

BOARD OF MEDICAL PRACTICE

In re: Gamal H. Eltabbakh, M.D.)
) Docket No. MPS 079-0612
)

STIPULATION AND CONSENT ORDER

NOW COME Gamal H. Eltabbakh, M.D., and the State of Vermont, by and through Vermont Attorney General Thomas J. Donovan, Jr., and hereby stipulate and agree to the following in the above-captioned matter:

- 1. Gamal H. Eltabbakh, M.D. (“Respondent”) holds Vermont medical license number 042.0009610 originally issued by the Vermont Board of Medical Practice on January 26, 1998.
- 2. Jurisdiction in this matter rests with the Vermont Board of Medical Practice (“the Board”), pursuant to 26 V.S.A. §§ 1353-1357, 3 V.S.A. §§ 809-814, and other authority.

FINDINGS OF FACT

- 3. Respondent is the owner of Lake Champlain Gynecologic Oncology, P.C. (“LCGO”). He is the sole physician for LCGO. LCGO provides care and treatment for gynecologic cancers, as well as regular gynecologic care. The LCGO office located in South Burlington, Vermont also has a chemotherapy infusion center, laboratory and pharmacy.
- 4. In June of 2012, the Board received information indicating that the U.S. Food and Drug Administration (“FDA”) contacted Respondent about medications that Respondent allegedly purchased from a Canadian distributor. An investigation was

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GENERAL
109 State Street
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opened and assigned to the South Investigative Committee of the Board (“the Committee”).

5. During the period from 2012 through late 2015, a federal investigation of Respondent’s purchase of foreign-sourced drugs was ongoing. The Board’s investigation was not based on patient complaints, as none have ever been received by the Board relating to this issue.
6. The Committee’s investigation revealed that, on February 8, 2016, Respondent and LCGO entered into a Settlement Agreement with the United States of America, acting through the United States Department of Justice, on behalf of the Office of Inspector General of the Department of Health and Human Services (“United States”). A copy of the Settlement Agreement is attached hereto as Exhibit A.
7. In the Settlement Agreement, the United States contended that it had civil claims against Respondent and LCGO as a result of the following conduct that occurred from approximately January 2010 through February 2012:
 - Purchasing seven different drugs used in chemotherapy from a Canadian drug distributor.
 - Some of these drugs were manufactured in institutions that were not registered with the FDA, and thus did not receive final FDA approval for commercial marketing.
 - Because the drugs were not approved by the FDA for commercial marketing, they were not covered by Medicare or Medicaid.
 - The drugs were administered to patients by Respondent and LCGO staff. Some of these patients were Medicare and Medicaid beneficiaries.

- By billing Medicare and Medicaid for the treatment of patients with these drugs, Respondent submitted false claims for payment to Medicare and Medicaid.

8. Pursuant to the Settlement Agreement, Respondent paid \$500,000.00 to the United States to settle the allegations listed above in paragraph seven. The Settlement Agreement included a statement that it was not an admission of liability by Respondent or LCGO.
9. The Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.* and its implementing regulations prohibits the introduction or delivery for introduction into interstate commerce any new drug, unless the FDA has approved an application for such drug. 21 U.S.C. §§ 331(d), 355(b). The Act and its implementing regulations require that the applications submitted to, and ultimately approved by, the FDA for consideration contain a variety of particular information; including, but not limited to: the drug's specifications, component, and composition; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; specifications related to containers and closure systems, packaging materials and methods; and product labeling. Once the FDA approves a drug application, the drug is considered FDA-approved only if all aspects of the drug are identical to the description in the FDA-approved application. This is true even if a drug has the exact same active ingredients and/or the exact same name as the FDA-approved drug. 21 U.S.C. §§ 355(j)(1)(B), (C), (D), (F) and 355(d) & 21 C.F.R. § 314.50, 21 U.S.C. § 355(j)(2)(A)(v)(vi) and 355(j)(4) & 21 C.F.R. § 314.94.

10. Two of the seven drugs that Respondent purchased from the Canadian distributor were docetaxel (brand name Taxotere) and gemcitabine. Docetaxel and gemcitabine had been, and continue to be, FDA-approved drugs that appear in the Orange Book, which lists FDA approved drugs. However, the foreign-sourced versions of docetaxel and gemcitabine purchased by Respondent and administered to patients did not meet FDA regulations because the labeling of the drugs was not in compliance with the description of the FDA-approved labeling found in the FDA-approved applications.
11. Respondent's purchase, possession and administration of the non-FDA approved docetaxel and gemcitabine was a violation of the Act and its implementing regulations.

CONCLUSIONS OF LAW

12. The Board shall find that "failure to comply with provisions of federal or state statutes or rules governing the practice of medicine or surgery" constitutes unprofessional conduct. 26 V.S.A. § 1354(a)(27)
13. The Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 *et seq.*, is a federal statute which governs the practice of medicine.
14. In the course of Respondent's medical practice, he purchased and administered drugs to patients that were not approved by the FDA, and thus violated provisions of the Act cited hereinabove.
15. Respondent acknowledges it is the Board's position that if the State were to file charges against him, it could satisfy its burden at a hearing and a finding adverse to him could be entered by the Board, pursuant to 26 V.S.A. §1354(a)(27).

16. Respondent agrees that the Board may enter as its facts and/or conclusions paragraphs 1 through 15 above, and further agrees that this is an adequate basis for the Board actions set forth herein. Any representation by Respondent herein is made solely for the purposes set forth in this agreement.
17. Therefore, in the interest of Respondent's desire to fully and finally resolve the matter presently before the Board, he has determined that he shall enter into the instant agreement with the Board. Respondent enters no further admission here, but to resolve this matter without further time, expense and uncertainty; he has concluded that this agreement is acceptable and in the best interest of the parties.
18. Respondent acknowledges that he is knowingly and voluntarily entering into this Stipulation and Consent Order with the Board. He acknowledges and agrees that he has had the advice of counsel regarding this matter and in the review of this Stipulation and Consent Order. Respondent is fully satisfied with the legal representation he has received in this matter.
19. Respondent agrees and understands that by executing this document he is waiving any right to challenge the jurisdiction and continuing jurisdiction of the Board in this matter, to be presented with a specification of charges and evidence, to cross-examine witnesses, and to offer evidence of his own to contest any allegations by the State.
20. The parties agree that upon their execution of this Stipulation and Consent Order, and pursuant to the terms herein, the above-captioned matter shall be administratively closed by the Board. Thereafter, the Board will take no further

action as to this matter absent non-compliance with the terms and conditions of this document by Respondent.

21. This Stipulation and Consent Order is conditioned upon its acceptance by the Vermont Board of Medical Practice. If the Board rejects any part of this document, the entire agreement shall be considered void. Respondent agrees that if the Board does not accept this agreement in its current form, he shall not assert in any subsequent proceeding any claim of prejudice from any such prior consideration. If the Board rejects any part of this agreement, none of its terms shall bind Respondent or constitute an admission of any of the facts of the alleged misconduct, it shall not be used against Respondent in any way, it shall be kept in strict confidence, and it shall be without prejudice to any future disciplinary proceeding and the Board's final determination of any charge against Respondent.
22. Respondent acknowledges and understands that this Stipulation and Consent Order shall be a matter of public record, shall be entered in his permanent Board file, shall constitute an enforceable legal agreement, and shall be reported to other licensing authorities, including but not limited to: the Federation of State Medical Boards Board Action Databank and the National Practitioner Data Bank. In exchange for the actions by the Board, as set forth herein, Respondent expressly agrees to be bound by all terms and conditions of this Stipulation and Consent Order.
23. The parties therefore jointly agree that should the terms and conditions of this Stipulation and Consent Order be deemed acceptable by the Board, it may enter an order implementing the terms and conditions herein.

ORDER

WHEREFORE, based on the foregoing, and the consent of Respondent, it is hereby ORDERED that:

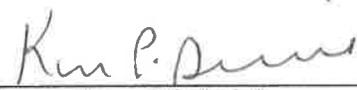
- a. Respondent shall be **REPRIMANDED** for the conduct set forth above.
- b. Respondent shall pay an administrative penalty of five thousand dollars (\$5,000.00) consistent with 26 V.S.A. § 1361(b). Payment shall be made to the "State of Vermont Board of Medical Practice," and shall be sent to the Vermont Board of Medical Practice at the following address: David Herlihy, Executive Director, Vermont Board of Medical Practice, P.O. Box 70, Burlington VT 05402. This payment will be due no more than sixty days after this Stipulation and Consent Order is approved by the Board.

SIGNATURES

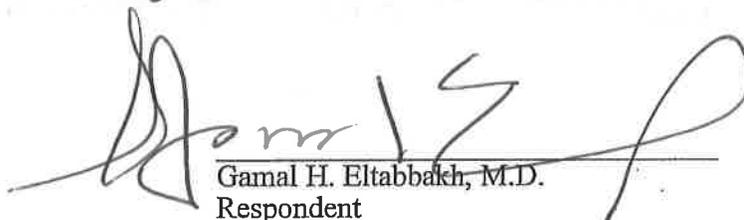
DATED at Montpelier, Vermont, this 12th day of October, 2018.

STATE OF VERMONT

THOMAS J. DONOVAN, JR
ATTORNEY GENERAL

By: 
Kassandra P. Diederich
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, VT 05609-1001

2018. DATED at S Burlington Vermont, this 5th day of October


Gamal H. Eltabbakh, M.D.
Respondent

Approved as to form:

2018. DATED at _____, Vermont, this _____ day of _____,

Office of the
ATTORNEY
GENERAL
109 State Street
Montpelier, VT
05609

Ian Carleton, Esquire
Sheehey Furlong & Behm P.C.
30 Main Street, 6th Floor
P.O. Box 66
Burlington, VT 05402-0066
Counsel for Respondent

SIGNATURES

DATED at Montpelier, Vermont, this _____ day of _____, 2018.

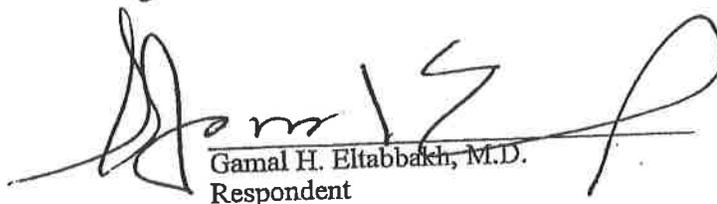
STATE OF VERMONT

THOMAS J. DONOVAN, JR.
ATTORNEY GENERAL

By:

Kassandra P. Diederich
Assistant Attorney General
Office of the Attorney General
109 State Street
Montpelier, VT 05609-1001

DATED at Burlington Vermont, this 5th day of October
2018.


Gamal H. Eltabbakh, M.D.
Respondent

Approved as to form:

DATED at Burlington, Vermont, this 5th day of October,
2018.


Ian Carleton, Esquire
Sheehey Furlong & Behm P.C.
30 Main Street, 6th Floor
P.O. Box 66
Burlington, VT 05402-0066
Counsel for Respondent

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109 State Street
Montpelier, VT
05609

AS TO GAMAL H. ELTABBAKH, M.D.
APPROVED AND ORDERED
VERMONT BOARD OF MEDICAL PRACTICE

Office of the
ATTORNEY
GENERAL
109 State Street
Montpelier, VT
05609

DATED: November 7th, 2018 ENTERED AND EFFECTIVE: November 7th, 2018

EXHIBIT A

SETTLEMENT AGREEMENT

This Settlement Agreement ("Agreement") is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the Office of Inspector General (OIG-HHS) of the Department of Health and Human Services (HHS) (collectively, the "United States"), Dr. Gamal H. Eltabbakh (Dr. Eltabbakh), and Lake Champlain Gynecologic Oncology, P.C., through its principal Dr. Eltabbakh (hereafter collectively referred to as "the Parties"), through their authorized representatives.

RECITALS

A. Lake Champlain Gynecologic Oncology, P.C. (LCGO) is a for-profit gynecologic oncology center located in South Burlington, Vermont. Its office includes examination rooms, a laboratory, and a chemotherapy infusion center. LCGO provides health care services to the general public and receives payment for those services in various ways, including, but not limited to, reimbursement from federal and state health care programs such as the Medicare and Medicaid Programs.

B. Dr. Gamal H. Eltabbakh is the owner of LCGO and the sole physician affiliated with the practice.

C. As a result of its investigation, the United States contends that Dr. Gamal H. Eltabbakh in his work with LCGO, submitted or caused to be submitted claims for payment to the Medicare Program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 ("Medicare"); and the Medicaid Program, 42 U.S.C. §§ 1396-1396w-5 ("Medicaid").

D. The United States contends that it has certain civil claims against Dr. Eltabbakh and LCGO arising from the following contentions:

1. From approximately January 2010 through February 29, 2012, LCGO purchased a portion of his drugs for use in chemotherapy, including Aloxi (for treatment

of chemotherapy-induced nausea and vomiting), Neulastum (to increase infection resistance during chemotherapy), Bevacizumab (for treatment of metastasized or recurring ovarian cancer and other recurring cancers), Taxotere (for treatment of ovarian and other cancers), Gemzar (for treatment of ovarian and other cancers), Hycamtin (an anti-tumor drug), and Alimta (for treatment of ovarian and other cancers), from a Canadian drug distributor and other sources. Some of these drugs were not manufactured in establishments that were registered with the United States Food and Drug Administration ("FDA"). The versions of the drugs from these non-registered establishments (the "Drugs") were "new drugs" within the meaning of 21 U.S.C. § 321(p) and they were not the subject of, and did not comply with, a new drug application, abbreviated new drug application, or biologics license application approved by the FDA for commercial marketing. Therefore, the Drugs were not covered by Medicare or Medicaid because they had not received final marketing approval from the FDA.

2. These Drugs were used in the treatment of patients, including Medicare and Medicaid beneficiaries, at LCGO by Dr. Eltabbakh. By treating Medicare and Medicaid beneficiaries at LCGO with these Drugs, Dr. Eltabbakh caused LCGO to submit false claims for payment to Medicare and Medicaid for the Drugs.

3. Between approximately January 2010 and February 29, 2012, LCGO, on behalf of Dr. Eltabbakh, billed for the provision of these above-described Drugs to patients, including billing to Medicare and Medicaid.

This conduct is referred to below as the "Covered Conduct."

E. This Settlement Agreement is neither an admission of liability by Dr. Eltabbakh or LCGO, nor a concession by the United States that its claims are not well founded.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Dr. Eltabbakh or LCGO shall pay to the United States \$500,000.00 ("Settlement Amount"), due no later than 30 days after the Effective Date of this Agreement by electronic funds transfer pursuant to written instructions to be provided by the United States Attorney's Office for the District of Vermont.

2. Subject to the exceptions in Paragraph 4 (concerning excluded claims) below, and conditioned upon Dr. Eltabbakh's full payment of the Settlement Amount, the United States releases Dr. Gamal H. Eltabbakh and LCGO from any and all civil or administrative monetary claims the United States has or may have for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of payment by mistake, unjust enrichment, and fraud.

3. OIG-HHS expressly reserves all rights to institute, direct, or to maintain any administrative action seeking exclusion against Dr. Gamal H. Eltabbakh and/or LCGO from Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. §1320a-7b(f)) under 42 U.S.C. §1320a-7(a) (mandatory exclusion), or 42 U.S.C. §1320a-7(b) or 42 U.S.C. §1320a-7a (permissive exclusion).

4. Notwithstanding the release given in paragraph 2 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);

- b. Except as explicitly stated in this Agreement, any administrative liability, including mandatory or permissive exclusion from Federal health care programs;
- c. Any liability, civil or criminal, to the United States (or its agencies) for any conduct other than the Covered Conduct;
- d. Any liability based upon obligations created by this Agreement;
- e. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- f. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; or
- g. Any criminal liability.

5. Dr. Eltabbakh and LCGO waive and shall not assert any defenses Dr. Eltabbakh and/or LCGO may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

6. Dr. Eltabbakh and LCGO fully and finally release the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Dr. Eltabbakh and/or LCGO have

asserted, could have asserted, or may assert in the future against the United States, and its agencies, officers, agents, employees, and servants related to the Covered Conduct and the United States' investigation and prosecution thereof.

7. The Settlement Amount shall not be decreased as a result of the denial of claims for payment now being withheld from payment by any Medicare contractor (e.g., Medicare Administrative Contractor, fiscal intermediary, carrier) or any state payer, related to the Covered Conduct; and Dr. Eltabbakh and LCGO agree not to resubmit to any Medicare contractor or any state payer any previously denied claims related to the Covered Conduct, agree not to appeal any such denials of claims, and agree to withdraw any such pending appeals.

8. Dr. Eltabbakh and LCGO agree to the following:

a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) incurred by or on behalf of Dr. Eltabbakh and LCGO, LCGO's present or former officers, directors, employees, shareholders, and Dr. Eltabbakh's and LCGO's agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil and any criminal investigation(s) of the matters covered by this Agreement;
- (3) Dr. Eltabbakh's and LCGO's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil and any criminal investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and

(5) the payment Dr. Eltabbakh and LCGO make to the United States pursuant to this Agreement,

are unallowable costs for government contracting purposes and under the Medicare Program, Medicaid Program, TRICARE Program, and Federal Employees Health Benefits Program (FEHBP) (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs shall be separately determined and accounted for by Dr. Eltabbakh and LCGO, and Dr. Eltabbakh and LCGO shall not charge such Unallowable Costs directly or indirectly to any contracts with the United States or any State Medicaid program, or seek payment for such Unallowable Costs through any cost report, cost statement, information statement, or payment request submitted by Dr. Eltabbakh or LCGO or any of its subsidiaries or affiliates to the Medicare, or Medicaid, TRICARE, or FEHBP Programs.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Dr. Eltabbakh and LCGO further agree that within 90 days of the Effective Date of this Agreement they shall identify to applicable Medicare and TRICARE fiscal intermediaries, carriers, and/or contractors, and Medicaid and FEHBP fiscal agents, any Unallowable Costs (as defined in this Paragraph) included in payments previously sought from the United States, or any State Medicaid program, including, but not limited to, payments sought in any cost reports, cost statements, information reports, or payment requests already submitted by Dr. Eltabbakh or LCGO or any of its subsidiaries or affiliates, and shall request, and agree, that such cost reports, cost statements, information reports, or payment requests, even if already settled, be adjusted to account for the effect of the inclusion of the unallowable costs. Dr. Eltabbakh and LCGO agree that the United States, at a minimum, shall be entitled to recoup from Dr. Eltabbakh and LCGO any overpayment plus applicable interest and penalties as a result of the inclusion of such

Unallowable Costs on previously-submitted cost reports, information reports, cost statements, or requests for payment.

Any payments due after the adjustments have been made shall be paid to the United States pursuant to the direction of the Department of Justice and/or the affected agencies. The United States reserves its rights to disagree with any calculations submitted by Dr. Eltabbakh or LCGO or any of its subsidiaries or affiliates on the effect of inclusion of Unallowable Costs (as defined in this Paragraph) on Dr. Eltabbakh or LCGO or any of its subsidiaries or affiliates' cost reports, cost statements, or information reports.

d. Nothing in this Agreement shall constitute a waiver of the rights of the United States to audit, examine, or re-examine Dr. Eltabbakh's or LCGO's books and records to determine that no Unallowable Costs have been claimed in accordance with the provisions of this Paragraph.

9. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity, except to the extent provided for in Paragraph 10 (waiver for beneficiaries paragraph), below.

10. Dr. Eltabbakh and LCGO agree that they waive and shall not seek payment for any of the health care billings covered by this Agreement from any health care beneficiaries or their parents, sponsors, legally responsible individuals, or third party payors based upon the claims defined as Covered Conduct.

11. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

12. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

13. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Vermont. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

14. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

15. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

16. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

17. This Agreement is binding on LCGO's successors, transferees, heirs, and assigns.

17. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

18. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles and electronic transmissions of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 1/18/16

BY: Eugenia A. P. Cowles
Eugenia A. P. Cowles
Assistant United States Attorney
District of Vermont

DATED: 1/21/16

BY: Robert K. DeConti
Robert K. DeConti
Assistant Inspector General for Legal Affairs
Office of Counsel to the Inspector General
Office of Inspector General
United States Department of Health and Human Services

Dr. Gamal H. Eltabbakh and Lake Champlain Oncologic Gynecology, P.C.

DATED: 1/22/16

BY: Dr. Gamal H. Eltabbakh
Dr. Gamal H. Eltabbakh (on behalf of himself and LCGO)

DATED: 2/8/16

BY: Ian P. Carleton
Ian P. Carleton
Counsel for Dr. Eltabbakh and LCGO