COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF MEDICINE

Commonwealth of Pennsylvania
Bureau of Professional and
Occupational Affairs

vs.

Nadiy Shapira, M.D.,
Respondent

File No.: 17-49-11294
Docket No: 2130-49-17

CONSENT AGREEMENT AND ORDER

PARTIES

The Commonwealth of Pennsylvania, Department of State, Bureau of Professional and
Occupational Affairs ("Commonwealth") and Nadiy Shapira, M.D. ("Respondent") stipulate as
follows in settlement of the above-captioned case.

APPLICABLE LAW

1. This matter is before the State Board of Medicine ("Board") pursuant to the Medical
422.1-422.53; the Medical Care Availability and Reduction of Error ("Mcare") Act, Act of
March 20, 2002, P.L. 154, No. 13, as amended, 40 P.S. §§ 1303.101-1303.910; and/or the Act of

LICENSURE STATUS

2. At all relevant and material times, Respondent held the following license to practice
as a medical physician and surgeon in the Commonwealth of Pennsylvania: license no.
MD040469E, which was originally issued on November 12, 1987, and which expired on
December 31, 2014.
STIPULATED FACTS

3. The Respondent admits that the following allegations are true:
   
   a. Absent additional Board action, Respondent's license may be continually reactivated, renewed, or reinstated upon the filing of the appropriate documentation and payment of the necessary fees.
   
   b. Respondent's last known address on file with the Board is: 2102 Wind Lane, Wilmington, DE 19810.
   
   c. At all relevant and material times, Respondent was authorized to practice medicine in the State of Delaware.
   
   d. On or about September 19, 2017, the Delaware Board of Medical Licensure and Discipline ("Delaware Board") approved a Consent Agreement and Order In Re: Nadiy Shapira, License No: C1-0003224 at Case No. 10-134-14.
   
   e. A true and correct copy of said Consent Agreement and Order approved by the Delaware Board is attached as Exhibit A and is incorporated by reference.
   
   f. Pursuant to the September 19, 2017 Consent Agreement and Order, the Delaware Board issued a letter of reprimand and ordered that Respondent pay a fine of $1000.00 to the State of Delaware, along with completing six (6) hours of continuing medical education.

ALLEGED VIOLATIONS

4. The Commonwealth alleges that the Board is authorized to suspend or revoke, or otherwise restrict Respondent's license under Sections 41 and 42 of the Act, 63 P.S. §§ 422.41 & 422.42; or impose a civil penalty under Section 908 of the Mcare Act, 40 P.S. §§ 1303.908, and/or Section 5(b)(4) of ACT 48, 63 P.S. §2205(b)(4) and/or impose the costs of investigation
under Section 5(b)(5) of ACT 48, 63 P.S. § 2205(b)(5), because Respondent violated the Act at
Section 41(4), 63 P.S. § 422.41(4), in that Respondent had a license or other authorization to
practice the profession disciplined by the proper licensing authority of another state.

PROPOSED ORDER

5. The parties, intending to be legally bound, consent to the issuance of the following
Order in settlement of this matter:

a. The Board finds that it is authorized to suspend or revoke, or otherwise
restrict Respondent's license under Sections 41 and 42 of the Act, 63 P.S. §§
422.41 & 422.42; or impose a civil penalty under Section 908 of the Mcare
Act, 40 P.S. §§ 1303.908, and/or Section 5(b)(4) of ACT 48, 63 P.S. §2205(b)(4)
and/or impose the costs of investigation under Section 5(b)(5) of ACT 48, 63 P.S.
§ 2205(b)(5), because Respondent violated the Act at Section 41(4), 63 P.S. §
422.41(4), in that Respondent had a license or other authorization to practice the
profession disciplined by the proper licensing authority of another state.

CIVIL PENALTY

b. A CIVIL PENALTY of five hundred dollars ($500.00) is levied upon
Respondent. Respondent shall tender the full sum of five hundred dollars
($500.00) with this executed Consent Agreement and shall be paid by certified
check, cashier's check, attorney's check, or money order issued by a usual,
customary, and reputable issuer (e.g. U.S. Postal Money Order, Western Union
Money Order, etc.). Payment shall be made payable to the "Commonwealth of
Pennsylvania," and shall be valid for a period of at least one hundred eighty (180)
days. Respondent agrees that payment shall only be made by one of the methods
indicated above and shall not be made by uncertified personal or corporate check.
c. This Order constitutes disciplinary action by the Board and shall be reported to other licensing authorities and any applicable national licensing databank as a disciplinary action by the Board.

d. This case shall be deemed settled and discontinued upon the Board issuing an Order adopting this Consent Agreement.

ADMISSIBILITY OF CONSENT AGREEMENT IN FUTURE PROCEEDINGS

6. Respondent agrees that if Respondent is charged with a violation of an Act enforced by this Board in the future, this Consent Agreement and Order shall be admitted into evidence without objection in that proceeding.

ACKNOWLEDGMENT OF NOTICE AND WAIVER OF HEARING

7. Respondent acknowledges receipt of an Order to Show Cause in this matter. Respondent knowingly and voluntarily waives the right to an administrative hearing in this matter, and knowingly and voluntarily waives the following rights related to that hearing: to be represented by counsel at the hearing; to present witnesses and testimony in defense or in mitigation of any sanction that may be imposed for a violation; to cross-examine witnesses and to challenge evidence presented by the Commonwealth; to present legal arguments by means of a brief; and to take an appeal from any final adverse decision.

ACKNOWLEDGMENT OF RIGHT TO ATTORNEY

8. Respondent acknowledges that he is aware that he has the right to consult with, and/or be represented by, private legal counsel of Respondent’s choosing and at Respondent’s expense when reviewing, considering and accepting the terms of this Consent Agreement. Respondent had an opportunity to consult with Attorney John A. Elzufon, regarding this Consent Agreement.
WAIVER OF CLAIM OF COMMINGLING AND OTHER CONSTITUTIONAL CLAIMS

9. Respondent expressly waives any constitutional rights and issues, such as commingling of prosecutorial and adjudicative functions by the Board or its counsel, which may arise or have arisen during the negotiation, preparation and/or presentation of this Consent Agreement. Respondent specifically agrees that if the Board rejects this agreement, it may assume that the facts and averments as alleged in this Consent Agreement are true and correct for the limited purpose of recommending a sanction, based on those assumed facts, that would be acceptable to the Board before hearing the case. In the event that the Board does assume the facts and averments as alleged in this Consent Agreement are true for purposes of making a recommendation as to an acceptable sanction, such action shall not constitute commingling of prosecutorial and adjudicative functions by the Board or its counsel, and the Respondent expressly waives any constitutional rights and issues related to alleged commingling, bias, or violation of due process rights to have an unbiased and impartial adjudicator in any subsequent hearing. If a hearing is subsequently held, neither this Consent Agreement nor the proposed terms of settlement may be admitted into evidence and any facts, averments, and allegations contained in the Consent Agreement must be proven at hearing unless otherwise separately stipulated. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

NO MODIFICATION OF ORDER

10. Respondent agrees, as a condition of entering into this Consent Agreement, not to seek modification at a later date of the Stipulated Order adopting and implementing this Consent Agreement without first obtaining the express written concurrence of the Prosecution Division.
AGREEMENT NOT BINDING ON OTHER PARTIES

11. The Office of General Counsel has approved this Consent Agreement as to form and legality; however, this Consent Agreement shall have no legal effect unless and until the Board issues an Order approving and adopting this Consent Agreement.

EFFECT OF BOARD’S REJECTION OF CONSENT AGREEMENT

12. Should the Board not approve this Consent Agreement, presentation to and consideration of this Consent Agreement and other documents and matters by the Board shall not prejudice the Board or any of its members from further participation in the adjudication of this matter. This paragraph is binding on the participants even if the Board does not approve this Consent Agreement.

AGREEMENT DOES NOT PREVENT ADDITIONAL DISCIPLINE BASED ON OTHER COMPLAINTS

13. Nothing in this Order shall preclude the Prosecution Division for the Commonwealth from filing charges or the Board from imposing disciplinary or corrective measures for violations or facts not contained in this Consent Agreement;

ENTIRE AGREEMENT

14. This agreement contains the whole agreement between the participants; provided however, that the captions printed in the various provisions of this agreement are for ease of reading only and are not to be interpreted as forming any part of this agreement. There are no other terms, obligations, covenants, representations, statements or conditions, or otherwise, of any kind whatsoever concerning this agreement.

VERIFICATION OF FACTS AND STATEMENTS

15. Respondent verifies that the facts and statements set forth in this Consent Agreement are true and correct to the best of Respondent’s knowledge, information and belief. Respondent understands that statements in this Consent Agreement are made subject to the criminal
penalties of 18 Pa.C.S. § 4904 relating to unsworn falsification to authorities.

Keith E. Bashore, Esq.
Prosecuting Attorney

DATED: 12/18

Nadya Shapira, M.D.
Respondent

DATED: 12-22-17

John A. Elzufon, Esq.
Attorney for Respondent

DATED: 12-22-17
BEFORE THE DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE

IN RE: NADIV SHAPIRA, M.D.  
LICENSE NO.: C1-0003224

ORDER

WHEREAS, the Board of Medical Licensure and Discipline has reviewed this matter; and finds that through his admitted actions, Dr. Shapira violated 24 Del. C. § 1731(b)(11).

WHEREAS, the Board of Medical Licensure and Discipline approves the Consent Agreement of the parties with this additional finding, and hereby enters the Consent Agreement, as amended, as an Order of the Board.

IT IS HEREBY ORDERED this 19 day of September, 2014.

[Signatures]

EXHIBIT A
BEFORE THE DELAWARE BOARD OF MEDICAL LICENSURE AND DISCIPLINE

IN RE: NADIV SHAPIRA )
LICENSE NO.: C1-0003224 ) Case No.: 10-134-14 )

CONSENT AGREEMENT

A written Complaint was filed with the Delaware Board of Medical Licensure and Discipline alleging that Nadiv Shapia ("Respondent"), a licensed physician M.D., engaged in conduct that constitutes grounds for discipline pursuant to Delaware's Medical Practice Act (24 Del. C. Ch. 17).

By the undersigned Deputy Attorney General, the State of Delaware and Respondent submit this Consent Agreement for approval by the Board as a means of resolving the pending administrative prosecution against Respondent pursuant to 24 Del. C. Ch. 17 and 29 Del. C. Ch. 101.

IT IS UNDERSTOOD AND AGREED THAT:

1. Respondent is a physician licensed in Delaware as an M.D. His license, number C1-0003224, was issued on February 21, 1989 and is currently active.

2. At all relevant times, Respondent was employed by Christiana Care Health Services ("Christiana Care") and practiced as a thoracic surgeon at Christiana Hospital, located at 4755 Ogletown Stanton Road, Newark, Delaware 19713.

3. At all relevant times, the standard of care applicable to the management and control of pain resulting from multiple rib fractures required adequate management and control of that pain, which is essential to permit the patient to breathe adequately to prevent pneumonia, lung collapse or other pulmonary complications that could lead to increased morbidity or even mortality. Adequate management and control of rib fracture pain is important with trauma
patients, especially those who are elderly and/or who already have compromised lung function. For many years the modalities available for traumatic rib fracture pain relief were limited to systemic administration of narcotics and if that did not provide the necessary level of pain relief, then administration of local anesthesia by means of epidural cannulation of the spinal cord was used.

4. As a means to both decrease the need for high doses of narcotics and reduce the necessity for spinal cannulation, the I-Flow Corporation began advocating the use of its On-Q post-surgical pain relief system for management and control of traumatic rib fracture pain. The On-Q system can provide a continuous infusion of local anesthetics via a small soaker catheter inserted subcutaneously over the area of the rib fractures.

5. The On-Q system was originally designed for post-surgical pain management and control and had been so used for several years. At all relevant times, however, use of the On-Q system for management and control of traumatic rib fracture pain was an "off-label" use of the product. That fact that such use was "off-label" does not mean that it cannot be used. FDA regulation of medical devices such as the On-Q system permits physicians to exercise judgment and discretion as to an "off-label" use of a device. A classic example of an "off-label" use of a medical product is the (now widespread) use of aspirin with a high index of suspicion of an acute myocardial infarction to prevent blood clots and cardiac vessel occlusion.

6. The On-Q system was already in use at Christiana Care for post-surgical pain relief, so when Respondent learned in 2004 or 2005 that the On-Q system was being used successfully for traumatic rib fractures in other parts of the country, he sought training from the I-Flow Corporation and subsequently began inserting the On-Q system into trauma patients admitted to Christiana Care with multiple traumatic rib fractures. However, Respondent would
only insert and use the On-Q system when he was consulted to do so by another Christiana Care trauma physician or surgeon. Respondent also tracked his results with the On-Q.

7. In 2007, the I-Flow Corporation invited Respondent to join its Speaker’s Bureau to share with his peers his experience with the On-Q system. In that capacity, Respondent gave presentations about the On-Q system to other physicians and also created a promotional pamphlet about the On-Q system which was distributed by I-Flow. Respondent was compensated by I-Flow for his time and expenses for these activities but he was not compensated on any sort of per capita patient basis. Furthermore, Respondent had no ownership interest in the I-Flow Corporation.

8. By December of 2009, Respondent had inserted and used the On-Q for the management and control of multiple rib fracture pain on over 140 patients with great success. There were a few minor complications, such as a wound site infection easily handled with antibiotics, none of which were similar to those experienced by patient J.H.

9. In December 2009, 72-year old patient J.H. presented to Christiana Care after falling off a ladder at home and suffering, inter alia, multiple non-displaced rib fractures. He was admitted to the trauma service at Christiana Hospital.

10. Because of J.H.’s persistent rib fracture pain, advanced age, increasing necessity for systemic narcotics, and his compromised respiratory function resulting from his pain, J.H.’s attending Christiana Care trauma physicians and surgeons requested a consult with Respondent so that Respondent could evaluate J.H. to determine if he was an appropriate candidate for the On-Q system to manage and control his multiple rib fracture pain.

11. As he did with all On-Q patients, after getting the consult request, Respondent made his own determination that the On-Q was indicated and that the patient would benefit from
its use. When Respondent met with J.H. to get his informed consent for the insertion, he discussed with J.H. the risks and benefits and alternatives of insertion and the use of the On-Q system to alleviate J.H.'s pain and also to explain the insertion procedure and use of the On-Q. Respondent did not inform J.H. about any relationship that he had with I-Flow (Trial Transcript November 5, 2012 page 23 lines 2-8) or that he was receiving compensation from I-Flow from being on the I-Flow Speakers Bureau. (Trial Transcript November 8, 2012 page 177 lines 8-11).

12. At the time of Respondent's consult, J.H. was already receiving systemic narcotics. Another method of pain control would be insertion of an epidural catheter in J.H.'s spinal column by the CCHS Anesthesia Department. In discussing his recommendation that the On-Q system be used to alleviate J.H.'s pain, Respondent advised J.H. that the CCHS trauma surgeons, by virtue of the fact that they consulted with him to put the On-Q for pain relief, considered the On-Q system to be superior to and safer than an epidural insertion. Respondent did offer J.H. the option of continuing systemic analgesics or consult anesthesia. Notably, J.H.'s Christiana Care trauma surgeons did not immediately request a consultation with Respondent. Systemic analgesics were used but when they did not produce the desired results the Christiana Care trauma surgeons then consulted Respondent for the specific reason of evaluating J.H. for the advisability of the insertion of the On-Q.

13. On December 8, 2009, Respondent inserted two On-Q catheters subcutaneously over J.H.'s rib fracture area without incident and J.H. began to experience immediate pain relief from the administration of local anesthesia through those catheters. Unfortunately, on the following day J.H. accidently pulled out both catheters. So, at the request of J.H.'s attending physicians, Respondent returned on December 10th and inserted two new catheters to replace those that J.H. had pulled out. Before inserting those replacement catheters Respondent engaged
in the same informed consent discussion that he had with J.H. prior to the insertion of the original catheters on December 8th. During the insertions on December 10th, one of the replacement catheters was placed appropriately but the other entered the abdominal cavity instead of the subcutaneous area over the rib cage as intended. That catheter perforated internal organs and J.H. had to have additional surgery to repair those perforations which lengthened and increased the acuity of J.H.'s in-patient course of treatment.

14. J.H. subsequently filed a civil suit against Respondent and Christiana Care alleging that Respondent was negligent both in the insertion and use of the On-Q system and in failing to get J.H.'s informed consent prior to insertion and use of the On-Q. J.H. also alleged that Respondent failed to adhere to Christiana Care policies because he did not sufficiently inform Christiana Care that he was receiving compensation as part of being on I-Flow’s Speaker’s Bureau. Jerry Castellano, chairman of the Christiana Care Institutional Review Board (IRB), testified that being on a speaker’s bureau is an area of concern for the hospital regarding conflicts of interest (Trial Testimony November 5, 2012 at page 36 lines 13-19). Dr. Shapira testified that he did not inform the IRB that he was on the I-Flow Speaker’s Bureau (Trial Testimony November 8, 2012 at page 151 lines 9-11) although he did tell the Chief of the Section of Cardiac Surgery (Trial Transcript November 8, 2012 at page 143 line 20 to page 150 line 5).

15. The case went to trial, and on November 14, 2012, a jury found that Respondent and Christiana Care were both generally and separately negligent in their respective care of J.H., but the jury did not separately analyze each allegation against Respondent and Christiana Care.

16. On information and belief, Respondent engaged in misconduct in violation of 24 Del. C. § 1731(b)(11), by failing on December 8, 2009 and December 10, 2009 to obtain the
proper informed consent of patient J.H. before inserting and using the On-Q by failing to inform patient J.H. that Respondent had received compensation from I-Flow for his time and expenses as a member of the I-Flow Speaker's Bureau and by failing to inform the Christiana Care IRB of this relationship with I-Flow.

17. Respondent admits that the facts set forth in paragraphs one (1) through fifteen (15) are true and correct. Respondent chooses not to contest the State's allegations set forth in paragraph sixteen (16) above.

18. The State and Respondent agree that the appropriate disciplinary sanctions are as follows:

A Letter of Reprimand;

A $1,000.00 fine; and

Requiring that Respondent complete six (6) acceptable continuing education contact hours within sixty (60) days of the Board's acceptance of this Consent as a final order of the Board. Of those six hours, three (3) hours must be in the subject of informed consent, and three (3) hours must be in the subject of research protocol. Those hours will be in addition to the hours Respondent needs to accrue to maintain his license.

19. The parties to this Consent Agreement are the State of Delaware and Respondent.

20. The parties agree and acknowledge that nothing contained in this Consent Agreement shall affect any rights or interests of any person not a party to this Agreement.

21. Respondent acknowledges that he is waiving his rights under 24 Del. C. Ch. 17 and 29 Del. C. Ch. 101 to a hearing before the Board prior to the imposition of disciplinary sanctions.

22. Respondent hereby acknowledges and agrees that he has carefully read and understands this Consent Agreement, and is entering into this Consent Agreement freely, knowingly, voluntarily, and after having received the advice of counsel.
23. Respondent acknowledges that this Consent Agreement is a public record within the meaning of 29 Del. C. § 10002 and will be available for public inspection and copying as provided for by 29 Del. C. § 10003.

24. The parties acknowledge and agree that this Consent Agreement is subject to approval by the Board.

25. The parties acknowledge and agree that if the Board does not accept this Consent Agreement, it shall have no force or effect, except as follows:

a. Neither Respondent, nor anyone on his behalf, will in any way or in any forum challenge the ability of the Board or any of its members to conduct an evidentiary hearing relating to the allegations in the subject Complaint;

b. The Consent Agreement, or conduct or statements made in negotiating the Consent Agreement, will be inadmissible at any administrative, civil or criminal legal proceeding; and

c. No provision contained in this Consent Agreement shall constitute or have the effect of an admission by Respondent as to any fact alleged in the Complaint in this matter or in this Consent Agreement.

26. If the Board accepts the Consent Agreement and enters it as an Order, the Consent Agreement shall be admissible as evidence at any future proceedings before the Board.

27. Respondent acknowledges and agrees that the Board will report this Consent Agreement to the licensing authority of any other state in which he is licensed to practice.

28. The parties acknowledge and agree that this Consent Agreement, along with any exhibits, addendums, or amendments hereto, encompasses the entire agreement of the parties and supersedes all previous understandings and agreements between the parties, whether oral or written. There are no other terms, obligations, covenants, representations, statements or conditions, or otherwise, of any kind whatsoever concerning this agreement.
29. This Consent Agreement shall be effective upon acceptance by the Board and entry of the Board’s Order.

Nadiv Shupli
Respondent

Dated: 1/1/17

Carla A.K. Jarosz (51424),
Deputy Attorney General

Dated: 4/4/17

Devashee Brinchman
Executive Director
Delaware Board of Medical Licensure and Discipline

Dated: 7/7/2017
COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF MEDICINE

Commonwealth of Pennsylvania
Bureau of Professional and
Occupational Affairs

vs.

Nadiv Shapira, M.D.,
Respondent

File No.: 17-49-11294
Docket No: 2130-49-17

ORDER

AND NOW, this 6th day of February, 2018, the STATE BOARD OF MEDICINE ("Board") approves and adopts the foregoing Consent Agreement and incorporates the terms of paragraph 5, which shall constitute the Board's Order and is now issued in resolution of this matter.

This Order shall take effect immediately.

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

[Signature]
Ian J. Harlow
Commissioner

For the Commonwealth:

[Signature]

For the Respondent:

[Signature]

Date of mailing:

February 9, 2018

BY ORDER:
STATE BOARD OF MEDICINE

[Signature]
Bruce A. Brod, M.D.
Chairman

Keith E. Bashore, Prosecuting Attorney
Pennsylvania Department of State
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