BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF
MOHAMED ASWAD, M.D.

License No. 2003-0043 No. 2014-044

Respondent.

DECISION AND ORDER OF THE BOARD

On April 27, 2015, a quorum of the New Mexico Medical Board ("Board"), having familiarized themselves with the entire record, voted unanimously to adopt the Final Report and Recommendations of the Hearing Officer Report dated April 14, 2015, with non-substantive amendments as reflected in the Amended Final Report and Recommendations of the Hearing Officer dated May 11, 2015. The Final Report and Recommendations of the Hearing Officer (dated May 11, 2015) is incorporated by reference herein and adopted as the Board's Finding of Fact and Conclusions of Law.

A preponderance of the evidence showed that Respondent:

1. Respondent administered misbranded drugs in his long-term treatment of numerous cancer patients as part of his oncology practice in Deming, New Mexico (January 15, 2015, Amended NCA, paragraph B).
2. Respondent did not inform any of his patients that he was administering non-FDA approved drugs (January 15, 2013 Amended NCA, paragraph C).
3. Misbranded non-FDA approved drugs carry the significant, unreasonable risk that safety and efficacy will be inferior to FDA-approved drugs, (January 15, 2015 Amended NCA paragraph E).

4. Many of Respondent's patient provided reimbursement for the cost of these non-FDA approved medications through the U.S. Medicaid or Medicare program. Respondent billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices. (January 15, 2015 Amended NCA, paragraph F).
5. On or about November 4, 2014 Respondent entered into a plea agreement with the United States, in which he admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G above, to wit, violation of 21 U.S.C Sections 331(a) and 333(a)(1). (January 15, 2015, Amended NCA, paragraph H).
6. Respondent continued practicing medicine for three days beyond the time when he had actual notice of the Board's decision to summarily suspend his license.

The findings constitute violation of:

1. Section 61-6-15(D)(18), conduct likely to deceive, defraud, or harm the public;
2. Section 61-6-15(D)(6), conviction of an offense punishable by incarceration in a federal prison or conviction of a misdemeanor associated with the practice of medicine.
3. Board Rule at NMAC 16.10.8.8(C), violating a drug law , promulgated pursuant to Section 61-6-15(D), to wit the Food Drug and Cosmetic Act, 21 USC Sections 331 (a) and 333(a)(1).
4. Board Rule at NMAC 16.10.8.8(A) practicing medicine without an active license.
5.

ORDER

Respondent previously was suspended from the practice of medicine from November 17, 2014 to December 5, 2014. Therefore, Respondent is hereby formally **REPRIMANDED** for the violations found in the Amended Report and Recommendations of the Hearing Officer as noted above. It is also recommended that Respondent seek assistance in maintaining proper office management.

IT IS SO ORDERED.

Stephen Jenkusky, M.D. Date
Vice Chairperson
New Mexico Medical Board

RIGHT TO JUDICIAL REVIEW

Respondent may seek judicial review of the Decision and Order pursuant to NMSA 1978, Sections 61-1-17 and 39-3-1.1 with thirty days from the date of filing of the Board's Decision and Order.

BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF
MOHAMED ASWAD, M.D.

License No. 2003-0043 No. 2014-044

Respondent.

AMENDED FINAL REPORT AND RECOMMENDATIONS OF HEARING OFFICER

Pursuant to Section 16.10.5.16 NMAC, the parties conducted a hearing on February 11, 2014 concerning the New Mexico Medical Board's January 15, 2015 Notice of Contemplated Action. The New Mexico Medical Board was represented by Prosecutor Dan Rubin,[1] and Mohamed Aswad, MD was represented by Molly Schmidt-Nowara and Nancy Hollander. The parties agreed that the evidence previously presented during the December 1, 2014 hearing concerning the New Mexico Medical Board's Notice of Summary Suspension is applicable to the issues presented by the Notice of Contemplated Action and should be considered by the Hearing Officer in formulating a final recommendation.

The parties presented the following witnesses and exhibits, which have been relied upon by the Hearing Officer to varying degrees:

Witnesses:

1. Special Agent Todd Blair, FDA
2. Mohamed Aswad, MD
3. Lt. John Mooradian
4. Magdalena Shores
5. Cynthia Gilbert

Prosecution's Exhibits:

1. Notice of Contemplated Action filed November 14, 2014

[1] Mr. Rubin resigned from his position in February of 2015, after the February 11, 2015 hearing and before the Prosecutor's Proposed Findings of Fact and Conclusions of Law were submitted in March of 2015. The Prosecutor in this matter is now Patrick McNertney.

2. Summary Suspension Notice filed November 14, 2014
3. Plea Agreement in the United States Court for the District of New Mexico, *US v. Mohamed Basel Aswad*, filed November 4, 2014.
4. Respondent's Selected Bank Statements, Wells Fargo Bank account #2169xxxxxx
5. Prescription Monitoring Program Report re: Respondent (selected dates)[2]
6. Selected copies of prescriptions written by Respondent[3]

Respondent's Exhibits:

A. March 13, 2013 Lab Analysis and July 2, 2013 Lab Analysis[4]
B. Dr. Aswad's Resume/CV
C. Summary of Pharmacy Purchases
D. FDA letters sent to practioners nationwide
E. Professional character reference letters
F. Patient character reference letters
G. Altuzan and Avastin photographs, submitted as demonstrative exhibits
H. March 11, 2015 Letter from Ms. Schmidt-Nowara to the Hearing Officer regarding Dr. Aswad's DEA registration.

Findings of Fact

1. Mohamed Aswad, MD is a Deming based physician who practices in the areas of internal medicine, hematology and oncology. (Tr. at p. 75-76; Exhibit B).

2. Dr. Aswad has been practicing in Deming since 2003, and is the only oncologist in Deming and the surrounding areas. (Tr. at p. 76; 179; Exhibit B). Dr. Aswad is the medical backup to many family practitioners in Deming when they have complicated cases and a backup to nurse practitioners and physician assistants which places a burden on patients to find another medical doctor once they establish with a medical doctor in the Deming area. (Tr. At p. 127; 181-182).

3. The Deming, New Mexico area is chronically underserved by medical personnel. In the time that Dr. Aswad has practiced in Deming, the number of physicians has decreased from 15 to 6. (Tr. at p. 179)

[2] This exhibit has been redacted to safeguard HIPAA protected information.
[3] This exhibit has been redacted to safeguard HIPAA protected information.
[4] This exhibit has been redacted to safeguard HIPAA protected information.

4. Although Dr. Aswad was once board certified in the areas of internal medicine, hematology and oncology, his certifications expired in 2013 (hematology and oncology) and in 2010 (internal medicine). (Tr. at p. 87-89; Exhibit H, Portion of Renewal Application to NMMB).

5. From approximately July of 2010 to February of 2012, Dr. Aswad purchased non-FDA approved chemotherapy drugs from various pharmaceutical companies, including Non-RX, Bridgewater and Northwest Pharmacy (hereinafter "Non-RX and Others"), that operate primarily through telephonic orders. (Tr. at p. 39-40; Exhibit 3, Plea Agreement, at p. 4).

6. There is no pharmacy in the Deming area that dispenses oncology medications. (Tr. at p. 172-173). As a result, Dr. Aswad has always ordered chemotherapy medications and supplies through remote pharmaceutical companies that operate primarily through 1-800 or 1-866 telephone numbers. (Tr. at p. 172-173).

7. Heidi Burgess was a sales representative for Non-RX who contacted Dr. Aswad's office repeatedly over the course of months prior to July of 2010 in an effort to persuade Dr. Aswad to purchase his oncology and chemotherapy supplies from Non-RX. (Tr. at p. 97-98).

8. Dr. Aswad's office began purchasing supplies and medications from Ms. Burgess and Non-RX and Others in or about July of 2010. (Tr. at p. 97; Exhibit 4, Bank Records). There was nothing significantly different in Dr. Aswad's interactions with Non-RX and Others as compared to his interactions with other suppliers who dispensed FDA-approved medications. (Tr. at p. 101).

9. Dr. Aswad ordered his supplies and medications from Non-RX and Others by calling a US toll free telephone number. (Tr. at p. 83; Exhibit 3, p. 4).

10. The supplies and medications that Dr. Aswad ordered from Non-RX and Others generally arrived within one day, and the supplies and medications that Dr. Aswad ordered were shipped to him from an Illinois address. (Tr. at p. 93).

11. The non-FDA approved medications had labels and packaging that were written in English and that contained the Roche logo. (Tr. at p. 93-95; Exhibit G, photographs, p. 1).

12. The non-FDA approved medications contained package inserts that were likely written in a language other than English. (Tr. at p. 93-94; Exhibit 3 at p. 4). However, Dr. Aswad does not read the package inserts for chemotherapy medications given his long-standing familiarity with the use of those medications. (Tr. at p. 95; 167).

13. If the non-FDA approved medications contained package inserts that were written in Turkish, Dr. Aswad did not notice. (Tr. at p. 190-192). Even if Dr. Aswad had noticed that the package inserts were written in a language other than English, he likely would not have assumed that the chemotherapy medications were not approved by the FDA. (Tr. at p. 191-192).

14. The non-FDA approved medications had labels that listed their scientific name as bevacizumab. (Tr. at p. 168-169; Exhibit G).

15. Dr. Aswad knew that the chemotherapy medications that he intended to administer to his patients were manufactured by Roche. (Tr. at p. 169).

16. Dr. Aswad was trained during his residency to identify and recognize medications by their scientific rather than market/brand names. (Tr. at p. 169-170).

17. Dr. Aswad identified the non-FDA approved medications he received from Non-RX and Others as bevacizumab, which is the scientific name of the chemotherapy medication that he intended to order and administer to his patients. (Tr. at p. 169-170; Exhibit 3 at p. 4).

18. Based on a representation from Ms. Burgess, Dr. Aswad believed that "Altuzan"(manufactured by Roche) was a generic name for "Avastin" (manufactured by Genentech, which is a corporate division of Roche). (Tr. at p. 57-58; 174; Exhibit G).

19. Dr. Aswad administered the non-FDA approved chemotherapy medications he obtained from Non-RX and Others to patients. (Tr. at p. 176; Exhibit 3 at p. 4).

20. Dr. Aswad did not inform his patients that he was administering non-FDA approved medications as he was not aware that the medications were not FDA approved. (Tr. at p. 203).

21. The FDA employs a process by which it researches and investigates the safety and efficacy of food and drugs that are sold or otherwise distributed in the United States. (Tr. at p. 25). The FDA further regulates that manufacturing process and labeling of food and drugs sold or otherwise distributed in the United States. (Tr. at p. 23; 25).

22. Dr. Aswad has always understood the role of the FDA in monitoring the safety and efficacy of food and drugs that are sold or otherwise distributed in the United States. (Tr. at p. 78-81).

23. The FDA began investigating the distribution of counterfeit chemotherapy medications in the United States in November of 2010. (Tr. at p. 30-31).

24. In an effort to identify and eliminate the distribution of counterfeit chemotherapy medications in the United States, the FDA sent letters to approximately 160 US physicians warning those physicians regarding the FDA's suspicions that the

chemotherapy medications that the physicians had ordered were counterfeit medications and/or were otherwise not approved by the FDA. (Tr. at p. 147-148; Exhibit D).

25. Dr. Aswad did not receive a warning letter from the FDA. (Tr. at p. 59-60).

26. The FDA executed on a search warrant and raided Dr. Aswad's practice in April of 2012. (Tr. at p. 32; Exhibit 3 at p. 4).

27. Prior to the FDA's raid of Dr. Aswad's practice, Dr. Aswad was not aware that the medications that he had ordered from Non-RX and Others were not approved by the FDA. (Tr. at p. 83; Exhibit 3, p. 4).

28. Dr. Aswad was surprised and shocked to learn that the medications that he had ordered were not FDA approved medications, and Dr. Aswad was cooperative with the FDA during the FDA's raid of his office. (Tr. at p. 60-62). Dr. Aswad answered all of the FDA agents' questions and made an effort to contact Heidi Burgess at the FDA's behest and while the FDA agents were still in his office. (Tr. at p. 62-63).

29. The active ingredient in the chemotherapy medication that Dr. Aswad ordered from Non-RX and Others is bevacizumab. (Tr. at p. 169).

30. The FDA seized many used vials of chemotherapy medications from Dr. Aswad's office during the raid. Many of the vials that were seized had been administered to patients, and the used vials did not contain sufficient product to run tests for dilution of bevacizumab. (Tr. at p. 33; 37; 42; Exhibit A, FDA Report).

31. However, the used vials contained sufficient product to determine that the medications ordered by Dr. Aswad from Non-RX and Others actually contained some quantity of the active ingredient bevacizumab. (Tr. at p. 41; Exhibit A).

32. According to FDA Special Agent Todd Blair, other chemotherapy medications from Non-RX and Others sold to other physicians were tested, and the FDA determined that some of those medications contained no active ingredient at all. (Tr. at p. 29).

33. Dr. Aswad did not intend to subject his patients to risk by administering non-FDA approved medications to them. (Tr. at p. 81-82; 103). Dr. Aswad would not have administered the chemotherapy medications to his patients if he had known that the medications had not been approved by the FDA. (Tr. at p. 176). Dr. Aswad is not as trusting of suppliers since the FDA raid on his office in 2012. (Tr. at p. 198).

34. The FDA did not make any effort to close Dr. Aswad's practice following the raid of Dr. Aswad's office. (Tr. at p. 65). Moreover, the FDA did not arrest Dr. Aswad or notify the DEA of the FDA's raid on Dr. Aswad's office or the FDA's findings concerning Dr. Aswad's administration of non-FDA approved medications. (Tr. at p. 65-66).

35. Dr. Aswad self-reported to the New Mexico Medical Board. (Tr. at p. 180).

36. Dr. Aswad paid $1,086,667.97 to Non-RX for the chemotherapy medications. (Tr. at p. 159; Exhibit C, Summary of Payments).

37. Dr. Aswad was reimbursed approximately $1,298,543.00 by Medicare, Medicaid and TriCare for the chemotherapy medications he purchased from Non-RX and Others. (Tr. at p. 160).

38. Dr. Aswad obtained a profit of $211,875.03 from the purchase of chemotherapy medications from Non-RX and Others. (Tr. at p. 160).

39. Special Agent Blair estimated that the chemotherapy medications supplied by Non-RX and Others were approximately 20% less expensive than FDA approved chemotherapy medications. (Tr. at p. 49).

40. Dr. Aswad testified that the cost of chemotherapy medications and supplies varies wildly, even between suppliers who dispense FDA approved medications. (Tr. at p. 173-174).

41. Dr. Aswad testified that the difference in cost per dose of non-FDA approved medications that he ordered from Non-RX and Others was approximately $100 to $150 per dose. (Tr. at p. 98). Dr. Aswad also testified that it is not uncommon for suppliers and manufacturers to provide physicians with significant discounts from time to time. (Tr. at p. 173-174).

42. Dr. Aswad maintains a total of four accounts at Wells Fargo in Deming, NM. Each of Dr. Aswad's accounts is in his name and/or the name of his medical practice. (Tr. at p. 51; 56-57; Exhibit 4).

43. Dr. Aswad made no efforts to try to hide the fact that he was ordering medications from Non-RX and Others, and the accounts in which Dr. Aswad deposited the reimbursements from Medicaid, Medicare and TriCare all bear his name. (Tr. at p. 56-57; Exhibit 4).

44. The reason that Dr. Aswad maintains several accounts at the same bank is that one of the bank employees advised Dr. Aswad to serially open new accounts as each account neared the $250,000 FDIC insured deposit limit. (Tr. at p. 170-171).

45. Special Agent Blair testified that the existence of several bank accounts is sometimes a hallmark of an effort to use the purchase of counterfeit or non-FDA approved medications as an opportunity to illegally launder funds. (Tr. at p. 52). However, Special Agent Blair admitted that there is no evidence that Dr. Aswad was engaged in money laundering or in any attempt to hide the fact that he was purchasing non-FDA approved medications. (Tr. at p. 56-57; 69-70).

46. There is no evidence that any of Dr. Aswad's patients were harmed by Dr. Aswad's administration of non-FDA approved medications. (Tr. at p. 67).

47. On November 4, 2014, Dr. Aswad pled guilty to a strict liability misdemeanor. (Exhibit 3).

48. In connection with Dr. Aswad's guilty plea, Dr. Aswad made certain representations and admissions concerning his purchase and administration of non-FDA approved medications. (Exhibit 3 at p. 4).

49. The plea agreement reflects that Dr. Aswad misrepresented that he remains board certified in the areas of oncology, hematology and internal medicine. (Exhibit 3 at p. 4).

50. Because Dr. Aswad pled guilty to a strict liability crime, the government did not have to establish that Dr. Aswad knowingly or intentionally purchased and administered non-FDA approved medications. (Tr. at p. 64-65).

51. As a result of the guilty plea, Dr. Aswad will reimburse Medicaid, Medicare and TriCare $1,298,543, pay an additional forfeiture of $750,000, and will remain on probation for a period of three years. (Exhibit 3).

52. As evidenced by the substance of the plea agreement (Exhibit 3), Dr. Aswad has pled guilty to an offense related to the practice of medicine. (Tr. at p. 84).

53. Cynthia Gilbert, who is an investigator who was hired by Dr. Aswad's counsel, testified that her investigation revealed that approximately 7 of the 160 physicians who received warning letters from the FDA were prosecuted. (Tr. at p. 148-149; Exhibit D). Of those 7 who were prosecuted, all but one still maintains an active medical license and is still practicing medicine. (Tr. at p. 149). The one Tennessee physician who is not still practicing relinquished his medical license when he was imprisoned in a federal

penitentiary. (Tr. at p. 149-151). According to Ms. Gilbert's investigation, the Tennessee physician engaged in conduct over a long period of time, even after being warned by the FDA, which suggested that he was intentionally violating the law for personal profit and attempting to evade detection. (Tr. at p. 149-150).

54. Ms. Gilbert also found that there were nine physicians, other than Dr. Aswad, who were prosecuted even though they had not received any warning letter from the FDA. (Tr. at p. 156). Of those nine physicians, all but one still maintains an active medical license and is still practicing medicine. (Tr. at p. 157). The one Ohio physician who is no longer practicing did not renew his license for unknown reasons. (Tr. at p. 157).

55. The New Mexico Medical Board summarily suspended Dr. Aswad's license on November 13, 2014, and the notice of summary suspension was dated November 17, 2014. (Exhibit 2). The Board simultaneously issued a Notice of Contemplated Action. (Exhibit 1). The Board amended its Notice of Contemplated Action on January 15, 2015.

56. The Amended Notice of Contemplated Action identifies nine bases for the summary suspension, including:

    A. From approximately July 2010 to February 2012, [Dr. Aswad] knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq.

    B. [Dr. Aswad] administered these misbranded drugs in [his] long-term treatment of numerous cancer patients as part of [his] oncology practice in Deming, New Mexico.

C. [Dr. Aswad] did not inform any of [his] patients that [he was] administering non-FDA approved drugs.

D. The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names.

E. Misbranded non-FDA approved drugs carry the significant, unreasonable risk that the safety and efficacy of the drugs will be inferior to the FDA-approved drugs.

F. Many of [Dr. Aswad's] patients provided reimbursement for the cost of these non-FDA approved medications through the U.S. Medicaid or Medicare program. [Dr. Aswad] billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices.

G. [Dr. Aswad] personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding one million dollars ($1,000,000.00), which was deposited into [his] personal banking accounts.

H. On or about November 4, 2014, [Dr. Aswad] entered into a plea agreement with the United States in which [he] admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S. C. Sections 331(a) and 333(a)(1).

I. After receiving actual notice of a summary suspension by the Board against [Dr. Aswad's] license, [Dr. Aswad] continued to prescribe controlled substances through November 20, 2014.

(January 15, 2015 Amended NCA).

57. Dr. Aswad's attorney was notified via email about Dr. Aswad's summary suspension late in the day on November 17, 2014, and Dr. Aswad was notified by his counsel by telephone on that same date about the summary suspension. (Tr. at p. 107).

58. Dr. Aswad's attorney advised him that he could continue working, despite the email notification of the suspension, until such time as he received the summary suspension notice via mail. (Tr. at p. 107-109). Dr. Aswad received the notification of summary suspension via mail on November 21, 2014. (Tr. at p. 108).

59. Dr. Aswad had actual knowledge of the summary suspension on November 17, 2014, but in reliance on the advice of counsel, Dr, Aswad continued working through November 20, 2014. (Tr. at p. 107-109).

60. Between November 17, 2014 and November 20, 2014, Dr. Aswad saw patients and prescribed medications to his patients. (Tr. at p. 107-109; 115; Exhibit 5, Prescriber Rx History Report; Exhibit 6, Selected prescriptions). The volume of medication that Dr. Aswad prescribed between November 17 and November 20, 2014 was greater than normal because Dr. Aswad was concerned about abandonment of patients in need of refills of maintenance medications. (Tr. at p. 115-119).

61. Two of Dr. Aswad's patients traveled from Deming to testify in support of Dr. Aswad, and several others wrote letters of support. (Tr. at p. 121;135; Exhibit F, Patient Letters). The evidence shows that Dr. Aswad's patients have a great deal of trust in and appreciation for Dr. Aswad's treatment of their various conditions, despite Dr. Aswad's guilty plea. Id.

62. All of the patients who provided testimony or wrote letters of support cite to their concerns about their ability to secure medical care if Dr. Aswad is not able to continue practicing in the Deming community. (Tr. at p. 127-128; 139; Exhibit F).

63. In addition, several practitioners in the Deming area wrote letters of support for Dr. Aswad. (Exhibit E, Practitioner letters). Each of the practitioners who wrote letters of support cite to Dr. Aswad's commitment to patient care, his integration into the Deming community, and the critical need for his services in the Deming and the surrounding areas. Id.

64. The parties have agreed to the following stipulation concerning Dr. Aswad's practice since 2012:

    a. Dr. Aswad voluntarily surrendered his DEA registration; and

    b. The DEA seized all controlled and non-controlled drugs form his office on December 4, 2014.

65. After Dr. Aswad's license was suspended on November 17, 2014, the following private insurance companies terminated his contracts: United Healthcare, Blue Cross-Blue Shield, Molina, Presbyterian, CIGNA, and Humana. (Tr. II at 7)[5].

66. Dr. Aswad relinquished his DEA registration at the time his license was suspended and reapplied for the registration. (Tr. II at 23-24). Dr. Aswad's DEA registration was restored by virtue of a Memorandum of Understanding entered into by Dr. Aswad and the DEA on or about March 11, 2015. (March 11, 2015 Correspondence from M. Schmidt-Nowara to J. Anderson).

67. All of the terminations of Dr. Aswad's contracts began after the suspension was put into effect. (Tr. II at 25).

[5] The transcript of the February 11, 2015 hearing is referred to herein as "Tr. II."

68. Dr. Aswad had a hearing on December 17, 2014, with Blue Cross-Blue Shield. Blue Cross agreed to reinstate Dr. Aswad's contract. (Tr. II at 8). Humana also reinstated its contract with Dr. Aswad. (Id.)

69. The remaining companies have not reinstated their contracts with Dr. Aswad. (Tr. II at 8).

70. Medicaid terminated its contract with Dr. Aswad effective November 17, 2014. (Tr. II at 8).

71. Dr. Aswad has filed an application to reinstate Medicaid which is currently pending. (Tr. II at 8).

72. Approximately 50% of Dr. Aswad's patients have Medicare and/or Medicaid. (Tr. II at 9).

73. Despite not being reimbursed currently, Dr. Aswad continues to treat some of his Medicaid patients with the hope Medicaid will reinstate his contract. (Tr. II at 9).

74. As a consequence of the contracts being terminated, Dr. Aswad is seeing only 30%-35% of the patients he saw before his contracts were terminated. (Tr. II at 10).

75. Dr. Aswad is attempting to see as many of his patients as possible because he does not want them to be abandoned. (Tr. II at 9-10).

76. There are currently five doctors other than Dr. Aswad practicing in the Deming, New Mexico area. (Tr. II at 10). Two of the doctors have suggested that they plan to retire this year. (Id.).

77. Only two other doctors are available to refer patients to at the local hospital and one of them is retiring shortly. (Tr. II at 10).

78. Since the suspension, Dr. Aswad's malpractice insurance was increased to a much higher rate—from $14,000.00 to $24,000.00 per year. (Tr. II at 11). Dr. Aswad's insurance company also placed him in a "high risk" category. (Id.).

79. Dr. Aswad has expressed a belief that if he is suspended again, it will be a "death sentence" to his practice. (Tr. II at 10).

80. Dr. Aswad believes that if his license is partially or fully suspended, the insurance companies will again terminate his contracts and may not reinstate them a second time. (Tr. II at 31-32).

81. Since his suspension, Dr. Aswad has also avoided community gatherings because of embarrassment and the stigma associated with his presence. (Tr. II at 12-13).

Conclusions of Law

1. The New Mexico Medical Board is authorized to conduct this hearing. See NMAC 16.10.6.3 (promulgated pursuant to and in accordance with the Medical Practice Act and the Uniform Licensing Act).

2. The standard of proof to be applied by the Board is by a preponderance of the evidence. NMSA. 1978 § 61-1-13; *Foster v. Board of Dentistry of State of N.M.*, 103 N.M. 776, 777-78, 714 P.2d 580, 581-82 (1986).

3. A professional license is a constitutionally protected property right, and professional licensees facing license revocation or suspension must be afforded due process. *Mills v. New Mexico State Bd. of Psychologist Exam'rs*, 1997 NMSC 28, P14, 123 N.M. 421, 426, 941 P.2d 502, 507.

4. A licensee is not required to comply with a summary action until service of the action has been made personally or by certified mail, return receipt requested, at the licensee's last

known address as shown in the board's records, or the licensee has actual knowledge of the order, whichever occurs first. Section 16.10.5.16 (B) NMAC.

5. The Prosecutor met his burden of establishing the following allegations from the Summary Suspension Notice (Exhibit 2) by the preponderance of the evidence:

   - Dr. Aswad administered misbranded drugs in his long-term treatment of numerous cancer patients as part of his oncology practice in Deming, New Mexico. (January 15, 2015 Amended NCA, paragraph B).
   - Dr. Aswad did not inform any of his patients that he was administering non-FDA approved drugs. (January 15, 2015 Amended NCA, paragraph C).
   - Misbranded non-FDA approved drugs carry the significant, unreasonable risk that the safety and efficacy will be inferior to FDA-approved drugs. (January 15, 2015 Amended NCA, paragraph E).
   - Many of Dr. Aswad's patients provided reimbursement for the cost of these non-FDA approved medications through the U.S. Medicaid or Medicare program. Dr. Aswad billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices. (January 15, 2015 Amended NCA, paragraph F).
   - On or about November 4, 2014, Dr. Aswad entered into a plea agreement with the United States, in which he admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S. C. Sections 331(a) and 333(a)(1). (January 15, 2015 Amended NCA, paragraph H).

4. The Prosecutor did not meet his burden of establishing the following allegations from the January 15, 2015 Amended NCA by the preponderance of the evidence:

    - From approximately July 2010 to February 2012, [Dr. Aswad] knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq. (January 15, 2015 Amended NCA, paragraph A).
    - The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names. (January 15, 2015 Amended NCA, paragraph D).
    - Dr. Aswad personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding one million dollars ($1,000,000.00), which was deposited into his personal banking accounts. (January 15, 2015 Amended NCA, paragraph G).

5. The Prosecutor met his burden of establishing by the preponderance of the evidence that Dr. Aswad continued practicing medicine for three days beyond the time when he had actual notice of the Board's decision to summary suspend his license.

Opinion and Recommendation

At the outset, it is worth noting that I appreciate the candor and cooperation of counsel in this case. Counsel worked hard to present evidence and testimony on some relatively complex claims and defenses.

The purpose of the December 1, 2014 hearing was to ascertain whether the summary suspension of Dr. Aswad is justified and should continue until such time as the issues presented in the November 17, 2014 Notice of Contemplated Action (NCA) were adjudicated. The Board amended its NCA on January 15, 2015 (Amended NCA), and the parties presented additional evidence related to the Amended NCA on February 11, 2015. This opinion and recommendation pertains to the issues presented by the Amended NCA, and is intended as a final opinion and recommendation.

The evidence presented conclusively establishes that Dr. Aswad ordered non-FDA approved chemotherapy medications and administered those medications to his oncology patients over the period of almost two years. The evidence also conclusively establishes that Dr. Aswad did not make any disclosure to his patients regarding his use of non-FDA approved medications and that there was the potential for risk to the health and well-being of Dr. Aswad's patients. However, the evidence reflects that Dr. Aswad's failure to make the necessary disclosures to his patients results from the fact that Dr. Aswad himself was unaware that he had ordered and administered non-FDA approved medications.

During the December 1, 2014 hearing, Dr. Aswad testified that Ms. Burgess from Non-RX made numerous telephonic sales calls to Dr. Aswad's office in an effort to get Dr. Aswad to order supplies and medications from Non-RX. Dr. Aswad eventually placed orders with Non-RX without any knowledge that the supplier was offering non-FDA approved medications for sale. The evidence shows that Dr. Aswad filled out a credit application for Non-RX and used a

1-866 phone number to place orders with Non-RX, which is no different than how he placed orders with other suppliers who were dispensing FDA approved medications. The medications that Dr. Aswad ordered from Non-RX and Others arrived from an Illinois location within a day or two of Dr. Aswad placing his order. The medications supplied by Non-RX and Others were packaged and labeled in English, not Turkish, and the medications all bore a label that reflected the scientific name of the medication (bevacizumab) and the Roche logo. (Exhibit G, page 1). Based on the representations of Ms. Burgess, Dr. Aswad apparently believed that the non-FDA approved medication Altuzan was a generic equivalent of the FDA approved medication Avastin. According to the testimony of Special Agent Blair, the package inserts in the boxes of medication that Dr. Aswad ordered from Non-RX and Others were written in the Turkish language. Dr. Aswad does not dispute this fact because Dr. Aswad claims that he never examined the package inserts of the medications given his familiarity with bevacizumab and its use as a chemotherapy medication. Simply stated, Dr. Aswad convincingly testified that he was unaware of the fact that the medications that he received from Non-RX and Others were not FDA approved medications.

Dr. Aswad's practice was raided by the FDA in April of 2012. During the raid, the FDA recovered many containers of already-administered medications. The FDA tested the trace amounts of medication remaining in the containers the FDA seized from Dr. Aswad, and the FDA's tests determined that all of the vials that were seized from Dr. Aswad contained bevacizumab. However, because the amount of medication remaining in each of the largely empty vials was so small, the FDA was unable to determine whether the bevacizumab was present in the medications in the appropriate and expected concentrations. The evidence suggests that Dr. Aswad was forthcoming and cooperative with the FDA and there is no evidence

to suggest that Dr. Aswad was anything other than shocked and dismayed to learn that the medications that Dr. Aswad had been administering to his patients were not FDA approved medications. Moreover, there is nothing in the record that establishes by a preponderance of the evidence that Dr. Aswad was engaging in any activity designed to conceal his orders from Non-RX and Others or to otherwise conceal his use of the non-FDA approved medications he received from Non-RX and Others.

Dr. Aswad signed a plea agreement on November 4, 2014. In that plea agreement, Dr. Aswad pled guilty to a strict liability misdemeanor associated with his practice of medicine. Dr. Aswad agreed to forego his right to trial, reimburse Medicare/Medicaid and TriCare in the amount of $1,298,543, pay a penalty of $750,000, and serve a three year term of probation. The evidence shows that Dr. Aswad did not personally profit from his transactions with Non-RX and Others in the amount of $1,000,000 as alleged. Instead, the evidence establishes that Dr. Aswad was originally reimbursed $211,873.03 more than what he initially spent on the medication that he ordered from Non-RX and Others. The testimony shows that the price for oncology medications and supplies varies drastically from supplier to supplier, and even from one time period to the next when ordering from the same supplier. Moreover, the testimony suggests that it took the FDA and Dr. Aswad's investigators, Ms. Gilbert, considerable time and effort to determine the amount by which Dr. Aswad was over-reimbursed for the medications. Under the circumstances, there is no basis on which one can draw a conclusion that Dr. Aswad knew that he had been over-reimbursed for the medications that he ordered from Non-RX and Others. This is important because of the implications concerning Dr. Aswad's ethics, but also because if Dr. Aswad had been collecting significantly more in reimbursements than he was paying for the medications that he received through Non-RX and Others, it arguably should have raised a red

flag for Dr. Aswad and should have prompted him to examine the reasons for the disparity. It appears that the over-reimbursement represents approximately 16% of the amount that Dr. Aswad paid for the non-FDA approved medications. The unrebutted testimony suggests that rebates and discounts in the range of 16% are neither unusual nor alarming.

There is absolutely no evidence that any of Dr. Aswad's patients were harmed by the administration of the non-FDA approved medications. As described in an earlier opinion, the fact that no one was apparently harmed is cold comfort to the Board given the undisputed risk of harm presented by the administration of non-FDA approved medications. Special Agent Blair testified that some of the vials seized from other physicians across the country contained no active ingredient at all. If none of Dr. Aswad's patients suffered any setbacks in their health or well-being after being infused with the medications obtained from Non-RX and Others, the lack of harm can only be attributable to good fortune. Arguably, an impaired physician who operates on a patient should still be subjected to discipline by the Board even if the patient does not suffer a negative outcome as a result of the impairment. This is true because it is the physician's willingness to engage in risky behavior and to jeopardize the health and well-being of one or more of his patients that raises a presumption of lack of fitness to practice and creates a danger to the public.

The Board bears the responsibility to protect the public from physicians who are not fit to practice, and it is a responsibility that the Board undertakes with great care. When a physician has pled guilty to criminal conduct in connection with the physician's practice of medicine, as Dr. Aswad did, the Board is specifically authorized to discipline the physician and to revoke a physician's license to practice medicine if necessary.

While Dr. Aswad unquestionably subjected his patients to the dangers associated with the use of non-FDA approved medications between July of 2010 and April of 2012, he did so unknowingly. Based on his testimony and the lack of any evidence to the contrary, I believe that Dr. Aswad never intended to subject his patients to risk and that Dr. Aswad thought that he was providing his patients with excellent care. I further find no support for the allegation that Dr. Aswad subjected his patients to risk in pursuit of personal gain. I note that the FDA did not make any efforts to stop Dr. Aswad from practicing medicine when it raided his office. Indeed, the FDA did not even report the fact of the raid or its findings to the Board or to the DEA. Moreover, in the almost 3 years that have elapsed between the raid and the guilty plea and resulting summary suspension and issuance of the NCA, there have been no concerns raised about Dr. Aswad's provision of care to his patients and there have been no new allegations concerning Dr. Aswad's administration of non-FDA approved medications. Dr. Aswad appears to be less trusting and savvier with respect to suppliers of oncology medications and supplies, and I genuinely believe that Dr. Aswad will not make the same unwitting mistake in the future.

However, the evidence presented in this matter is clear that, as alleged in the Amended NCA, Dr. Aswad failed to immediately abide by the notice of summary suspension once he was aware of its issuance. As noted in an earlier opinion concerning the summary suspension, the Board expects that physicians will timely and thoroughly adhere to the Board's orders, and the Board further expects nothing less than the complete cooperation of its licensees. Dr. Aswad's counsel admitted that Dr. Aswad continued to practice for three days after Dr. Aswad and his counsel had actual notice of the summary suspension, and counsel admitted during the hearing and in her closing brief that it was her mistaken advice to Dr. Aswad that resulted in Dr. Aswad's short-term non-compliance with the notice. It appears that Dr. Aswad's short term non-

compliance was also motivated by a desire to avoid abandoning patients who use maintenance medications and who may have experienced difficulties in obtaining those medications from other, scarce practitioners in Deming. Whatever the motivation and the cause of the non-compliance, Dr. Aswad is strongly cautioned not to defy future orders and notices of the Board. That said, it is recommended that the Board take no further action on this item as it is assumed that the caution contained herein will suffice to prevent any similar future infraction.

Based on the testimony and letters of support of Dr. Aswad's patients and colleagues, there is a real risk of harm to the Deming community if Dr. Aswad is unable to practice medicine. The evidence offered at the hearings shows that Deming is an underserved community, and the patients who need oncology services have expressed a concern that they will have to travel several hours from home in order to obtain the necessary treatment of their conditions. The reports and testimony offered by Dr. Aswad's patients and colleagues show that Dr. Aswad is a talented and compassionate practitioner whose professional absence in the community would cause hardship for patients and other providers.

Dr. Aswad testified at the February 11, 2015 hearing concerning his difficulties in continuing to run his practice in the wake of the summary suspension. Dr. Aswad's contracts with various providers (including Medicaid) were temporarily, or in some cases permanently, revoked. Dr. Aswad continues to treat some of his Medicaid patients despite the fact that he is currently not eligible to seek compensation from Mediaid out of concern that his patients will be without care if he does not continue to treat them. Dr. Aswad has expressed a concern that his practice will not likely survive another setback associated with further action against his license, and his patients have expressed concerns related to their access to care if Dr. Aswad is unable to continue his practice.

After hearing all of the evidence, I do not believe that Dr. Aswad intentionally committed any of the violations set forth in the Amended NCA (other than the failure to immediately abide by the order of suspension, as discussed above), and I am convinced that Dr. Aswad's practice may be fatally impacted if any additional action is taken against his license at the present time. Given Dr. Aswad's expressions of dismay and remorse and my belief that he will refrain from any future infractions, I recommend that the Board close this matter without taking any further action against Dr. Aswad's license that will materially hinder his ability to serve the community of Deming.

However, given the seriousness of the allegations, the real risk of harm to which Dr. Aswad's patients were subjected, and the concerns about Dr. Aswad's compliance with the suspension order, the Board may want to consider placing a letter of reprimand in Dr. Aswad's file. In determining whether a letter of reprimand is appropriate under the circumstances presented, the Board should weigh whether the placement of a letter of reprimand (or imposition of educational requirements, as urged by the Prosecutor) will carry an unintended or impractical precedential value in cases involving similar allegations and whether such a letter will materially hinder Dr. Aswad's ability to continue to practice medicine.

Respectfully Submitted,

Jennifer G. Anderson
New Mexico Medical Board Member
Hearing Officer

May 11, 2015

BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF
MOHAMED ASWAD, M.D.

License No. 2003-0043 No. 2014-044

Respondent.

AMENDED REPORT AND RECOMMENDATIONS OF HEARING OFFICER

Pursuant to Section 16.10.5.16 NMAC, the parties conducted a hearing on December 1, 2014 concerning the New Mexico Medical Board's November 17, 2014 Notice of Summary Suspension. The New Mexico Medical Board was represented by Prosecutor Dan Rubin, and Mohamed Aswad, MD was represented by Molly Schmidt-Nowara and Nancy Hollander.

The parties presented the following witnesses and exhibits, which have been relied upon by the Hearing Officer to varying degrees:

Witnesses:

1. Special Agent Todd Blair, FDA
2. Mohamed Aswad, MD
3. Lt. John Mooradian
4. Magdalena Shores
5. Cynthia Gilbert

Prosecution's Exhibits:

1. Notice of Contemplated Action filed November 14, 2014
2. Summary Suspension Notice filed November 14, 2014
3. Plea Agreement in the United States Court for the District of New Mexico, *US v. Mohamed Basel Aswad*, filed November 4, 2014.
4. Respondent's Selected Bank Statements, Wells Fargo Bank account #2169xxxxxx
5. Prescription Monitoring Program Report re: Respondent (selected dates)[1]
6. Selected copies of prescriptions written by Respondent[2]

[1] This exhibit has been redacted to safeguard HIPAA protected information.
[2] This exhibit has been redacted to safeguard HIPAA protected information.

Respondent's Exhibits:

A. March 13, 2013 Lab Analysis and July 2, 2013 Lab Analysis[3]
B. Dr. Aswad's Resume/CV
C. Summary of Pharmacy Purchases
D. FDA letters sent to practioners nationwide
E. Professional character reference letters
F. Patient character reference letters
G. Altuzan and Avastin photographs, submitted as demonstrative exhibits

Findings of Fact

1. Mohamed Aswad, MD is a Deming based physician who practices in the areas of internal medicine, hematology and oncology. (Tr. at p. 75-76; Exhibit B).

2. Dr. Aswad has been practicing in Deming since 2003, and is the only oncologist in Deming and the surrounding areas. (Tr. at p. 76; 179; Exhibit B).

3. The Deming, New Mexico area is chronically underserved by medical personnel. In the time that Dr. Aswad has practiced in Deming, the number of physicians has decreased from 15 to 6. (Tr. at p. 179)

4. Although Dr. Aswad was once board certified in the areas of internal medicine, hematology and oncology, his certifications expired in 2013 (hematology and oncology) and in 2010 (internal medicine). (Tr. at p. 87-89; Exhibit H, Portion of Renewal Application to NMMB).

5. From approximately July of 2010 to February of 2012, Dr. Aswad purchased non-FDA approved chemotherapy drugs from various pharmaceutical companies, including Non-RX, Bridgewater and Northwest Pharmacy (hereinafter "Non-RX and Others"), that operate primarily through telephonic orders. (Tr. at p. 39-40; Exhibit 3, Plea Agreement, at p. 4).

[3] This exhibit has been redacted to safeguard HIPAA protected information.

6. There is no pharmacy in the Deming area that dispenses oncology medications. (Tr. at p. 172-173). As a result, Dr. Aswad has always ordered chemotherapy medications and supplies through remote pharmaceutical companies that operate primarily through 1-800 or 1-866 telephone numbers. (Tr. at p. 172-173).
7. Heidi Burgess was a sales representative for Non-RX who contacted Dr. Aswad's office repeatedly over the course of months prior to July of 2010 in an effort to persuade Dr. Aswad to purchase his oncology and chemotherapy supplies from Non-RX. (Tr. at p. 97-98).
8. Dr. Aswad's office began purchasing supplies and medications from Ms. Burgess and Non-RX and Others in or about July of 2010. (Tr. at p. 97; Exhibit 4, Bank Records). There was nothing significantly different in Dr. Aswad's interactions with Non-RX and Others as compared to his interactions with other suppliers who dispensed FDA-approved medications. (Tr. at p. 101).
9. Dr. Aswad ordered his supplies and medications from Non-RX and Others by calling a US toll free telephone number. (Tr. at p. 83; Exhibit 3, p. 4).
10. The supplies and medications that Dr. Aswad ordered from Non-RX and Others generally arrived within one day, and the supplies and medications that Dr. Aswad ordered were shipped to him from an Illinois address. (Tr. at p. 93).
11. The non-FDA approved medications had labels and packaging that were written in English and that contained the Roche logo. (Tr. at p. 93-95; Exhibit G, photographs, p. 1).
12. The non-FDA approved medications contained package inserts that were likely written in a language other than English. (Tr. at p. 93-94; Exhibit 3 at p. 4). However, Dr. Aswad

does not read the package inserts for chemotherapy medications given his long-standing familiarity with the use of those medications. (Tr. at p. 95; 167).

13. If the non-FDA approved medications contained package inserts that were written in Turkish, Dr. Aswad did not notice. (Tr. at p. 190-192). Even if Dr. Aswad had noticed that the package inserts were written in a language other than English, he likely would not have assumed that the chemotherapy medications were not approved by the FDA. (Tr. at p. 191-192).
14. The non-FDA approved medications had labels that listed their scientific name as bevacizumab. (Tr. at p. 168-169; Exhibit G).
15. Dr. Aswad knew that the chemotherapy medications that he intended to administer to his patients were manufactured by Roche. (Tr. at p. 169).
16. Dr. Aswad was trained during his residency to identify and recognize medications by their scientific rather than market/brand names. (Tr. at p. 169-170).
17. Dr. Aswad identified the non-FDA approved medications he received from Non-RX and Others as bevacizumab, which is the scientific name of the chemotherapy medication that he intended to order and administer to his patients. (Tr. at p. 169-170; Exhibit 3 at p. 4).
18. Based on a representation from Ms. Burgess, Dr. Aswad believed that "Altuzan"(manufactured by Roche) was a generic name for "Avastin" (manufactured by Genentech, which is a corporate division of Roche). (Tr. at p. 57-58; 174; Exhibit G).
19. Dr. Aswad administered the non-FDA approved chemotherapy medications he obtained from Non-RX and Others to patients. (Tr. at p. 176; Exhibit 3 at p. 4).

20. Dr. Aswad did not inform his patients that he was administering non-FDA approved medications as he was not aware that the medications were not FDA approved. (Tr. at p. 203).

21. The FDA employs a process by which it researches and investigates the safety and efficacy of food and drugs that are sold or otherwise distributed in the United States. (Tr. at p. 25). The FDA further regulates that manufacturing process and labeling of food and drugs sold or otherwise distributed in the United States. (Tr. at p. 23; 25).

22. Dr. Aswad has always understood the role of the FDA in monitoring the safety and efficacy of food and drugs that are sold or otherwise distributed in the United States. (Tr. at p. 78-81).

23. The FDA began investigating the distribution of counterfeit chemotherapy medications in the United States in November of 2010. (Tr. at p. 30-31).

24. In an effort to identify and eliminate the distribution of counterfeit chemotherapy medications in the United States, the FDA sent letters to approximately 160 US physicians warning those physicians regarding the FDA's suspicions that the chemotherapy medications that the physicians had ordered were counterfeit medications and/or were otherwise not approved by the FDA. (Tr. at p. 147-148; Exhibit D).

25. Dr. Aswad did not receive a warning letter from the FDA. (Tr. at p. 59-60).

26. The FDA executed on a search warrant and raided Dr. Aswad's practice in April of 2012. (Tr. at p. 32; Exhibit 3 at p. 4).

27. Prior to the FDA's raid of Dr. Aswad's practice, Dr. Aswad was not aware that the medications that he had ordered from Non-RX and Others were not approved by the FDA. (Tr. at p. 83; Exhibit 3, p. 4).

28. Dr. Aswad was surprised and shocked to learn that the medications that he had ordered were not FDA approved medications, and Dr. Aswad was cooperative with the FDA during the FDA's raid of his office. (Tr. at p. 60-62). Dr. Aswad answered all of the FDA agents' questions and made an effort to contact Heidi Burgess at the FDA's behest and while the FDA agents were still in his office. (Tr. at p. 62-63).

29. The active ingredient in the chemotherapy medication that Dr. Aswad ordered from Non-RX and Others is bevacizumab. (Tr. at p. 169).

30. The FDA seized many used vials of chemotherapy medications from Dr. Aswad's office during the raid. Many of the vials that were seized had been administered to patients, and the used vials did not contain sufficient product to run tests for dilution of bevacizumab. (Tr. at p. 33; 37; 42; Exhibit A, FDA Report).

31. However, the used vials contained sufficient product to determine that the medications ordered by Dr. Aswad from Non-RX and Others actually contained some quantity of the active ingredient bevacizumab. (Tr. at p. 41; Exhibit A).

32. According to FDA Special Agent Todd Blair, other chemotherapy medications from Non-RX and Others sold to other physicians were tested, and the FDA determined that some of those medications contained no active ingredient at all. (Tr. at p. 29).

33. Dr. Aswad did not intend to subject his patients to risk by administering non-FDA approved medications to them. (Tr. at p. 81-82; 103). Dr. Aswad would not have administered the chemotherapy medications to his patients if he had known that the medications had not been approved by the FDA. (Tr. at p. 176). Dr. Aswad is not as trusting of suppliers since the FDA raid on his office in 2012. (Tr. at p. 198).

34. The FDA did not make any effort to close Dr. Aswad's practice following the raid of Dr. Aswad's office. (Tr. at p. 65). Moreover, the FDA did not arrest Dr. Aswad or notify the DEA of the FDA's raid on Dr. Aswad's office or the FDA's findings concerning Dr. Aswad's administration of non-FDA approved medications. (Tr. at p. 65-66).

35. Dr. Aswad self-reported to the New Mexico Medical Board. (Tr. at p. 180).

36. Dr. Aswad paid $1,086,667.97 to Non-RX for the chemotherapy medications. (Tr. at p. 159; Exhibit C, Summary of Payments).

37. Dr. Aswad was reimbursed approximately $1,298,543.00 by Medicare, Medicaid and TriCare for the chemotherapy medications he purchased from Non-RX and Others. (Tr. at p. 160).

38. Dr. Aswad obtained a profit of $211,875.03 from the purchase of chemotherapy medications from Non-RX and Others. (Tr. at p. 160).

39. Special Agent Blair estimated that the chemotherapy medications supplied by Non-RX and Others were approximately 20% less expensive than FDA approved chemotherapy medications. (Tr. at p. 49).

40. Dr. Aswad testified that the cost of chemotherapy medications and supplies varies wildly, even between suppliers who dispense FDA approved medications. (Tr. at p. 173-174).

41. Dr. Aswad testified that the difference in cost per dose of non-FDA approved medications that he ordered from Non-RX and Others was approximately $100 to $150 per dose. (Tr. at p. 98). Dr. Aswad also testified that it is not uncommon for suppliers and manufacturers to provide physicians with significant discounts from time to time. (Tr. at p. 173-174).

42. Dr. Aswad maintains a total of four accounts at Wells Fargo in Deming, NM. Each of Dr. Aswad's accounts is in his name and/or the name of his medical practice. (Tr. at p. 51; 56-57; Exhibit 4).

43. Dr. Aswad made no efforts to try to hide the fact that he was ordering medications from Non-RX and Others, and the accounts in which Dr. Aswad deposited the reimbursements from Medicaid, Medicare and TriCare all bear his name. (Tr. at p. 56-57; Exhibit 4).

44. The reason that Dr. Aswad maintains several accounts at the same bank is that one of the bank employees advised Dr. Aswad to serially open new accounts as each account neared the $250,000 FDIC insured deposit limit. (Tr. at p. 170-171).

45. Special Agent Blair testified that the existence of several bank accounts is sometimes a hallmark of an effort to use the purchase of counterfeit or non-FDA approved medications as an opportunity to illegally launder funds. (Tr. at p. 52). However, Special Agent Blair admitted that there is no evidence that Dr. Aswad was engaged in money laundering or in any attempt to hide the fact that he was purchasing non-FDA approved medications. (Tr. at p. 56-57; 69-70).

46. There is no evidence that any of Dr. Aswad's patients were harmed by Dr. Aswad's administration of non-FDA approved medications. (Tr. at p. 67).

47. On November 4, 2014, Dr. Aswad pled guilty to a strict liability misdemeanor. (Exhibit 3).

48. In connection with Dr. Aswad's guilty plea, Dr. Aswad made certain representations and admissions concerning his purchase and administration of non-FDA approved medications. (Exhibit 3 at p. 4).

49. The plea agreement reflects that Dr. Aswad misrepresented that he remains board certified in the areas of oncology, hematology and internal medicine. (Exhibit 3 at p. 4).

50. Because Dr. Aswad pled guilty to a strict liability crime, the government did not have to establish that Dr. Aswad knowingly or intentionally purchased and administered non-FDA approved medications. (Tr. at p. 64-65).

51. As a result of the guilty plea, Dr. Aswad will reimburse Medicaid, Medicare and TriCare $1,298,543, pay an additional forfeiture of $750,000, and will remain on probation for a period of three years. (Exhibit 3).

52. As evidenced by the substance of the plea agreement (Exhibit 3), Dr. Aswad has pled guilty to an offense related to the practice of medicine. (Tr. at p. 84).

53. Cynthia Gilbert, who is an investigator who was hired by Dr. Aswad's counsel, testified that her investigation revealed that approximately 7 of the 160 physicians who received warning letters from the FDA were prosecuted. (Tr. at p. 148-149; Exhibit D). Of those 7 who were prosecuted, all but one still maintains an active medical license and is still practicing medicine. (Tr. at p. 149). The one Tennessee physician who is not still practicing relinquished his medical license when he was imprisoned in a federal penitentiary. (Tr. at p. 149-151). According to Ms. Gilbert's investigation, the Tennessee physician engaged in conduct over a long period of time, even after being warned by the FDA, which suggested that he was intentionally violating the law for personal profit and attempting to evade detection. (Tr. at p. 149-150).

54. Ms. Gilbert also found that there were nine physicians, other than Dr. Aswad, who were prosecuted even though they had not received any warning letter from the FDA. (Tr. at p. 156). Of those nine physicians, all but one still maintains an active medical license

and is still practicing medicine. (Tr. at p. 157). The one Ohio physician who is no longer practicing did not renew his license for unknown reasons. (Tr. at p. 157).

55. The New Mexico Medical Board summarily suspended Dr. Aswad's license on November 13, 2014, and the notice of summary suspension was dated November 17, 2014. (Exhibit 2). The Board simultaneously issued a Notice of Contemplated Action. (Exhibit 1).

56. The Notice of Summary Suspension identifies nine bases for the summary suspension, including:

    A. From approximately July 2010 to February 2012, [Dr. Aswad] knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq.

    B. [Dr. Aswad] administered these misbranded drugs in [his] long-term treatment of numerous cancer patients as part of [his] oncology practice in Deming, New Mexico.

    C. [Dr. Aswad] did not inform any of [his] patients that [he was] administering non-FDA approved drugs.

    D. The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names.

    E. Misbranded non-FDA approved drugs carry the significant, unreasonable risk that the safety and efficacy of the drugs will be inferior to the FDA-approved drugs.

F. Many of [Dr. Aswad's] patients provided reimbursement for the cost of these non-FDA approved medications through the U.S. Medicaid or Medicare program. [Dr. Aswad] billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices.

G. [Dr. Aswad] personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding two million dollars ($2,000,000.00), which was deposited into [his] personal banking accounts.

H. On or about November 4, 2014, [Dr. Aswad] entered into a plea agreement with the United States in which [he] admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S. C. Sections 331(a) and 333(a)(1).

I. Based upon the allegations in A-H, above, the evidence in support of such allegations, and pursuant to Section 61-6-15.1(A) of the Act, [Dr. Aswad] currently [poses] a clear and immediate danger to the public health and safety if [he continues] to practice medicine, and further [has] pled guilty or been found guilty of any (sic) offense related to the practice of medicine.

(Exhibit 2).

57. Dr. Aswad's attorney was notified via email about Dr. Aswad's summary suspension late in the day on November 17, 2014, and Dr. Aswad was notified by his counsel by telephone on that same date about the summary suspension. (Tr. at p. 107).

58. Dr. Aswad's attorney advised him that he could continue working, despite the email notification of the suspension, until such time as he received the summary suspension

notice via mail. (Tr. at p. 107-109). Dr. Aswad received the notification of summary suspension via mail on November 21, 2014. (Tr. at p. 108).

59. Dr. Aswad had actual knowledge of the summary suspension on November 17, 2014, but in reliance on the advice of counsel, Dr, Aswad continued working through November 20, 2014. (Tr. at p. 107-109).

60. Between November 17, 2014 and November 20, 2014, Dr. Aswad saw patients and prescribed medications to his patients. (Tr. at p. 107-109; 115; Exhibit 5, Prescriber Rx History Report; Exhibit 6, Selected prescriptions). The volume of medication that Dr. Aswad prescribed between November 17 and November 20, 2014 was greater than normal because Dr. Aswad was concerned about abandonment of patients in need of refills of maintenance medications. (Tr. at p. 115-119).

61. Two of Dr. Aswad's patients traveled from Deming to testify in support of Dr. Aswad, and several others wrote letters of support. (Tr. at p. 121;135; Exhibit F, Patient Letters). The evidence shows that Dr. Aswad's patients have a great deal of trust in and appreciation for Dr. Aswad's treatment of their various conditions, despite Dr. Aswad's guilty plea. Id.

62. All of the patients who provided testimony or wrote letters of support cite to their concerns about their ability to secure medical care if Dr. Aswad is not able to continue practicing in the Deming community. (Tr. at p. 127-128; 139; Exhibit F).

63. In addition, several practitioners in the Deming area wrote letters of support for Dr. Aswad. (Exhibit E, Practitioner letters). Each of the practitioners who wrote letters of support cite to Dr. Aswad's commitment to patient care, his integration into the Deming

community, and the critical need for his services in the Deming and the surrounding areas. Id.

64. The parties have agreed to the following stipulation concerning Dr. Aswad's practice since 2012:

    a. Dr. Aswad voluntarily surrendered his DEA registration (and his state registration with the Board of Pharmacy); and

    b. The DEA seized all controlled and non-controlled drugs form his office on December 4, 2014.

Conclusions of Law

1. The New Mexico Medical Board may summarily suspend or restrict a license issued by the board without a hearing, simultaneously with . . . the issuance of a notice of contemplated action (NCA) . . . if the board finds that evidence in its possession indicates that the licensee:

    (1) Poses a clear and immediate danger to the public health and safety if the licensee continues to practice;

    (2) Has been adjudged mentally incompetent by a final order or adjudication by a court of competent jurisdiction; or

    (3) Has pled guilty to or been found guilty of any offense related to their practice or for any violent criminal offense in this state or a substantially equivalent criminal offense in another U.S. jurisdiction.

Section 16.10.5.16 (A) NMAC.

2. A licensee is not required to comply with a summary action until service of the action has been made personally or by certified mail, return receipt requested, at the licensee's last known address as shown in the board's records, or the licensee has actual knowledge of the order, whichever occurs first. Section 16.10.5.16 (B) NMAC.
3. The Prosecutor met his burden of establishing the following allegations from the Summary Suspension Notice (Exhibit 2) by the preponderance of the evidence:
    - Dr. Aswad administered misbranded drugs in his long-term treatment of numerous cancer patients as part of his oncology practice in Deming, New Mexico. (Exhibit 2, paragraph B).
    - Dr. Aswad did not inform any of his patients that he was administering non-FDA approved drugs. (Exhibit 2, paragraph C).
    - Misbranded non-FDA approved drugs carry the significant, unreasonable risk that the safety and efficacy will be inferior to FDA-approved drugs. (Exhibit 2, paragraph E).
    - Many of Dr. Aswad's patients provided reimbursement for the cost of these non-FDA approved medications through the U.S. Medicaid or Medicare program. Dr. Aswad billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices. (Exhibit 2, paragraph F).
    - On or about November 4, 2014, Dr. Aswad entered into a plea agreement with the United States, in which he admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S. C. Sections 331(a) and 333(a)(1). (Exhibit 2, paragraph H).

flag for Dr. Aswad and should have prompted him to examine the reasons for the disparity. It appears that the over-reimbursement represents approximately 16% of the amount that Dr. Aswad paid for the non-FDA approved medications. The unrebutted testimony suggests that rebates and discounts in the range of 16% are neither unusual nor alarming.

There is absolutely no evidence that any of Dr. Aswad's patients were harmed by the administration of the non-FDA approved medications. However, that is cold comfort to the Board given the undisputed risk of harm presented by the administration of non-FDA approved medications. Special Agent Blair testified that some of the vials seized from other physicians across the country contained no active ingredient at all. If none of Dr. Aswad's patients suffered any setbacks in their health or well-being after being infused with the medications obtained from Non-RX and Others, the lack of harm can only be attributable to good fortune. To borrow an analogy from Mr. Rubin, an impaired physician who operates on a patient should still be subjected to discipline by the Board even if the patient does not suffer a negative outcome as a result of the impairment. This is true because it is the physician's willingness to engage in risky behavior and to jeopardize the health and well-being of one or more of his patients that raises a presumption of lack of fitness to practice and creates a danger to the public.

The Board bears the responsibility to protect the public from physicians who are not fit to practice, and it is a responsibility that the Board undertakes with great care. Indeed, given the testimony offered by Ms. Gilbert regarding the fact that many physicians across the country ordered non-FDA approved medications from Non-RX and/or other suppliers and still maintain active medical licenses, it appears that this Board is more diligent than the Boards of other states in fulfilling its obligations to the public. When a physician has pled guilty to criminal conduct in connection with the physician's practice of medicine, as Dr. Aswad has, the Board is specifically

authorized to summarily suspend the physician's license to practice medicine. That said, the statute does not require the Board to summarily suspend the license of a physician who pleads guilty to such criminal conduct. For reasons described below, I recommend that the Board vacate its notice of summary suspension and allow Dr. Aswad to return to the practice of medicine pending the outcome of the hearing on the NCA allegations.

I am convinced that based on the evidence presented to date, Dr. Aswad does not represent a clear and immediate danger to his patients at the present time.[4] While Dr. Aswad unquestionably subjected his patients to the dangers associated with the use of non-FDA approved medications between July of 2010 and April of 2012, he did so unknowingly. Based on his testimony and the lack of any evidence to the contrary, I believe that Dr. Aswad never intended to subject his patients to risk and that Dr. Aswad thought that he was providing his patients with excellent care. I further find no support for the allegation that Dr. Aswad subjected his patients to risk in pursuit of personal gain. I note that the FDA did not make any efforts to stop Dr. Aswad from practicing medicine when they raided his office. Indeed, the FDA did not even report the fact of the raid or its findings to the Board or to the DEA. Moreover, in the 30 months that have elapsed between the raid and the guilty plea and resulting summary suspension, there have been no concerns raised about Dr. Aswad's provision of care to his patients and there have been no new allegations concerning Dr. Aswad's administration of non-FDA approved medications. Dr. Aswad appears to be less trusting and savvier with respect to suppliers of

[4] Based on the stipulation of the parties (Fact No. 64), it appears that the DEA took some action against Dr. Aswad, in response to which Dr. Aswad voluntarily surrendered his DEA registration and his state Board of Pharmacy registration. It also appears that the DEA seized items from Dr. Aswad's office on December 4, 2014. I have no way, at the present time, to determine whether the actions of the DEA and the Board of Pharmacy suggest that Dr. Aswad poses a threat to his patients. I am also uncertain how the actions of the DEA might affect Dr. Aswad's plea deal and his probationary status. My current determination that Dr. Aswad does not present a clear and immediate danger to the public is predicated solely upon the evidence presently in the record as of the date of this report.

oncology medications and supplies, and I genuinely believe that Dr. Aswad will not make the same unwitting mistake in the future.[5]

Based on the testimony and letters of support of Dr. Aswad's patients and colleagues, the real risk of harm to the Deming community arises from Dr. Aswad's inability to practice medicine. The evidence offered at the hearing shows that Deming is an underserved community, and the patients who need oncology services have expressed a concern that they will have to travel several hours from home in order to obtain the necessary treatment of their conditions. The reports and testimony offered by Dr. Aswad's patients and colleagues show that Dr. Aswad is a talented and compassionate practitioner whose professional absence in the community is causing hardship for patients and other providers. Under these circumstances, I cannot articulate a principled reason why Dr. Aswad's license should remain suspended pending the hearing and ultimate decision on the allegations set forth in the NCA.

Respectfully Submitted,

Jennifer G. Anderson
New Mexico Medical Board Member
Hearing Officer

January 29, 2015

[5] A word of caution to Dr. Aswad is appropriate with respect to Dr. Aswad's failure to immediately abide by the notice of summary suspension once he was aware of its issuance. The Board expects that physicians will timely and thoroughly adhere to the Board's orders, and the Board further expects nothing less than the complete cooperation of its licensees. Dr. Aswad's counsel admitted that Dr. Aswad continued to practice for three days after Dr. Aswad and his counsel had actual notice of the summary suspension, and counsel admitted that it was her mistaken advice to Dr. Aswad that resulted in Dr. Aswad's short-term non-compliance with the notice. It appears that Dr. Aswad's short term non-compliance was also motivated by a desire to avoid abandoning patients who use maintenance medications and who may have experienced difficulties in obtaining those medications from other, scarce practitioners in Deming. Whatever the motivation and the cause of the non-compliance, Dr. Aswad is strongly cautioned not to defy future orders and notices of the Board. It is also recommended that the NCA be amended to include the issue of temporary non-compliance as described herein.

BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF MOHAMED ASWAD, M.D.	)	
License No.	)	**No. 2014-044**
Respondent.	)	

AMENDED NOTICE OF CONTEMPLATED ACTION

YOU ARE HEREBY NOTIFIED that pursuant to provisions of Section 61-1-4 NMSA 1978 of the Uniform Licensing Act ("ULA"), the New Mexico Medical Board ("Board") has before it sufficient evidence that, if not rebutted or explained, will justify the Medical Board imposing sanctions that could include restricting, revoking or suspending your license to practice medicine in the State of New Mexico.

1. Respondent is subject to action by the Board pursuant to Sections 61-1-1 et seq. NMSA 1978 of the Uniform Licensing Act and Sections 61-6-1 et seq., NMSA 1978 of the Medical Practice Act.

2. This contemplated action is based on the following allegations:

A. From approximately July 2010 to February 2012, you knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq.

B. You administered these misbranded drugs in your long-term treatment of numerous cancer patients as part of your oncology practice in Deming, New Mexico.

C. You did not inform any of your patients that you were administering non-FDA approved drugs.

D. The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names.

E. Misbranded non-FDA-approved drugs carry the significant, unreasonable risk that the safety and efficacy of the drugs will be inferior to FDA-approved drugs.

F. Many of these patients provided reimbursement for the cost of these non-FDA-approved medications through the U.S. Medicaid or Medicare program. You billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices.

G. You personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding one million dollars ($1,000,000.00), which was deposited into your personal banking accounts.

H. On or about November 4, 2014, you entered into a plea agreement with the United States, in which you admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S.C. Sections 331(a) and 333(a)(1).

I. After receiving actual notice of a summary suspension by the Board against your license on November 17, 2014, you continued to prescribe controlled substances through November 20, 2014.

3. The above allegations, if proven, would constitute a violation of the following sections of the Medical Practice Act, Section 61-6-1 et seq.:

a. Section 61-6-15(D)(4), obtaining a fee by fraud or misrepresentation,

b. Section 61-6-15(D)(9), making false or misleading statements regarding the efficacy or value of the treatment administered by the licensee,

c. Section 61-6-15(D)(12), gross negligence in the practice of a licensee,

d. Section 61-6-15(D)(15), the use of a false, fraudulent, or deceptive statement in a document connected with the practice of a license,

e. Section 61-6-15(D)(18), conduct likely to deceive, defraud, or harm the public,

f. Section 61-6-15(D)(19), repeated similar negligent acts,

g. Section 61-6-15(D)(29), conduct unbecoming in a person licensed to practice or detrimental to the best interests of the public,

h. Section 61-6-15(D)(20), employing abusive billing practices;

i. Section 61-6-15(D)(6), conviction of an offense punishable by incarceration in a federal prison or conviction of a misdemeanor associated with the practice of medicine;

j. Board Rule at NMAC 16.10.8.8(C), violating a drug law, promulgated pursuant to Section 61-6-15(D), to wit, the Food Drug and Cosmetic Act, 21 U.S.C. Sections 331(a) and 333(a)(1);

k. Board Rule at NMAC 16.10.8.8(A), practicing medicine without an active license.

4. Please take notice that pursuant to Section 61-1-4, you may secure a hearing before the Board by depositing in the mail within twenty (20) days after service of this notice a certified return receipt requested letter addressed to the Board and containing a request for a hearing. If you do not request a hearing within twenty (20) days after service of this notice as described above, the Board will take the contemplated action, i.e., imposing sanctions that could include the revocation or suspension of your license to practice medicine in the State of New Mexico, and there will be no judicial review of their decision.

5. Pursuant to Section 61-1-8 NMSA 1978, you have the right to be represented by

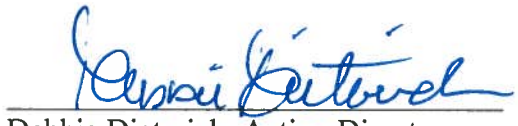
counsel or by a licensed member of your profession or both, and to present all relevant evidence by means of witnesses, books, papers, documents and other evidence; to examine all opposing witnesses who may appear on any matter relevant to the issues and have subpoenas duces tecum issued as of right prior to the commencement of the hearing, to compel the attendance of witnesses and the production of relevant books, papers, documents and other evidence upon making a written request therefore to the Board. The issuance of such subpoenas after commencement of the hearing rests with the discretion of the Board or Hearing Officer.

6. The issuance of this Notice of Contemplated Action is not a disciplinary event reportable to any data bank but is a public document open to public inspection.

7. In the event that the Board takes a final action against you as specified in Section 61-1-3 of the ULA, you shall bear all costs of disciplinary proceedings unless excused by the Board pursuant to Section 61-1-4(G) of the ULA.

Dated this 14th day of January, 2015.

NEW MEXICO MEDICAL BOARD



Debbie Dieterich, Acting Director
NM Medical Board
2055 S. Pacheco, #400
Santa Fe, New Mexico 87505
(505) 476-7240

BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF
MOHAMED ASWAD, M.D.

License No. 2003-0043 No. 2014-044

Respondent.

DECISION AND ORDER OF THE BOARD
LIFTING SUMMARY SUSPENSION

This matter came before the New Mexico Medical Board on December 5, 2014 based on the issuance of a Report And Recommendations Of Hearing Officer on the summary suspension of Respondent, Dr. Mohamed Aswad.

Procedural Background

A Notice of Summary Suspension was issued by the Board on November 17, 2014. A Hearing in the Summary Suspension was conducted by duly appointed Hearing Officer, Jennifer Anderson, on December 1, 2014. Ms. Anderson is also a member of the New Mexico Medical Board.

Pursuant to Section 61-6-15.1 NMSA 1978, the New Mexico Medical Board may summarily suspend or restrict a license issued by the board without a hearing, simultaneously with . . . the issuance of a notice of contemplated action (NCA) . . . if the board finds that evidence in its possession indicates that the licensee:

(1) Poses a clear and immediate danger to the public health and safety if the licensee continues to practice;
(2) Has been adjudged mentally incompetent by a final order or adjudication by a court of competent jurisdiction; or
(3) Has pled guilty to or been found guilty of any offense related to their practice or for any violent criminal offense in this state or a substantially equivalent criminal offense in another U.S. jurisdiction.

Pursuant to Section 61-6-15.1 (C) NMSA 1978 a person whose license is suspended or restricted is entitled to a hearing within fifteen days from the date the licensee requests a

hearing. Respondent requested a hearing and a hearing was timely held within fifteen days of the request. The hearing was conducted on December 1, 2014.

DECISION

The Board received the draft Report and Recommendations of the Hearing Officer on December 3, 2014 and received the final Report and Recommendations of the Hearing Officer on December 4, 2014. The Board also received the transcript and exhibits of the Summary Suspension Hearing on December 4, 2014. After having reviewed the Report and Recommendations of the Hearing Officer, the transcript and the exhibits, the Board hereby finds the following:

1. A hearing on the Summary Suspension was conducted pursuant to the authority under the Uniform Licensing Act, Section 61-1-1 to 61-1-33 NMSA 1978.
2. The Board has jurisdiction to both impose and lift a suspension under Section 61-6-15.1 NMSA 1978.
3. A hearing was timely held in this matter in accordance with the provisions of the Uniform Licensing Act.
4. The Report and Recommendations of the Hearing Officer, dated December 4, 2014, are accepted and incorporated in the entirety as the Board's Findings of Fact and Conclusions of Law.

ORDER

The Report and Recommendations of the Hearing Officer contains an opinion and recommendation and the recommendation is accepted by the Board and therefore, the Board **ORDERS** the following:

1. The Notice of Summary Suspension is **LIFTED** and Respondent may resume the practice of Medicine in the State of New Mexico immediately upon the signing of this Order.

This Order reflects only the findings and conclusions as to the Summary Suspension, not the Notice of Contemplated Action.

IT IS SO ORDERED.

Steve Weiner, M.D.
Chair New Mexico Medical Board

December 05, 2014

BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF
MOHAMED ASWAD, M.D.

License No. 2003-0043 No. 2014-044

Respondent.

REPORT AND RECOMMENDATIONS OF HEARING OFFICER

Pursuant to Section 16.10.5.16 NMAC, the parties conducted a hearing on December 1, 2014 concerning the New Mexico Medical Board's November 17, 2014 Notice of Summary Suspension. The New Mexico Medical Board was represented by Prosecutor Dan Rubin, and Mohamed Aswad, MD was represented by Molly Schmidt-Nowara and Nancy Hollander.

The parties presented the following witnesses and exhibits, which have been relied upon by the Hearing Officer to varying degrees:

Witnesses:

1. Special Agent Todd Blair, FDA
2. Mohamed Aswad, MD
3. Lt. John Mooradian
4. Magdalena Shores
5. Cynthia Gilbert

Prosecution's Exhibits:

1. Notice of Contemplated Action filed November 14, 2014
2. Summary Suspension Notice filed November 14, 2014
3. Plea Agreement in the United States Court for the District of New Mexico, *US v. Mohamed Basel Aswad*, filed November 4, 2014.
4. Respondent's Selected Bank Statements, Wells Fargo Bank account #2169xxxxxx
5. Prescription Monitoring Program Report re: Respondent (selected dates)[1]
6. Selected copies of prescriptions written by Respondent[2]

[1] This exhibit has been redacted to safeguard HIPAA protected information.
[2] This exhibit has been redacted to safeguard HIPAA protected information.

Respondent's Exhibits:

A. March 13, 2013 Lab Analysis and July 2, 2013 Lab Analysis[3]
B. Dr. Aswad's Resume/CV
C. Summary of Pharmacy Purchases
D. FDA letters sent to practioners nationwide
E. Professional character reference letters
F. Patient character reference letters
G. Altuzan and Avastin photographs, submitted as demonstrative exhibits

Findings of Fact

1. Mohamed Aswad, MD is a Deming based physician who practices in the areas of internal medicine, hematology and oncology. (Tr. at p. 75-76; Exhibit B).
2. Dr. Aswad has been practicing in Deming since 2003, and is the only oncologist in Deming and the surrounding areas. (Tr. at p. 76; 179; Exhibit B).
3. The Deming, New Mexico area is chronically underserved by medical personnel. In the time that Dr. Aswad has practiced in Deming, the number of physicians has decreased from 15 to 6. (Tr. at p. 179)
4. Although Dr. Aswad was once board certified in the areas of internal medicine, hematology and oncology, his certifications expired in 2013 (hematology and oncology) and in 2010 (internal medicine). (Tr. at p. 87-89; Exhibit H, Portion of Renewal Application to NMMB).
5. From approximately July of 2010 to February of 2012, Dr. Aswad purchased non-FDA approved chemotherapy drugs from various pharmaceutical companies, including Non-RX, Bridgewater and Northwest Pharmacy (hereinafter "Non-RX and Others"), that operate primarily through telephonic orders. (Tr. at p. 39-40; Exhibit 3, Plea Agreement, at p. 4).

[3] This exhibit has been redacted to safeguard HIPAA protected information.

6. There is no pharmacy in the Deming area that dispenses oncology medications. (Tr. at p. 172-173). As a result, Dr. Aswad has always ordered chemotherapy medications and supplies through remote pharmaceutical companies that operate primarily through 1-800 or 1-866 telephone numbers. (Tr. at p. 172-173).
7. Heidi Burgess was a sales representative for Non-RX who contacted Dr. Aswad's office repeatedly over the course of months prior to July of 2010 in an effort to persuade Dr. Aswad to purchase his oncology and chemotherapy supplies from Non-RX. (Tr. at p. 97-98).
8. Dr. Aswad's office began purchasing supplies and medications from Ms. Burgess and Non-RX and Others in or about July of 2010. (Tr. at p. 97; Exhibit 4, Bank Records). There was nothing significantly different in Dr. Aswad's interactions with Non-RX and Others as compared to his interactions with other suppliers who dispensed FDA-approved medications. (Tr. at p. 101).
9. Dr. Aswad ordered his supplies and medications from Non-RX and Others by calling a US toll free telephone number. (Tr. at p. 83; Exhibit 3, p. 4).
10. The supplies and medications that Dr. Aswad ordered from Non-RX and Others generally arrived within one day, and the supplies and medications that Dr. Aswad ordered were shipped to him from an Illinois address. (Tr. at p. 93).
11. The non-FDA approved medications had labels and packaging that were written in English and that contained the Roche logo. (Tr. at p. 93-95; Exhibit G, photographs, p. 1).
12. The non-FDA approved medications contained package inserts that were likely written in a language other than English. (Tr. at p. 93-94; Exhibit 3 at p. 4). However, Dr. Aswad

does not read the package inserts for chemotherapy medications given his long-standing familiarity with the use of those medications. (Tr. at p. 95; 167).

13. If the non-FDA approved medications contained package inserts that were written in Turkish, Dr. Aswad did not notice. (Tr. at p. 190-192). Even if Dr. Aswad had noticed that the package inserts were written in a language other than English, he likely would not have assumed that the chemotherapy medications were not approved by the FDA. (Tr. at p. 191-192).

14. The non-FDA approved medications had labels that listed their scientific name as bevacizumab. (Tr. at p. 168-169; Exhibit G).

15. Dr. Aswad knew that the chemotherapy medications that he intended to administer to his patients were manufactured by Roche. (Tr. at p. 169).

16. Dr. Aswad was trained during his residency to identify and recognize medications by their scientific rather than market/brand names. (Tr. at p. 169-170).

17. Dr. Aswad identified the non-FDA approved medications he received from Non-RX and Others as bevacizumab, which is the scientific name of the chemotherapy medication that he intended to order and administer to his patients. (Tr. at p. 169-170; Exhibit 3 at p. 4).

18. Based on a representation from Ms. Burgess, Dr. Aswad believed that "Altuzan"(manufactured by Roche) was a generic name for "Avastin" (manufactured by Genentech, which is a corporate division of Roche). (Tr. at p. 57-58; 174; Exhibit G).

19. Dr. Aswad administered the non-FDA approved chemotherapy medications he obtained from Non-RX and Others to patients. (Tr. at p. 176; Exhibit 3 at p. 4).

20. Dr. Aswad did not inform his patients that he was administering non-FDA approved medications as he was not aware that the medications were not FDA approved. (Tr. at p. 203).

21. The FDA employs a process by which it researches and investigates the safety and efficacy of food and drugs that are sold or otherwise distributed in the United States. (Tr. at p. 25). The FDA further regulates that manufacturing process and labeling of food and drugs sold or otherwise distributed in the United States. (Tr. at p. 23; 25).

22. Dr. Aswad has always understood the role of the FDA in monitoring the safety and efficacy of food and drugs that are sold or otherwise distributed in the United States. (Tr. at p. 78-81).

23. The FDA began investigating the distribution of counterfeit chemotherapy medications in the United States in November of 2010. (Tr. at p. 30-31).

24. In an effort to identify and eliminate the distribution of counterfeit chemotherapy medications in the United States, the FDA sent letters to approximately 160 US physicians warning those physicians regarding the FDA's suspicions that the chemotherapy medications that the physicians had ordered were counterfeit medications and/or were otherwise not approved by the FDA. (Tr. at p. 147-148; Exhibit D).

25. Dr. Aswad did not receive a warning letter from the FDA. (Tr. at p. 59-60).

26. The FDA executed on a search warrant and raided Dr. Aswad's practice in April of 2012. (Tr. at p. 32; Exhibit 3 at p. 4).

27. Prior to the FDA's raid of Dr. Aswad's practice, Dr. Aswad was not aware that the medications that he had ordered from Non-RX and Others were not approved by the FDA. (Tr. at p. 83; Exhibit 3, p. 4).

28. Dr. Aswad was surprised and shocked to learn that the medications that he had ordered were not FDA approved medications, and Dr. Aswad was cooperative with the FDA during the FDA's raid of his office. (Tr. at p. 60-62). Dr. Aswad answered all of the FDA agents' questions and made an effort to contact Heidi Burgess at the FDA's behest and while the FDA agents were still in his office. (Tr. at p. 62-63).

29. The active ingredient in the chemotherapy medication that Dr. Aswad ordered from Non-RX and Others is bevacizumab. (Tr. at p. 169).

30. The FDA seized many used vials of chemotherapy medications from Dr. Aswad's office during the raid. Many of the vials that were seized had been administered to patients, and the used vials did not contain sufficient product to run tests for dilution of bevacizumab. (Tr. at p. 33; 37; 42; Exhibit A, FDA Report).

31. However, the used vials contained sufficient product to determine that the medications ordered by Dr. Aswad from Non-RX and Others actually contained some quantity of the active ingredient bevacizumab. (Tr. at p. 41; Exhibit A).

32. According to FDA Special Agent Todd Blair, other chemotherapy medications from Non-RX and Others sold to other physicians were tested, and the FDA determined that some of those medications contained no active ingredient at all. (Tr. at p. 29).

33. Dr. Aswad did not intend to subject his patients to risk by administering non-FDA approved medications to them. (Tr. at p. 81-82; 103). Dr. Aswad would not have administered the chemotherapy medications to his patients if he had known that the medications had not been approved by the FDA. (Tr. at p. 176). Dr. Aswad is not as trusting of suppliers since the FDA raid on his office in 2012. (Tr. at p. 198).

34. The FDA did not make any effort to close Dr. Aswad's practice following the raid of Dr. Aswad's office. (Tr. at p. 65). Moreover, the FDA did not arrest Dr. Aswad or notify the DEA of the FDA's raid on Dr. Aswad's office or the FDA's findings concerning Dr. Aswad's administration of non-FDA approved medications. (Tr. at p. 65-66).

35. Dr. Aswad self-reported to the New Mexico Medical Board. (Tr. at p. 180).

36. Dr. Aswad paid $1,086,667.97 to Non-RX for the chemotherapy medications. (Tr. at p. 159; Exhibit C, Summary of Payments).

37. Dr. Aswad was reimbursed approximately $1,298,543.00 by Medicare, Medicaid and TriCare for the chemotherapy medications he purchased from Non-RX and Others. (Tr. at p. 160).

38. Dr. Aswad obtained a profit of $211,875.03 from the purchase of chemotherapy medications from Non-RX and Others. (Tr. at p. 160).

39. Special Agent Blair estimated that the chemotherapy medications supplied by Non-RX and Others were approximately 20% less expensive than FDA approved chemotherapy medications. (Tr. at p. 49).

40. Dr. Aswad testified that the cost of chemotherapy medications and supplies varies wildly, even between suppliers who dispense FDA approved medications. (Tr. at p. 173-174).

41. Dr. Aswad testified that the difference in cost per dose of non-FDA approved medications that he ordered from Non-RX and Others was approximately $100 to $150 per dose. (Tr. at p. 98). Dr. Aswad also testified that it is not uncommon for suppliers and manufacturers to provide physicians with significant discounts from time to time. (Tr. at p. 173-174).

42. Dr. Aswad maintains a total of four accounts at Wells Fargo in Deming, NM. Each of Dr. Aswad's accounts is in his name and/or the name of his medical practice. (Tr. at p. 51; 56-57; Exhibit 4).

43. Dr. Aswad made no efforts to try to hide the fact that he was ordering medications from Non-RX and Others, and the accounts in which Dr. Aswad deposited the reimbursements from Medicaid, Medicare and TriCare all bear his name. (Tr. at p. 56-57; Exhibit 4).

44. The reason that Dr. Aswad maintains several accounts at the same bank is that one of the bank employees advised Dr. Aswad to serially open new accounts as each account neared the $250,000 FDIC insured deposit limit. (Tr. at p. 170-171).

45. Special Agent Blair testified that the existence of several bank accounts is sometimes a hallmark of an effort to use the purchase of counterfeit or non-FDA approved medications as an opportunity to illegally launder funds. (Tr. at p. 52). However, Special Agent Blair admitted that there is no evidence that Dr. Aswad was engaged in money laundering or in any attempt to hide the fact that he was purchasing non-FDA approved medications. (Tr. at p. 56-57; 69-70).

46. There is no evidence that any of Dr. Aswad's patients were harmed by Dr. Aswad's administration of non-FDA approved medications. (Tr. at p. 67).

47. On November 4, 2014, Dr. Aswad pled guilty to a strict liability misdemeanor. (Exhibit 3).

48. In connection with Dr. Aswad's guilty plea, Dr. Aswad made certain representations and admissions concerning his purchase and administration of non-FDA approved medications. (Exhibit 3 at p. 4).

49. The plea agreement reflects that Dr. Aswad misrepresented that he remains board certified in the areas of oncology, hematology and internal medicine. (Exhibit 3 at p. 4).

50. Because Dr. Aswad pled guilty to a strict liability crime, the government did not have to establish that Dr. Aswad knowingly or intentionally purchased and administered non-FDA approved medications. (Tr. at p. 64-65).

51. As a result of the guilty plea, Dr. Aswad will reimburse Medicaid, Medicare and TriCare $1,298,543, pay an additional forfeiture of $750,000, and will remain on probation for a period of three years. (Exhibit 3).

52. As evidenced by the substance of the plea agreement (Exhibit 3), Dr. Aswad has pled guilty to an offense related to the practice of medicine. (Tr. at p. 84).

53. Cynthia Gilbert, who is an investigator who was hired by Dr. Aswad's counsel, testified that her investigation revealed that approximately 7 of the 160 physicians who received warning letters from the FDA were prosecuted. (Tr. at p. 148-149; Exhibit D). Of those 7 who were prosecuted, all but one still maintains an active medical license and is still practicing medicine. (Tr. at p. 149). The one Tennessee physician who is not still practicing relinquished his medical license when he was imprisoned in a federal penitentiary. (Tr. at p. 149-151). According to Ms. Gilbert's investigation, the Tennessee physician engaged in conduct over a long period of time, even after being warned by the FDA, which suggested that he was intentionally violating the law for personal profit and attempting to evade detection. (Tr. at p. 149-150).

54. Ms. Gilbert also found that there were nine physicians, other than Dr. Aswad, who were prosecuted even though they had not received any warning letter from the FDA. (Tr. at p. 156). Of those nine physicians, all but one still maintains an active medical license

and is still practicing medicine. (Tr. at p. 157). The one Ohio physician who is no longer practicing did not renew his license for unknown reasons. (Tr. at p. 157).

55. The New Mexico Medical Board summarily suspended Dr. Aswad's license on November 13, 2014, and the notice of summary suspension was dated November 17, 2014. (Exhibit 2). The Board simultaneously issued a Notice of Contemplated Action. (Exhibit 1).

56. The Notice of Summary Suspension identifies nine bases for the summary suspension, including:

    A. From approximately July 2010 to February 2012, [Dr. Aswad] knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq.

    B. [Dr. Aswad] administered these misbranded drugs in [his] long-term treatment of numerous cancer patients as part of [his] oncology practice in Deming, New Mexico.

    C. [Dr. Aswad] did not inform any of [his] patients that [he was] administering non-FDA approved drugs.

    D. The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names.

    E. Misbranded non-FDA approved drugs carry the significant, unreasonable risk that the safety and efficacy of the drugs will be inferior to the FDA-approved drugs.

F. Many of [Dr. Aswad's] patients provided reimbursement for the cost of these non-FDA approved medications through the U.S. Medicaid or Medicare program. [Dr. Aswad] billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices.

G. [Dr. Aswad] personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding two million dollars ($2,000,000.00), which was deposited into [his] personal banking accounts.

H. On or about November 4, 2014, [Dr. Aswad] entered into a plea agreement with the United States in which [he] admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S. C. Sections 331(a) and 333(a)(1).

I. Based upon the allegations in A-H, above, the evidence in support of such allegations, and pursuant to Section 61-6-15.1(A) of the Act, [Dr. Aswad] currently [poses] a clear and immediate danger to the public health and safety if [he continues] to practice medicine, and further [has] pled guilty or been found guilty of any (sic) offense related to the practice of medicine.

(Exhibit 2).

57. Dr. Aswad's attorney was notified via email about Dr. Aswad's summary suspension late in the day on November 17, 2014, and Dr. Aswad was notified by his counsel by telephone on that same date about the summary suspension. (Tr. at p. 107).

58. Dr. Aswad's attorney advised him that he could continue working, despite the email notification of the suspension, until such time as he received the summary suspension

notice via mail. (Tr. at p. 107-109). Dr. Aswad received the notification of summary suspension via mail on November 21, 2014. (Tr. at p. 108).

59. Dr. Aswad, in reliance on the advice of counsel, continued working through November 20, 2014. (Tr. at p. 107-109).

60. Between November 17, 2014 and November 20, 2014, Dr. Aswad saw patients and prescribed medications to his patients. (Tr. at p. 107-109; 115; Exhibit 5, Prescriber Rx History Report; Exhibit 6, Selected prescriptions). The volume of medication that Dr. Aswad prescribed between November 17 and November 20, 2014 was greater than normal because Dr. Aswad was concerned about abandonment of patients in need of refills of maintenance medications. (Tr. at p. 115-119).

61. Two of Dr. Aswad's patients traveled from Deming to testify in support of Dr. Aswad, and several others wrote letters of support. (Tr. at p. 121;135; Exhibit F, Patient Letters). The evidence shows that Dr. Aswad's patients have a great deal of trust in and appreciation for Dr. Aswad's treatment of their various conditions, despite Dr. Aswad's guilty plea. Id.

62. All of the patients who provided testimony or wrote letters of support cite to their concerns about their ability to secure medical care if Dr. Aswad is not able to continue practicing in the Deming community. (Tr. at p. 127-128; 139; Exhibit F).

63. In addition, several practitioners in the Deming area wrote letters of support for Dr. Aswad. (Exhibit E, Practitioner letters). Each of the practitioners who wrote letters of support cite to Dr. Aswad's commitment to patient care, his integration into the Deming community, and the critical need for his services in the Deming and the surrounding areas. Id.

64. The parties have agreed to the following stipulation concerning Dr. Aswad's practice since 2012:

a. Dr. Aswad voluntarily surrendered his DEA registration (and his state registration with the Board of Pharmacy); and

b. The DEA seized all controlled and non-controlled drugs form his office on December 4, 2014.

Conclusions of Law

1. The New Mexico Medical Board may summarily suspend or restrict a license issued by the board without a hearing, simultaneously with . . . the issuance of a notice of contemplated action (NCA) . . . if the board finds that evidence in its possession indicates that the licensee:

(1) Poses a clear and immediate danger to the public health and safety if the licensee continues to practice;

(2) Has been adjudged mentally incompetent by a final order or adjudication by a court of competent jurisdiction; or

(3) Has pled guilty to or been found guilty of any offense related to their practice or for any violent criminal offense in this state or a substantially equivalent criminal offense in another U.S. jurisdiction.

Section 16.10.5.16 (A) NMAC.

2. A licensee is not required to comply with a summary action until service of the action has been made personally or by certified mail, return receipt requested, at the licensee's last

known address as shown in the board's records, or the licensee has actual knowledge of the order, whichever occurs first. Section 16.10.5.16 (B) NMAC.

3. The Prosecutor met his burden of establishing the following allegations from the Summary Suspension Notice (Exhibit 2) by the preponderance of the evidence:
    - Dr. Aswad administered misbranded drugs in his long-term treatment of numerous cancer patients as part of his oncology practice in Deming, New Mexico. (Exhibit 2, paragraph B).
    - Dr. Aswad did not inform any of his patients that he was administering non-FDA approved drugs. (Exhibit 2, paragraph C).
    - Misbranded non-FDA approved drugs carry the significant, unreasonable risk that the safety and efficacy will be inferior to FDA-approved drugs. (Exhibit 2, paragraph E).
    - Many of Dr. Aswad's patients provided reimbursement for the cost of these non-FDA approved medications through the U.S. Medicaid or Medicare program. Dr. Aswad billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices. (Exhibit 2, paragraph F).
    - On or about November 4, 2014, Dr. Aswad entered into a plea agreement with the United States, in which he admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S. C. Sections 331(a) and 333(a)(1). (Exhibit 2, paragraph H).
4. The Prosecutor did not meet his burden of establishing the following allegations from the Summary Suspension Notice (Exhibit 2 by the preponderance of the evidence:

- From approximately July 2010 to February 2012, [Dr. Aswad] knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq. (Exhibit 2, paragraph A).
- The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names. (Exhibit 2, paragraph D).
- Dr. Aswad personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding two million dollars ($2,000,000.00), which was deposited into his personal banking accounts. (Exhibit 2, paragraph G).
- Dr. Aswad currently poses a clear and immediate danger to the public health and safety if he continues to practice medicine. (Exhibit 2, paragraph I as redacted).

5. The Prosecutor met his burden of establishing by the preponderance of the evidence that Dr. Aswad continued practicing medicine for three days beyond the time when he had actual notice of the Board's decision to summary suspend his license.

Opinion and Recommendation

At the outset, it is worth noting that the legal counsel for the parties did an excellent job of presenting evidence in this complex and difficult matter. I appreciate their candor and their efforts to thoroughly present the evidence despite the fact that they had minimal time to prepare for the hearing.

The purpose of the December 1, 2014 hearing was to ascertain whether the summary suspension of Dr. Aswad is justified and should continue until such time as the issues presented in the November 17, 2014 Notice of Contemplated Action (NCA) can be adjudicated. Stated differently, the scope of the hearing was limited to the issue of whether the Board has an adequate basis for summary suspension of Dr. Aswad's license, and this opinion and recommendation has no predictive value with respect to the outcome of the proceeding concerning the (admittedly overlapping) allegations of the NCA.

The evidence presented conclusively establishes that Dr. Aswad ordered non-FDA approved chemotherapy medications and administered those medications to his oncology patients over the period of almost two years. The evidence also conclusively establishes that Dr. Aswad did not make any disclosure to his patients regarding his use of non-FDA approved medications and that there was the potential for risk to the health and well-being of Dr. Aswad's patients. However, the evidence reflects that Dr. Aswad's failure to make the necessary disclosures to his patients results from the fact that Dr. Aswad himself was unaware that he had ordered and administered non-FDA approved medications.

Dr. Aswad testified that Ms. Burgess from Non-RX made numerous in person and telephonic sales calls to Dr. Aswad's office in an effort to get Dr. Aswad to order supplies and medications from Non-RX. Dr. Aswad eventually placed orders with Non-RX without any knowledge that the supplier was offering non-FDA approved medications for sale. The evidence shows that Dr. Aswad filled out a credit application for Non-RX and used a 1-866 phone number to place orders with Non-RX, which is no different than how he placed orders with other suppliers who were dispensing FDA approved medications. The medications that Dr. Aswad ordered from Non-RX and Others arrived from an Illinois location within a day or two of Dr.

Aswad placing his order. The medications supplied by Non-RX and Others were packaged and labeled in English, not Turkish, and the medications all bore a label that reflected the scientific name of the medication (bevacizumab) and the Roche logo. (Exhibit G, page 1). Based on the representations of Ms. Burgess, Dr. Aswad apparently believed that the non-FDA approved medication Altuzan was a generic equivalent of the FDA approved medication Avastin. According to the testimony of Special Agent Blair, the package inserts in the boxes of medication that Dr. Aswad ordered from Non-RX and Others were written in the Turkish language. Dr. Aswad does not dispute this fact because Dr. Aswad claims that he never examined the package inserts of the medications given his familiarity with bevacizumab and its use as a chemotherapy medication. Simply stated, Dr. Aswad convincingly testified that he was unaware of the fact that the medications that he received from Non-RX and Others were not FDA approved medications.

Dr. Aswad's practice was raided by the FDA in April of 2012. During the raid, the FDA recovered many containers of already-administered medications. The FDA tested the trace amounts of medication remaining in the containers the FDA seized from Dr. Aswad, and the FDA's tests determined that all of the vials that were seized from Dr. Aswad contained bevacizumab. However, because the amount of medication remaining in each of the largely empty vials was so small, the FDA was unable to determine whether the bevacizumab was present in the medications in the appropriate and expected concentrations. The evidence suggests that Dr. Aswad was forthcoming and cooperative with the FDA and there is no evidence to suggest that Dr. Aswad was anything other than shocked and dismayed to learn that the medications that Dr. Aswad had been administering to his patients were not FDA approved medications. Moreover, there is nothing in the record that establishes by a preponderance of the

evidence that Dr. Aswad was engaging in any activity designed to conceal his orders from Non-RX and Others or to otherwise conceal his use of the non-FDA approved medications he received from Non-RX and Others.

Dr. Aswad signed a plea agreement on November 4, 2014. In that plea agreement, Dr. Aswad pled guilty to a strict liability misdemeanor associated with his practice of medicine. Dr. Aswad agreed to forego his right to trial, reimburse Medicare/Medicaid and TriCare in the amount of $1,298,543, pay a penalty of $750,000, and serve a three year term of probation. The evidence shows that Dr. Aswad did not personally profit from his transactions with Non-RX and Others in the amount of $2,000,000 as alleged. Instead, the evidence establishes that Dr. Aswad was originally reimbursed $211,873.03 more than what he initially spent on the medication that he ordered from Non-RX and Others. The testimony shows that the price for oncology medications and supplies varies drastically from supplier to supplier, and even from one time period to the next when ordering from the same supplier. Moreover, the testimony suggests that it took the FDA and Dr. Aswad's investigators, Ms. Gilbert, considerable time and effort to determine the amount by which Dr. Aswad was over-reimbursed for the medications. Under the circumstances, there is no basis on which one can draw a conclusion that Dr. Aswad knew that he had been over-reimbursed for the medications that he ordered from Non-RX and Others. This is important because of the implications concerning Dr. Aswad's ethics, but also because if Dr. Aswad had been collecting significantly more in reimbursements than he was paying for the medications that he received through Non-RX and Others, it arguably should have raised a red flag for Dr. Aswad and should have prompted him to examine the reasons for the disparity. It appears that the over-reimbursement represents approximately 16% of the amount that Dr.

Aswad paid for the non-FDA approved medications. The unrebutted testimony suggests that rebates and discounts in the range of 16% are neither unusual nor alarming.

There is absolutely no evidence that any of Dr. Aswad's patients were harmed by the administration of the non-FDA approved medications. However, that is cold comfort to the Board given the undisputed risk of harm presented by the administration of non-FDA approved medications. Special Agent Blair testified that some of the vials seized from other physicians across the country contained no active ingredient at all. If none of Dr. Aswad's patients suffered any setbacks in their health or well-being after being infused with the medications obtained from Non-RX and Others, the lack of harm can only be attributable to good fortune. To borrow an analogy from Mr. Rubin, an impaired physician who operates on a patient should still be subjected to discipline by the Board even if the patient does not suffer a negative outcome as a result of the impairment. This is true because it is the physician's willingness to engage in risky behavior and to jeopardize the health and well-being of one or more of his patients that raises a presumption of lack of fitness to practice and creates a danger to the public.

The Board bears the responsibility to protect the public from physicians who are not fit to practice, and it is a responsibility that the Board undertakes with great care. Indeed, given the testimony offered by Ms. Gilbert regarding the fact that many physicians across the country ordered non-FDA approved medications from Non-RX and/or other suppliers and still maintain active medical licenses, it appears that this Board is more diligent than the Boards of other states in fulfilling its obligations to the public. When a physician has pled guilty to criminal conduct in connection with the physician's practice of medicine, as Dr. Aswad has, the Board is specifically authorized to summarily suspend the physician's license to practice medicine. That said, the statute does not require the Board to summarily suspend the license of a physician who pleads

guilty to such criminal conduct. For reasons described below, I recommend that the Board vacate its notice of summary suspension and allow Dr. Aswad to return to the practice of medicine pending the outcome of the hearing on the NCA allegations.

I am convinced that based on the evidence presented to date, Dr. Aswad does not represent a clear and immediate danger to his patients at the present time.[4] While Dr. Aswad unquestionably subjected his patients to the dangers associated with the use of non-FDA approved medications between July of 2010 and April of 2012, he did so unknowingly. Based on his testimony and the lack of any evidence to the contrary, I believe that Dr. Aswad never intended to subject his patients to risk and that Dr. Aswad thought that he was providing his patients with excellent care. I further find no support for the allegation that Dr. Aswad subjected his patients to risk in pursuit of personal gain. I note that the FDA did not make any efforts to stop Dr. Aswad from practicing medicine when they raided his office. Indeed, the FDA did not even report the fact of the raid or its findings to the Board or to the DEA. Moreover, in the 30 months that have elapsed between the raid and the guilty plea and resulting summary suspension, there have been no concerns raised about Dr. Aswad's provision of care to his patients and there have been no new allegations concerning Dr. Aswad's administration of non-FDA approved medications. Dr. Aswad appears to be less trusting and savvier with respect to suppliers of

[4] Based on the stipulation of the parties (Fact No. 64), it appears that the DEA took some action against Dr. Aswad, in response to which Dr. Aswad voluntarily surrendered his DEA registration and his state Board of Pharmacy registration. It also appears that the DEA seized items from Dr. Aswad's office on December 4, 2014. I have no way, at the present time, to determine whether the actions of the DEA and the Board of Pharmacy suggest that Dr. Aswad poses a threat to his patients. I am also uncertain how the actions of the DEA might affect Dr. Aswad's plea deal and his probationary status. My current determination that Dr. Aswad does not present a clear and immediate danger to the public is predicated solely upon the evidence presently in the record as of the date of this report.

oncology medications and supplies, and I genuinely believe that Dr. Aswad will not make the same unwitting mistake in the future.[5]

Based on the testimony and letters of support of Dr. Aswad's patients and colleagues, the real risk of harm to the Deming community arises from Dr. Aswad's inability to practice medicine. The evidence offered at the hearing shows that Deming is an underserved community, and the patients who need oncology services have expressed a concern that they will have to travel several hours from home in order to obtain the necessary treatment of their conditions. The reports and testimony offered by Dr. Aswad's patients and colleagues show that Dr. Aswad is a talented and compassionate practitioner whose professional absence in the community is causing hardship for patients and other providers. Under these circumstances, I cannot articulate a principled reason why Dr. Aswad's license should remain suspended pending the hearing and ultimate decision on the allegations set forth in the NCA.

Respectfully Submitted,

Jennifer G. Anderson
New Mexico Medical Board Member
Hearing Officer

December 4, 2014

[5] A word of caution to Dr. Aswad is appropriate with respect to Dr. Aswad's failure to immediately abide by the notice of summary suspension once he was aware of its issuance. The Board expects that physicians will timely and thoroughly adhere to the Board's orders, and the Board further expects nothing less than the complete cooperation of its licensees. Dr. Aswad's counsel admitted that Dr. Aswad continued to practice for three days after Dr. Aswad and his counsel had actual notice of the summary suspension, and counsel admitted that it was her mistaken advice to Dr. Aswad that resulted in Dr. Aswad's short-term non-compliance with the notice. It appears that Dr. Aswad's short term non-compliance was also motivated by a desire to avoid abandoning patients who use maintenance medications and who may have experienced difficulties in obtaining those medications from other, scarce practitioners in Deming. Whatever the motivation and the cause of the non-compliance, Dr. Aswad is strongly cautioned not to defy future orders and notices of the Board. It is also recommended that the NCA be amended to include the issue of temporary non-compliance as described herein.

BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF	)	
MOHAMED ASWAD, M.D.	)	
	)	
License No. 2003-0043	)	**No. 2014-044**
	)	
Respondent.	)	

NOTICE OF CONTEMPLATED ACTION

YOU ARE HEREBY NOTIFIED that pursuant to provisions of Section 61-1-4 NMSA 1978 of the Uniform Licensing Act ("ULA"), the New Mexico Medical Board ("Board") has before it sufficient evidence that, if not rebutted or explained, will justify the Medical Board imposing sanctions that could include restricting, revoking or suspending your license to practice medicine in the State of New Mexico.

1. Respondent is subject to action by the Board pursuant to Sections 61-1-1 et seq. NMSA 1978 of the Uniform Licensing Act and Sections 61-6-1 et seq., NMSA 1978 of the Medical Practice Act.

2. This contemplated action is based on the following allegations:

A. From approximately July 2010 to February 2012, you knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq.

B. You administered these misbranded drugs in your long-term treatment of numerous cancer patients as part of your oncology practice in Deming, New Mexico.

C. You did not inform any of your patients that you were administering non-FDA approved drugs.

D. The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names.

E. Misbranded non-FDA-approved drugs carry the significant, unreasonable risk that the safety and efficacy of the drugs will be inferior to FDA-approved drugs.

F. Many of these patients provided reimbursement for the cost of these non-FDA-approved medications through the U.S. Medicaid or Medicare program. You billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices.

G. You personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding two million dollars ($2,000,000.00), which was deposited into your personal banking accounts.

H. On or about November 4, 2014, you entered into a plea agreement with the United States, in which you admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S.C. Sections 331(a) and 333(a)(1).

3. The above allegations, if proven, would constitute a violation of the following sections of the Medical Practice Act, Section 61-6-1 et seq.:

a. Section 61-6-15(D)(4), obtaining a fee by fraud or misrepresentation,

b. Section 61-6-15(D)(9), making false or misleading statements regarding the efficacy or value of the treatment administered by the licensee,

c. Section 61-6-15(D)(12), gross negligence in the practice of a licensee,

d. Section 61-6-15(D)(15), the use of a false, fraudulent, or deceptive statement in a document connected with the practice of a license,

e. Section 61-6-15(D)(18), conduct likely to deceive, defraud, or harm the public,

f. Section 61-6-15(D)(19), repeated similar negligent acts,

g. Section 61-6-15(D)(29), conduct unbecoming in a person licensed to practice or detrimental to the best interests of the public,

h. Section 61-6-15(D)(20), employing abusive billing practices;

i. Section 61-6-15(D)(6), conviction of an offense punishable by incarceration in a federal prison or conviction of a misdemeanor associated with the practice of medicine; and

j. Board Rule at NMAC 16.10.8.8(C), violating a drug law, promulgated pursuant to Section 61-6-15(D), to wit, the Food Drug and Cosmetic Act, 21 U.S.C. Sections 331(a) and 333(a)(1).

4. Please take notice that pursuant to Section 61-1-4, you may secure a hearing before the Board by depositing in the mail within twenty (20) days after service of this notice a certified return receipt requested letter addressed to the Board and containing a request for a hearing. If you do not request a hearing within twenty (20) days after service of this notice as described above, the Board will take the contemplated action, i.e., imposing sanctions that could include the revocation or suspension of your license to practice medicine in the State of New Mexico, and there will be no judicial review of their decision.

5. Pursuant to Section 61-1-8 NMSA 1978, you have the right to be represented by counsel or by a licensed member of your profession or both, and to present all relevant evidence by means of witnesses, books, papers, documents and other evidence; to examine all opposing witnesses who may appear on any matter relevant to the issues and have subpoenas duces tecum issued as of right prior to the commencement of the hearing, to compel the attendance of witnesses and the production of relevant books, papers, documents and other evidence upon making a written request

therefore to the Board. The issuance of such subpoenas after commencement of the hearing rests with the discretion of the Board or Hearing Officer.

6. The issuance of this Notice of Contemplated Action is not a disciplinary event reportable to any data bank but is a public document open to public inspection.

7. In the event that the Board takes a final action against you as specified in Section 61-1-3 of the ULA, you shall bear all costs of disciplinary proceedings unless excused by the Board pursuant to Section 61-1-4(G) of the ULA.

Dated this 14th day of November, 2014.

NEW MEXICO MEDICAL BOARD

Lynn Hart, Executive Director
NM Medical Board
2055 S. Pacheco, #400
Santa Fe, New Mexico 87505
(505) 476-7220

BEFORE THE NEW MEXICO MEDICAL BOARD

IN THE MATTER OF	)	
MOHAMED ASWAD, M.D.	)	
	)	
License No. 2003-0043	)	**No. 2014-044**
	)	
Respondent.	)	

NOTICE OF SUMMARY SUSPENSION

YOU ARE HEREBY NOTIFIED that your license to practice medicine is hereby **IMMEDIATELY SUSPENDED** pursuant to Section 61-6-15.1 of the New Mexico Practice Act ('the Act"), and that pursuant to Section 61-1-4 NMSA 1978 of the Uniform Licensing Act ("ULA"), the New Mexico Medical Board ("Board") has before it sufficient evidence that, if not rebutted or explained, will justify the Board's suspension of your license to practice medicine in the State of New Mexico. This suspension is based on the following:

A. From approximately July 2010 to February 2012, you knowingly purchased misbranded non-FDA approved chemotherapy drugs, including injectable Altuzan, from several sources outside the United States. These drugs are not approved by the U.S. Food and Drug Administration ("FDA"), but are instead marketed and misbranded as chemotherapy drugs in violation of the Food Drug and Cosmetic Act, 21 U.S.C. Sections 301, et seq.

B. You administered these misbranded drugs in your long-term treatment of numerous cancer patients as part of your oncology practice in Deming, New Mexico.

C. You did not inform any of your patients that you were administering non-FDA approved drugs.

D. The cost of these misbranded drugs is significantly less than the FDA-approved drugs bearing the same brand or generic names.

E. Misbranded non-FDA-approved drugs carry the significant, unreasonable risk that the safety and efficacy of the drugs will be inferior to FDA-approved drugs.

F. Many of these patients provided reimbursement for the cost of these non-FDA-approved medications through the U.S. Medicaid or Medicare program. You billed the Medicaid or Medicare program for the cost of these misbranded drugs at the price for FDA-approved drugs bearing the same brand or generic names, and received such reimbursement at such prices.

G. You personally profited from the acts described in paragraphs A-F, above, in an amount approximating or exceeding two million dollars ($2,000,000.00), which was deposited into your personal banking accounts.

H. On or about November 4, 2014, you entered into a plea agreement with the United States, in which you admitted to committing a federal crime in connection with some or all of the allegations set forth in A-G, above, to wit, violation of 21 U.S.C. Sections 331(a) and 333(a)(1).

I. Based upon the allegations in A-H, above, the evidence in support of such allegations, and pursuant to Section 61-6-15.1(A) of the Act, you currently pose a clear and immediate danger to the public health and safety if you continue to practice medicine, and furthermore have pled guilty or been found guilty of any offense related to the practice of medicine.

IN CONSIDERATION OF THE FORGOING, IT IS HEREBY ORDERED that your New Mexico license to practice as a physician is hereby SUSPENDED until further Order of the Board.

PLEASE TAKE FURTHER NOTICE THAT:

1. Pursuant to Board Rule at NMAC 16.10.5.16, you are entitled to a hearing on the

merits of your summary suspension within fifteen (15) days of a request for such hearing. This hearing request shall be in writing, addressed to the Board, delivered by certified mail, return receipt requested. You are not required to comply with this summary action until service of this action has been made personally or by certified mail, return receipt requested, at your last known address as shown in the Board's records, or you have actual knowledge of this order, whichever comes first.

2. Pursuant to Section 61-1-8 NMSA 1978, you have the right to be represented by counsel or by a licensed member of your profession or both, and to present all relevant evidence by means of witnesses, books, papers, documents and other evidence; to examine all opposing witnesses who may appear on any matter relevant to the issues and have subpoenas duces tecum issued as of right prior to the commencement of the hearing, to compel the attendance of witnesses and the production of relevant books, papers, documents and other evidence upon making a written request therefore to the Board. The issuance of such subpoenas after commencement of the hearing rests with the discretion of the Board or Hearing Officer.

3. The issuance of this Summary Suspension is a disciplinary event and will be reported to the National Practitioners Data Bank and is a public document, open to public inspection.

Dated this 17th day of November, 2014.

NEW MEXICO MEDICAL BOARD

Lynn Hart

Lynn Hart, Executive Director
NM Medical Board
2055 S. Pacheco, #400
Santa Fe, New Mexico 87505
(505) 476-7220

CERTIFICATE OF SERVICE

I hereby certify that a true copy of the Notice of Contemplated Action and Notice of Summary Suspension was sent certified mail return receipt to Respondent on November 17, 2014.

Mohamed Aswad, MD
2104 S Shelly Dr
Deming, NM 88030

HAND DELIVERED TO:

Dan Rubin
2055 S. Pacheco Bldg 400
Santa Fe, NM 87505

Samantha Breen