

CAUSE NO.

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
	§	
VS.	§	TARRANT COUNTY, TEXAS
	§	
LAURIE D'ALLEVA d/b/a DISCOUNT	§	
MEDSPA a/k/a ONTARIO MEDSPA,	§	
	§	
Defendant.	§	_____ JUDICIAL DISTRICT

**PLAINTIFF'S ORIGINAL PETITION AND APPLICATION FOR EX PARTE TEMPORARY RESTRAINING ORDER, TEMPORARY INJUNCTION, AND PERMANENT INJUNCTION**

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW, the STATE OF TEXAS, Plaintiff, acting by and through Attorney General Greg Abbott, and files this its Original Petition and Application for Ex Parte Temporary Restraining Order, Temporary Injunction, and Permanent Injunction complaining of and against LAURIE D'ALLEVA d/b/a DISCOUNT MEDSPA a/k/a ONTARIO MEDSPA (hereinafter "Defendant or D'ALLEVA"), and would respectfully show the court the following:

**DISCOVERY CONTROL PLAN**

1. Discovery is intended to be conducted under Level 2 of Texas Civil Procedure Rule 190.

**AUTHORITY**

2. This action is brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §431.047 and §431.0585 of the Texas Food, Drug and Cosmetic Act, TEX. HEALTH & SAFETY CODE ANN. §431.001 *et seq.* ("TFDCA"). Section

431.047 authorizes the Attorney General to seek injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. Section 431.0585 authorizes the Attorney General, after a referral from the Commissioner, to seek civil penalties in favor of the State for any violation of §431.021 of the TFDCA and regulations pursuant to this Act.

3. This action is brought by Attorney General Greg Abbott, through his Consumer Protection and Public Health Division, in the name of the STATE OF TEXAS and in the public interest under the authority granted him by §17.47 of the Texas Deceptive Trade Practices - Consumer Protection Act, TEX. BUS. & COM. CODE ANN. §17.41 *et seq.* (“DTPA”), upon the grounds that Defendant has engaged in false, misleading, or deceptive acts or practices in the course of trade and commerce as defined in, and declared unlawful by §§17.46(a) and (b) of the DTPA.

#### **PARTY DEFENDANT**

4. Defendant D’ALLEVA is a resident of Texas, and may be served with process at her residence and place of business at 207 Crenshaw Drive, Mansfield, Texas 76063. Alternatively, Defendant D’ALLEVA can be served at the following address: 2020 E. Pioneer Parkway, Suite 200, Arlington, Texas 76010.

#### **VENUE**

5. Venue of this action is proper in Tarrant County on the basis of §431.047(c) and §431.0585(d) of the TFDCA because violations or the threat of violations have occurred in Tarrant County.

6. Venue of this action is proper in Tarrant County on the basis of §17.47(b) of the DTPA because Defendant resides in and has engaged in the business of advertising, offering to

sell, and selling prescription drugs and devices in Tarrant County.

### **PUBLIC INTEREST**

7. By reason of the institution and operation of the unlawful practices set forth herein, Defendant has caused immediate and irreparable injury, loss and damage to the State of Texas, and its citizens, and has also caused adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Attorney General of the State of Texas believes and is of the opinion that these proceedings are in the public interest.

### **TRADE AND COMMERCE**

8. Defendant D'ALLEVA has, at all times described below, engaged in conduct which constitutes "trade" and "commerce" as those terms are defined by §17.45(6) of the DTPA.

### **ACTS OF AGENTS**

9. Whenever it is alleged in this petition that Defendant did any act or thing, it is meant that Defendant performed or participated in such act or thing or that such act was performed by the officers, agents or employees of said Defendant, and in each instance, the officers, agents or employees of said Defendant that were then authorized to act did in fact act on behalf of Defendant or otherwise acted under the guidance and direction of the Defendant.

### **NOTICE BEFORE SUIT**

10. The State did not inform Defendant D'ALLEVA herein at least seven (7) days before instituting this action of the alleged unlawful conduct of which complaint is now made, pursuant to DTPA §17.47(a), for the reason that the State is of the opinion that there is good cause to believe that such an emergency exists that immediate and irreparable injury, loss, or

damage would occur as a result of such delay in obtaining a temporary restraining order by allowing Defendant to continue to advertise, offer for sale, and sell prescription drugs and devices.

### **NATURE OF DEFENDANT'S OPERATION**

11. Defendant D'ALLEVA advertises, offers to sell, and/or sells prescription drugs including Dysport®; a product called "Freeze" which contains botulinum toxin; Renova ®; bacteriostatic saline; EMLA® cream; prescription strength orlistat; Revitalash®; prescription anti-depressants; and the human chorionic gonadotropin (HCG) hormone in Texas. Defendant D'Alleva also offers to sell and/or sells a prescription device, which she calls Restylin and one which she calls Artefil<sup>1</sup>. Defendant D'Alleva advertises her products and solicits customers for her business through websites, as shown below. (See Exhibits 1, 2, 3, and 6)

12. Defendant D'ALLEVA advertised, offered to sell, and/or sold prescription drugs and devices to individuals through the website domain [www.discountmedspa.com](http://www.discountmedspa.com), and she currently advertises, offers to sell and/or sells products through the domain [www.ontariomedspa.com](http://www.ontariomedspa.com). (See Exhibits 1, 2, and 3) The web site agent, Domains by Proxy, Inc, has confirmed that the discount medspa website domain, along with others, are registered to Defendant D'Alleva. The Twitter page for discount medspa confirms that the company can now be found on the internet at the [www.ontariomedspa.com](http://www.ontariomedspa.com) domain. (See Exhibits 4 and 5)

13. D'ALLEVA advertises, offers to sell, and/or sells prescription drugs containing the botulinum toxin, Dysport® and one which she calls "Freeze". D'ALLEVA advertises, offers

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<sup>1</sup>Restylin is advertised by D'Alleva as a dermal filler with similar uses as the name brand prescription device, Restylane®. Artefil is advertised by D'Alleva as a dermal filler. Artefill® is a name brand prescription device used as a dermal filler. The reason for D'Alleva's alternate spelling of these product names is unclear. See exhibit 6.

to sell and/or sells the prescription drug Renova® cream. D'ALLEVA advertises, offers to sell and/or sells the prescription drug Revitalash®. Additionally, D'ALLEVA advertises, offers to sell and/or sells a prescription anti-depressant, Wellbutrin SR® 150, and markets it as an "Energy and Libido Pill." (See Exhibits 1, 2, 3, and 6).

14. D'ALLEVA advertises, offers to sell and/or, and sells the prescription drug Human Chorionic Gonadotrophin (HCG) hormone as a means of weight loss. (See Exhibits 1, 2, 3, and 6) D'Alleva also linked an email advertising HCG to the Discount Medspa Twitter page. This email lists the mailing address for Discount Medspa as 207 Crenshaw Dr., Mansfield, Texas 76063. (See Exhibit B to Exhibit 3)

15. Additionally, D'ALLEVA has indicated, on the website domain [www.ontariomedspa.com](http://www.ontariomedspa.com), that she will begin selling an injectable product for spider vein treatment in the near future. (See Exhibit 2).

16. D'ALLEVA provided links to how-to videos for the injections as a means of instructing her customers on how to self-administer the drugs and devices. D'ALLEVA provided links to the videos on the website domain [www.discountmedspa.com](http://www.discountmedspa.com). (See Exhibit B to Exhibit 7).

17. D'ALLEVA advertises that the products she sells are "real, pharmaceutical grade treatment solutions," and that she "...belongs to the Texas Medical Council and is licensed to sell these products..." (See Exhibits 1 and 2).

18. On November 9, 2009, an investigator with the Office of the Attorney General placed an order for the "Newbie Starter Kit" on [www.ontariomedspa.com](http://www.ontariomedspa.com). The order was received on November 13, 2009, and contained Restylane®, one fifty unit Freeze product

containing purified neurotoxin complex, two empty syringes, two syringe needles, one thirty milliliter vial of Bacteriostatic 0.9% Sodium Chloride, one foil package of Bacitracin, and seven instruction sheets. (See Exhibit 7 and Exhibits D and E to Exhibit 7)

## **OVERVIEW OF THE REGULATION OF PRESCRIPTION DRUGS AND DEVICES**

19. All drugs and devices regulated by the federal Food and Drug Administration (“FDA”) are required to have “adequate directions for use,” which means directions under which a layman can use a drug or device safely for its intended use as determined by the manufacturer. 21 C.F.R. §201.5 (drugs), 21 C.F.R. §801.5 (devices).

20. Exemptions to the requirement of adequate directions for use exist for prescription drugs and devices. 21 C.F.R. §201.100 (drugs), 21 C.F.R. §801.109 (devices). These exemptions only apply, however, in certain circumstances, such as when the drug or device is in the possession of a practitioner licensed by state law to prescribe the use of the drug or device or if a practitioner orders the drug or device.<sup>2</sup>

21. Prescription devices, including but not limited to Restylin and Artefil, are also “restricted devices” under the federal Food, Drug and Cosmetic Act (“FFDCA”). §520 of the FFDCA, 21 U.S.C. §360j(e)(1). The plain language of this statute indicates the restricted nature of prescription devices:

The Secretary may by regulation require that a device be restricted to sale, distribution or use--

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<sup>2</sup>The exemption will also apply to prescription drugs if the drug is in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of the drugs or if the prescription drug is in the possession of a pharmacy or public health agency regularly and lawfully engaged in dispensing prescription drugs. The exemption will also apply to prescription devices if the device is in the possession of a person regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of the devices.

(A) only upon the written or oral authorization of a practitioner licensed by law to administer or use such device, or

(B) upon such other conditions as the Secretary may prescribe in such regulation, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, the Secretary determines that there cannot otherwise be reasonable assurance of its safety and effectiveness. No condition prescribed under subparagraph (B) may restrict the use of a device to persons with specific training or experience in its use or to persons for use in certain facilities unless the Secretary determines that such a restriction is required for the safe and effective use of the device. No such condition may exclude a person from using a device solely because the person does not have the training or experience to make him eligible for certification by a certifying board recognized by the American Board of Medical Specialties or has not been certified by such a Board. A device subject to a regulation under this subsection is a restricted device.

§520(e)(1) of the FFDCA, 21 U.S.C. §360j(e)(1).

22. Another federal regulation, 21 C.F.R. §807.3(i), confirms the restricted nature of prescription devices, by defining restricted device as “a device for which the Commissioner, by regulation under §801.109 of this chapter or otherwise under §520(e)(1) of the FFDCA, 21 U.S.C. §360j(e)(1), has restricted sale, distribution, or use only upon the written or oral authorization of a practitioner licensed by law to administer or use the device or upon such other conditions as the Commissioner may prescribe.” 21 C.F.R. §807.3(i). Since Restylin and Artefil are prescription devices, by application of 21 C.F.R. §807.3(i) and §520(e)(1) of the FFDCA, 21 U.S.C. §360j(e)(1), these products are also restricted devices.

23. State rules adopted pursuant to the TFDCA track the federal definition of restricted device, defining prescription devices as restricted devices because they are subject to certain controls related to sale, distribution, or use. 25 Tex. Admin. Code §229.433(22), (26).

#### **REFERRAL FROM THE TEXAS DEPARTMENT OF STATE HEALTH SERVICES**

24. The Texas Department of State Health Services captured and reviewed the

websites found at [www.discountmedspa.com](http://www.discountmedspa.com) and [www.ontariomedspa.com](http://www.ontariomedspa.com). Based on a review of the websites, TDSHS determined that Defendant D'ALLEVA advertises, offers to sell, and/or sells prescription drugs, including those identified in paragraphs 11 through 23 above, directly to consumers over the internet without an order or prescription from a practitioner licensed by law in the state in which the drugs were sold, in violation of §§431.021(a) and (b) of the TFDCA. (See Exhibit 6)

25. TDSHS determined that Defendant D'ALLEVA advertises, offers to sell, and/or sells restricted, prescription devices, including those identified in paragraphs 11 through 23 above, directly to consumers over the internet without an order or prescription from a practitioner licensed by law in the state in which the devices were sold, in violation of §§431.021(a) and (b) of the TFDCA. (See Exhibit 6)

26. TDSHS determined that the labeling for the prescription drugs and devices that Defendant D'ALLEVA offers to sell and/or sells do not have adequate directions for a layperson for the intended use of the prescription drugs and device in violation of §§431.021(a) and (b) of the TFDCA. (See Exhibit 6)

27. TDSHS determined that Defendant D'ALLEVA offers to sell and/or sells restricted, prescription devices directly to consumers in violation of the regulations prescribed under §520(e) of the FFDCA, 21 U.S.C. §360j(e), which is a violation of §§ 431.021(a) and (b) of the TFDCA. (See Exhibit 6)

28. TDSHS determined that Defendant D'ALLEVA distributed devices in Texas without obtaining a license to do so, in violation of §431.021(x) of the TFDCA. (See Exhibit 6)

29. TDSHS determined that Defendant D'ALLEVA disseminated false

advertisements, in violation of §431.021(f) of the TFDCA. (See Exhibit 6).

30. After reviewing Defendant D'ALLEVA's websites, the Texas Department of State Health Services ("TDSHS") referred the case to the Office of the Attorney General for legal action. (See Exhibit 6)

### **VIOLATIONS OF THE TFDCA**

31. Defendant D'ALLEVA advertises restricted prescription devices as being available for purchase directly by consumers. Defendant D'ALLEVA offers to sell and/or sells restricted prescription devices directly to consumers. Therefore, Defendant D'ALLEVA's advertisement, offer to sell, and/or sale of restricted prescription devices misbrand these devices pursuant to §431.112(o) of the TFDCA.

32. Defendant D'ALLEVA's advertisement, offer to sell, and/or sale of prescription drugs and devices to members of the public without labeling bearing adequate directions for use by the layperson misbrands these drugs and devices under §431.112(e)(1) of the TFDCA.

33. Defendant D'ALLEVA's advertisements for the prescription drugs and devices are deemed to be false under §431.182 of the TFDCA because they are false or misleading in any particular. Specifically, Defendant D'ALLEVA's advertisements convey the message that prescription drugs and devices are available to the general public without the involvement of a practitioner licensed by a state to order the use of the prescription drugs or devices. Defendant D'ALLEVA's advertisements are also false because she claims to be licensed to sell the prescription drugs and devices when she is not so licensed.

34. Defendant D'ALLEVA offers to sell, and/or sells devices in the State of Texas without having a license to do so as required by §431.272 of the TFDCA.

### **PROHIBITED ACTS UNDER THE TFDCA**

35. Based on the conduct alleged above, Defendant D'ALLEVA has committed or caused to be committed the following acts prohibited and declared to be unlawful by §431.021 of the TFDCA:

- a. Introducing and delivering into commerce misbranded devices in violation of §431.021(a);
- b. Misbranding devices in commerce in violation of §431.021(b);
- c. Introducing and delivering into commerce misbranded drugs in violation of §431.021(a);
- d. Misbranding prescription drugs in commerce in violation of §431.021(b);
- e. Disseminating false advertisements in violation of §431.021(f); and
- f. Engaging in the distribution of medical devices in Texas without a license in violation of §431.021(x).

### **VIOLATIONS OF THE DTPA**

36. Defendant D'ALLEVA, as forth above, in the course and conduct of trade and commerce, has directly and indirectly engaged in false, misleading, deceptive and unconscionable acts and practices declared unlawful by §§17.46 (a) and (b) of the Texas Deceptive Trade Practices Act, including but not limited to:

- a. Causing confusion or misunderstanding as to the approval of a good by selling prescription drugs and devices directly to consumers;
- b. Representing that goods have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have by advertising and selling

prescription drugs and devices directly to consumers;

- c. Representing that a person has a sponsorship, approval, status, affiliation, or connection which she does not by representing that she is a member of the Texas Medical Council, which does not exist, and is licensed to sell prescription drugs and devices;
- d. Representing that goods are of a particular standard, quality, or grade or that goods are of a particular style or model, if they are of another by advertising and selling prescription drugs and devices directly to consumers;
- e. Failing to disclose that prescription drugs and devices can only be sold by those authorized to distribute or dispense them, and can only be dispensed upon the order of a physician.

#### **PROHIBITED ACTS UNDER THE DTPA**

37. Defendant D'ALLEVA's conduct as set forth above, specifically violates §17.46

(a) and the following provisions of §17.46 of the DTPA:

- (b)(2) causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
- (b)(5) representing that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits or quantities which they do not have;
- (b)(7) representing that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another; and
- (b)(24) failing to disclose information concerning goods or services which was known at the time of the transaction when such failure to disclose such information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed.

#### **INJURY TO CONSUMERS**

38. By means of the foregoing unlawful acts and practices which were producing

causes of injury to the persons affected, Defendant D'ALLEVA has acquired money or other property from identifiable persons to whom such money or property should be restored, or who in the alternative are entitled to an award of damages.

**APPLICATION FOR EX PARTE TEMPORARY RESTRAINING ORDER,  
TEMPORARY INJUNCTION, AND PERMANENT INJUNCTION**

39. The State alleges that by reason of the foregoing, Defendant should not continue to operate as a drug and device distributor, receive, advertise, offer to sell, hold, or sell prescription drugs and devices in violation of the laws of Texas. Because Defendant has engaged in the unlawful acts and practices described above, Defendant has violated and will continue to violate the laws as alleged in this Petition. Unless immediately restrained by this Honorable Court, the Defendant will continue to violate the laws of the STATE OF TEXAS and cause immediate, irreparable injury, loss and damage to the State of Texas and to the general public. The interests of the State of Texas and the public require immediate action to keep Defendant from illegally selling prescription drugs and devices in Texas. Therefore, the State requests an Ex Parte Temporary Restraining Order, Temporary Injunction, and Permanent Injunction, as indicated below.

**REQUEST TO CONDUCT DISCOVERY PRIOR TO TEMPORARY  
INJUNCTION HEARING**

40. The State requests leave of this Court to conduct telephone, oral, written, and other depositions of witnesses, including Defendant or employees of Defendant, prior to any scheduled Temporary Injunction Hearing and prior to Defendant's answer date. There could be a number of witnesses who may need to be deposed prior to any scheduled Temporary Injunction Hearing. Any depositions, telephonic or otherwise, would be conducted with reasonable shortened notice to Defendant and her attorneys if known.

## PRAYER

41. WHEREFORE, PREMISES CONSIDERED, the STATE OF TEXAS prays that Defendant LAURIE D'ALLEVA d/b/a DISCOUNT MEDSPA a/k/a ONTARIO MEDSPA be cited according to law to appear and answer herein; that before notice and hearing a TEMPORARY RESTRAINING ORDER be issued; that after due notice and hearing a TEMPORARY INJUNCTION be issued; and upon final hearing a PERMANENT INJUNCTION be issued restraining and enjoining Defendant individually, her successors, assigns, agents, servants, employees, and any other person in active concert or participation with Defendant from engaging in the following acts or practices:

- a. Transferring, concealing, destroying or removing from the jurisdiction of this Court any books, records, documents, invoices, or other written materials relating to these allegations which are in Defendant's possession, custody, or control, except in response to further orders or subpoenas in this cause;
- b. Purchasing and/or possessing prescription drugs or devices for the purpose of offering to sell, selling, distributing, or dispensing the drugs and devices to members of the public;
- c. Operating or posting, either directly or indirectly through the use of a website hosting company, any website advertising, offering for sale and/or selling any prescription drug or device;
- d. Operating or posting, either directly or indirectly through the use of a website hosting company, any website through which individuals can purchase prescription drugs and devices;
- e. Delivering, receiving, offering for sale, distributing, selling, giving away prescription drugs and devices, or using any other means of introducing into commerce prescription drugs and devices;
- f. Introducing misbranded drugs and devices into commerce;
- g. Misbranding drugs and devices in commerce;
- h. Falsely advertising or falsely representing that prescription drugs and devices are available to and can be purchased by individuals without the involvement of a practitioner licensed to order the use of the prescription drugs or devices;

- i. Causing confusion or misunderstanding as to the source, sponsorship, approval, or certification of goods by selling prescription drugs and devices to individuals;
- j. Representing that goods have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities which they do not have by selling prescription drugs and devices to individuals;
- k. Representing that goods or services are of a particular standard, quality, or grade if they are of another standard, quality, or grade by selling prescription drugs and devices to individuals;
- l. Representing that a person has a sponsorship, approval, status, affiliation, or connection which she does not by representing that she is a member of the Texas Medical Council, which does not exist, and is licensed to sell prescription drugs and devices;
- m. Advertising, offering for sale, and/or selling prescription drugs and devices through any means, including, but not limited to, email, internet social sites such as facebook, twitter, and myspace, regular mail, flyers, and brochures; and
- n. Failing to provide written notice to any agent, servant, employee or representative of the existence and terms of any injunction entered in this case, and of their duty to comply with the terms set forth herein.

42. The STATE OF TEXAS further prays that upon final hearing this Court order Defendant LAURIE D'ALLEVA d/b/a DISCOUNT MEDSPA a/k/a ONTARIO MEDSPA to pay civil penalties to the State of Texas up to \$25,000 per violation per day for each violation of §431.021 of the TFDCA, as provided in §431.0585(b) of the TFDCA.

43. The STATE OF TEXAS further prays, that upon final hearing, this Court order Defendant LAURIE D'ALLEVA d/b/a DISCOUNT MEDSPA a/k/a ONTARIO MEDSPA to pay civil penalties of not more than \$20,000.00 per violation, as provided in §17.47(c)(1) of the DTPA.

44. The STATE OF TEXAS further prays that upon final hearing this Court order Defendant LAURIE D'ALLEVA d/b/a DISCOUNT MEDSPA a/k/a ONTARIO MEDSPA to pay an additional amount in civil penalties, not to exceed a total of \$250,000.00, to the State of

Texas, for any act or practice that was calculated to acquire or deprive money or other property from a consumer who was 65 years of age or older when the act or practice occurred as provided in §17.47(c)(2) of the DTPA.

45. The STATE OF TEXAS further prays that the Office of the Attorney General and the Commissioner of Health be awarded their investigative costs, court costs, reasonable attorneys' fees, expenses, and witness fees pursuant to the laws of the State of Texas including, but not limited to, TEX. HEALTH & SAFETY CODE ANN. §431.047(d) and TEX. GOV'T CODE ANN. §402.006(c).

46. The STATE OF TEXAS further prays that upon final hearing that this Court grant all other relief to which the STATE OF TEXAS may be justly entitled.

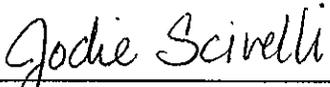
**Plaintiff State of Texas**

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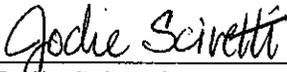
  
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### CERTIFICATE

To the best of my knowledge defendant Laurie D'Alleva is not represented by counsel in the matter made the basis of this suit.

The State brings this suit for violations of the DTPA, which, in section 17.47, provides for a temporary restraining order without prior contact to the defendant in certain circumstances, including, but not limited to, when immediate and irreparable injury, loss, or damage would occur as a result of a delay in obtaining a temporary restraining order. The State also brings this suit for violations of the TFDCA, which, in section 431.047, provides for a temporary restraining order to restrain continuing violations or threats of continuing violations of the Act.

  
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Jodie Scivetti