

CAUSE NO.: \_\_\_\_\_

STATE OF TEXAS,	§	IN THE DISTRICT COURT OF
Plaintiff	§	
	§	
v.	§	
	§	
WOMEN'S INTEGRATED	§	
HEALTHCARE, P.A.;	§	
ANGELA L. COPE, M.D.,	§	
individually;	§	TARRANT COUNTY, TEXAS
BARBARA COULTER-SMITH, D.O.,	§	
individually;	§	
KATRINA E. ALLEN, M.D.,	§	
individually;	§	
COURTNEY WALTERS, M.D.,	§	
individually;	§	
MONICA E. LOPEZ, M.D.,	§	
individually; and	§	
WENDY A. KINDRICK, D.O.,	§	
individually,	§	
Defendants.	§	_____ JUDICIAL DISTRICT

**PLAINTIFF'S ORIGINAL PETITION**

COMES NOW, THE STATE OF TEXAS, acting by and through Greg Abbott, Attorney General of Texas, complaining of WOMEN'S INTEGRATED HEALTHCARE, P.A.; ANGELA L. COPE, M.D., individually; BARBARA COULTER-SMITH, D.O., individually; KATRINA E. ALLEN, M.D., individually; COURTNEY WALTERS, M.D., individually; MONICA E. LOPEZ, M.D., individually; and WENDY A. KINDRICK, D.O., individually ("Defendants") and for cause of action would show as follows:

**Introduction**

During an inspection of Defendants offices, the Texas Department of State Health Services ("DSHS") determined that Defendants were purchasing and selling patients Mirena®

IUDs whose labeling was not in English. It was discovered that Defendants obtained the Mirena® IUDs from a Canadian online foreign pharmacy, Medisave. DSHS also determined that the Mirena® IUDs from Canada were not identical to FDA-approved IUDs, and that the Mirena® IUDs had not been approved by the FDA for use or distribution within the United States. Finally, DSHS determined that Defendants sold approximately 490 of these non-FDA approved Mirena® IUDs from to their patients without disclosing such information. Defendants conduct violates several different Texas laws.

### **1. Discovery Control Plan**

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

### **2. Authority**

2.1 This action is brought by Attorney General Greg Abbott, through his Consumer Protection & Public Health Division, in the name of the State of Texas and in the public interest under the authority granted to the Attorney General by §17.47, TEXAS DECEPTIVE TRADE PRACTICES--CONSUMER PROTECTION ACT, TEX. BUS. & COM. CODE §§17.41 *et seq.* (“DTPA”), upon the grounds that Defendants have 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.

2.2 This action is also brought by Attorney General Greg Abbott 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 of the TFDCA authorizes the Attorney General to

seek injunctive relief under certain circumstances and recover any costs and attorney fees incurred in obtaining that relief. In addition, §431.0585 of the TFDCA authorizes the Commissioner of Health to refer persons who violate §431.021 of the TFDCA and its associated regulations to the Attorney General for civil penalties against such violators.

### **3. Defendants**

3.1 Defendant WOMEN'S INTEGRATED HEALTHCARE, P.A. is a Texas professional association and may be served with process by serving its registered agent, Barbara Coulter-Smith, at Defendant's principal place of business at 1625 Lancaster Drive, Grapevine, Tarrant County, Texas 76051 or Barbara Coulter-Smith's residence at 1921 Fair Field Drive, Grapevine, Texas 76051.

3.2 Defendant ANGELA L. COPE M.D., individually, is a Texas resident and may be served with process at her place of business at 1625 Lancaster Drive, Grapevine, Tarrant County, Texas 76051 or her residence at 1006 Turnberry Lane, Southlake, Texas 76092.

3.3 Defendant BARBARA COULTER-SMITH, D.O., individually, is a Texas resident and may be served with process at her place of business at 1625 Lancaster Drive, Grapevine, Tarrant County, Texas 76051 or her residence at 1921 Fair Field Drive, Grapevine, Texas 76051.

3.4 Defendant KATRINA E. ALLEN, M.D., individually, is a Texas resident and may be served with process at her place of business at 1625 Lancaster Drive, Grapevine, Tarrant County, Texas 76051 or her residence at 1413 Savannah Court, Grapevine, Texas 76051.

3.5 Defendant COURTNEY WALTERS, M.D., individually, is a Texas resident and may be served with process at her place of business at 1625 Lancaster Drive, Grapevine, Tarrant

County, Texas 76051 or her residence at 2809 Dove Pond Drive, Grapevine, Texas 76051.

3.6 Defendant MONICA E. LOPEZ, M.D., individually, is a Texas resident and may be served with process at her place of business at 1625 Lancaster Drive, Grapevine, Tarrant County, Texas 76051 or her residence at 2014 Willowood Drive #106F, Grapevine, Texas 76051.

3.7 Defendant WENDY A. KINDRICK, D.O., individually, is a Texas resident and may be served with process at her place of business at 1625 Lancaster Drive, Grapevine, Tarrant County, Texas 76051 or her residence at 2700 Waltham Drive, Grapevine, Texas 76051.

#### **4. Venue**

4.1 Venue of this action lies in Tarrant County pursuant to §431.047(c) and §431.0585(d) of the TFDCa, and §17.47(b) of the DTPA. The violations of the TFDCa and DTPA occurred in Tarrant County.

#### **5. Public Interest**

5.1 Because the State of Texas has reason to believe that Defendants have engaged in, and will continue to engage in, the unlawful practices set forth below, the Attorney General has reason to believe that Defendants have caused, and will cause, adverse effects to legitimate business enterprise which conducts its trade and commerce in a lawful manner in this State. Therefore, the Consumer Protection & Public Health Division of the Office of the Attorney General of Texas believes and is of the opinion that these proceedings are in the public interest.

#### **6. Trade and Commerce**

6.1 Defendants have, at all times described below, engaged in conduct which

constitutes “trade” and “commerce” in the State of Texas as defined by §17.45(6) of the DTPA, in that Defendants engaged in the business of purchasing, receiving, holding for sale, offering for sale, selling, and delivery of drugs to patients.

**7. Notice Before Suit**

7.1 Defendants were informed in general of the alleged unlawful conduct described below as may be required by §17.47(a) of the DTPA at least seven days before filing suit.

**8. Acts of Agents**

8.1 Whenever in this petition it is alleged that Defendants did any act or thing, it is meant that Defendants performed or participated in such act or thing jointly and severally or that such act was performed by the officers, agents, or employees of Defendants, and in each instance, the officers, agents, or employees of Defendants that were then authorized to act did in fact act on behalf of Defendants or otherwise acted under the guidance and direction of the Defendants jointly and severally, in that the Defendants acted and conducted their business operations in combination, concert and in conjunction with each other.

8.2 Defendants ANGELA L. COPE, M.D., BARBARA COULTER-SMITH, D.O., KATRINA E. ALLEN, M.D., COURTNEY WALTERS, M.D., MONICA E. LOPEZ, M.D., and WENDY A. KINDRICK, D.O., operate Defendant WOMEN’S INTEGRATED HEALTHCARE, P.A., as its Officers and Directors. As such, ANGELA L. COPE, M.D., BARBARA COULTER-SMITH, D.O., KATRINA E. ALLEN, M.D., COURTNEY WALTERS, M.D., MONICA E. LOPEZ, M.D., and WENDY A KINDRICK, D.O., are controlling persons and have the responsibility for the overall management and oversight of the professional

association, including compliance with all state and federal statutes regulating drugs, including Mirena® IUDs, and false, misleading, or deceptive acts and practices. Defendants also have the responsibility of supervising and directing employees of the professional association. Additionally, Defendants ANGELA L. COPE, M.D., BARBARA COULTER-SMITH, D.O., KATRINA E. ALLEN, M.D., COURTNEY WALTERS, M.D., MONICA E. LOPEZ, M.D., and WENDY A. KINDRICK, D.O., as individuals have to comply with federal and state laws regulating drugs, including Mirena® IUDs, and false, misleading, or deceptive acts and practices in the conduct of their business and to see that their employees also comply with such laws. As a result, each individual Defendant directs and has personal knowledge of the everyday activities of the association and their individual acts and practices in the purchasing, receiving, holding for sale, offering for sale, selling, and/or delivery of drugs, including Mirena® IUDs, to patients.

## **9. Nature of Defendants' Conduct**

### **Overview of the Regulation of Prescription Drugs**

9.1 The United States Food and Drug Administration (“FDA”) is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Federal Food, Drug and Cosmetic Act (“FFDCA”), 21 U.S.C. § 301 *et seq.*, including but not limited to approving all prescription drugs that can legally be used in the United States. The FFDCA requires drug manufacturers to submit a new drug application (“NDA”) for each prescription drug the manufacturer wants to sell in the United States to ensure that all such drugs are safe and effective for every use for which the drug is sold. Any drug without an NDA specifically for that drug is illegal to purchase, receive, hold for sale, offer for

sale, sell, or deliver in the United States under federal law. Likewise, any drug without an NDA specifically for that drug is illegal to purchase, receive, hold for sale, offer for sale, sell, or deliver in Texas under Texas law.

9.2 In Finland, Bayer Shering Pharma OY (“Bayer”) manufactures several versions of levonorgestrel-releasing intrauterine systems (often called intrauterine devices or “IUDs”), known as Mirena® IUDs. These Mirena® IUDs are classified as drugs, rather than devices, because of the levonorgestrel that is released in the body. Even though it manufactures more than one version, Bayer chose only to submit one version of the Mirena® IUD to FDA for approval as a prescription drug for distribution within the United States, with New Drug Application number 21-225 which was approved by FDA on December 6, 2000. Only this FDA-approved version of the Mirena® IUD can legally be purchased, received, held, possessed, offered for sale, delivered, or sold in the United States.

9.3 The Texas Department of State Health Services (“DSHS”) contacted Bayer to determine if there were product differences between the FDA-approved Mirena® IUD and the Mirena® IUDs approved for other countries, besides the lack of the required federal legend, the lack of other FDA-labeling requirements, and not being labeled in English. Bayer indicated that there were other differences between the FDA-approved Mirena® IUD and the ones manufactured for other countries. Bayer indicated that the FDA-approved Mirena® IUDs were manufactured on separate production lines than the Mirena® IUDs manufactured for other countries with different specifications for various countries. Bayer indicated that there were differences in the inserters and thread lengths for the Mirena® IUDs manufactured for other

countries. Bayer also indicated to DSHS that if there was a problem requiring a recall of a Mirena® IUDs approved only for distribution in a country other than the United States, Bayer would not send recall notices to doctors or patients in the United States since that version of the Mirena® IUDs was not cleared for distribution in the United States.

9.4 Bayer, the manufacturer of both the FDA-approved Mirena® IUD and the unapproved Mirena® IUDs, sent a letter to healthcare professionals in May, 2008 describing the illegality of purchasing Mirena® IUDs, other than the FDA-approved one, and selling them in the United States. (See Exhibit 1, Bayer’s May 22, 2008 letter.) Bayer indicated that there are problems with the use of non-FDA-approved Mirena® IUDs, including but not limited to:

“We understand that product available from a foreign Internet pharmacy may be less expensive....However, the foreign product is *not* FDA approved, and use of the foreign product raises important patient care and legal considerations.” (First paragraph, second and third sentences, Exhibit 1, Bayer’s May 22, 2008 letter.)

“Thread lengths, inserters, and other product differences also exist from country to country, as do the patient support and other materials in the product package. These differences can affect insertion and appropriate post-insertion monitoring and patient care.” (Second paragraph, last two sentences, Exhibit 1, Bayer’s May 22, 2008 letter.)

“There is no assurance that the product is genuine and not a counterfeit, or that the product contains the correct active ingredient in the specified amount, has been protected from temperature fluctuations, and otherwise meets standards of quality, purity, and potency.” (Second paragraph, second and third sentences, Exhibit 1, Bayer’s May 22, 2008 letter.)

9.5 Under the FDCA, the FDA has the sole responsibility for approving prescription drugs and also regulates the manufacture, labeling, and distribution of all drugs and drug components in the United States. Federal regulations determine what must be on labels and labeling of prescription drugs, including what must be on the label of the FDA-approved

Mirena® IUD, which can legally be purchased, received, held for sale, possessed, offered for sale, delivered, or sold in the United States, including, but not limited to the following:

- A. All labels and labeling are required to be in the English language, 21 C.F.R. §201.15(c)(1);
- B. The label or labeling must contain the federal caution statement pursuant to 21 C.F.R. §201.100(b); and
- C. The label or labeling must contain the FDA-approved product description, indications for use, contraindications, warnings, precautions, and patient disclosure information, 21 C.F.R. §201.100(d).

If Defendants purchase any prescription drug for use in the United States, including the Mirena® IUD, the drug must be FDA-approved and meet all of the above labeling requirements and all other applicable requirements of federal law. A prescription drug that does not have an NDA and/or is not labeled in English, does not bear the federal caution statement, or does not have the other required statements or information is both misbranded and an unapproved new drug and cannot be legally purchased, delivered, received, held for sale, possessed, offered for sale or sold in the United States.

**Defendants’ Acts**

9.6 Defendants purchased, received, possessed, held for sale, offered for sale, delivered, and/or sold prescription drugs—two versions of the Mirena® IUDs—one was FDA-approved and meets the FDA labeling requirements and the other is not FDA-approved and does not meet the FDA labeling requirements.

9.7 Prior to April, 2008 Defendants only purchased Mirena® IUDs from Bayer’s sole

distributor of the FDA-approved Mirena® IUD in the U.S., TheraCom, who is a licensed wholesale drug distributor in Texas.

9.8 After April, 2008, in an effort to save money, Defendants began to purchase, receive, hold for sale, possess, offer for sale, deliver, and/or sell non-FDA-approved Mirena® IUDs that Defendants purchased on-line from a Canadian pharmacy called MediSave, at a lesser cost than from Bayer's sole distributor of the FDA-approved Mirena® IUD.

9.9 Defendants allegedly purchased the lower cost Mirena® IUDs because of the increasing number of uninsured patients seen by them and the fact that they were losing money each time they provided a Mirena® IUD purchased from the authorized distributor, TheraCom, to its insured patients. Defendants violated federal and Texas laws by purchasing and/or receiving prescription drugs, Mirena® IUDs, from the on-line Canadian pharmacy, Medisave. Additionally, Defendants violated Texas law by purchasing and/or receiving prescription drugs, Mirena® IUDs, from an on-line Canadian pharmacy, Medisave, who is not licensed in Texas as a wholesale distributor of prescription drugs as required.

9.10 The language printed on the packaging of the Mirena® IUDs Defendants purchased from the on-line Canadian pharmacy differed from that of the TheraCom distributed product. Defendants admit that the packaging of the Mirena® IUDs purchased and received from the on-line Canadian pharmacy was labeled in "Swedish, Norwegian, Danish, and Icelandic." (See Exhibit 2, outside of packaging on unapproved Mirena® IUDs.) Additionally, the package inserts with patient information and physician instructions for inserting and advising patients were all written in "Swedish," according to Defendants (See Exhibit 3, package inserts.)

9.11 Defendants' nurse practitioner would open each Mirena® IUD box purchased

from the on-line Canadian pharmacy and take out the “Swedish” package patient insert and replace it with an English insert, downloaded from the Bayer website, containing information for the patient about the FDA-approved Mirena® IUDs.

9.12 Defendants used an insert that accompanied the FDA-approved Mirena® IUDs purchased from TheraCom to ensure that labeling was available to the physician inserting an unapproved Mirena® IUD purchased from the on-line Canadian pharmacy. Since Defendants could not read the foreign language physician instructions, Defendants substituted the English-language physician insert in case the physician needed to refer to the package insert during insertion of the drug.

9.13 The Mirena® IUDs purchased and received by Defendants from the on-line Canadian pharmacy are unapproved new drugs as they were not the FDA-approved Mirena® IUD, approved as a prescription drug for distribution within the United States pursuant to New Drug Application number 21-225. Additionally, these Mirena® IUDs purchased and received by Defendants from the on-line Canadian pharmacy are misbranded because they fail to conform with the federal requirements for labels and labeling to be in English, to bear the federal legend required after FDA approval, and to have the approved labeling, including but not limited to FDA-approved product description, indications for use, contraindications, warnings, precautions, and patient disclosure information.

9.14 Bayer, the manufacturer of both the FDA-approved Mirena® IUD and the unapproved Mirena® IUDs, mailed six letters—one to each individual Defendant—in May, 2008, describing the illegality of purchasing Mirena® IUDs, other than the FDA-approved one, and selling them in the United States. (See Exhibit 1, Bayer’s May 22, 2008 letter.) Bayer mailed

such a letter to each of the six individual Defendants notifying them of problems as identified in the letter and referenced in paragraph 9.4 above.

9.15 Additionally, a TheraCom drug representative and her manager went to Defendants' offices on or about March 30, 2009, to discuss Defendants' lack of purchases of the FDA-approved Mirena® IUD and told Defendants' representative that the Mirena® IUDs purchased from the Canadian pharmacy were not FDA-approved. The pharmaceutical representatives told Defendants' representative that Defendants were using "black Market IUDs from Canada."

9.16 Despite being told that the Mirena® IUDs purchased from the on-line Canadian pharmacy were not FDA-approved (May, 2008) and having personal knowledge that they were not labeled in English and did not have the FDA-required labels and labeling that Defendants saw on the FDA-approved Mirena® IUDs, including but not limited to the federal legend required after FDA approval, FDA-approved product description, indications for use, contraindications, warnings, precautions, and patient disclosure information (April, 2008), Defendants persisted in violating the law and purchasing, receiving, possessing, holding for sale, offering for sale, delivering, and selling unapproved and misbranded Mirena® IUDs in Texas until DSHS stopped them on or about December 29, 2009.

9.17 Defendants did not inform their patients prior to offering for sale, selling, or delivery of the cheaper Mirena® IUDs that the cheaper IUDs were a version of the Mirena® IUDs that were not approved by the FDA; that the cheaper Mirena® IUDs were purchased from an on-line Canadian pharmacy; that these cheaper Mirena® IUDs were illegal to sell in the United States; and/or that these cheaper Mirena® IUDs were labeled in a foreign language only

and not in English; did not bear the federal legend that all FDA-approved drugs are required to bear; and/or did not have the required FDA-approved product description, indications for use, contraindications, warnings, precautions, and patient disclosure information. Defendants also failed to disclose to their patients prior to offering for sale, selling, or delivering of the cheaper Mirena® IUDs labeled only in a foreign language that Defendants substituted patient disclosure information with information in English printed off the Internet and substituted foreign language physician insertion instructions with instructions from previously purchased FDA-approved Mirena® IUDs.

#### **Inspection by Texas Department of State Health Services**

9.18 The DSHS inspected Defendants' facilities at 1625 Lancaster Drive, Grapevine, TX 76051, on December 29, 2009, and determined that Defendants were purchasing, receiving, holding for sale, offering for sale, and selling Mirena® IUDs whose labeling was not in English to patients. TDSHS determined that Defendants obtained the Mirena® IUDs from an online foreign pharmacy, Medisave.

9.19 The DSHS found that Defendants purchased and received the unapproved and misbranded Mirena® IUDs and sold them to patients as a form of contraception in substitution of the FDA-approved Mirena® IUD. TDSHS determined that the Mirena® IUDs that Defendants purchased and received from the Canadian pharmacy had **not** been approved by the FDA for use or distribution within the United States.

9.20 The DSHS determined that Defendants were in possession of 33 unapproved and misbranded Mirena® IUDs labeled in a language other than English. TDSHS detained 32 of the unapproved and misbranded Mirena® IUDs. Defendants voluntarily destroyed, under the

supervision of the DSHS, these unapproved and misbranded Mirena® IUDs.

9.21 The DSHS determined that after purchasing and receiving the unapproved and misbranded Mirena® IUDs, Defendants replaced the foreign language patient disclosure information inserts accompanying the Mirena® IUDs with patient information inserts in English, printed from the internet. The DSHS also determined that the labeling on these unapproved Mirena® IUDs lacked, among other things, the federally required caution statement or legend, product description, indications for use, contraindication, warnings, precautions, and patient disclosure information.

9.22 The DSHS determined that Defendants purchased, received, held for sale, offered for sale, delivered, and sold hundreds of the Mirena® IUDs not approved by FDA to patients in Texas. Defendants purchased approximately 490 unapproved Mirena® IUDs from the on-line Canadian pharmacy, Medisave. Defendants then received, held for sale, offered for sale, and sold to their patients these misbranded and unapproved Mirena® IUDs that were not the FDA-approved IUDs; that were not labeled in English; and/or that did not have the FDA-required labeling.

**Defendants’ False, Misleading, or Deceptive Acts and Practices**

9.23 Defendants’ representations, acts, and practices related to the offering for sale and selling to patients unapproved Mirena® IUDs purchased from an on-line Canadian pharmacy caused confusion or misunderstanding that these unapproved Mirena® IUDs were FDA-approved; were identical to the FDA-approved Mirena® IUDs; could legally be sold in Texas; were labeled in English as required for FDA-approved drugs; and/or had FDA-required caution statement or legend, product description, indications for use, contraindication, warnings, precautions, and

patient disclosure information.

9.24 Defendants' representations, acts, and practices related to the offering for sale and selling to patients unapproved Mirena® IUDs purchased from an on-line Canadian pharmacy represented that the Mirena® IUDs purchased from an on-line Canadian pharmacy were of a particular standard, quality, or grade, when they are of another, since these unapproved Mirena® IUDs were not FDA-approved; were not identical to the FDA-approved Mirena® IUDs; could not legally be sold in Texas; were not labeled in English as required for FDA-approved drugs; and/or did not have the FDA-required caution statement or legend, product description, indications for use, contraindication, warnings, precautions, and/or patient disclosure information.

9.25 Defendants' representations, acts, and practices related to the offering for sale and selling to patients unapproved Mirena® IUDs purchased from an on-line Canadian pharmacy represented that these unapproved Mirena® IUDs have approval or characteristics which they do not have including, but not limited to that these Mirena® IUDs purchased from an on-line Canadian pharmacy were FDA-approved; were identical to the FDA-approved Mirena® IUDs; could legally be sold in Texas; were labeled in English as required for FDA-approved drugs; and/or had FDA-required caution statement or legend, product description, indications for use, contraindication, warnings, precautions, and/or patient disclosure information.

9.26 Defendants' representations, acts, and practices related to the removing of the non-English patient disclosure information and substituting of patient disclosure information written in English taken from the manufacturer's website represented that these unapproved Mirena® IUDs purchased from an on-line Canadian pharmacy were of a particular standard, quality, or grade, if they were of another, since the patient disclosure information was not in English as required for

FDA-approved drugs.

9.27 Defendants' representations, acts, and practices related to the removing of the non-English patient disclosure information and substituting of patient disclosure information written in English taken from the manufacturer's website caused confusion or misunderstanding that these unapproved Mirena® IUDs purchased from an on-line Canadian pharmacy were FDA-approved; could legally be sold in Texas; and the FDA-required patient disclosure information was in English.

9.28 Defendants' representations, acts, and practices related to the removing of the non-English patient disclosure information and substituting of patient disclosure information written in English taken from the manufacturer's website represented that these unapproved Mirena® IUDs purchased from an on-line Canadian pharmacy had approval or characteristics which they do not have, since the patient disclosure information was not in English as required for FDA-approved drugs, were not FDA-approved drugs; and/or these drugs could not legally be sold in Texas.

9.29 Defendants failed to disclose to their patients prior to offering for sale and selling the unapproved Mirena® IUDs purchased at a cheaper price from an on-line Canadian pharmacy that the Mirena® IUD being offered for sale and sold was not labeled in English; were identical to the FDA-approved Mirena® IUDs; did not bear the federal legend that all FDA-approved drugs are required to bear; did not have the required FDA-approved product description, indications for use, contraindications, warnings, precautions, and/or patient disclosure information; were a version of the Mirena® IUDs not approved by the FDA, and/or were illegal to sell in the United States, and such failure to disclose that information was intended to induce the consumer into a

transaction into which the consumer would not have entered had the information been disclosed.

## **10. Violations of the Texas Food, Drug, and Cosmetic Act**

10.1 Based on the conduct alleged above, Defendants have introduced into commerce an unapproved new drug, introduced misbranded drugs into commerce, and received misbranded drugs in commerce or caused the above illegal acts.

10.2 The two versions of Mirena® IUDs, one FDA-approved and the other not approved by FDA, that Defendants purchased, received, possessed, held for sale, offered for sale, delivered, and sold are both drugs within the meaning of §431.002(14) of the TFDCA because these products are intended to cure, mitigate, treat, or prevent disease or affect the structure or function of the body of man.

### **Unapproved New Drug**

10.3 The Mirena® IUDs from the on-line Canadian pharmacy that Defendants purchased, received, possessed, held for sale, offered for sale, delivered, and sold as a form of contraception are additionally classified as “new drugs” within the meaning of §431.002(25) of the TFDCA because the DSHS is unaware of any evidence that establishes that this version of the Mirena® IUD is generally recognized as safe and effective for its intended uses in the United States since Defendants do not have a NDA as required by federal law for this specific version.

10.4 Accordingly, the purchase, receipt, holding for sale, offer for sale, delivery, or sale of any new drugs without an FDA approved new drug application violates §431.114(a)(1) of the TFDCA. The introduction or delivery for introduction into commerce of any article or the causing of the introduction or delivery for introduction into commerce of any article in violation of

§431.114 of the TFDCA is prohibited pursuant to §431.021(e) of that Act.

### **Misbranded Drug**

10.5 Both federal and state law have requirements for labels and labeling of prescription drugs and failing to comply with such requirements misbrands the drug pursuant to §431.112 of the TFDCA. This provision declares that a “drug or device shall be deemed to be misbranded..... (c) if any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; or ..... (e) unless its labeling bears adequate directions for use. Specifically, §431.112(e)(1) of the TFDCA states that a drug is deemed to be misbranded unless its labeling bears adequate directions for use, unless the drug has been exempted from those requirements by regulations adopted by the Secretary of the United States Department of Health and Human Services.

10.6 Federal regulations determine what must be on prescription drug labels and labeling, including, but not limited to the following:

- A. Labeling in English language is required, 21 C.F.R. §201.15(c)(1);
- B. The federal caution statement pursuant to 21 C.F.R. §201.100(b); and
- C. Product description, indications for use, contraindications, warnings, precautions, and patient disclosure information, 21 C.F.R. §201.100(d).

The failure to comply with these federal requirements on the label and in labeling also misbrands the Mirena® IUDs purchased and received from the on-line Canadian pharmacy, Medisave, pursuant to §431.112(c) of the TFDCA since any word, statement, or other information required

by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

10.7 The federal regulatory scheme creates exemptions from “adequate directions for use” for prescription drugs, but this exemption only applies when the drug is approved by the FDA in response to a New Drug Application. Prescription drugs purchased or sold in Texas must have adequate directions for use by a layperson, as required by 21 C.F.R. §201.5, or comply with one of the exemptions to this requirement found in 21 C.F.R. §201.100.

10.8 By federal regulation “adequate directions for use” means directions under which the layman can use a drug safely and for the purposes for which it is intended. The unapproved Mirena® IUDs purchased from the Canadian pharmacy and received, possessed, held for sale, offered for sale, delivered, and sold by Defendants fail to bear adequate directions for their intended use as a drug as required, since adequate directions for use by a layperson cannot be written for an unapproved drug under the terms of the TFDCA and federal regulation. The lack of adequate directions for use misbrands the Mirena® IUDs purchased from the on-line Canadian pharmacy, Medisave, pursuant to §431.112(e)(1) of the TFDCA.

10.9 Misbranded drugs are illegal to purchase, receive, possess, hold for sale, offer for sale, deliver, and/or sell in Texas. The introduction or delivery for introduction into commerce or the causing of the introduction or delivery for introduction into commerce within the State of Texas of any misbranded drug, such as Defendants’ Mirena® IUDs purchased from Medisave, is prohibited by §431.021(a) of the TFDCA.

## **11. Prohibited Acts Under the Texas Food, Drug, and Cosmetic Act**

11.1 Defendants have committed or caused to be committed the following acts prohibited and declared unlawful by §431.021 of the TFDCA:

A. Introducing or delivering into commerce or causing the introducing or delivering into commerce a misbranded drug, in violation of §431.021(a) of the TFDCA;

B. Receiving in commerce a drug that is misbranded and the delivery or proffered delivery thereof for pay or otherwise or the causing of receiving in commerce a drug that is misbranded and the delivery or proffered delivery thereof for pay or otherwise, in violation of §431.021(c) of the TFDCA; and

C. Introducing into commerce an unapproved new drug or the causing of the introducing into commerce an unapproved drug, in violation of Section 431.114 of the TFDCA, prohibited by §431.021(e) of the TFDCA.

## **12. Violations of the Texas Deceptive Trade Practices Act**

12.1 Based on the conduct alleged above, Defendants have in the course of trade and commerce, directly and indirectly, engaged in false, misleading, or deceptive acts and practices declared unlawful by §17.46(a) and (b) of the DTPA, including but not limited to:

A. Causing confusion or misunderstanding as to the approval of the Mirena® IUDs purchased from the on-line Canadian pharmacy, Medisave, that Defendants offered for sale and/or sold in violation of §17.46(b)(2) of the DTPA;

- B. Representing that the Mirena® IUDs purchased from the on-line Canadian pharmacy, Medisave, that Defendants offered for sale and/or sold have approval or characteristics which they do not have, in violation of §17.46(b)(5) of the DTPA;
- C. Representing that the Mirena® IUDs purchased from the on-line Canadian pharmacy, Medisave, that Defendants offered for sale and/or sold are of a particular standard, quality, or grade, or that drugs are of a particular style or model, if they are of another, in violation of §17.46(b)(7) of the DTPA; and
- D. Failing to disclose that the Mirena® IUDs purchased from the on-line Canadian pharmacy, Medisave, that Defendants offered for sale and/or sold have not been approved by the FDA for sale in the United States, were not labeled in English as required by federal law; did not bear the federal legend that all FDA-approved drugs are required to bear; did not have the required FDA-approved product description, indications for use, contraindications, warnings, precautions, and patient disclosure information; and/or were illegal to sell in the United States, when such failure to disclose that information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed, in violation of §17.46(b)(24) of the DTPA.

**13. Request for Permanent Injunction**

13.1 Defendants have violated and could continue to violate the laws of Texas as

hereinabove alleged. Defendants WOMEN'S INTEGRATED HEALTHCARE, P.A.; ANGELA L. COPE, M.D., individually; BARBARA COULTER-SMITH, D.O., individually; KATRINA E. ALLEN, M.D., individually; COURTNEY WALTERS, M.D., individually; MONICA E. LOPEZ, M.D., individually; and WENDY A. KINDRICK, D.O., individually, unless restrained by this Honorable Court for past violations and the threat of continuing violations of the TFDCA and the DTPA could continue to violate the laws of Texas.

#### **14. Prayer**

14.1 WHEREFORE, Plaintiff prays that Defendants WOMEN'S INTEGRATED HEALTHCARE, P.A.; ANGELA L. COPE, M.D., individually; BARBARA COULTER-SMITH, D.O., individually; KATRINA E. ALLEN, M.D., individually; COURTNEY WALTERS, M.D., individually; MONICA E. LOPEZ, M.D., individually; and WENDY A. KINDRICK, D.O., individually, be cited according to law to appear and answer herein; that after due notice and upon final hearing a PERMANENT INJUNCTION be issued, restraining and enjoining Defendants WOMEN'S INTEGRATED HEALTHCARE, P.A.; ANGELA L. COPE, M.D., individually; BARBARA COULTER-SMITH, D.O., individually; KATRINA E. ALLEN, M.D., individually; COURTNEY WALTERS, M.D., individually; MONICA E. LOPEZ, M.D., individually; and WENDY A. KINDRICK, D.O., individually, their successors, assigns, officers, agents, servants, employees, and any other person in active concert or participation with Defendants from engaging in the following acts or practices:

- A. Purchasing, receiving, possessing, holding for sale, offering for sale, delivering, or selling new drugs, including but not limited to Mirena® IUDs, that are not approved by the FDA;
- B. Purchasing, receiving, possessing, holding for sale, offering for sale, delivering, or

selling misbranded drugs, including but not limited to Mirena® IUDs, whose labels and labeling are not in English;

- C. Purchasing, receiving, possessing, holding for sale, offering for sale, delivering, or selling misbranded drugs, including but not limited to the Mirena® IUDs, whose labels and labeling lack the required federal caution statement for prescription drugs or devices (legend) and lack the FDA-approved product description, indications for use, contraindications, warnings, precautions, and patient disclosure information;
- D. Purchasing, receiving, possessing, holding for sale, offering for sale, delivering, or selling misbranded drugs, including but not limited to the Mirena® IUDs, whose labels and labeling fail to bear adequate directions for use because the drugs are not approved for use in the United States by FDA;
- E. Introducing misbranded drugs into commerce;
- F. Receiving misbranded drugs in commerce;
- G. Introducing unapproved drugs into commerce;
- H. Falsely representing that unapproved drugs, including Mirena® IUDs not approved by FDA for use in the United States, can legally be purchased, received, possessed, held for sale, offered for sale, delivered, or sold in the United States;
- I. Changing or substituting patient or physician information that accompanies drugs;
- J. Making a determination of safety or effectiveness for a drug that is not approved by the FDA, including but not limited to the Mirena® IUD, to justify using the drug in the United States;
- K. Purchasing drugs from wholesale drug distributors without verifying that the distributor is licensed in Texas with the Texas Department of State Health Services to distribute the drugs;
- L. Causing confusion or misunderstanding as to the source or approval of drugs, including but not limited to the Mirena® IUDs, that are not approved by the FDA or that do not have the correct labels or labeling required by FDA;
- M. Representing that drugs have approval, characteristics, uses, or benefits which they do not have by purchasing, receiving, possessing, holding for sale, offering for sale, or selling drugs, including but not limited to the Mirena® IUDs, that are not approved by FDA or that do not have the correct labels or labeling required by

FDA;

- N. Representing that goods or services are of a particular standard, quality, or grade if they are of another standard, quality, or grade by purchasing, receiving, possessing, holding for sale, offering for sale, or selling drugs, including but not limited to the Mirena® IUDs, that are not approved by FDA or that do not have the correct labels or labeling required by FDA;
- O. Failing to disclose information, when such failure to disclose that information was intended to induce the consumer into a transaction into which the consumer would not have entered had the information been disclosed;
- P. Representing that their business is approved by the Texas Department of State Health Services or the Office of the Attorney General for the State of Texas; and
- Q. 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.

14.2 Plaintiff further prays that this court upon final hearing order Defendants

WOMEN'S INTEGRATED HEALTHCARE, P.A.; ANGELA L. COPE, M.D., individually;  
BARBARA COULTER-SMITH, D.O., individually; KATRINA E. ALLEN, M.D., individually;  
COURTNEY WALTERS, M.D., individually; MONICA E. LOPEZ, M.D., individually; and  
WENDY A. KINDRICK, D.O., individually, to pay civil penalties in favor of the STATE OF  
TEXAS up to \$25,000.00 per day per violation of §431.021 of the TFDCA pursuant to §431.0585  
of the TFDCA.

14.3 Plaintiff further prays that, upon final hearing, this Court will order Defendants

WOMEN'S INTEGRATED HEALTHCARE, P.A.; ANGELA L. COPE, M.D., individually;  
BARBARA COULTER-SMITH, D.O., individually; KATRINA E. ALLEN, M.D., individually;  
COURTNEY WALTERS, M.D., individually; MONICA E. LOPEZ, M.D., individually; and  
WENDY A. KINDRICK, D.O., individually, to pay civil penalties in favor of the STATE OF

TEXAS of not more than \$20,000.00 per violation of the DTPA pursuant to of §17.47(c)(1) of the DTPA.

14.4 Plaintiff 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).

14.5 The State asks for such other and further relief to which it is justly entitled.

Respectfully submitted,

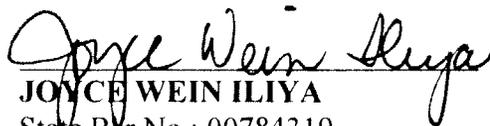
GREG ABBOTT  
Attorney General of Texas

DANIEL T. HODGE  
First Assistant Attorney General

BILL COBB  
Deputy Attorney General for Civil Litigation

PAUL D. CARMONA  
Chief, Consumer Protection & Public Health  
Division

D. ESTHER CHAVEZ  
Deputy Chief, Consumer Protection & Public Health  
Division



JOYCE WEIN ILIYA  
State Bar No.: 00784319  
Assistant Attorney General  
JODIE SCIVETTI  
Assistant Attorney General  
State Bar No. 24058099

Consumer Protection & Public Health Division  
1412 Main St., Ste. 810  
Dallas, Texas 75202  
(214) 969-7639, ext. 8811  
(214) 969-7615 fax

**Attorneys for the STATE OF TEXAS**