engage in a licensed profession. The duty to cooperate requires a licensee to provide complete and truthful responses to inquiries from the Board. Pursuant to N.J.A.C. 13:45C-1.2(b) a licensee who fails to cooperate with a Board investigation is deemed to have engaged in occupational or professional misconduct in violation of N.J.S.A. 45:1-21(e).

In light of the finding that Williams provided false testimony before the Review Panel with regard to her prescribing of Duragesic after 2004, I **CONCLUDE** that she engaged in occupational and professional misconduct in violation of N.J.S.A. 45:1-

21(e). I also **CONCLUDE** that Williams has engaged in the use of dishonesty, deception and misrepresentation in violation of N.J.S.A. 45:1-21(b).

PENALTY

As set forth above, Williams engaged in both gross negligence and gross malpractice and repeated acts of negligence. Although there clearly was no intent to do harm to her patients, she wantonly and recklessly disregarded warnings about which she was aware; repeatedly departed from expected standards of care which imperiled the life, health, welfare and safety of multiple patients; and unfortunately led to the demise of one patient. The patient records do not reflect a careful assessment of postoperative pain-management needs. Her after-the-fact, yet unrecorded, expression of reasons for prescribing Duragesic postoperatively to each of the above-opioid-intolerant patients, despite contraindications, is unavailing and unpersuasive.

The past record of Williams unfortunately constitutes an aggravating rather than mitigating factor in assessing an appropriate penalty. In 2005, she agreed with the Board that she had engaged in repeated acts of negligence based on her failure to send pathological tissue for microscopic examination in a timely manner and inadequate record keeping. She was subject to a reprimand, remedial coursework, and the payment of costs. (P-23.) In 2011, Williams agreed with the Board that she was grossly negligent and that her actions resulted in the death of her patient. (P-24.) For this gross negligence, Dr. Williams received a stayed suspension, remedial coursework, and a civil penalty of \$5,000. (Ibid.)

Finally, Williams gave misleading and deceptive testimony under oath before an investigative panel of the Board. "Physicians are presented with situations daily where their fundamental honesty must be trusted." In re Karakashian, BDS 8660-07, Final Decision at *12. As the Board in Karakashian recognized, "there is no cookie-cutter penalty imposed for all physicians who are found to have engaged in dishonesty, as not all cases involve the same degree of misconduct, and not all cases deserve equal sanction." Id. at *13. Williams's breach of trust here exacerbates an already tarnished record.

In light of the specific violations of the above statutes and her prior record, I **CONCLUDE** that a significant penalty of suspension of Williams's license for at least five years with a three-year active term is appropriate.

I further **CONCLUDE** that a meaningful monetary penalty is warranted in order to further the Board's obligation to protect the public health, safety, and welfare. N.J.S.A. 45:1-25 provides for a civil penalty of not more than \$10,000 for a first violation and not more than \$20,000 for the second and each subsequent violation. I **CONCLUDE** that an appropriate civil penalty should be \$50,000 in light of violations occurring under each of the three counts

The assessment of costs is authorized by N.J.S.A. 45:1-25(d). I **CONCLUDE** that, in light of the above **FINDINGS** and **CONCLUSIONS**, the Attorney General should be awarded its full costs in the investigation and prosecution of this matter. As requested by the Attorney General, the final monetary amount of these costs should be set by the Board in its final decision, since costs will continue to accrue through the final hearing before the Board.

ORDER

It is **ORDERED** that Counts 1, 2, and 3 of the Administrative Complaint of the Attorney General of New Jersey against Dione Williams, M.D., License No. 25MA04572300, be **AFFIRMED**.

It is further **ORDERED** that Williams receive a five-year suspension with a three-year active term.

It is further **ORDERED** that Williams pay a civil penalty of \$50,000.

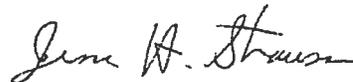
It is further **ORDERED** that Williams pay costs to the Attorney General in an amount to be set by the Board in its Final Decision.

I hereby **FILE** my Initial Decision with the **BOARD OF MEDICAL EXAMINERS** for consideration.

This recommended decision may be adopted, modified or rejected by the **BOARD OF MEDICAL EXAMINERS**, which by law is authorized to make a final decision in this matter. If the Board of Medical Examiners does not adopt, modify or reject this decision within forty-five days and unless such time limit is otherwise extended, this recommended decision shall become a final decision in accordance with N.J.S.A. 52:14B-10.

Within thirteen days from the date on which this recommended decision was mailed to the parties, any party may file written exceptions with the **EXECUTIVE DIRECTOR OF THE BOARD OF MEDICAL EXAMINERS, 140 East Front Street, 2nd Floor, Trenton, New Jersey 08608**, marked "Attention: Exceptions." A copy of any exceptions must be sent to the judge and to the other parties.

April 17, 2015



DATE

JESSE H. STRAUSS, ALJ

Date Received at Agency:

4/17/15

Date Mailed to Parties:

4/17/15

id

APPENDIX

LIST OF WITNESSES

For Complainant:

Paul Carniol

For Respondent:

Dione Williams

EXHIBITS IN EVIDENCE

For Complainant:

- P-1 C.V. of Paul J. Carniol
- P-2 Expert Report of Carniol
- P-3 Physicians Desk Reference, 2006, pp. 2448-2453, Duragesic Prescribing Information
- P-4 Janssen Duragesic Warnings, 2005
- P-5 FDA Alert, July 2005
- P-6 East Orange General Hospital (E.O.) Surgical Record for Patient A.Q.
- P-7 East Orange General Hospital (E.O.) Surgical Record for Patient Ra.A.
- P-8 East Orange General Hospital (E.O.) Surgical Record for Patient Ro.A.
- P-9 East Orange General Hospital (E.O.) Surgical Record for Patient Ar.B.
- P-10 East Orange General Hospital (E.O.) Surgical Record for Patient Ad.B.
- P-11 East Orange General Hospital (E.O.) Surgical Record for Patient V.C.
- P-12 East Orange General Hospital (E.O.) Surgical Record for Patient L.C.
- P-13 East Orange General Hospital (E.O.) Surgical Record for Patient D.F.
- P-14 East Orange General Hospital (E.O.) Surgical Record for Patient B.H.
- P-15 East Orange General Hospital (E.O.) Surgical Record for Patient L.M.
- P-16 East Orange General Hospital (E.O.) Surgical Record for Patient A.M.
- P-17 East Orange General Hospital (E.O.) Surgical Record for Patient M.O.
- P-18 East Orange General Hospital (E.O.) Surgical Record for Patient E.R.

- P-19 East Orange General Hospital (E.O.) Surgical Record for Patient S.S.
- P-20 East Orange General Hospital (E.O.) Surgical Record for Patient G.T.
- P-21 Transcript excerpt, NJ Medical Practitioner Review Panel, February 17, 2012
- P-22 Not in Evidence
- P-23 Consent Order between Williams and Medical Board, March 16, 2005
- P-24 Consent Order between Williams and Medical Board, June 14, 2011

For Respondent:

- R-1 FDA Public Health Advisory for Fentanyl Transdermal System, June 18, 2009

**DIRECTIVES APPLICABLE TO ANY MEDICAL BOARD LICENSEE
WHO IS DISCIPLINED OR WHOSE SURRENDER OF LICENSURE
HAS BEEN ACCEPTED**

APPROVED BY THE BOARD ON MAY 10, 2000

All licensees who are the subject of a disciplinary order of the Board are required to provide the information required on the Addendum to these Directives. The information provided will be maintained separately and will not be part of the public document filed with the Board. Failure to provide the information required may result in further disciplinary action for failing to cooperate with the Board, as required by N.J.A.C. 13:45C-1 et seq. Paragraphs 1 through 4 below shall apply when a license is suspended or revoked or permanently surrendered, with or without prejudice. Paragraph 5 applies to licensees who are the subject of an order which, while permitting continued practice, contains a probation or monitoring requirement.

1. Document Return and Agency Notification

The licensee shall promptly forward to the Board office at Post Office Box 183, 140 East Front Street, 2nd floor, Trenton, New Jersey 08625-0183, the original license, current biennial registration and, if applicable, the original CDS registration. In addition, if the licensee holds a Drug Enforcement Agency (DEA) registration, he or she shall promptly advise the DEA of the licensure action. (With respect to suspensions of a finite term, at the conclusion of the term, the licensee may contact the Board office for the return of the documents previously surrendered to the Board. In addition, at the conclusion of the term, the licensee should contact the DEA to advise of the resumption of practice and to ascertain the impact of that change upon his/her DEA registration.)

2. Practice Cessation

The licensee shall cease and desist from engaging in the practice of medicine in this State. This prohibition not only bars a licensee from rendering professional services, but also from providing an opinion as to professional practice or its application, or representing him/herself as being eligible to practice. (Although the licensee need not affirmatively advise patients or others of the revocation, suspension or surrender, the licensee must truthfully disclose his/her licensure status in response to inquiry.) The disciplined licensee is also prohibited from occupying, sharing or using office space in which another licensee provides health care services. The disciplined licensee may contract for, accept payment from another licensee for or rent at fair market value office premises and/or equipment. In no case may the disciplined licensee authorize, allow or condone the use of his/her provider number by any health care practice or any other licensee or health care provider. (In situations where the licensee has been suspended for less than one year, the licensee may accept payment from another professional who is using his/her office during the period that the licensee is suspended, for the payment of salaries for office staff employed at the time of the Board action.)

A licensee whose license has been revoked, suspended for one (1) year or more or permanently surrendered must remove signs and take affirmative action to stop advertisements by which his/her eligibility to practice is represented. The licensee must also take steps to remove his/her name from professional listings, telephone directories, professional stationery, or billings. If the licensee's name is utilized in a group practice title, it shall be deleted. Prescription pads bearing the licensee's name shall be destroyed. A destruction report form obtained from the Office of Drug Control (973-504-6558) must be filed. If no other licensee is providing services at the location, all medications must be removed and returned to the manufacturer, if possible, destroyed or safeguarded. (In situations where a license has been suspended for less than one year, prescription pads and medications need not be destroyed but must be secured in a locked place for safekeeping.)

3. Practice Income Prohibitions/Divestiture of Equity Interest in Professional Service Corporations and Limited Liability Companies

A licensee shall not charge, receive or share in any fee for professional services rendered by him/herself or others while barred from engaging in the professional practice. The licensee may be compensated for the reasonable value of services lawfully rendered and disbursements incurred on a patient's behalf prior to the effective date of the Board action.

A licensee who is a shareholder in a professional service corporation organized to engage in the professional practice, whose license is revoked, surrendered or suspended for a term of one (1) year or more shall be deemed to be disqualified from the practice within the meaning of the Professional Service Corporation Act. (N.J.S.A. 14A:17-11). A disqualified licensee shall divest him/herself of all financial interest in the professional service corporation pursuant to N.J.S.A. 14A:17-13(c). A licensee who is a member of a limited liability company organized pursuant to N.J.S.A. 42:1-44, shall divest him/herself of all financial interest. Such divestiture shall occur within 90 days following the the entry of the Order rendering the licensee disqualified to participate in the applicable form of ownership. Upon divestiture, a licensee shall forward to the Board a copy of documentation forwarded to the Secretary of State, Commercial Reporting Division, demonstrating that the interest has been terminated. If the licensee is the sole shareholder in a professional service corporation, the corporation must be dissolved within 90 days of the licensee's disqualification.

4. Medical Records

If, as a result of the Board's action, a practice is closed or transferred to another location, the licensee shall ensure that during the three (3) month period following the effective date of the disciplinary order, a message will be delivered to patients calling the former office premises, advising where records may be obtained. The message should inform patients of the names and telephone numbers of the licensee (or his/her attorney) assuming custody of the records. The same information shall also be disseminated by means of a notice to be published at least once per month for three (3) months in a newspaper of

general circulation in the geographic vicinity in which the practice was conducted. At the end of the three month period, the licensee shall file with the Board the name and telephone number of the contact person who will have access to medical records of former patients. Any change in that individual or his/her telephone number shall be promptly reported to the Board. When a patient or his/her representative requests a copy of his/her medical record or asks that record be forwarded to another health care provider, the licensee shall promptly provide the record without charge to the patient.

5. Probation/Monitoring Conditions

With respect to any licensee who is the subject of any Order imposing a probation or monitoring requirement or a stay of an active suspension, in whole or in part, which is conditioned upon compliance with a probation or monitoring requirement, the licensee shall fully cooperate with the Board and its designated representatives, including the Enforcement Bureau of the Division of Consumer Affairs, in ongoing monitoring of the licensee's status and practice. Such monitoring shall be at the expense of the disciplined practitioner.

(a) Monitoring of practice conditions may include, but is not limited to, inspection of the professional premises and equipment, and inspection and copying of patient records (confidentiality of patient identity shall be protected by the Board) to verify compliance with the Board Order and accepted standards of practice.

(b) Monitoring of status conditions for an impaired practitioner may include, but is not limited to, practitioner cooperation in providing releases permitting unrestricted access to records and other information to the extent permitted by law from any treatment facility, other treating practitioner, support group or other individual/facility involved in the education, treatment, monitoring or oversight of the practitioner, or maintained by a rehabilitation program for impaired practitioners. If bodily substance monitoring has been ordered, the practitioner shall fully cooperate by responding to a demand for breath, blood, urine or other sample in a timely manner and providing the designated sample.

**NOTICE OF REPORTING PRACTICES OF BOARD
REGARDING DISCIPLINARY ACTIONS**

Pursuant to N.J.S.A. 52:14B-3(3), all orders of the New Jersey State Board of Medical Examiners are available for public inspection. Should any inquiry be made concerning the status of a licensee, the inquirer will be informed of the existence of the order and a copy will be provided if requested. All evidentiary hearings, proceedings on motions or other applications which are conducted as public hearings and the record, including the transcript and documents marked in evidence, are available for public inspection, upon request.

Pursuant to 45 CFR Subtitle A 60.8, the Board is obligated to report to the National Practitioners Data Bank any action relating to a physician which is based on reasons relating to professional competence or professional conduct:

- (1) Which revokes or suspends (or otherwise restricts) a license,
- (2) Which censures, reprimands or places on probation,
- (3) Under which a license is surrendered.

Pursuant to 45 CFR Section 61.7, the Board is obligated to report to the Healthcare Integrity and Protection (HIP) Data Bank, any formal or official actions, such as revocation or suspension of a license (and the length of any such suspension), reprimand, censure or probation or any other loss of license or the right to apply for, or renew, a license of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender, non-renewability, or otherwise, or any other negative action or finding by such Federal or State agency that is publicly available information.

Pursuant to N.J.S.A. 45:9-19.13, if the Board refuses to issue, suspends, revokes or otherwise places conditions on a license or permit, it is obligated to notify each licensed health care facility and health maintenance organization with which a licensee is affiliated and every other board licensee in this state with whom he or she is directly associated in private medical practice.

In accordance with an agreement with the Federation of State Medical Boards of the United States, a list of all disciplinary orders are provided to that organization on a monthly basis.

Within the month following entry of an order, a summary of the order will appear on the public agenda for the next monthly Board meeting and is forwarded to those members of the public requesting a copy. In addition, the same summary will appear in the minutes of that Board meeting, which are also made available to those requesting a copy.

Within the month following entry of an order, a summary of the order will appear in a Monthly Disciplinary Action Listing which is made available to those members of the public requesting a copy.

On a periodic basis the Board disseminates to its licensees a newsletter which includes a brief description of all of the orders entered by the Board.

From time to time, the Press Office of the Division of Consumer Affairs may issue releases including the summaries of the content of public orders.

Nothing herein is intended in any way to limit the Board, the Division or the Attorney General from disclosing any public document.