

IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

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U.S. DISTRICT COURT
MIDDLE GEORGIA
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DEPUTY CLERK

THE NATIONAL ASSOCIATION OF)
BOARDS OF PHARMACY,)

Plaintiff,)

v.)

THE BOARD OF REGENTS OF THE)
UNIVERSITY SYSTEM OF GEORGIA)
and FLYNN WARREN, JR.,)

Defendants.)

FILED UNDER SEAL

CIVIL ACTION NO.:
FILED UNDER SEAL

3-07-CV-84 (COL)

DECLARATION OF CARMEN CATIZONE

I, Carmen Catizone, make the following Declaration in support of Plaintiff's Application for Temporary Restraining Order and Motion For Preliminary Injunction in the above-styled matter.

1. I am of legal age, I am competent to give this Declaration, and I make this Declaration on the basis of my personal knowledge of the facts set forth herein.

2. I am the Executive Director/Secretary (referred to as Executive Director) of the National Association of Boards of Pharmacy ("NABP"), a position I have held since 1988.

3. As Executive Director, I report directly to the NABP Executive Committee, and my duties include the day-to-day oversight and leadership of all NABP operations, including acting as Chief Operating Officer of NABP and its 85 full-time employees and six part-time employees. As such, I am involved with and have knowledge of all matters involving NABP and, more specifically with regard to the

current situation, knowledge of the North American Pharmacist Licensure Examination (“NAPLEX”).

4. Prior to accepting the position of Executive Director of NABP, I was employed by NABP as the Test and Measurement Director. As Test and Measurement Director, my duties and responsibilities involved oversight of all NABP testing programs, including test development, administration, maintenance, as well as security, defensibility and psychometrics of the programs.

5. I have a Bachelor of Science degree in pharmacy and a Master’s in Pharmacy Administration from the University of Illinois and am a licensed pharmacist in good standing in the State of Illinois.

6. NABP was incorporated in 1904 to provide a uniform mechanism of licensure transfer among pharmacists moving from state to state. NABP is a not-for-profit 501(c)(3) Kentucky corporation with headquarters at 1600 Feehanville in Mount Prospect, Illinois.

7. NABP membership consists solely of the Boards of Pharmacy (or other state regulatory agencies) of all United States jurisdictions, including all the states, commonwealths, the District of Columbia, Guam, and the Virgin Islands. Additionally, international membership includes governing entities which regulate pharmacists in eight Canadian provinces, the Republic of South Africa, the states of Victoria and New South Wales in Australia, as well as New Zealand. For purposes of this Declaration, all NABP members shall be collectively referred to as “member boards,” understanding that jurisdictions have varying regulatory schemes that may include departments or other state agencies.

8. Individual pharmacists are not eligible for membership in NABP, which distinguishes it from professional associations such as the American Pharmacists Association (APhA).

9. Each NABP member board is represented at the Annual Meeting through a delegate selected by such member board. Business conducted at the NABP Annual Meeting includes elections of Executive Committee members, discussions and votes on resolutions, as well as updates on NABP programs and services, financial issues, committee reports, and educational sessions. Attached as Exhibit A to this Declaration is a copy of the NABP Constitution and Bylaws.

10. NABP provides programs and services to assist its member boards in fulfilling their statutory mandates to regulate the pharmacy profession in the interest of protecting the public health. The member boards provide expertise and advice on pharmacy regulatory matters and legislation and participate in disciplinary hearings. NABP provides programs and services that allow its member boards of pharmacy to assess pharmacists' competency prior to licensure and to verify the ongoing competence of licensed pharmacists. NABP also provides input on new and existing laws and related legal matters, and generally assists in the regulation of the practice of pharmacy for the protection of the public.

11. Specifically, NABP provides programs to its member boards that include the North American Pharmacist Licensure Examination™ (“NAPLEX®”), the Multistate Pharmacy Jurisprudence Examination® (“MPJE®”), the Electronic Licensure Transfer Program® (“ELTP®”), and accreditation programs for Internet pharmacies, wholesale

drug distributors, and pharmacies providing durable medical equipment through NABP's Verified Internet Pharmacy Practice Sites™ program ("VIPPS®"), the Verified-Accredited Wholesaler Distributors® program ("VAWD®"), and the Durable Medical Equipment, Prosthetics, Orthotics and Supplies ("DMEPOS") program. All such programs are intended to assist the member boards fulfill their respective statutory mandates to regulate the pharmacy profession in their state in the interest of protecting the public.

12. The NAPLEX is a computer-adaptive examination that consists of 185 multiple-choice test questions developed by NABP (of the 185 multiple-choice NAPLEX test questions, 150 questions are used to calculate the test score – the remaining 35 items serve as pre-test questions, which do not affect the NAPLEX score, but are administered to statistically evaluate the item's performance and difficulty level for possible inclusion as a scored question in future examinations) and utilized by all member boards as part of their assessment of competence to practice pharmacy. The NAPLEX was developed over many years beginning in 1952, when the concept of a uniform examination to promote the competent practice of pharmacy among jurisdictions and enhance licensure transfer was identified through meetings of member boards. In 1968, NABP convened a Blue Ribbon Committee of member board members and educators who developed the examination blueprint, examination items, and other necessary components for administering and maintaining a valid uniform exam program. The prototype Blue Ribbon Exam was used by 32 states in 1971. In 1975 NABP's exam was named NAPLEX, and was nationally introduced in 1976 when it was used as a licensing criterion by a majority of U.S. state Boards of Pharmacy. By 1986, all state Boards of

Pharmacy (except California) used the NABPLEX. In 1997, NABP implemented the North American Pharmacist Licensure Examination (NAPLEX), a computerized successor to the NABPLEX. With the addition of California's use of the NAPLEX in 2004, all state Boards of Pharmacy use the exam as one of a number of criteria a candidate must meet in order to be licensed as a pharmacist.

13. NABP develops, administers, and maintains the NAPLEX in compliance with recognized testing standards and practices. The NAPLEX is a computerized-adaptive examination that assesses a candidate's competence in the following areas of entry-level pharmacy practice that are required in all states to reflect the practice of pharmacy across the country: Assure Safe and Effective Pharmacotherapy and Optimize Therapeutic Outcomes; Assure Safe and Accurate Preparation and Dispensing of Medications; and Provide Health Care Information and Promote Public Health.

14. By following recognized testing standards and practices in the development, administration and maintenance of the NAPLEX, NABP ensures that the test is psychometrically sound, legally defensible, and free of bias. Examination development generally follows principles set forth in the Standards for Educational and Psychological Testing endorsed by the American Educational Research Association, American Psychological Association, and National Council on Measurement in Education. As such, the NAPLEX development process is both time-consuming and expensive.

15. Exam development first requires a national practice analysis to identify and assess the entry-level practice areas that a pharmacy candidate must know for competent practice. Based on an analysis of the national survey responses, a blueprint of

the content areas that will need to be assessed is then developed. Once the blueprint is identified, test items are developed to meet the content areas. Item writing is a learned skill and test-item writers need to be trained. An NABP committee of content experts (called the NAPLEX Review Committee, or "NRC") convenes several times per year to draft and edit test items and responses. Once approved, an item is pre-tested for statistical analysis to ensure that it meets content and psychometrics standards. Assuming that the item survives, it is then placed in the "item bank" for use. The item bank is a "pool" of questions from which questions are drawn for each administration of the NAPLEX.

16. NAPLEX materials, from inception through use and beyond, are developed, administered, and maintained under extremely secure conditions. Security measures include the use of confidentiality agreements with volunteers and employees, as well as contractual agreements with candidates, member boards, third-party vendors, and others. NABP headquarters and computer systems are maintained under highly secure conditions to prevent unnecessary exposure.

17. Administration of the NAPLEX is an ongoing process, meaning that a candidate can take the NAPLEX by computer at any of over 200 testing centers throughout the country, Monday through Saturday during normal business hours. This type of continuous testing provides a valuable service to both the state Boards and the test-takers, and is available due to the strength of the item bank. As items are selected from the item bank, sophisticated software ensures that each administration of the exam includes questions that cover the required various content areas without overexposing

questions to similarly situated candidates. The currency, validity, and exposure rates of test items, among other things, are closely monitored to ensure the integrity of the exams.

18. The NAPLEX is administered under highly secure conditions commencing with the check-in procedures and candidate identification through photo IDs for entry, as well as digital photos and fingerprints taken at the test center. Candidates are not allowed to bring any materials into the test center. Once admitted to the test, candidates' examination experiences are continuously monitored by proctors, including video cameras throughout the test centers. Candidates may be supplied with a calculator as well as a dry-erase marker boards for notes and calculations. The calculators and dry-erase boards are provided and collected by the test center personnel. Candidates do not have the ability to write or copy exam items onto paper, diskettes, or CDs, nor do they have access to send emails or engage in other electronic transmissions. Further, candidates cannot go back to a test item once an answer has been provided. Breaks are limited and monitored.

19. NABP uses the services of volunteers, in-house staff, outside consultants, and testing services to maintain the psychometrics of its examination programs, and vendors that provide examinees access to computer test sites throughout the United States. Relationships with third parties are contractually entered into and focus on legal defensibility and security of the programs.

20. Volunteers that provide expertise in content issues related to the development, administration, and maintenance of the NAPLEX enter into a Confidentiality Agreement identifying the responsibilities and prohibitions related to the NAPLEX and access to confidential information, including the recognition of ownership

by NABP and, to the extent necessary, transfer of ownership of all materials, work product, and actual items generated. Attached to this Declaration as Exhibit B is a generic Confidentiality Agreement that is signed by all such participants, including members of the NRC.

21. Candidates who sit for the NAPLEX register with NABP and provide demographic data and agree and acknowledge that the exam is proprietary and subject to copyright protections, and that activities or behavior that compromise the integrity of the exam will be pursued by NABP and reported to the state Boards of Pharmacy. Such warnings are contained in the Candidate Handbook and the registration materials.

22. As with all regulated professions, review courses designed to prepare candidates for the NAPLEX exam are widespread and generate significant revenue. As part of its security measures, NABP tracks these review courses, as well as the Internet, to ensure that no secure test questions are compromised. NABP staff also participate in NAPLEX review courses to monitor their content. Occasionally, egregious exam security issues such as the one in this case are uncovered.

23. Based upon information received by NABP regarding the provision of confidential NAPLEX test questions to attendees of review courses given by Flynn Warren (“Warren”) through the University of Georgia (and other universities as well) NABP launched an investigation into such allegations.

24. Two informants, professors at two schools of pharmacy, informed NABP of alleged dissemination and availability of NAPLEX items gathered and distributed via email by Warren. Such emails and attachments were forwarded to NABP as part of the investigation.

25. In particular, an email dated June 20, 2007 from Warren to a student at Samford University identifying NAPLEX items was forwarded to me and was received July 20, 2007 at 9:32am via my email address at NABP. I have maintained custody of this email and its attachments and have used it for purposes of NABP's investigation and assessment of the materials referenced therein. Affixed to the email was an attachment containing six-hundred and thirty-three (633) items, some containing boastful comments that the items were from the NAPLEX (referred to as the "633 items"). The June 20th email and attachment are affixed to this Declaration as Exhibit C.

26. Based upon NABP research, it was discovered that, in addition to previous review courses, a review course taught by Warren through the University of Georgia is scheduled to be given on August 8, 2007. Materials to be used in such course were purchased by Ms. Kerri Hochgesang from the Continuing Education Department of the University of Georgia. Such materials shall be referred to as "purchased materials." Ms. Hochgesang will provide a Declaration regarding the acquisition and contents of the purchased materials.

27. NABP is the holder of multiple copyright registration certificates for its NAPLEX examination questions because the NAPLEX item pool is regularly updated to reflect the changes related to modern-day pharmacy practice. The October 2006 copyright registration certificate for the entire pool of NAPLEX test questions, Registration No. TXu1-295-893, covers the NAPLEX examination questions that NABP staff have evaluated for purposes of comparison with the Warren materials, as more fully described below.

28. Under my direction and oversight, an assessment of both the “633 items” and the “purchased materials” was undertaken and, as of this Declaration, evaluation of the purchased materials is ongoing. NABP staff members Maria Boyle, Competency Assessment Manager, and Christy Lamb, Competency Assessment Program Analyst, performed the analyses.

29. For purposes of all assessments conducted by NABP related to this Declaration, including the “633 items” assessment and the “purchased materials” evaluation, such assessments were undertaken comparing such Warren materials against the NABP owned and copyrighted NAPLEX examination questions currently residing in the NABP item bank.

30. Specifically, the assessment involves a review of the numbered items in the “633 items” and the “purchased materials” and such materials prompt key-word searches in the NAPLEX operational pool. The operational pool consists of examination questions (items) that are classified as either being associated with a patient profile scenario or as a stand alone item. Key-word searches included drug names, diagnoses, disease states, dates on profiles, and drug therapy and outcomes. Many of the items contained in the attachments made references to options for keys (answers) and distracters (incorrect answers) for what appeared to be questions on the NAPLEX. The NAPLEX items that were located in the operational pool and appeared to be substantially similar to, or contained terms or phrases within the text of, the “633 items” or “purchased materials,” were identified and matched to the corresponding text from the “633 items” or “purchased materials.”

31. Ms. Boyle is a licensed pharmacist in good standing by the State of Illinois. She received her Bachelor of Science Degree in Pharmacy from the University of Illinois, her Masters of Science Degree in Biological Sciences from Chicago State University and is an Adjunct Faculty member teaching healthcare courses at Moraine Valley Community College. On a part-time basis, she practices pharmacy in a community practice setting.

32. Ms. Lamb is a licensed pharmacist in good standing by the State of Illinois. She received her Bachelor of Science Degree in Pharmacy from Midwestern University, and is certified by the American Pharmacists Association in Asthma, Osteoporosis, and Immunization as related to pharmacy practice. She is an Adjunct faculty member at Midwestern University teaching pharmacy courses. On a part-time basis, she practices pharmacy in a retail setting.

33. Ms. Boyle and Ms. Lamb have been involved in the assessment of the “633 items” and “purchased materials” and have, to date, spent in excess of 45 hours undertaking this complex analysis. The assessment of the “633 items” is complete and the assessment of the “purchased materials” is approximately 20% complete. I anticipate a significant increase in infringing items as the “purchased materials” are continuing to be assessed.

34. As of 12:00pm August 2, 2007, the assessment of the “633 items” reveals the duplication of numerous copyrighted items currently in use within the NABP NAPLEX item bank. Approximately fifty percent (50%) of the “633 items” are substantially similar to current NAPLEX test questions residing in the NABP item bank to the extent that, from a psychometric and statistical validity perspective, merit removal

from the NABP item bank, which would result in the loss of such items for inclusion on future NAPLEX examinations.

35. An assessment, as of 12:00pm August 2, 2007, of three of the .pdf files titled NAPLEX MATERIAL PART 2, 2006 INFO FOR NAPLEX, and NAPLEX SAMPLE TEST W ANSWERS on the disk titled NAPLEX REVIEW 2007 from the “purchased materials” reveals numerous copyrighted NAPLEX examination questions currently in the NABP item bank, and thus currently used on the NAPLEX. As of this Declaration, NABP has assessed approximately 20% of the “purchased materials,” and the evaluation continues. The substantially similar items number in excess of 150. Based upon the “purchased materials” reviewed to date, it is anticipated that the substantially similar numbers will increase.

36. Attached to this Declaration as Exhibit D is a report comparing infringing items from the “purchased materials” to copyrighted NAPLEX examination questions retrieved from NABP’s NAPLEX test question item bank. This report contains comparison data categorized by colors: green designates materials from NAPLEX MATERIAL PART 2, yellow designates 2006 INFO FOR NAPLEX, and blue designates NAPLEX SAMPLE TEST W ANSWERS. The first two pages of Exhibit D designate verbatim items, and the remainder of Exhibit D designates near verbatim or substantially similar items.

37. Further, the “purchased materials” contain a notation by Warren that he has retired from the University of Georgia as of July 1, 2007, but will continue to be providing the review courses. The notation references Warren’s continued availability through the University of Georgia. Attached as Exhibit E is a copy of such notation.

38. Also, through informants, NABP discovered that Warren was distributing a CD to attendees of his review courses. I received an email on July 20, 2007 with a string of emails between various individuals. Dr. Alan Spies and Dr. W. Steven Pray are professors that have identified certain activities and identifying materials (including a CD) that were available to participants in the Warren review courses. The string of emails was received by me on July 20, 2007 at 9:32 am at my email address at NABP. Attached to this Declaration as Exhibit F is a copy of such emails. These emails identify a CD distributed by Warren at the review courses.

39. Dr. Spies sent, via Federal Express, a copy of the CD, as well as what appear to be 2006 and 2007 pharmacy examination review course materials prepared for course attendees through the Samford University School of Pharmacy. I received such materials on July 31, 2007. Staff has not evaluated these materials; however I am maintaining them as of the date of this Declaration.

40. In the summer of 1994, based upon "tips" from multiple volunteers to NABP committees as well as an Executive Director of a member board, Warren was identified as an individual who was possibly gathering NAPLEX items (at the time the exam was referred to as the NABPLEX) through students and other means. At the time Warren, though already licensed as a pharmacist in North and South Carolina, was also seeking licensure in Alabama. Rather than relying on "licensure transfer," whereby his previous NAPLEX results could be used to substantiate competence without the necessity of taking the exam again, Warren had instead elected to sit for the NAPLEX again. Such activity raised concern that Warren was taking the NAPLEX in order to gather items rather than to attempt to "pass" the exam. NABP has since adopted exam

policies that prohibit individuals who have already passed the test from taking the NAPLEX again, unless it is required by the state into which licensure is sought.

41. Such informants alleged that Warren was asking students to remember NAPLEX items and tell him about them for placement in his review course materials. In fact, it was alleged that Warren “bet” with students on score issues and the like.

42. NABP undertook an investigation of Warren in mid-1994. This investigation ultimately culminated with a letter to Warren from counsel for NABP, to which Warren responded with a letter from Susan L. Jones, Associate Vice President for Legal Affairs at the University of Georgia. Negotiations ensued and the matter was eventually referred to Georgia Assistant Attorney General Patricia Guilday. The matter culminated in a Settlement Agreement and Release and exhibits, which is attached as Exhibit G to this Declaration. During the course of resolving that matter, counsel for NABP interviewed Warren regarding the nature of his illicit activities and the dissemination of course materials to candidates taking the NAPLEX. Warren informed NABP at that time that he had no materials in his possession that would indicate the individuals to whom his course materials were distributed, and he indicated that he did not regularly maintain such information while teaching his review courses. It was NABP’s suspicion that Warren intentionally destroyed or otherwise disposed of records that could be used to establish the students who received the infringing materials and whose minimum competence for licensure to practice pharmacy was in question.

43. NABP undertakes great measures to ensure validity and security as it develops, administers, and maintains the NAPLEX. Ensuring minimum competence

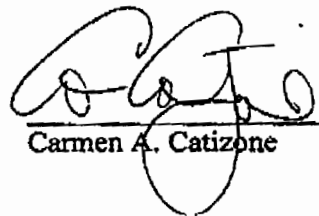
through an examination process as required by statutes for applicants seeking licensure as pharmacists is essential to the protection of public health.

44. A compromise of examination items will result not only in monetary damages to NABP, but will also compromise the licensure process used by the member boards, ultimately placing at risk the health, safety, and welfare of patients who rely upon pharmacists for competent pharmaceutical care.

45. Finally, the American Association of Colleges of Pharmacy (“AACP”) and NABP will be jointly hosting the District 3 annual meeting in Orlando, Florida from Sunday, August 5, 2007 through Tuesday, August 7, 2007. This annual meeting is attended by the executive director and/or management from NABP, as well as various representatives from the AACP and Colleges of Pharmacy from Georgia, Alabama, and Florida. The annual meeting is an opportunity for pharmacy professionals to meet and discuss issues of pharmacy policy and trends in the industry. It is NABP’s understanding that the Dean for the University of Georgia School of Pharmacy will be in attendance at this event, and while there, may gain some awareness of the actions being taken by NABP against Warren. If this occurs, Warren will inevitably receive notification and warning of the pending legal action.

46. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 02 day of August, 2007.



Carmen A. Catizone