

Public

STATE OF NEW YORK DEPARTMENT OF HEALTH
STATE BOARD FOR PROFESSIONAL MEDICAL CONDUCT

IN THE MATTER

OF

HANIMI REDDY CHALLA, M.D.
CO-05-02-0778-A

COMMISSIONER'S
SUMMARY
ORDER

TO: HANIMI REDDY CHALLA, M.D.
134 NW 88 Terrace
Gainesville, FL 32607

HANIMI REDDY CHALLA, M.D.
9401 SW State Road 200
Bldg. 700- Suite 701
Ocala, FL 34481

The undersigned, Antonia C. Novello, M.D., M.P.H., Dr. P.H., Commissioner of Health, pursuant to New York Public Health Law §230, upon the recommendation of a committee on Professional Medical Conduct of the State Board for Professional Medical Conduct, has determined that the duly authorized professional disciplinary agency of another jurisdiction, the State of Florida, Department of Health (hereinafter "Florida Board") has made a finding substantially equivalent to a finding that the practice of medicine by **HANIMI REDDY CHALLA, M.D.**, Respondent, licensed to practice medicine in New York state on October 5, 1979, by license number 139884, in that jurisdiction, constitutes an imminent danger to the health, safety, and welfare of its people, as is more fully set forth in documents of the State of Florida, attached hereto, as "Appendix A," and made a part hereof.

It is, therefore:

ORDERED, pursuant to New York Public Health Law Section 230(12)(b), that effective immediately, the license of, **HANIMI REDDY CHALLA, M.D.**, Respondent, is restricted, in that he shall not himself or through any other person, administer, dispense, inject, mix or otherwise prepare a legend drug, including any controlled substance, in the

state of New York or in any other jurisdiction where that practice is dependent on a valid New York state license to practice medicine.

Any practice of medicine, in violation of this restriction, in the state of New York or in any other jurisdiction where that practice is dependent on a valid New York state license to practice medicine in violation of this Commissioner's Summary Order shall constitute Professional Misconduct within the meaning of New York Education Law §6530 and may constitute unauthorized medical practice, a felony defined by New York Education Law §6512.

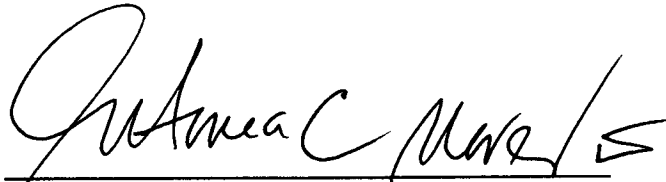
This Order shall remain in effect until the final conclusion of a hearing that shall commence within thirty (30) days after the final conclusion of the disciplinary proceeding in the state of Florida. The hearing will be held pursuant to the provisions of New York Public Health Law §230, and New York State Administrative Procedure Act §301-307 and 401. The hearing will be conducted before a committee on professional conduct of the State Board for Professional Medical Conduct, on a date and at a location to be set forth in a written Notice of Referral Proceeding, together with a Statement of Charges, to be provided to Respondent after the final conclusion of the Florida proceeding. Said written Notice may be provided in person, by mail or by other means. If Respondent wishes to be provided said written notice at an address other than those set forth above, Respondent shall so notify, in writing, both the attorney whose name is set forth on this Order and the Director of the Office of Professional Medical Conduct, at the addresses set forth below.

Respondent shall notify the Director of the Office of Professional Medical Conduct, New York State Department of Health, 433 River Street, Suite 303, Troy, NY 12180-2299 via Certified Mail, Return Receipt Requested, of the final conclusion of the Florida proceeding, immediately upon such conclusion.

**THESE PROCEEDINGS MAY RESULT IN A
DETERMINATION THAT YOUR LICENSE TO
PRACTICE MEDICINE IN NEW YORK STATE BE
REVOKED OR SUSPENDED AND/OR THAT YOU
BE FINED OR SUBJECT TO OTHER SANCTIONS
SET FORTH IN NEW YORK PUBLIC HEALTH LAW
SECTION 230-A. YOU ARE URGED TO OBTAIN AN
ATTORNEY FOR THIS MATTER.**

DATE: Albany, New York

July, 6, 2005



ANTONIA C. NOVELLO, M.D., M.P.H, Dr. P. H.
Commissioner

Inquires should be addressed to:

Robert Bogan
Associate Counsel
Office of Professional Medical Conduct
433 River Street – Suite 303
Troy, New York 12180
(518) 402-0828

STATE OF FLORIDA
DEPARTMENT OF HEALTH

By: Heather Coleman
Deputy Agency Clerk

IN RE: The Emergency Restriction of the License of
Hanimi Reddy Challa, M.D.
License Number: ME 40003
Case Number 2004-39429

ORDER OF EMERGENCY RESTRICTION OF LICENSE

John O. Agwunobi, M.D., M.B.A., M.P.H., Secretary of the Department of Health, hereby ORDERS the emergency restriction of the license of Hanimi Reddy Challa, M.D., ("Dr. Challa") to practice medicine in the State of Florida. Dr. Challa holds license number ME 40003. His address of record is 9401 SW State Road 200, Building #700, Suite 701, Ocala, Florida 34481. The following Findings of Fact and Conclusions of Law support the emergency restriction of Dr. Challa's license to practice medicine in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state department charged with regulating the practice of medicine, pursuant to Chapters 20, 456, and 458, Florida Statutes. Section 456.073, Florida Statutes, empowers the Secretary of the Department to summarily suspend Dr. Challa's license to practice medicine in the State of Florida, in accordance with Section 120.60(6), Florida Statutes.
2. At all times material to this order, Dr. Challa was licensed to practice medicine in the State of Florida, pursuant to Chapter 458, Florida Statutes.

IN RE: The Emergency Suspension of the License of
Hanimi Reddy Challa, M.D.
License Number: ME 40003
Case Number 2004-39429
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3. On or about November 18, 2004, the United States Food and Drug Administration ("FDA") notified the Department that the FDA had received an anonymous complaint that Dr. Challa was dispensing Canadian flu vaccine to patients.

4. On or about December 7, 2004, the Department conducted an inspection of Dr. Challa's office and interviewed him regarding the flu vaccines.

5. Dr. Challa admitted that he had purchased two flu vaccines from a Canadian pharmacy: Vaxigrip (apparently manufactured in France) and Fluviral (apparently manufactured by Shire in Canada).

6. Neither Vaxigrip nor Fluviral are FDA approved drugs.

7. Dr. Challa purchased these vaccines from Health 2000 Pharmacy, a Canadian pharmacy. Health 2000 Pharmacy does not have a permit to operate as a pharmacy or as a wholesale pharmaceutical distributor in the State of Florida. Section 499.01(1), Florida Statutes (2004), requires a permit to operate as an out-of-state prescription drug wholesaler prior to engaging in the wholesale distribution of a prescription drug into the State of Florida. "Wholesale distribution" is defined in Section 499.012(1)(a), Florida Statutes (2004), as, "the distribution of prescription drugs to persons other than a consumer or patient," with certain statutory exceptions, none of which are applicable.

8. Dr. Challa admitted that he administered these vaccines to several thousand patients (approximately 5,900 to 6,000 patients), including the residents at

eight assisted living facilities.

9. Under Section 499.003(17), Florida Statutes (2004), a "drug" includes, in pertinent part, any article that is recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications, or any article intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals.

10. Flu vaccines, and specifically the vaccines at issue in this case, fall within the statutory definition of "drugs" under Chapter 499, Florida Statutes. Flu vaccines, and specifically the vaccines at issue in this case, fall within the statutory definition of "legend drugs" under Chapter 499, Florida Statutes.

11. Section 458.331(1)(g), Florida Statutes (2004), subjects a doctor to discipline, including suspension or restriction, for "[f]ailing to perform any statutory or legal obligation placed upon a licensed physician."

12. A. Under Section 499.005(1), Florida Statutes (2004), it is unlawful to perform or cause the performance of the following acts:

The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

Section 499.005(1), Florida Statutes (2004), places a statutory or legal obligation upon Dr. Challa.

B. Under Section 499.006(10), Florida Statutes (2004), a drug or device is adulterated if it is a legend drug that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.

C. Dr. Challa violated Section 499.005(1), Florida Statutes (2004), by manufacturing, repackaging, selling, delivering, or holding or offering for sale a drug (the unapproved flu vaccine) that was adulterated because it had been purchased, held, sold or distributed by a person not authorized under federal or state law to do so (Health 2000 Pharmacy).

13. A. Under Section 499.005(3), Florida Statutes (2004), it is unlawful to perform or cause the performance of the following acts:

The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise.

Section 499.005(3), Florida Statutes (2004), places a statutory or legal obligation upon Dr. Challa.

B. Under Section 499.006(10), Florida Statutes (2004), a drug or device is adulterated if it is a legend drug that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.

C. Dr. Challa violated Section 499.005(3), Florida Statutes (2004), by receiving a drug (the unapproved flu vaccine) that had been adulterated because it had been purchased, held, sold, or distributed by a person not authorized under federal or

state law to do so (Health 2000 Pharmacy).

14. Under Section 499.005(4), Florida Statutes (2004), it is unlawful to perform or cause the performance of the following acts:

The sale, distribution, purchase, trade, holding or offering of any drug, device, or cosmetic in violation of ss. 499.001-499.081.

Section 499.005(4), Florida Statutes (2004), places a statutory or legal obligation upon Dr. Challa.

15. A. Under Section 499.005(14), Florida Statutes (2004), it is unlawful to perform or cause the performance of the following acts:

The purchase or receipt of a legend drug from a person that is not authorized under this chapter to distribute legend drugs to that purchaser or recipient.

Section 499.005(14), Florida Statutes (2004), places a statutory or legal obligation upon Dr. Challa.

B. Dr. Challa violated Section 499.005(14), Florida Statutes (2004), by purchasing or receiving a legend drug (the unapproved flu vaccines) from a person not authorized under Chapter 499, Florida Statutes (2004), to distribute legend drugs to him (Health 2000 Pharmacy).

16. A. Under Section 499.023, Florida Statutes (2004),

A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health

and Human Services for shipment in interstate commerce.

Section 499.023, Florida Statutes (2004), places a statutory or legal obligation upon Dr. Challa. The FDA is the designee of the Secretary of United States Department of Health and Human Services for approving drugs under Section 505 of the federal act.

B. Dr. Challa violated Section 499.023, Florida Statutes (2004), by selling, offering for sale, holding for sale, distributing, or giving away a new drug that had not obtained FDA approval.

17. A. Section 458.331(1)(q), Florida Statutes (2004), subjects a doctor to discipline, including suspension or restriction, for:

Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

B. Dr. Challa prescribed, dispensed, administered, mixed or otherwise prepared a legend drug other than in the course of his professional practice and prescribed, dispensed, administered, mixed, or otherwise prepared a legend drug inappropriately when he dispensed, administered, mixed, or otherwise prepared an unapproved flu vaccine to several thousand patients.

18. Section 120.60(6), Florida Statutes (2004), authorizes the Department to

restrict a physician's license if the Department finds that the physician presents an immediate serious danger to the public health, safety, or welfare.

19. Physicians are trusted with patient health and safety every day. A physician who abuses this trust is dangerous, as his or her judgment and integrity cannot be guaranteed. Administering or dispensing an unapproved drug is inherently dangerous as there is no mechanism for inspection or verification of product contents, efficacy, or safety. Similarly, purchasing drugs from an unlicensed source is inherently dangerous as there is no mechanism for quality assurance. Outside of the parameters of lawful regulatory processes, there is no mechanism to ascertain whether a product is safe and effective, or adulterated and hazardous. When Dr. Challa disregarded that regulatory system by administering or dispensing an unapproved drug which he obtained from an unlicensed source, he disregarded the health, safety, and welfare of the public. Nothing short of immediate restriction of Dr. Challa's license to practice medicine will protect the public.

CONCLUSIONS OF LAW

1. The Secretary for the Department of Health has jurisdiction over this matter pursuant to Sections 20.43 and 456.073, Florida Statutes, and Chapter 458, Florida Statutes, as set forth above.

2. Based on the foregoing Findings of Fact, the Secretary concludes that Dr. Challa has violated Section 458.331(1)(g), Florida Statutes (2004), by failing to perform

any statutory or legal obligation placed upon a licensed physician by violating numerous provisions of Chapter 499, Florida Statutes, as described above.

3. Based on the foregoing Findings of Fact, the Secretary concludes that Dr. Challa has violated Section 458.331(1)(q), Florida Statutes (2004), by prescribing, dispensing, administering, mixing or otherwise preparing a legend drug other than in the course of his professional practice and by inappropriately prescribing, dispensing, administering, mixing, or otherwise preparing an unapproved flu vaccine to several thousand patients.

4. Based on the foregoing Findings of Fact, the Secretary finds that Dr. Challa's continued unrestricted practice as a physician constitutes an immediate serious danger to the health, safety, and welfare of the public and that this summary procedure is fair under the circumstances to adequately protect the public.

WHEREFORE, in accordance with Section 120.60(6), Florida Statutes, it is


THEREUPON ORDERED THAT:

1. The license of Hanimi Reddy Challa, M.D., license number ME 40003, is hereby immediately restricted, as follows:

Dr. Challa shall not, himself or through any other person, administer, dispense, inject, mix or otherwise prepare a legend drug, including any controlled substance.

2. A proceeding seeking formal discipline of the license of Dr. Challa to practice medicine in the State of Florida will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statutes.

DONE and ORDERED this 30th day of January, 2005.


John O. Agwunobi, M.D., M.B.A., M.P.H.
Secretary, Department of Health

PREPARED BY:

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NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Sections 120.60(6), and 120.68, Florida Statutes, the Department's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the Department of Health and a second copy of the petition accompanied by a filing fee prescribed by law with the District Court of Appeal within thirty (30) days of the date this Order is filed.