

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS.

SUPERIOR COURT DEPARTMENT
CIVIL ACTION NO.

15-1968H

COMMONWEALTH OF MASSACHUSETTS,

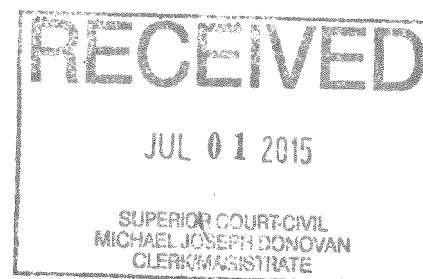
Plaintiff,

v.

FLORIDA MEN'S MEDICAL CLINIC, LLC
d/b/a MASSACHUSETTS MEN'S MEDICAL CLINIC,
MASSACHUSETTS MEN'S MEDICAL and MEN'S
MEDICAL CLINIC, MEN'S MEDICAL CLINIC, LLC,
KEVIN HORNSBY, M.D. and HEIDI HORNSBY,

Defendants.

COMPLAINT



I. INTRODUCTION

1. Attorney General Maura Healey, on behalf of the Commonwealth of Massachusetts, brings this civil action in the public interest, pursuant to G.L. c. 93A, § 4, and G.L. c. 12, § 10. Defendants engaged in a panoply of unlawful, unfair and deceptive acts and practices in the marketing, sale, delivery and billing for medications and services relating to the treatment of erectile dysfunction.

2. The Commonwealth of Massachusetts (the "Commonwealth") alleges that Defendants, collectively, unfairly and deceptively advertised the medical services and medications sold at their Framingham, Massachusetts medical facility, including misrepresenting the medications they sold for erectile dysfunction as new, unique to each patient, painless and with minimal or no side effects. In fact, these medications were not new, not unique to each patient, had pain as a known and common side effect and had a host of additional, potentially serious side effects, including priapism, which can itself cause penile tissue toxicity and worsen erectile dysfunction.

3. The treatment marketed by Defendants involved penile injections – a fact they deliberately omitted from their advertising and marketing. Defendants knew this omission was material and that if consumers knew that the procedure involved a needle, Defendants’ success at marketing and selling their treatment would have been, in Defendant Kevin Hornsby’s words, “dead in the water.” The Commonwealth alleges that while Defendants deceptively downplayed the risks of the treatment they marketed, they also deceptively exaggerated the failings of other medications and treatments for erectile dysfunction.

4. The Commonwealth also alleges that the Defendants collectively violated G.L. c. 111, § 56 by advertising, announcing, establishing, maintaining and being concerned in establishing and maintaining in Framingham, Massachusetts a clinic within the meaning of G.L. c. 111, § 52 without the required license.

5. The Commonwealth alleges as well that Defendant Florida Men’s Medical Clinic, LLC (“FMMC”) engaged in unfair and deceptive high-pressure sales tactics in the marketing and sale of medications in Massachusetts.

6. The Commonwealth alleges further that Defendant FMMC unfairly and deceptively represented that all medication sales were final and that medication could not legally be returned.

7. Finally, pursuant to the illegal, unfair and deceptive direction of Defendant FMMC, its employees who were not physicians, nurses or physician assistants performed medical services at Defendants’ Framingham facility relating to priapism, including penile injections, when there were no physicians present at that facility, in violation of Department of Public Health regulation.

8. Defendants’ advertising in Massachusetts was widespread, appearing in the Boston Herald, the Boston Globe, on the television and on the radio.

9. More than 4,000 consumers went to Defendants' Massachusetts facility and paid over \$5 million.

10. The Commonwealth seeks to enjoin Defendants from further unlawful conduct, recover payments taken from harmed consumers, require Defendants to disgorge ill-gotten gains and obtain civil penalties, attorneys' fees and costs.

II. JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to G.L. c. 93A, § 4, and G.L. c. 214, § 1 and over Defendants pursuant to G.L. c. 223A, § 3. Venue in this Court is proper under G. L. c. 93A, § 4, G.L. c. 214, § 5 and G.L. c. 223, § 5.

III. PARTIES

12. The Plaintiff is the Commonwealth of Massachusetts, represented by Attorney General Maura Healey, who brings this action in the public interest pursuant to the authority granted under G.L. c. 93A, § 4 and G.L. c. 12, §10.

13. Defendant Florida Men's Medical Clinic, LLC is a Florida limited liability company with its principal place of business registered with the Florida Secretary of State as 5728 Major Blvd., Suite 750, Orlando, FL 32819. It is not currently registered with the Secretary of the Commonwealth as a foreign corporation doing business in Massachusetts.

14. Defendant Men's Medical Clinic, LLC ("MMC") is a Florida limited liability company with its principal place of business registered with the Florida Secretary of State as 5728 Major Blvd., Suite 750, Orlando, FL 32819. It is currently registered with the Secretary of the Commonwealth as a foreign limited liability company doing business in Massachusetts with a business address of its principal office in the Commonwealth listed as 463 Worcester Road, Suite 206, Framingham MA 01701 and with FMMC listed as its manager.

15. Defendant Kevin Hornsby, M.D. (“Kevin Hornsby”) is a resident of Florida. He is a co-owner and a managing member of FMMC and the manager of MMC. He is not and has never been authorized, registered or licensed to practice medicine in the Commonwealth.

16. Upon information and belief, Heidi Hornsby is a resident of Florida. Heidi Hornsby was the Chief Executive Officer of FMMC starting in early 2014 and in that role had responsibility for FMMC’s marketing.

IV. FACTS

A. Background

17. In April 2012, FMMC filed a business certificate in Framingham, Massachusetts declaring that business was being conducted by FMMC under the name of Massachusetts Men’s Medical Clinic at 463 Worcester Road, # 206 in Framingham.

18. In April 2012, FMMC also registered with the Secretary of the Commonwealth as a foreign limited liability company doing business in Massachusetts.

19. Starting in or about May 2012, FMMC operated a medical facility at 463 Worcester Road, Suite 206, Framingham, Massachusetts that was referred to variously as Massachusetts Men’s Medical Clinic, Massachusetts Men’s Medical and Men’s Medical Clinic (“MMM”) that engaged in the provision of medical services, including the injection of medications.

20. FMMC has had a number of such medical facilities in several other states, including, but not limited to, Florida.

21. The Massachusetts Department of Public Health (hereafter “DPH”), an agency of the Commonwealth of Massachusetts that licenses “clinics,” as that term is defined by G.L. c. 111, § 52, never issued a license for MMM.

22. FMMC advertised MMM using the names Massachusetts Men's Medical Clinic, Massachusetts Men's Medical and Men's Medical Clinic.
23. FMMC advertised MMM in a variety of media, including, but not limited to, print, radio, television and the Internet.
24. Kevin Hornsby appeared in various advertisements for MMM.
25. FMMC contracted with third-party entities for physician services to be performed at MMM.
26. At MMM, Kevin Hornsby trained one or more of the physicians who worked there.
27. FMMC contracted directly with one or more physicians for the physician to be medical director of MMM.
28. FMMC hired, employed, trained and oversaw sales and other personnel at MMM, including non-physicians that performed penile injections.
29. Bills for services rendered at MMM contained FMMC's tax identification number.
30. Credit card payments for services rendered at MMM were directed to an FMMC bank account.
31. FMMC was lessee for MMM's offices at 463 Worcester Road, Suite 206, Framingham, Massachusetts.
32. In February 2013, FMMC cancelled its registration as a foreign limited liability company doing business in Massachusetts, stating as the basis for its cancellation that it was not conducting business activities in Massachusetts.

33. In fact, FMMC continued to operate MMM, as described herein, after February 2013.

34. Through June 6, 2014, over 4,300 patients had been seen at MMM and had paid over \$5,960,000.

35. In September 2014, MMC registered with the Secretary of the Commonwealth as a foreign limited liability company doing business in Massachusetts.

36. Defendants were well aware that FMMC needed significant volumes of patients at MMM and for those patients to pay amounts averaging in the hundreds of dollars for FMMC to generate net revenue on MMM's operations.

37. For example, in September 2014, FMMC needed patients at MMM to pay over \$987 each to cover the costs of advertising alone (not covering other overhead such as lease payments and salaries).

38. FMMC's high volume business model increased the pressure to attract many patients and to get them each to buy thousands of dollars of medication.

39. In 2014, the Attorney General's Office issued a civil investigative demand to FMMC pursuant to G.L. c. 93A, § 6 (the "CID").

B. Unfair and Deceptive Advertising

40. Defendants' advertising for MMM's services and medications was unfair and deceptive in a host of ways, including:

- a. referring to the medications they advertised as new or "newest" when, in fact, they were decades old and older than the approval by the United States Food and Drug Administration ("FDA") of medications such as Viagra for treating erectile dysfunction;

- b. stating or implying that the medications they advertised were “unique,” “individually blended,” “custom blended just for you,” and personalized based on the patient’s biochemistry when (i) the advertised medications were generally known combinations of medication, (ii) the medications were not unique to any patient, (iii) the test dose given to patients was generally taken off the shelf rather than individually or custom blended for them and (iv) the medications were not personalized based upon patients’ biochemistry, which Defendants did not test;
- c. stating that the treatment they advertised was painless or virtually painless when pain was a known potential side effect;
- d. stating or implying that the medications they advertised had no side effects, minimal side effects or were without the side effects of Viagra and similar medications, when the medications they advertised have, among many other side effects, the serious side effect of priapism, which is also a potential side effect of Viagra;
- e. in order to make deceptive comparisons, implicit or explicit, to the medications they were advertising, stating without sufficient scientific basis that Viagra, Levitra and Cialis do not work for 70% or most of men (or that they are only successful in 30% of men);
- f. referring to MMM as a “clinic” when it was not a DPH-licensed clinic;
- g. stating or implying that the treatment they advertised would work for all men regardless of medical condition when there are known contraindications for it;

- h. stating or implying that the treatment they advertised eliminates erectile dysfunction in just one visit, even though FMMC acknowledges that it does not do so;
- i. using false testimonials in advertisements;
- j. stating or implying in advertising that Kevin Hornsby was involved in treatment at MMM when he has never been licensed to practice medicine in Massachusetts;
- k. referring to a local doctor, physician, doctors or physicians in advertisements where the only named doctor was Kevin Hornsby who never has been licensed to practice medicine in Massachusetts; and
- l. stating falsely that the “first 37 callers” would receive special treatment or otherwise creating false urgency with respect to seeking Defendants’ services.

i. Newspaper Advertising

41. Around the time of FMMC’s opening of MMM in May 2012, FMMC advertised MMM in print in Massachusetts, including in the Boston Herald, with an advertisement announcing the opening of an “Erectile Dysfunction Clinic” (“the Opening Ad”). Attached as Exhibit 1 hereto is a true and correct copy of this advertisement.

42. The Opening Ad discussed “Local physicians at a new medical clinic in Framingham” but named only one doctor – Kevin Hornsby.

43. In fact, Kevin Hornsby has never been registered with the Massachusetts Board of Registration in Medicine or authorized to practice medicine in Massachusetts and, thus, has never been an authorized local physician in Massachusetts.

44. The Opening Ad stated the “[l]ocal physicians” at MMM were “offering the first 37 callers a free in-office medication dose” and that “[o]penings are filling quickly for the free in-office medication dose, after that the normal fees will be charged.”

45. In a letter produced by FMMC to the Commonwealth pursuant to the CID, FMMC wrote to the Massachusetts Better Business Bureau in October 2012 stating, “We initially decided to offer a free in-office medication test dose to the first thirty-seven men, which gives them a \$100 savings, instead paying only \$199. We have decided to continue this free offer past the first thirty-seven patients for a bit longer, so we can continue to offer this great savings.”

46. Upon information and belief, FMMC did not charge anyone separately for the first in-office medication dose.

47. The Opening Ad did not disclose that the medications it referenced were applied by an injection into the penis.

48. This treatment is known as intracavernous injection (“ICI”).

49. The Opening Ad’s failure to disclose that the medications it referenced were applied by an injection into the penis was a deliberate omission.

50. The fact that the medications were applied by an injection to the penis was a material fact.

51. FMMC advertised MMM in print in Massachusetts, including in the Boston Herald in 2013, with an advertisement containing the statement “Local Doctor Says Suitable for Any Age or Medical History” (the “Local Doc - Any Medical History Ad”). Attached as Exhibit 2 hereto is a true and correct copy of this advertisement.

52. In fact, ICI, which was generally used at MMM, is contraindicated for certain medical conditions, including sickle cell disease.

53. The only doctor named in The Local Doc - Any Medical History Ad was Kevin Hornsby, whose picture also appeared in it.

54. Thus, the Local Doc - Any Medical History Ad unfairly and deceptively held Kevin Hornsby out as an authorized local, Massachusetts doctor.

55. The Local Doc - Any Medical History Ad contained the statement

"One-size-fits-all medication may soon be a thing of the past." That statement from the renowned Johns Hopkins Hospital refers to modern medicine's new ability to personalize prescription medications to the biochemistry of the patient. Personalized prescription medicine is also the basis of a successful erectile dysfunction clinic in Framingham boasting a 98% success rate ... and an amazing guarantee!

56. In fact, no testing of patients' biochemistry (or blood work of any kind) was done at MMM, and patients at MMM were not prescribed medication personalized on the basis of their biochemistry.

57. The Local Doc - Any Medical History Ad contained the statement

The doctors at Massachusetts Men's Medical Clinic review the patient's medical history and conduct a thorough examination including a sonogram. Based on these findings the clinic's pharmacy custom blends 4 FDA-approved ingredients into one of 180 different combinations.

58. Patients' test doses at MMM were generally not blended by a pharmacy based upon examination findings, rather patients' test doses were chosen from fewer than twenty formulas, consisting of four combinations of two to four medications combined in particular ratios, that had been pre-blended by a compounding pharmacy.

59. The Local Doc - Any Medical History Ad did not disclose that the blended medications it referenced were applied by an injection into the penis.

60. The Local Doc - Any Medical History Ad stated, "The first 37 callers will receive their in-office personalized prescription medication dose free. To get your FREE medication dose, call NOW. After that, normal office rates will be charged."

61. FMMC advertised MMM in print in Massachusetts, including in the Boston Globe in 2013, with an advertisement containing the headline "*I used* to have Erectile Dysfunction" attributed to an unnamed "Massachusetts Men's Medical Clinic patient" (the "Cured Testimonial Ad"). Attached as Exhibit 3 hereto is a true and correct copy of this advertisement.

62. FMMC was not able, in responding to the CID, to identify the patient whom its advertisement claimed gave this statement.

63. Indeed, an FMMC advertising agency stated that the advertisement was run "across all markets with the same 'customer testimonial' and just changing the name of the clinic that the person had said it at."

64. The Cured Testimonial Ad was unfair and deceptive in ways similar to other of FMMC's advertising.

65. FMMC advertised MMM in print in Massachusetts, including in the Boston Herald in 2014, with an advertisement containing the statement "Local Doctor Says . . . Your Sex Life Is Not Over!" (the "Local Doc - Not Over Ad"). Attached as Exhibit 4 hereto is a true and correct copy of this advertisement.

66. The Local Doc - Not Over Ad was unfair and deceptive in ways similar to other of FMMC's advertising.

67. The Local Doc - Not Over Ad referred to MMM as "Men's Medical Clinic."

68. The Local Doc - Not Over Ad stated, "The clinic is now offering an in-office trial-dose of medication while supplies last."

69. FMMC offered an in-office trial dose of medication at MMM from MMM's opening in 2012, and it was FMMC's intention that supplies of trial doses never run out at MMM.

70. FMMC repeatedly advertised MMM in print in Massachusetts, including in the Boston Herald in October 2014, with an advertisement containing the bolded headline "Erectile Dysfunction Clinic in Boston" (the "Boston Ad").

71. The Boston Ad was unfair and deceptive in ways similar to other of FMMC's advertising.

72. The Boston Ad stated "Local physicians at a medical clinic in Framingham are so sure their medication will help men with erectile dysfunction, they are offering the first 37 callers an in-office trial dose."

73. In fact, the offer of the in-office trial dose was not limited to the first 37 callers.

74. The Boston Ad stated, "Men's Medical Clinic custom blends over 180 combinations of medications for each patient. It's called the 'Hornsby Method' developed by Kevin Hornsby, M.D. author of the book, *'A Doctor's Guide to Erectile Dysfunction.'*"

75. In fact, FMMC has stated that MMM did not blend any medications.

76. The "Hornsby Method" is terminology that appeared only in FMMC's advertising.

ii. Radio Advertising

77. Starting in 2012, FMMC ran radio advertisements in Massachusetts for MMM in which the speaker was identified as "Kevin Hornsby, MD."

78. Some of FMMC's radio advertisements in Massachusetts for MMM in and after 2012 in which the speaker was identified as "Kevin Hornsby, MD" stated "Men's Medical can help you now, regardless of your age, medical history, prostate problems or diabetes."

79. Some of FMMC's radio advertisements in Massachusetts for MMM in and after 2012 in which the speaker was identified as "Kevin Hornsby, MD" stated "There's no surgery, just the newest available safe and effective medications, custom blended just for you."

80. In fact, the medications that were injected in a blended form at MMM were not the newest available but have been available since as early as the 1980s, earlier than the medications marketed as Viagra, Cialis and Levitra were FDA-approved to treat erectile dysfunction.

81. Some of FMMC's radio advertisements in Massachusetts for MMM in which the speaker was identified as "Kevin Hornsby, MD" stated "Our doctors create a custom blend of safe FDA medications just right for you."

82. The doctors at MMM did not blend medications for individual patients (or otherwise).

83. Some of FMMC's radio advertisements in Massachusetts for MMM described a "Men's Medical Clinic \$99 February Special" and stated that Kevin Hornsby and "his team of doctors can help you now, regardless of your age or medical history, even if you have prostate problems or diabetes" and that "The clinic's goal is to deliver immediate results – there's no surgery, just the newest available safe and effective medications, custom blended just for you."

84. Radio ads as recently as May 2014 advertising a "Men's Medical Clinic \$99 June Special" also stated that Kevin Hornsby and "his team of doctors can help you now, regardless of your age or medical history, even if you have prostate problems or diabetes" and that "The

clinic's goal is to deliver immediate results – there's no surgery, just the newest available safe and effective medications, custom blended just for you."

85. FMMC's radio advertisements in Massachusetts did not disclose that the blended medications they marketed were applied by an injection into the penis.

iii. Television Advertising

86. In and/or after 2012, FMMC ran television advertisements on Massachusetts television stations for MMM featuring Kevin Hornsby.

87. In one such television advertisement, Kevin Hornsby was shown and stated:

Please listen to me. I'm Doctor Kevin Hornsby, and if you suffer from any type of ED or PE, I can help you now regardless of your age or medical history, even if you have prostate problems or diabetes. There's no pain or surgery – just the newest safe and effective medications custom blended just for you. I'm so sure you'll have a positive reaction to the medication the first visit that if you don't it's free, guaranteed. If Viagra and Cialis have let you down, call now.

88. At different points during this television commercial the following text appeared on the screen: "Dr. Kevin Hornsby, M.D. Men's Medical Clinic," "Call now for a free offer (617) 849-9745" and "Call Dr. Hornsby's office near you for this FREE offer! (617) 849-9745 www.MassMensMedical.com."

iv. Internet Advertising

a. MMM Websites

89. Starting in 2012, FMMC advertised MMM through websites, including websites at the addresses www.massmensclinic.com and www.mensmedicalclinic.com/massachusetts (each an "MMM Website").

90. A page on an MMM Website advertising MMM in 2012 that was available for viewing in Massachusetts at the web address www.massmensclinic.com/index (the "2012 MMM

Homepage”), a page on an MMM Website advertising MMM in 2013 that was available for viewing in Massachusetts (the “2013 MMM Homepage”) and a page on an MMM Website advertising MMM in 2014 that was available for viewing in Massachusetts at the web address www.mensmedicalclinic.com/massachusetts (“2014 MMM Homepage” and, collectively with the 2012 MMM Homepage and the 2013 MMM Homepage, the “MMM Homepages”) stated, “Our medical doctors can help you eliminate erectile dysfunction and premature ejaculation with JUST ONE VISIT.”

91. In fact, Defendants and the physicians at MMM were not able to eliminate erectile dysfunction with just one visit.

92. Kevin Hornsby was the only doctor named on the MMM Homepages and his picture appeared on them.

93. The 2014 MMM Homepage had “Men’s Medical Clinic” at its top left and referred to “Massachusetts Men’s Medical Clinic.”

94. The 2012 MMM Homepage and 2013 MMM Homepage under the heading “Popular Prescriptions Don’t Always Work and Can Be Dangerous” stated, “An estimated 70% of men do not respond to Viagra, Levitra or Cialis, medications which can also have serious side effects. Our custom blended medication works for 98% of men – without those side-effects – even if you don’t respond to other pills and drugs.”

95. The 2014 MMM Homepage stated, “Many men do not respond to Viagra, Levitra or Cialis. Our custom blended medication works for 98% of men – without those side-effects – even if you don’t respond to other pills and drugs.”

96. In fact, priapism is a serious side effect of Viagra, Levitra, Cialis and the blended medications injected and sold by FMMC at MMM.

97. Indeed, in the period August 22, 2013 – May 21, 2014, FMMC received calls from approximately 100 MMM patients relating to priapism.

98. FMMC was unable to provide, in response to the CID, a basis for its blanket claims that an estimated 70% of men do not respond to Viagra, Levitra or Cialis.

99. Medical literature produced by FMMC indicates that significantly more than 30% of men respond to Viagra, Levitra or Cialis.

100. Further, FMMC has, in fact, sold consumers at MMM medications with the active ingredients in Viagra, Levitra and Cialis, including when the consumer has suffered priapism from ICI.

101. In at least one instance, FMMC prescribed tadalafil to a consumer who had reported having poor results with Cialis – whose active ingredient is tadalafil – before coming to MMM.

102. The MMM Homepages stated, “Our doctors evaluate you to find the unique blend of medications that work”

103. In fact, patients at MMM did not receive a unique blend of medications; multiple patients at MMM received the same medications blended in the same ratios, even in the same dosage.

104. The 2012 MMM Homepage and 2013 MMM Homepage stated “It’s safe, easy, virtually painless, and for most men works regardless of your past medical history.”

105. In fact, pain is a known side effect to the injection of the blended medications referenced by FMMC’s advertisements for MMM.

106. The MMM Homepages did not disclose that the blended medications they marketed were applied by an injection into the penis.

107. In 2012 and 2013, the MMM Website had a “testimonials” webpage (the “Testimonial Webpage”).

108. The Testimonials Webpage contained false testimonials.

b. KevinHornsby.com

109. The website at www.kevinhornsby.com contained a webpage of blog entries that were available in Massachusetts as recently as October 2014 (the “Hornsby Blog”).

110. The Hornsby Blog contained a number of entries that are described as written by Kevin Hornsby and dated in 2014.

111. One post on the Hornsby Blog listed as “Written by Kevin Hornsby,” dated July 10, 2014, stated, “Dr. Kevin Hornsby has worked extensively trying to find each patient the right medicine, as a result, the clinics boast over 180 different medications.”

112. In fact, MMM had fewer than twenty medications and only five that were used in the blended medication.

113. Another post on the Hornsby Blog listed as “Written by Kevin Hornsby,” dated June 17, 2014, stated, “At one of Kevin Hornsby’s many Men’s Medical Clinics, physicians make a diagnosis based on the patient’s medical and sexual history.”

114. In fact, FMMC’s employees at MMM were directed by FMMC to input the same diagnosis into the medical records for every patient.

115. Another post on the Hornsby Blog listed as “Written by Kevin Hornsby,” dated April 11, 2014, stated, “More than 70% of men have tried Viagra, Cialis, and Levitra and failed to see results.”

c. Superpages Ad

116. As recently as October 2014, there was an advertisement for MMM, which referred to it as “Massachusetts Men’s Medical Clinic” and was available in Massachusetts on the website www.superpages.com (the “Superpages Ad”).

117. The Superpages Ad contained the statement “The Massachusetts Men’s Medical Clinic’s physicians deliver results for 98% of patients, compared to the 30% success rate seen among users of Levitra, Viagra and Cialis.”

118. FMMC was unable to provide, in response to the CID, a basis for its claims that there is only a 30% success rate among users of Viagra, Levitra or Cialis and has produced medical literature that indicates that, in fact, there is a success rate of substantially greater than 30% for users of Viagra, Levitra or Cialis.

v. Other Printed Media

a. Brochures

119. FMMC mailed, and made available at MMM, a brochure to market MMM (the “Brochure”), which referred to MMM as Massachusetts Men’s Medical Clinic.

120. The Brochure was given to every consumer coming to MMM.

121. The Brochure contained the statement “Our medical doctors can help most men eliminate erectile dysfunction and premature ejaculation with JUST ONE VISIT.”

122. The Brochure contained the statement “Our prescription medication, individually blended for each patient, works when everything else fails.”

123. The test doses given to patients at MMM were generally not individually blended for them.

124. The Brochure contained the statement “It’s safe, easy, virtually painless and works regardless of your past medical history.”

125. The Brochure contained the question and answer

Who are the doctors treating me?

- Headed up by our national medical director Dr. Kevin Hornsby, M.D., the physicians at Massachusetts Men’s Medical Clinic have a strong track record in the area of men’s sexual health and are committed to your satisfaction. They are experienced professionals who understand your needs and are dedicated to providing safe and effective treatments on an individual basis, regardless of age or medical condition.

126. Urology is the medical specialty for the treatment of erectile dysfunction.

127. No urologist worked at MMM.

128. Kevin Hornsby has not been a urologist.

129. The State of Florida Department of Health filed an administrative complaint (the “Florida Administrative Complaint”) against Kevin Hornsby in 2013 that alleged, among other things, that he failed to refer a patient to a urologist and treated the patient for erectile dysfunction by prescribing an injection.

130. In June 2014, the Florida Board of Medicine entered a final order approving and adopting a settlement agreement with Kevin Hornsby relating to the Florida Administrative Complaint that, among other things, imposed a \$20,000 fine.

131. The Brochure under the heading “Popular Prescriptions Don’t Always Work and Can be Dangerous” contained the statement “An estimated 70% of men do not respond to Viagra, Levitra or Cialis, medications which can also have serious side effects. Our custom blended medications works for 98% of men – without those side-effects – even if you don’t respond to other pills and drugs.”

132. The Brochure under the heading “We offer safe treatment by caring, licensed professionals...” contained the statement “The patients at Massachusetts Men’s Medical Clinic receive top-quality care by licensed physicians who are extensively trained in erectile dysfunction. Our experienced staff has over 50 combinations of medications available to customize a treatment plan for your unique situation.”

b. Magazine article reprints

133. FMMC made available in Massachusetts to market MMM a reprint of an article from Physician Times Today (the “Reprint”).

134. The Reprint contained the statement

When experiencing issues with their sexual health, most men handle the problem in one of two ways. They either accept the loss of their sex life as inevitable, or they follow the advice seen on thousands of TV commercials and ask their doctor about one of the well-known prescription options available.

What they might not know is that for 70% of patients – that’s 70%! - these medications simply don’t work. In fact, for some men, they can even be dangerous. Luckily, there is a third, better way that goes beyond the ‘one-size-fits-all’ approach to sexual dysfunction. Dr. Kevin Hornsby and the Men’s Medical Clinics are revolutionizing the way doctors deal with male dysfunction, with completely personalized treatments that are fast, non-surgical, easy and painless.

C. Unfair and Deceptive Marketing and Sales

135. FMMC engaged in unfair and deceptive acts and practices in marketing and selling MMM’s services and medications.

a. Telephone Scripts

136. FMMC’s employees had scripts for use in their telephone interactions with potential patients, including those who called in response to advertisements.

137. An FMMC script from April 2012 contained the preface “Since Dr. Hornsby is not licensed in Massachusetts please use the script below when discussing what doctor Boston patients will be seeing,” but the script began, “this is Dr. Hornsby’s office.”

138. An email in April 20, 2012 from an individual with an FMMC email address to others involved in marketing for FMMC stated, “based on the script information you sent for Boston, I have a question: If Dr. Hornsby isn’t licensed in Mass, should we still begin the script with ‘this is Dr. Hornsby’s office’?”

139. Another FMMC script from 2012 with “Boston” at the top (the “Massachusetts Script”), also directed the FMMC employee to say “this is Dr. Hornsby’s office.” Attached as Exhibit 5 hereto is a true and correct copy of this script.

140. The Massachusetts Script bore a copyright mark of “2012 FMMC, LLC.”

141. The Massachusetts Script contained a “WARNING: UNDER NO CIRCUMSTANCES SHOULD THIS SCRIPT BE MODIFIED IN ANY WAY. YOU MUST FOLLOW IT AT ALL TIMES, WITHOUT EXCEPTION. DEVIATING FROM THIS SCRIPT IS GROUNDS FOR IMMEDIATE TERMINATION.”

142. An FMMC Script named by FMMC as “Call Center Script” (the “Call Center Script”) began, “Thank you for calling the Men’s Medical Clinic.” Attached as Exhibit 6 hereto is a true and correct copy of this script.

143. The same is true of a script named by FMMC as “MMC Inbound Script 10-2014” (the “MMC Script,” along with the Call Center Script, the “General Scripts” and along with the Massachusetts Script and the Call Center Script, the “Pitch Scripts”), which also began, “Thank you for calling the Men’s Medical Clinic.” Attached as Exhibit 7 hereto is a true and correct copy of the MMC Script.

144. The Pitch Scripts directed the FMMC employees to state to consumers, “I can tell you the cost” and will be “more than happy to answer any questions you” may have.

145. The Pitch Scripts, deceptively suggested that FMMC would disclose the cost of the treatment FMMC marketed.

146. The Pitch Scripts, while directing that the \$199 price be stated, deliberately sought to avoid any further discussion of price - because FMMC, in fact, hoped to sell to patients medication for which it would charge them thousands of dollars - by moving to a deceptive disparagement of Viagra, Levitra and Cialis.

147. For example, the General Scripts directed the FMMC employees to state to consumers that the cost of the appointment, ultrasound and light dose (or just the appointment and ultrasound) was “only \$199.00” and then directed the FMMC employees to continue, without a pause, by asking “Have you tried Viagra, Cialis or L[e]vitra?” and then stating “Those drugs have mixed results, they help less than half the men, and there can be serious side effects. There’s better and more effective medications out there. Our Doctor uses over 180 combinations of medications, all FDA approved and custom blended for each patient.”

148. The Pitch Scripts did not disclose the side effects of the medications used by MMM in ICI.

149. Thus, the Pitch Scripts deceptively exaggerated the failings of Viagra, Levitra and Cialis while deceptively concealing side effects from the injection and medication used by FMMC, including at MMM, and deceptively misrepresenting that the combined medications were custom blended for each patient.

150. The Pitch Scripts directed the FMMC employees to state to consumers, “Normally, we’re way overbooked, but I might be able to squeeze you in the next few days.”

151. The Massachusetts Script contained the direction “ALWAYS PUSH FOR FAST APPOINTMENTS – SAME DAY OR NEXT DAY!!”

152. The Call Center Script directed the FMMC employees “Use your normal technique for creating urgency and that we book up quickly.”

153. Thus, FMMC directed its employees to deceptively create a false sense of urgency to convince consumers to book appointments, including at MMM.

154. The Massachusetts Script contained answers to “frequently asked questions.”

155. The Massachusetts Script directed FMMC’s employees to respond to the question “What about the ‘Free’ first 37 patients offer?” by stating,

We’ve got 12 of those spots left, and I can lock one in for you. It’s normally \$299, but with the free in-office medication dose you only have to pay \$199, which is for the doctor exam and ultra-sound test. It’s important we book an appointment now to save this \$100, you can always call and change it later.

156. The Massachusetts Script directed FMMC’s employees to respond to the question “How much does the medication cost?” by stating,

It depends on what medication the doctor prescribes and also how often you have sexual activity. It IS affordable and we have patients from all walks of life, elderly, social security, fixed income, the cost IS reasonable and affordable and we take all the credit cards.

157. In fact, FMMC routinely charged patients at MMM thousands of dollars for medication.

158. The Massachusetts Script directed FMMC’s employees to respond to the question “What kind of medicine do you use?” by stating,

We try to give every patient what’s called a sublingual. A sublingual, as opposed to a pill that goes down your stomach and mixes with the food you eat, you put the sublingual underneath your tongue and let it dissolve, it never goes through your stomach. It’s MUCH more effective and without the side effects of Viagra, Livitra or Cialis. We also have medicine that’s applied directly to the penis. It depends on what the doctor thinks will work best for you.

159. FMMC did not try to give a sublingual to every patient.

160. The sublinguals sold by FMMC contained the same active ingredients as Viagra, Cialis or Levitra and, thus, had the capacity to cause similar side effects as theirs.

161. The Massachusetts Script directed FMMC's employees to respond to the question "Is this an injection?" by stating,

We try to give every patient a sublingual. When you come in, the doctor is going to perform the ultrasound test and try to qualify you for the sublingual. At that time he'll give any other options that you have.

The Massachusetts Script then directed FMMC's employees "ONLY if they still ask 'Is this an injection?'" to say "Have you tried an injection, or is that what you want?" The Massachusetts Script then directed FMMC's employees to get consumers' response and if the consumers said yes and that it did not work, to then say,

The doctor might have given you Caveject, some urologists use this, you stick a large needle in your penis, and it doesn't work for most men. That medicine is the same for everybody, one-size-fits-all. Our medication is custom blended just for you, guaranteed to work. We don't have patients stabbing a needle in their penis, but one of our treatments uses a little push-button applicator, it looks kind of like a flash-light, and it applies medicine to the penis. It's virtually painless, but there are other options, and the doctor will determine what's best for you."

162. The ICI treatment advertised, marketed and sold by FMMC, including at MMM, required patients to inject their penises with a needle (or to have someone else inject the patients' penises) each time they wanted to use the medication. The ICI treatment was not applied "to the penis" it is injected into the penis and generally contained amongst its blended ingredient the main ingredient in Caverject, prostaglandin E1 (in the form alprostadil).

b. Consent Form

163. FMMC required consumers at MMM to sign an "Informed Patient Consent Form" ("Consent Form") in order to receive treatment.

164. The Consent Form stated “In the next step, the doctor often uses an auto-applicator to apply medication to the spongy tissue of the penis. This is a painless procedure.”

165. The Consent Form did not disclose that the “auto-applicator” injected the medication into the penis and did not disclose that pain is a known side effect of ICI.

166. Consumers at MMM generally did not learn that they would be undergoing a penile injection until minutes before the procedure.

167. Some consumers upon learning that the medication was applied by an injection into the penis refused to go forward with the treatment.

168. One Massachusetts consumer wrote to Kevin Hornsby saying

The Doctor who interviewed me was very professional but left the ‘kicker’ until the end. “Stick a sharp object into my junk?” That’s a ‘Non Starter’ in any interview. I find the propo[]s[al] to be mis[]leading and dishonest[]. If your medicine is such a wonder, why not a[n] oral application?

c. Physician Script

169. In May 2012, Kevin Hornsby sent an email to physicians, including at MMM, with the subject of “Mens Clinic Physician Script” (“Hornsby Script Email”).

170. Kevin Hornsby stated in the Hornsby Script Email

Please use this physician script as a guideline for you. It all boils down to words: 20 or less probably-which ones we choose , when we say them and the way we say them. I have made these statements to thousands of men, refining them and picking them down to single words and timing. Patients quickly exclude themselves from effective therapies all too often and too quickly because they conjure up a fantastical image of a syringe 1 foot long and a needle used to torture prisoners in medieval times. Once they see the procedure- they then understand,

We all must choose our words with care in this business; needles and penis’s [sic] in popular culture don’t mix- but they are the key to a miracle to restoring a mans [sic] sex life- a priceless part of life.

Please hold these words with care and do not distribute them. They are intellectual property and protected for clinic use only.

171. Within the portion of the Hornsby Script Email headed "General Script for ED" (the "Hornsby ED Script"), Kevin Hornsby wrote,

-The last time you took Viagra/Cialis/Levitra...did you have moderate or poor results?
-side effects? headache, congestion, blue vision? see these meds dilate vessels all over your body- can be dangerous...

172. Within the Hornsby ED Script, Kevin Hornsby also wrote,

- [] Sir.....the medicine that will help you is a liquid....it is a liquid
- we place it in an applicator shaped like my pen (holding it up...NOT the actual applicator-use your ball point pen.[]]"

173. Within the Hornsby ED Script, Kevin Hornsby wrote,

- when you push a button a SMALL HAIRLINE INJECTOR WILL DROP DOWN AND SLIP UNDER THE SKIN- IT WONT HURT...WILL FEEL LIKE A THUMP BECAUSE ITS ABOVE THE NERVES IN THE PENIS (Theres [sic] your twenty critical words- if you say shot/gun/needle.....we are dead in the water and the patient will RUN out fast- i wouldn't blame him).

d. Deceptive reassurance by those giving injections

174. All or almost all penile injections at MMM were given by FMHC employees who were not physicians, physicians' assistants or nurses (the "Injectors").

175. At least at certain times, the Injectors selected the formula of medications to inject into consumers' penises.

176. FMHC directed the Injectors that after giving injections of the blended medications "No matter the firmness of the reaction, sound optimistic and happy for the patient."

177. FMHC paid the Injectors in part on commission, at least at certain times determined as a percentage of net sales.

178. At least for certain time periods, FMMC paid the Injectors more in commission-based pay than in non-commission-based pay.

e. Clothing and Lack of Identification

179. FMMC's employees at MMM, including individuals without any medical licensure, wore white lab coats or medical scrubs.

180. Through May 2014, FMMC required its employees, including at MMM, who sold quantities of medication to consumers, but had no medical licensure, to wear white lab coats.

181. As medical scrubs and white coats are generally worn in medical settings by medical personnel, these practices falsely suggested to consumers that these unlicensed personnel were licensed medical professionals.

182. In May 2012, FMMC did not require employees at MMM who treated patients to wear identification badges.

183. At least at certain times, FMMC's employees and physicians at MMM who examined, observed and treated patients failed to wear identification badges that readily disclosed their first name, licensure status, if any, and staff position.

184. This fostered the false suggestion that unlicensed personnel at MMM were licensed medical professionals.

f. High Pressure Sales

185. FMMC sold quantities of medication to consumers at MMM after the consumers were injected with a test dose, and sometimes after they received antidotes to counteract the effects of the test dose.

186. The FMMC employees selling the quantities of medication at MMM (the "Salesmen") held no medical licensure or certification from the Commonwealth or elsewhere.

187. Salesmen engaged in high-pressure sales of medication to consumers at MMM.

188. At times, Salesmen told consumers that they could only buy the blended medications in quantities of hundreds of doses, costing thousands of dollars.

189. Salesmen dressed in white coats like the physicians at MMM or in medical scrubs like the Injectors.

190. FMMC's acts misled consumers into believing that Salesmen were medical personnel.

D. Unfair and Deceptive Misrepresentations as to Refunds and Returns

191. The Consent Form stated "Any medications ordered by me are *non-returnable* in accord with applicable laws."

192. FMMC was not able, in responding to the CID, to identify any laws that support its claim that applicable laws made medications categorically non-returnable.

193. In fact, there are no such laws.

194. Indeed, 21 CFR § 211.204 regulates returned drug products, reflecting that the return of drug products is contemplated by Federal regulation.

195. FMMC required consumers at MMM to sign an "Acknowledgement of Receipt of Materials & Information" form ("Acknowledgement of Receipt Form").

196. The Acknowledgement of Receipt Form stated "I also agree to abide to the clinic's policy and adherence to the Federal Law which states the absolute no return policy of prescribed medications."

197. FMMC was not able, in responding to the CID, to identify any Federal law that states an "absolute no return policy of prescribed medications" or otherwise supports its claim about Federal law.

198. In fact, there is no such Federal law.

199. FMMC had consumers at MMM sign a medical chart form (the “Medical Chart Form”).

200. The Medical Chart Form contained the following statement above the patient’s signature line, “by law prescription drugs are not returnable.”

201. FMMC was unable to articulate, in response to the CID, any law that makes prescription drugs generally not returnable.

202. In fact, there is no such law.

203. The Medical Chart Form also contained text indicating that services were rendered at MMM, which text lists FMMC’s tax identification number.

204. FMMC provided consumers at MMM with credit card slips that stated “Final Sale, No Refunds.”

205. These forms made no exceptions for defective, non-conforming, or unmerchantable goods or goods not fit for their particular purpose.

E. Unlawful Provision of Medical Services Unsupervised by Physicians

206. At FMMC’s direction, the Injectors performed medical services at MMM relating to priapism, including penile injections, when there were no physicians present at MMM.

F. Notice of Consumer Harm

207. FMMC received scores of complaints, including complaints directed specifically to Defendant Kevin Hornsby.

G. Notice from DPH

208. Since 2012, DPH communicated to Defendants FMMC and Kevin Hornsby that a clinic, within the meaning of G.L. c. 111, § 52, must have a license from DPH pursuant to G.L.

c. 111, § 51, and that operation of a non-licensed clinic is subject to penalties under G.L. c. 111, § 56.

209. Despite such notification from DPH, FMMC and Kevin Hornsby failed to obtain a clinic license for MMM.

V. NOTICE UNDER G.L. C. 93A

210. On February 5, 2015, the Attorney General's Office notified Defendants of its intention to file this suit and offered Defendants an opportunity to confer regarding this action, as required by G.L. c. 93A, § 4.

FIRST CAUSE OF ACTION
(Violation of G.L. c. 93A, § 2)

211. The Commonwealth incorporates by reference the allegations in the foregoing paragraphs of this Complaint as if fully alleged herein.

212. Defendants engaged in unfair and deceptive acts and practices in Massachusetts in violation of G.L. c. 93A, and the regulations promulgated thereunder, including but not limited to 940 CMR 3.00 et seq., by, without limitation, using misleading advertising and misleading marketing.

213. Defendants' misleading advertising and marketing of the services and medications FMMC sold had the effect of deceiving buyers or prospective buyers in violation of 940 C.M.R. §§ 3.05(1) and 3.16(2).

214. Defendants engaged in unfair and deceptive acts and practices and violated G.L. c. 93A directly (and by operation of 940 C.M.R. § 3.16(3) through violating G.L. c. 111, § 56, which is intended to protect the public's health, safety and welfare) by, without limitation, falsely advertising MMM as a clinic, without having a clinic license from DPH.

215. Defendant FMMC also engaged in unfair and deceptive acts and practices and violated G.L. c. 93A directly (and by operation of 940 C.M.R. § 3.16(3) through violating G.L. c. 111, §§ 56, 70E, 105 CMR 140.000 et seq. and 940 CMR 6.00 et seq., which are intended to protect the public's health, safety and welfare) by, without limitation,

- a. operating MMM as a clinic, without having a clinic license from DPH,
- b. failing to require personnel at MMM who examined, observed or treated patients to wear identification badges that readily disclosed their first name, licensure status, if any, and staff position,
- c. operating MMM to have FMMC employees who were not licensed physician assistants or nurses performing medical services without physicians present,
- d. Using high-pressure sales tactics, and
- e. Using misrepresentations about returns of medication and refunds.

216. Defendant Kevin Hornsby also engaged in unfair and deceptive acts and practices and violated G.L. c. 93A directly (and by operation of 940 C.M.R. § 3.16(3) through violating G.L. c. 111, § 56 and G.L. c. 112, §§ 6, 8A, which are intended to protect the public's health, safety and welfare) by, without limitation,

- a. holding himself out as a practitioner of medicine without being lawfully authorized to practice medicine in the Commonwealth and
- b. using the term physician in advertising to imply that he offered to engage in the practice of medicine in the Commonwealth when he was not registered with the Board of Registration of Medicine as a physician.

217. Defendants knew or should have known that their conduct was unfair and/or deceptive in violation of G.L. c. 93A, § 2.

218. Defendants have harmed Massachusetts consumers through their unfair and deceptive acts and practices.

SECOND CAUSE OF ACTION

(Violation of G.L. c. 111, § 56 and 105 CMR 140.000 et seq.)

219. The Commonwealth incorporates by reference the allegations in the foregoing paragraphs of this Complaint as if each were fully set forth herein.

220. Defendants violated G.L. c. 111, § 56, by advertising, announcing, establishing, maintaining and being concerned in establishing and maintaining a clinic, within the meaning of G.L. c. 111, § 52, without a license granted under G.L. c. 111, § 51.

221. Defendant FMMC violated 105 CMR 140.000 et seq. by, among other things, (a) owning and operating a clinic within the meaning of G.L. c. 111, § 52 without obtaining a clinic license from DPH and (b) not having at least one physician present at MMM when medical services were provided by personnel not licensed as physician assistants or nurses.

PRAYER FOR RELIEF

WHEREFORE, the Attorney General respectfully requests that this Court grant the following relief:

- 1) Issue a preliminary injunction;
- 2) Issue a permanent injunction enjoining Defendants and their subsidiaries, divisions, affiliates, agents, employees, servants, successors, attorneys, assigns and all other persons and entities, corporate or otherwise, in active concert or participation with them, whether acting individually, or through any corporation, trust or other device, from:

- a) establishing, maintaining or being concerned in establishing or maintaining in Massachusetts a clinic, as defined by G.L. c. 111, § 52, without a license granted by DPH under G.L. c. 111, § 51,
- b) permitting in Massachusetts any person or persons not licensed as a physician, physician assistant or nurse in Massachusetts at a clinic, as defined by G.L. c. 111, § 52, to provide medical services without a physician present or otherwise in violation of 105 CMR 140.313(B),
- c) engaging in Massachusetts in any unfair or deceptive act or practice in violation of G.L. c. 93A, § 2, in connection with the advertising, marketing, sale or delivery of any medication or medical service relating to the treatment of erectile dysfunction,
- d) In any advertising or marketing televised, broadcast, published, presented, distributed or disseminated in Massachusetts (including, without limitation, any advertising or marketing originating outside Massachusetts that may reasonably be expected to be seen or heard in Massachusetts)
 - i) stating or implying that any treatment by intracavernous injection or the medication injected in that treatment
 - i. is new or is the newest treatment or medication available,
 - ii. is a method invented by Kevin Hornsby or any other individual physician,
 - iii. is a revolutionary treatment,
 - iv. is based on a consumer's biochemistry,
 - v. is suitable for patients regardless of their medical history,

- vi. is painless, is virtually painless, has no side effects, has minimal side effects, has no serious side effects, or lacks serious side effects of Viagra, Levitra or Cialis, or
- vii. is the most effective erectile dysfunction treatment, without clearly and conspicuously in close proximity to that claim, disclosing its risk of causing priapism and other side effects,
- ii) stating or implying that any Defendant, including any of their agents or employees, can eliminate erectile dysfunction in one visit,
- iii) referring, directly or indirectly, to any treatment by intracavernous injection or the medication injected in that treatment without disclosing that the treatment or medication involves a penile injection,
- iv) stating or implying that any Defendant, including their agent physicians or employees, blends medications,
- v) stating or implying that any consumer will receive a unique medication,
- vi) using any testimonial or quotation attributed to a patient unless that testimonial or quotation is a true statement of the patient, any payment to that patient is disclosed, Defendants are able to identify that patient and the experience of the patient is typical of patients in Massachusetts,
- vii) making any claim of safety or efficacy of any medication without a reasonable basis therefor, consisting of competent and reliable scientific evidence,

- viii) using the term clinic in reference to or representing as a clinic anything that does not have a license granted by DPH under G.L. c. 111, § 51,
- ix) with respect to any person not authorized to practice to engage in the practice of medicine in the Commonwealth and/or not registered with the Board of Registration of Medicine as a physician
 - i. stating or implying that any such person is a practitioner of medicine in the Commonwealth
 - ii. using the term physician to state or imply that any such person, offers to engage in the practice of medicine in the Commonwealth,
 - iii. stating or implying that any such person is a local doctor or physician, and
- x) making statements that create a false sense of urgency, including, but not limited to, stating or implying that the first group of callers in response to an advertisement will receive better treatment if they will not in fact receive better treatment,
- e) Making any communication in Massachusetts (including, without limitation any communication outside of Massachusetts that may reasonably be expected to be seen or heard in Massachusetts) that
 - i) states, suggests or implies that consumers in order to obtain medication must purchase a certain quantity of the medication greater than one dose

- ii) falsely stating or implying the any Defendant is prevented by law from accepting the return of medication or providing any refund and
 - iii) using any words or phrases that state or imply a limitation on the implied warranties of merchantability and fitness for a particular purpose, including phrases such as, as is, with all faults, and all sales final,
 - i. except that Defendants may adopt an all sales final return policy, if it clearly and conspicuously discloses that policy in its advertisements and in-office signs and includes in such disclosures the following or substantially similar language: “All Sales Final Except for Defective or Non-conforming Goods,”
 - f) Operating in Massachusetts a clinic, as defined by G.L. c. 111, § 52 without requiring, that any personnel who examine, observe or treat patients wear identification badges that readily disclose their first name, licensure status, if any, and staff position, and
 - g) Having sales personnel dress in Massachusetts in clothing, including white coats or medical scrubs, that falsely suggests they hold medical licenses;
- 3) Declare that Defendants have engaged in unfair and deceptive acts and practices in violation of G.L. c. 93A, § 2, that Defendants also violated G.L. c. 111, § 56, that FMMC also violated G.L. c. 111, § 70E, and that Kevin Hornsby also violated G.L. c. 112, § 6, 8A;
- 4) Order each Defendant to pay full and complete restitution to all Massachusetts patients who were harmed as a result of each Defendants’ unlawful, unfair or


deceptive acts or practices;

- 5) Order each Defendant to disgorge all payments received as a result of their unlawful, unfair or deceptive acts or practices;
- 6) Order Defendants to pay civil penalties of up to \$5,000 for each violation of G.L. c. 93A;
- 7) Award the Attorney General's Office the reasonable costs of investigation and litigation of such violations, including reasonable attorneys' fees; and
- 8) Grant all other relief as the Court may deem just and proper.

Dated: July 1, 2015

Respectfully submitted,

COMMONWEALTH OF MASSACHUSETTS
By its Attorney,
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ATTORNEY GENERAL



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Advertorial

FREE MEDICATION DOSE

Erectile Dysfunction Clinic Opens in Boston

BY STEVE MUELLER

Men's Health Consultant

FRAMINGHAM • Local physicians at a new medical clinic in Framingham are so sure their medication will help men with erectile dysfunction, they are offering the first 37 callers a free in-office medication dose.

Erectile dysfunction and premature ejaculation have long been a problem for millions of men, in spite of the popularity of Viagra, Cialis and Levitra. Many men aren't helped by these pills or cannot take them due to adverse side effects.

Massachusetts Men's Medical Clinic custom blends over 180 combinations of medications for each patient. "That's why our success rate is so high," says Dr. Kevin Hornsby, M.D. "We help men as old as ninety-four, with diabetes, prostate surgery and heart conditions. Regardless of their age or medical history our results everyday are amazing."

All medications are FDA approved, and no surgery is involved.

"We adjust the prescription for a man's performance to 45-minutes, an hour, 90-minutes or longer," according to Dr. Hornsby, "and patients see results right in our office. After climax the patient stays erect the entire period of time. This allows them to achieve a second climax and adequately satisfy their partner. No other medication can do this. We offer a simple guarantee: If you don't respond to the medication on the first visit the office visit is free." With that guarantee, local patients have nothing to lose.

Openings are filling quickly for the free in-office medication dose, after that the normal fees will be charged. Patients are assured of utmost privacy and professionalism with private waiting rooms and an all-male staff. Further information is available by calling **(508) 401-7290**.

Massachusetts Men's Medical Clinic, 463 Worcester Rd., Suite 206, Framingham, MA, just off Mass Pike/I-90. For patients more than 60 miles away the doctor will pay your gas.

www.MassMensClinic.com

LOCAL DOCTOR SAYS SUITABLE FOR ANY AGE OR MEDICAL HISTORY

FREE Erectile Dysfunction Medication for Massachusetts Men!

BY STEVE MUELLER

Men's Health Consultant

FRAMINGHAM • "One-size-fits-all medication may soon be a thing of the past." That statement from the renowned **Johns Hopkins Hospital** refers to modern medicine's new ability to personalize prescription medications to the biochemistry of the patient.

Personalized prescription medicine is also the basis of a successful erectile dysfunction clinic in Framingham boasting a 98% success rate ... and an amazing guarantee!

That's right: The Massachusetts Men's Medical Clinic promises you'll have a positive response to a FREE test dose of medication -- right in the doctor's office -- or else your visit to the clinic is free. That way, you risk nothing.

BETTER THAN VIAGRA

"Viagra, Cialis, and Levitra are 'off-the-shelf' potency drugs," says Dr. Kevin Hornsby, M.D. whose clinics have been featured on ABC, CBS, NBC, CNN, and Fox. "As such, they are a mass-produced product and not tailored to the individual patient's needs."

The doctors at Massachusetts Men's Medical Clinic review the patient's medical history and conduct a thorough examination including a sonogram.

Based on these findings the clinic's pharmacy custom blends 4 FDA-approved ingredients into one of 180 different combinations.

Most patients achieve an erection after taking a test dosage of their custom-blended formulation. If you do not respond to the medication, there is no charge for your office visit -- or the medication dose.

"I had tried everything else out there and nothing had worked for me. When I heard the commercial I thought that it was just another false advertisement. Boy was I wrong.

This clinic is a great place, my sex life is back on track," says RH, Men's Medical patient.

MAKES LOVE ... LAST LONGER

The Clinic's pharmacy experts can also adjust the potency of your custom-blended formulation.

That way, you can choose how long you want your erection to last -- from 30 minutes to as long as 90 minutes or more ... enough for you to orgasm a second time and fully satisfy your partner.

"Some men come to me unable to even achieve an erection, and our personalized

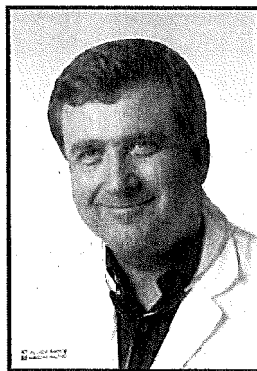
ED medication allows them to perform in the bedroom again," says Dr. Hornsby. "For others, we can restore them to an active sex life."

GET YOUR ED MEDICATION FREE

The Men's Medical doctors' schedule at the clinic fills quickly, so patients are urged to call (508) 401-7288 to secure an appointment. The first 37 callers will receive their in-office personalized prescription medication dose free. To get your FREE medication dose, call NOW.

After that, normal office rates will be charged. Private waiting rooms with an all-male staff keep your visit confidential.

Massachusetts Men's Medical Clinic, 463 Worcester Rd., Suite 206, Framingham, MA 01701. Off the Mass Pk/1-90 on Worcester Rd/Rt. 9, just down from the Natick Mall.



DR. KEVIN HORNSBY, MD, MEN'S SEXUAL HEALTH EXPERT AND AUTHOR OF THE BOOK *A DOCTOR'S GUIDE TO ERECTILE DYSFUNCTION*.

**"Personalized"
potency medication
gives men
longer-lasting
erections**

www.MassMensClinic.com

Board Certified Urologist Endorsed

“I used to have Erectile Dysfunction.”



“It started after I got diabetes. I tried all the pills, pumps and potions, and two doctors told me my sex life was over. I visited the doctor at Massachusetts Men’s Medical Clinic, he examined me and on the first visit gave me my sex life back. I will be forever grateful.”

Massachusetts Men’s Medical Clinic patient

Regardless of your age or medical history, the doctors at Massachusetts Men’s Medical Clinic are so sure they can help you with erectile dysfunction and premature ejaculation that if you don’t respond to their custom blended prescription medication on the first visit, right in their office, there’s no charge, guaranteed. Call (508) 401-7288 today for full information.



**MASSACHUSETTS
MEN’S MEDICAL CLINIC**

463 Worcester Rd., Suite 206
Framingham, MA 01701
www.MassMensClinic.com

Board Certified Urologist endorsed

LOCAL DOCTOR SAYS...

YOUR SEX LIFE IS NOT OVER!

MASSACHUSETTS • The doctors at Men's Medical Clinic now have available over 180 custom blends of prescription medication so they can treat almost any man – regardless of his age or medical history – for erectile dysfunction and premature ejaculation. It's called "The Hornsby Method", developed by Kevin Hornsby, M.D., author of the popular book ***A Doctor's Guide to Erectile Dysfunction***. The clinic is now offering an in-office trial-dose of medication while supplies last. If you don't have a positive reaction to the medication in the office on your first visit, there's *no charge, GUARANTEED*. If you've been to several doctors, tried all the pills, and nothing works, you owe it to yourself and your partner to call today for more information.

508-401-7288

Board Certified Urologist Endorsed



MEN'S
MEDICAL CLINIC

463 Worcester Rd.
Suite 206

Framingham, Massachusetts 01701

BOSTON

INQUIRY OUTLINE

Speak w/enthusiasm, loudly, slowly, pause 1-second at • and punch (emphasize) the word(s) underlined

Good (*morning/afternoon*) doctor's office, this is (*your first name*), can I help you? Sure, I'd be glad to give you some information. How did you hear about us? (*Find out if newspaper or what specific radio station*) And what's your first name? (*name*), this is Dr. Hornsby's office • we're located here in Framingham • and our doctors are all licensed Massachusetts physicians • they specialize in just this one area • erectile dysfunction.

Let me ask you a couple quick questions to make sure the doctor can help you • and then I can tell you the cost • and I'm more than happy to answer any questions YOU might have. • Do you mind if I ask your age? (*Joke and say "You're just a young man!"*) Are you taking any prescription medications • for high blood pressure • cholesterol • diabetes? (*After answer say:*) This can be part of the problem. • Are you having trouble GETTING an erection • or MAINTAINING one • or a little bit of BOTH? (*If under 60 say:*) Any problem with premature ejaculation?

I'm sure we can definitely help you. What you need to do. • you would come into the clinic one time. • The doctor performs a test called an ultrasound. • It takes less than two minutes and it's totally painless. • We get the results instantly. • Based on the results • your age, health and medications you may be taking • the doctor gives you a custom-blended medication • ONE minute from the time you take this you start getting an erection • and within eight or nine minutes you'll

HAVE an erection • this erection can last 45-minutes • an hour • an hour and a half • or longer • whichever YOU choose • and it works virtually 100 out of 100 times. • The doctor can set the time your erection lasts to within 5 to 10 MINUTES of the time you desire • and with this medicine, AFTER you climax your penis will stay erect for the whole 90-minutes • this allows you to have a SECOND climax • the sensation is greater each time • plus you can also satisfy your partner • but you'll see it work first. If for ANY reason we cannot do this for you, there's NO CHARGE, not one penny. That's our guarantee. • but if it WORKS • and almost every patient we do help • the cost of the appointment, ultrasound and test dose is only One Hundred and Ninety Nine Dollars. Have you tried Viagra, Cialis, or Livitra? • These drugs have mixed results • they help less than half the men • and there can be serious side effects. There's better and more effective medications out there • Our doctors use over 185 combinations of medications, all FDA approved and custom blended for each patient. That's why our success rate is so high.

Normally we're WAY overbooked but I might be able to squeeze you in the next few days... Tell me what days you're off work and I'll see what I can do for you? You tell me what time is good? (*Book appointment, or if any questions, answer them with quick, short answers. Say the following immediately after their question:*)

We can fit you in (*name a day or two*) • does that work for you? (*If thinking about it, say*) that's not a problem, but we're booked far in advance • I know we can help you • it's 100% guaranteed • why not go ahead and set a time now • you can always re-schedule if you need to.

**ALWAYS PUSH FOR FAST APPOINTMENTS –
SAME DAY OR NEXT DAY!!**

*When booking appoints say: **DO YOU HAVE A PENCIL HANDY?** Get full spelling of first name and last name, full ADDRESS with ZIP CODE, and try for at least TWO different phone numbers, cell and home). Our office is centrally located at 463 Worcester Rd., Framingham, in the all glass “Crown Office Building.” We are just minutes from either exit 12 or 13 off the Mass Pike/I-90 on Worcester Road/Rt. 9, just down from the Natick Mall and across the street from the State Police Barracks. There is plenty of free parking. Take elevator to Suite 206 on the second floor.*

The only thing we ask • is that when you come in for your appointment • please make sure you’re on time • We’re very private and discreet, and we don’t want you to have to wait.

We’ll call you the day before your appointment to remind you. And please don’t use Viagra or any other ED medications 48 hours prior to your appointment. Be sure to take all your other medications. I’m sure we can help you, and get ready to have one of the biggest and best surprises of your life. We’ll see you (day, month and date) at (time.)

ONLY AFTER THREE (3) TIMES ASKING FOR APPOINTMENT SAY: “I’d be glad to send you a FREE color brochure in a plain unmarked envelope.” *If they say ‘yes,’ get full mailing address with zip code. Spell the street, town, etc. for accuracy. If they say ‘no,’ offer our website www.massmensclinic.com, SLOWLY spelling out the words.*

FREQUENTLY ASKED QUESTIONS

Tell everybody:

Our website has 12 different little short 2-minute videos with Dr. Hornsby answering questions. You should definitely check it out. www.massmensclinic.com

WHAT ABOUT THE “FREE” FIRST 37 PATIENTS OFFER?

We've got 12 of those spots left, and I can lock one in for you. It's normally \$299, but with the free in-office medication dose you only have to pay \$199, which is for the doctor exam and ultra-sound test. It's important we book an appointment now to save this \$100, you can always call and change it later.

DOES HEALTH INSURANCE COVER THIS? Yes, some insurance may reimburse. We don't process insurance here but we give you a special coded receipt to send to your insurance company and they would reimburse you direct. (*NEVER promise any kind of insurance reimbursement*)

DOES MEDICARE COVER THIS? No, they don't, I'm sorry, but your supplemental insurance might.

HOW MUCH DOES THE MEDICATION COST? It depends on what medication the doctor prescribes and also how often you have sexual activity. It IS affordable and we have patients from all walks of life, elderly, social security, fixed income, the cost IS reasonable and affordable and we take all the credit cards.

IF PATIENT STILL PUSHES FOR A COST: It's not a whole lot more than Viagra, around \$19 or so per dose, but again, that's just a ballpark, it's gonna vary depending on what medication the doctor actually prescribes for you and how frequently you have sexual activity.

WHAT KIND OF MEDICINE DO YOU USE? We try to give every patient what's called a sublingual. A sublingual, as opposed to a pill that goes down your stomach and mixes with the food you eat, you put the sublingual underneath your tongue and let it dissolve, it never goes through your stomach. It's MUCH more effective and without the side effects of Viagra, Livitra or Cialis. We also have medicine that's applied directly to the penis. It depends on what the doctor thinks will work best for you.

IS THIS AN INJECTION? We try to give every patient a sublingual. When you come in, the doctor is going to perform the ultrasound test and try to qualify you for the sublingual. At that time he'll give any other options that you have. (ONLY if they still ask 'Is this an injection?' say "Have you tried an injection, or is that what you want?" (Get their response) If they say yes, and it didn't work, say: "The doctor might have given you Caveject, some urologists use this, you stick a large needle in your penis, and it doesn't work for most men. That medicine is the same for everybody, one-size-fits-all. Our medication is custom blended just for you, guaranteed to work. We don't have patients stabbing a needle in their penis, but one of our treatments uses a little push-button applicator, it looks kind of like a flash-light, and it applies medicine to the penis. It's virtually painless, but there are other options, and the doctor will determine what's best for you."

HOW ARE YOU DIFFERENT FROM THE BOSTON CLINIC? I

know we've treated a lot of their patients and they tell us our medication works a lot better. Our medication is applied differently. They're a large national company and we're much smaller, we're locally owned by Dr. Kevin Hornsby.

PREMAURE EJACULATION: Our success rate with Premature Ejaculation is almost 100%. We can set your medication to cause your erection to last for a set time, let's say 90-minutes. **AFTER YOU CLIMAX** your penis stays erect for the full 90-minutes. This let's you to climax a 2nd or 3rd time, and the sensation is greater each time, and you can satisfy your female partner. This takes the pressure off and the PE problem begins to cure itself.

WHO IS THE DOCTOR? At our Framingham clinic you'll see Dr. William Cristo, MD. He's Board Certified and trained at New York Medical College and was rotating surgeon at Lenox Hill Hospital in New York. He's been on staff at St. Vincents, Vencor and University Hospitals in Massachusetts as an Assistant Professor and Chief of Radiology. He's great and his bio and photo are on our website.

I'M MORE THAN 60-MILES AWAY. HOW DOES THE GAS REIMBURSEMENT WORK? The doctor will deduct \$40 for gasoline from the \$199 office visit, so it would be \$159 for you.

FOR DIFFICULT QUESTIONS: You know (*name*) that's exactly why you need to come into the clinic so you can meet the doctor and we can answer all your questions. Remember, this is fully guaranteed. • If we can't help you • you won't pay a penny. Is (*name a day*) good for you?

WARNING: UNDER NO CIRCUMSTANCES SHOULD THIS SCRIPT BE MODIFIED IN ANY WAY. YOU MUST FOLLOW IT AT ALL TIMES, WITHOUT EXCEPTION. DEVIATING FROM THIS SCRIPT IS GROUNDS FOR IMMEDIATE TERMINATION.

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**LOCAL PHONE NUMBER FOR CLINIC
(508) 309-6355**

Thank you for calling the Men's Medical Clinic, my name is _____, how can I help you today?

I'd be glad to give you some information. Let me ask you a couple of quick questions to make sure the doctor can help you. Then I can tell you the cost, and I'll be more than happy to answer any questions you may have.

Do you mind if I ask you your age? Are you taking any prescription medications like for high blood pressure, cholesterol, or diabetes? (let them answer). If they are "This can be part of the problem". Are you having a problem getting an erection, maintaining one, or would you say it's a little bit of both? (if under 60). Any problem with premature ejaculation?

I'm sure we can definitely help you. What you need to do is you would come into our office for a one time visit, your visit usually lasts from 1-2 hours. The doctor will perform an ultrasound test and a brief exam. Based on those results, your age, health, and medications that you are taking, the doctor will give you a light dose of our custom blended medication. Within minutes you will have a reaction to the medication. Based on your reaction, the doctor will prescribe a medication and treatment plan customized just for you. At home your medication should last between 45 minutes up to an hour and a half, depending on the patient. The great news is even after you climax your penis will stay erect as long as the medication stays effective. This will allow you to have a second climax, plus this gives you time to also satisfy your partner. If for any reason you do not have a reaction in the office, there is no charge, not a penny. But if it works, and almost every patient we are able to help, the cost of the appointment, ultrasound and light dose is only \$199.00→Have you tried Viagra, Cialis, or Levitra? Those drugs have mixed results, they help less than half the men, and there can be serious side effects. There's better and more effective medications out there. Our Doctor uses over 180 combinations of medications, all FDA approved, and custom blended for each patient. That's why our success rate is so high→Normally, we're way overbooked, but I might be able to squeeze you in the next few days. All I would need to do is get some additional information from you since we tend to fill our schedule up rather quickly. What day works best for you? (Use your normal technique for creating urgency and that we book up quickly).

Finishing call:

Mr. _____ do you have a pen or pencil handy so I can give you directions to the clinic? (give directions and also give patient rules, no ED meds 48 hours prior, etc)

Also, Mr. _____, here is the direct number to the front desk in (City). They can assist you further for directions or anything else regarding your appointment. Thank you and we will see you soon!

(when you see the → do not pause continue through script, when you ask patient any question allow them to respond and use that to engage and show knowledge then lead the patient to the appointment). ! (revision 3)

Thank you for calling the Men's Medical Clinic. This is _____, how can I help you today?

I'd be glad to give you some information. Our clinic is located (give city) and our doctor is a licensed physician in (give state). We specialize in just this area, erectile dysfunction and premature ejaculation. Sir, if you don't mind I need to ask you a couple of questions to make sure the Dr. can help you, then I can tell you the cost. And I'm more than happy to answer any questions you may have.

Do you mind if I ask you your age? Ok, are you currently taking any prescription medications, like for cholesterol, high blood pressure, diabetes? *(let patient answer)*. If patient says "yes". Say, "That could be part of the problem." So, are you having a problem getting an erection, maintaining one, or would you say it's a little bit of both? *(let patient answer)* If under 60 ask "Any problem with premature ejaculation?"

I'm sure we can definitely help you. What you need to do is come into our clinic for a one time visit. The visit usually lasts between 1-2 hrs. The doctor performs a test called an ultrasound. It takes just a few minutes and it's totally painless. We get the results instantly. And based on those results, your age, health, and medications you may be taking. The doctor will administer a light dose of our custom blended medication. After a minute you take this you will begin having a reaction to the medication. The doctor can then prescribe based on your results an erection that will last from 45 minutes up to an hour and a half. And your medication will work virtually 100 out of 100 times. With this medication, after you climax your penis will stay erect for the duration the medication remains effective. You could possibly have a second climax. And this will also give you time to satisfy your partner.

If for any reason you do not get a reaction to our medication, there is no charge for the Dr. visit. Not one penny. But if it works, and almost every patient we do help, the cost of the appointment, the ultrasound test is 199.00(no pause) Have you tried Viagra, Cialis, Or Levitra? *(wait for response)* Those drugs have mixed results and there can be serious side effects. There are better and more effective medications out there. Our Dr. uses over 180 combinations of medications, all drugs are FDA approved, and custom blended for each patient. That is why our success rate is so high.

Normally we're WAY overbooked. But I might be able to squeeze you in the next few days. Tell me what days you're off work and I'll see what I can do for you. You tell me what time is good. We can fit you in. *(day/time)*. Does that work for you? I know we can help you. The office visit is 100% guaranteed, why not go ahead and set a time now. You can always reschedule if you need to. Just let me get some additional information from you since we tend to fill our schedule up rather quickly.

ENDING THE CALL

Mr. _____ do you have a pen or pencil handy so I can give you directions to the clinic? (Give Directions).

Give them the information they need to follow before they come to the clinic.

Also Mr. _____ here is the direct number to our front desk in (city of clinic), They can assist you further regarding your appointment. Thank you and we will see you soon!