FEDERAL SECURITY AGENCY

FOOD AND DRUG ADMINISTRATION

NOTICES OF JUDGMENT UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

[Given pursuant to section 705 of the Food, Drug, and Cosmetic Act]

751–800

DRUGS AND DEVICES

The cases reported herewith, commenced prior to June 30, 1940, were instituted in the United States District Courts by the United States attorneys acting upon reports submitted by direction of the Secretary of Agriculture; and those commenced on and after that date were similarly instituted upon reports submitted by direction of the Federal Security Administrator.

PAUL V. MCNUTT, *Administrator, Federal Security Agency.*

WASHINGTON, D. C., *July 19, 1943.*

CONTENTS [1]

DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

751. Action to enjoin and restrain interstate shipments of a drug designated as Dependon Products Intrauterine Paste and the same drug designated as Dependon Products Paste. U. S. v. Anne M. Jenks doing business as Dependon Products and Jenks Physicians' Supplies. Permanent injunction granted. (Inj. No. 35.)

On October 16, 1942, the United States attorney for the District of Minnesota filed a complaint against Anne M. Jenks, doing business as Dependon Products and Jenks Physicians' Supplies at White Bear Lake, Minn., alleging that since 1930 the defendant had been the sole owner and operator of said business and had been engaged in the sale and distribution of gynecological specialties; that about the latter part of 1938 the defendant had become engaged in the sale and distribution in interstate commerce of an article labeled in part, "Dependon Products Intrauterine Paste"; that the article was offered for sale for injection into the pregnant uterus and as an effective medicament for the treatment of abnormal conditions which prevail in a nonpregnant uterus; that it was a viscous yellowish liquid consisting of a water solution of potassium soap, alcohol, glycerin, and iodine compounds and was a drug within the meaning of the law; that accompanying said drug in interstate commerce so as to consti-

[1] For reduction of quality because of extraneous material, see No. 756 (triple-distilled water); omission of, or unsatisfactory, active ingredients statements, Nos. 754, 756–758, 761, 764, 775, 782, 790, 791, 793; inconspicuousness of warning statement, No. 754; omission of name and place of business of manufacturer, packer, or distributor, No. 758; omission of accurate statement of quantity of contents, Nos. 758, 760; deceptive packaging, No. 782, 790, 791.

533413—43——1

tute labeling within the meaning of the law was a circular specifying the dosage, frequency, and duration of administration.[2]

The complaint alleged further: I. That the drug was misbranded: (1) In that it was dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling for the purposes of terminating pregnancy, for inducing labor, and for removing the retained portions of the products of conception. (2) In that the words "Intrauterine Paste," borne on the label, and statements in an accompanying circular represented and suggested that it was safe and appropriate for introduction into the uterine cavity for the purposes of terminating pregnancy, for inducing labor, and for removing retained portions of the products of conception; whereas it was not safe or appropriate for such purposes but was unsafe and dangerous and was capable of producing serious or even fatal consequences. (3) In that the following statements, "For Dysmenorrhea From 5 to 10 cc's of the Paste applied shortly before the period is considered helpful in some cases. The insertion of the Cannula may be considered to act as a dilatation. For Endometritis Cervical and Uterine Discharges. Application of from 5 to 10 cc's of the paste, as needed, is suggested by many physicians," represented and suggested that it was an effective medicament for the treatment of dysmenorrhea, endometritis, and cervical and uterine discharges; whereas it was not an effective medicament for such purposes.

II. (1) That in or about December 1941, and since that time up to the filing of the complaint, the drug had been subject to numerous libel or seizure actions commenced by the Government in various Federal judicial districts throughout the country for the purpose of condemning the quantities seized as misbranded within the meaning of the law; that in at least five instances decrees in favor of the United States had been entered condemning, forfeiting, and ordering destruction of the seized goods; and that other cases were awaiting trial. [These have since been terminated by the entry of decrees in favor of the Government.] (2)

---

[2] The following statements appeared in the circular: "For Physicians Only Nod-Nep-Ed Sterile Intrauterine Paste * * * Non-Toxic * * * Instillation of the Paste may be made by means of a Cannula attached to the tube, or by transferring the Paste to a syringe and then attaching the special syringe type Cannula to the syringe. * * * When using the Paste to terminate a pregnancy, or to induce labor it is usually considered that best results are obtained when the available space in the uterus is filled with the Paste. * * * Dependon Intrauterine Paste should be used only by a Physician, with adequate and continuous supervision of the case. For Therapeutic Termination of Pregnancy * * * Technique of Application of Paste—With self-supporting vaginal speculum in place, *very* slowly pass Cannula thru cervix until the tip has reached the uterine cavity. During this procedure keep expelling small amounts of the Paste. Thus the canal is continually lubricated and readily opened. After Cannula has reached the uterine cavity, even more slowly continue its insertion until a slight back pressure is felt—then slightly withdraw Cannula and turn it to one side (quarter turn)—now instill the desired amount of Paste into the uterus. If the uterus tips forward, the Cannula is turned to point downward. Undue pressure in applying the Paste must be avoided—should tension, pain, bleeding or expulsion of Paste develop, arrest instillation. After Paste instillation keep patient in Trendelenburg's position (hips higher than shoulders) for some moments. Later when Patient is resting she should be advised to place feet higher than her head. Should the cervical canal be enlarged, a small amount of sterile cotton may be placed so as to retain the Paste. The use of a rubber plug for this purpose is not recommended. Treatment during early stages of pregnancy: Dependon Intrauterine Paste may be used in the very early stages. Extreme gentleness and care is advised at this difficult time. It is essential that the Paste be deposited at the vault of the uterus, otherwise some bleeding; but no evacuation may be the result. Depending on the size of the uterus, from 10 to 15 cc's applied after effects of sedatives are noted, is suggested. Treatment during later stages of pregnancy: (after eight weeks)—Best dosage is usually from 7 to 10 cc's per month of pregnancy. Larger dosages (up to capacity of uterus to receive Paste) often produce stronger and quicker action. Maximum dosage, ordinarily should not exceed 30 to 40 cc's. Precautions—Always before using Paste a careful diagnosis should be made. * * * Under some conditions the Paste may not bring on the desired results. * * * It may also be observed that unless the Paste is properly placed and in sufficient amount, no results following its use may be looked for. In cases where the Paste fails to bring the desired results, and there are no contra-indications for its use, it is the usual practice to repeat the treatment after a few days * * * Then pains set in with rhythmic and sustained contractions. * * * In a few cases, spotting may be looked for, following the Paste treatment. This condition may ordinarily be expected to shortly correct itself. However, if spotting continues over a period of weeks, the possibility of only partial expulsion should be considered and proper therapy instituted. Generally massage of the uterus is sufficient. * * * Comments of Physicians indicate that *practically every case is uneventful,* and that in the very rare event that the Paste fails to bring the desired results no harm develops from the trial of the Paste treatment. We believe this is due to the fact that Dependon Intrauterine Paste is nontoxic and sterile. For Induction of Labor. Dosage is usually from 30 to 40 cc's, accompanied by quinine or other indicated therapy. For Incomplete Miscarriage. Usually from 10 to 15 cc's of the Paste is sufficient. Proper therapy should accompany use of Paste. * * * When using Dependon Intrauterine Paste it is suggested that a syringe be employed in some cases. * * * pressure can be accurately controlled. * * * In cases where Paste is used for the therapeutic termination of pregnancy * * * as the ability to conceive seems to be greatly enhanced following use of Dependon Intrauterine Paste."

That notwithstanding the fact that the Federal Security Agency had informed the defendant the drug was dangerous to health and misbranded in violation of the law, she in complete disregard of the decrees which had been entered condemning the drug had continued to introduce or deliver it for introduction into interstate commerce. (3) That in or about April 1942, the defendant relabeled her product under the name of "Dependon Products Paste," but that it was in fact the same drug as that formerly known as Dependon Products Intrauterine Paste; and that although she was not shipping it under the former designation, she was continuing to ship the same product under the latter designation to and through States other than Minnesota.

III. That the drug labeled "Dependon Products Paste" was misbranded: (1) In that it was dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, namely, "The use of this product in uterine therapy (which is still medically controversial) should be by physicians only * * * maximum dosage * * * in pregnant uterus 30 C. C. actual dosage to be determined by the physician for the individual patient." (2) In that the statements, "Dependon Products Paste * * * The use of this product in uterine therapy (which is still medically controversial) should be by Physicians only. * * * Maximum dosage to be determined by the Physician for the individual patient. Undue pressure in applying paste must be avoided," represented and suggested that it was safe and appropriate for introduction into the pregnant uterus; whereas it was not safe and appropriate for such purpose but was unsafe and dangerous and capable of producing serious injury or even fatal consequences. (3) In that the said statements represented and suggested that it was an effective medicament for the treatment of abnormal conditions in a nonpregnant uterus; whereas it was not an effective medicament for such purposes.

IV. That the shipments subsequent to 1938 of Dependon Products Intrauterine Paste and subsequent to April 1942 of Dependon Products Paste were in violation of section 301 of the act which makes it a criminal offense to cause the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded drug; and that in order to protect the public of the United States from dangers inherent in the use of the article it was necessary that an injunction issue; and praying that after proper notice and hearing a preliminary injunction issue restraining such unlawful acts by the defendant, and that after due proceedings the preliminary injunction be made permanent.

On October 29, 1942, the defendant having filed an answer denying the material allegations of the complaint and having appeared by counsel, the case came on for hearing to show cause why a temporary injunction should not issue. As a result of the hearing, the court found in substance that the defendant was engaged in the distribution in interstate commerce of the drug product alleged in the complaint, that it was offered for the purposes therein alleged, that the court had jurisdiction to restrain violations of section 301 of the act "for cause shown," and that irreparable injury need not be established as a prerequisite to the issuance of such preliminary injunction. The court stated further that the position taken by the Government was supported by the sworn statement of three leading doctors and that sufficient cause for the issuance of a temporary injunction had been shown; and on October 31, 1942, a temporary injunction against the defendant was entered.

On January 5, 1943, the case came on for trial on the merits as to why a permanent injunction should not issue, the trial continuing until and through January 18, 1943. During the trial no evidence was introduced on behalf of the defendant in opposition to the contentions of the Government; and on January 19, 1943, the court after consideration of the evidence submitted by the Government in the form of files, records, and exhibits, of the testimony of witnesses, and of arguments of counsel, made the following Findings of Fact, Conclusions of Law, and Order for Judgment (BELL, *District Judge*):

FINDINGS OF FACT

I

"Defendant, Anne M. Jenks, resides in the City of White Bear Lake, Ramsey County, State of Minnesota, and within the jurisdiction of this court, where for a number of years she has been engaged under the name and style of Dependon Products and Jenks Physicians' Supplies in the sale and distribution in interstate commerce of gynecological specialties.

II

"Since about 1933 defendant has manufactured, sold, and distributed in interstate commerce an article which has been labeled in part as 'Intrauterine Paste Gynecological Soap' and 'Dependon Products Paste'; said article has been composed mainly of potassium soap or other soft soap base, with small quantities of alcohol, iodine, and distilled water added, although its formula and composition has not been entirely consistent; said article is offered for sale and intended for use by licensed physicians in the performance of therapeutic abortions, in the treatment of incomplete abortions and miscarriages, for the induction of labor and as a medicament for the treatment of endometritis, cervicitis, dysmenorrhea, and cervical and uterine discharges.

III

"In connection with the interstate distribution of the said article, defendant has distributed written, printed, and graphic matter in the form of circulars containing suggestions and recommendations as to usage, technique of use, dosage, frequency, and duration of administration—at times, by enclosing the same in the retail cartons containing said article, and at times by enclosing the same in the shipping carton in which several of said retail cartons have been shipped in interstate commerce, and at other times by sending such matter by separate mail at or about the same time the article itself was shipped: that where the latter practice has been followed, the article and such matter, although separately shipped, arrived at destination at or about the same time.

IV

"Such written, printed, and graphic matter as well as the various labels which have been affixed to said article, represent and suggest that said article is safe and appropriate for introduction into the pregnant uterus, for the purpose of inducing labor, terminating pregnancy, and removing the retained portions of the products of conception.

V

"Such written, printed, and graphic matter as well as the various labels which have been affixed to said article, represent and suggest that said article is an effective medicament for the treatment of cervicitis, endometritis, dysmenorrhea and cervical and uterine discharges.

VI

"Said article when used for the purposes of the induction of labor, termination of pregnancy, and the removal of the retained portions of the products of conception, is unsafe and dangerous to health and has caused fatalities and serious injury. Among the specific dangers which are involved in and have resulted from its use are the extensive destruction of tissue, hemolysis or the destruction of the cellular portions of the blood, systemic potassium poisoning, extensive hemorrhage and prolonged bleeding, sterility, peritonitis, pulmonary embolism, damage to kidneys, liver and other internal organs, and increased susceptibility to infection.

VII

"The dangers to health hereinbefore enumerated in Paragraph VI for the most part are the result of the physiological action of the soap ingredient present in said article or any article of drug having soap as a base.

VIII

"The dangers to health hereinbefore enumerated in Paragraph VI are present when said article is used by licensed physicians or anyone, in any quantity, or for any duration, or with any frequency of usage, for the treatment of any conditions which prevail in the pregnant uterus.

IX

"Said article is ineffective for the treatment of cervicitis, endometritis, dysmenorrhea, and cervical and uterine discharges, or the treatment of any other condition prevailing in a non-pregnant uterus.

X

"Heretofore on October 31, 1942, this court made its order that a temporary injunction should issue restraining defendant and any of her agents or associates from introducing or delivering for introduction into interstate commerce, and from causing the introduction or delivery for introduction into interstate commerce of said article or an article of substantially similar composition.

XI

"The dangers inherent in the use of said article, or any other article having a soap for its base, with or without small quantities of iodine, alcohol, and distilled water added, when used for introduction into a pregnant uterus, and its ineffectiveness when used for the conditions suggested in a non-pregnant uterus, make essential the issuance of a permanent injunction restraining henceforth the interstate distribution of said article for introduction into a pregnant or non-pregnant uterus, or for any other purpose unless application therefor is made to the court."

CONCLUSIONS OF LAW

I

"The court is specifically authorized by section 302 (a) of the Federal Food, Drug, and Cosmetic Act to restrain the introduction or delivery for introduction or the causing of the introduction or delivery for introduction into interstate commerce of a drug which is misbranded.

II

"Cause has been shown justifying the issuance of a permanent injunction.

III

"Said article, whether labeled in part 'Intrauterine Paste Gynecological Soap' or 'Dependon Products Paste' is a drug within the meaning of section 201 (g) (2) and (3) of said act.

IV

"The written, printed, or graphic matter distributed by defendant enclosed either in retail cartons containing said drug or within shipping packages containing said retail cartons, or shipped separately from said drug accompanies said drug within the meaning of section 201 (m) of the act and hence constitutes 'labeling.' The labels which have been affixed by defendant to said drug also constitute 'labeling' within the meaning of section 201 (m).

V

"Said drug is misbranded within the meaning of section 502 (a) of said act in that its labeling is false and misleading, for the reason that it represents and suggests that said drug when used for induction of labor, termination of pregnancy, or the removal of the retained portions of the products of conception, is safe and appropriate; whereas in truth and in fact it is unsafe and dangerous and has caused serious and fatal consequences.

VI

Said drug is misbranded within the meaning of section 502 (a) of said act in that its labeling is false and misleading for the reason that it represents and suggests that said drug is an effective medicament for the treatment of cervicitis, endometritis, dysmenorrhea, and uterine and cervical discharges; whereas in truth and in fact it is ineffective for such purposes.

VII

"Said drug is misbranded within the meaning of section 502 (j) in that it is dangerous to health when used in any dosage or with any frequency or with any duration of administration prescribed, recommended, or suggested in its labeling, for the purposes of induction of labor, termination of pregnancy, and removal of the retained portions of the products of conception.

ORDER FOR JUDGMENT

"Upon the basis of the foregoing Findings of Fact and Conclusions of Law,

"It is hereby *Ordered*, That a Permanent Injunction be entered accordingly, without costs to either party."

PERMANENT INJUNCTION

"It is hereby *Ordered and Decreed*, That defendant, her employees, servants, agents, distributors, assigns, and any and all persons in active concert or participation with them be, and they are, hereby permanently enjoined from introducing or delivering for introduction into interstate commerce and from causing the introduction or delivery for introduction into interstate commerce of the article of drug, labeled in part, 'Intrauterine Paste' or 'Dependon Products Paste,' or under any other name, containing soft soap or other soap base with or without distilled water, iodine, and alcohol or other ingredients added, under labeling recommending or suggesting its use for introduction into the uterus for the purpose of terminating pregnancy, treating incomplete abortions or miscarriages, for inducing labor, or as a medicament for the treatment of dysmenorrhea, endometritis, cervicitis, cervical or uterine discharges, or for any intrauterine or cervical therapy whatever.

"In order to effectuate the purposes of the act and to prevent the article of drug from being used in uterine and cervical therapy, defendant, her employees, servants, agents, distributors, assigns, and any and all persons in active concert or participation with them, are specifically enjoined from introducing or delivering for introduction or causing the introduction or delivery for introduction into interstate commerce of said article of drug or any similar article of drug for any purpose whatsoever in violation of the Federal Food, Drug, and Cosmetic Act, and amendments thereto."

732. Introduction and delivery for introduction in interstate commerce of quantities of Dependon Products Paste in violation of preliminary injunction. U. S. v. Anne M. Jenks, W. S. Jenks, and C. H. Jenks. Plea of guilty by W. S. Jenks; fine $500. Plea of not guilty by Anne M. Jenks. Tried to the court. Judgment of guilty; fine $250. Action against C. H. Jenks dismissed. (Inj. No. 35.)

On January 19, 1943, the United States attorney for the District of Minnesota filed an information against Anne M. Jenks, W. S. Jenks, and C. H. Jenks, alleging that Anne M. Jenks was trading as the Dependon Products and Jenks Physicians' Supplies at White Bear Lake, Minn., that defendant W. S. Jenks was the husband and that defendant C. H. Jenks was the brother-in-law of the said Anne M. Jenks, and that the two defendants last named were at that time actively associated with her in the business and on the dates hereinafter mentioned were the agents of and were acting in concert with defendant Anne M. Jenks.

The complaint alleged further that an injunction proceeding was commenced under section 302 of the Federal Food, Drug, and Cosmetic Act by the filing on October 16, 1942, of a complaint and petition for issuance of an order to show cause why a temporary injunction should not issue restraining the defendant Anne M. Jenks, her agents, and all those acting on her behalf from introducing or delivering for introduction into interstate commerce a drug product under the name "Dependon Products Intrauterine Paste" or the same product under the name "Dependon Products Paste," and that on October 29, 1942, a preliminary injunction issued in accordance with the prayer of said complaint; that on or about November 15, 1942, Anne M. Jenks knowingly and willfully, in violation of the preliminary injunction, introduced or delivered for introduction or caused such delivery or introduction into interstate commerce from White Bear Lake, Minn., by making personal delivery of 2 tubes of Dependon Products Paste to a physician at Hannibal, Mo., in contemptuous disregard of the preliminary injunction.

The information alleged further that since January 1, 1943, the three above-named defendants had introduced or delivered for introduction into interstate commerce from White Bear Lake, Minn., (or, had caused such acts) various quantities of the said drug under the designation "Dependon Products Paste" to various physicians in the States of Missouri, Iowa, Oklahoma, Wisconsin, Pennsylvania, and Massachusetts, in contempt of the preliminary injunction and that such acts were willfully and knowingly made in violation of the said injunction.

On January 19, 1943, the defendants were arraigned and W. S. Jenks entered a plea of nolo contendere, which plea was rejected by the court, whereupon he