

PLEA: Guilty—by corporation and Werlin to all counts and by Portnoy to counts 1, 2, and 5.

DISPOSITION: 4-4-55. Corporation—\$1,000 fine; Werlin and Portnoy—each fined \$500, given jail sentence of 6 months, which was suspended, and placed on probation for 2 years.

4640. (F. D. C. No. 35805. S. Nos. 69-804/6 L, 69-808 L, 69-810 L, 69-812 L.)

INFORMATION FILED: 10-14-53, Dist. Utah, against Clearfield Pharmacy, a partnership, Clearfield, Utah, and Glade R. Day and Leslie B. Otte (partners).

CHARGE: Between 11-12-52 and 8-27-53, *secobarbital sodium capsules* were dispensed 3 times (counts 2, 3, and 6), *sulfadiazine tablets* were dispensed twice (counts 1 and 5), and a quantity of *procaine penicillin G* was dispensed once (count 4), without a prescription.

PLEA: Guilty—by partnership to all 6 counts of information; by Day to counts 1, 2, 3, 4, and 6; and by Otte to count 5.

DISPOSITION: 6-7-54. Partnership fined \$6,000; Day given suspended prison sentence of 5 years and placed on probation for 5 years; Otte fined \$1,000 and given suspended prison sentence of 1 year and placed on probation for 1 year.

INDEX TO NOTICES OF JUDGMENT D. D. N. J. NOS. 4601 TO 4640

PRODUCTS

N. J. No.	N. J. No.
Amphetamine sulfate tablets----- 4621, 4622, 4635, 4636, 4639	Dibenzylethylenediamine dipeni- cillin G, sulfadiazine, sulfa- merazine, and sulfametha- zine, tablets containing a mixture of----- 4626
dextro-, sulfate tablets-- 4603, 4609, 4615, ¹ 4617-4620, 4631, 4633	Emmenagogues-- 4606, 4631, 4632, 4638
Amytal Sodium capsules----- 4618	Ergoapiol capsules----- 4631
Androgenic substances----- 4609, 4613, ¹ 4616-4618, 4632, 4633	Ergonovine maleate tablets----- ¹ 4617
Apiol capsules----- 4632	<i>See also</i> Ergotrate Maleate tablets.
-ergot capsules----- 4638	Ergot, apiol, savin oil, and castor oil, capsules containing----- 4606
Benzedrine Sulfate tablets----- 4636	Ergotrate Maleate tablets--- 4606, 4639
<i>See also</i> Amphetamine sul- fate tablets.	Estrogenic substances, conju- gated ----- 4621, 4622, 4635-4637
Chloral hydrate capsules----- 4605	Gantrisin tablets----- 4607
Chloromycetin capsules----- 4637	Metandren Linguets----- 4616
Conjugated estrogens tablets. 4621, 4622	Methamphetamine hydrochloride tablets ----- 4608
Cortisone acetate tablets----- 4633, 4634	Methyltestosterone tablets----- 4609, 4613, ¹ 4617, 4632, 4633
Desoxyn Hydrochloride tablets-- ¹ 4614	Nembutal Sodium capsules----- 4634
Dexedrine Spansules----- 4611, 4612	Oreton-M tablets----- 4618
Sulfate tablets----- 4610, 4616, 4634	Oxytocic substances----- 4606, ¹ 4617, 4631, 4638, 4639
Dextro-amphetamine sulfate tab- lets----- 4603, 4609, 4615, ¹ 4617-4620, 4631, 4633	
Dibenzylethylenediamine dipeni- cillin G, procaine penicillin G, and potassium penicillin G for aqueous injection, drug consisting of----- 4630	

¹ (4614, 4617, 4623, 4624) Prosecution contested.

U. S. Department of Health, Education, and Welfare

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]

4641-4660

DRUGS AND DEVICES

The cases reported herewith were instituted in the United States district courts by United States attorneys, acting upon reports submitted by the Department of Health, Education, and Welfare. They involve drugs and devices which were adulterated or misbranded within the meaning of the Act when introduced into and while in interstate commerce. These cases involve (1) seizure proceedings in which decrees of condemnation were entered after default, consent, or trial; (2) criminal proceedings which were terminated upon pleas of guilty or *nolo contendere*; and (3) injunction proceedings in which decrees of injunction were entered with the consent of the parties or after trial. The seizure proceedings are civil actions taken against the *goods* alleged to be in violation, and the criminal and injunction proceedings are against the *firms* or *individuals* charged to be responsible for violations.

Similar actions with respect to products alleged to be in violation while held for sale after shipment in interstate commerce are reported in other supplements.

Published by direction of the Secretary of Health, Education, and Welfare.

GEO. P. LARRICK, *Commissioner of Food and Drugs.*

WASHINGTON, D. C., *May 9, 1956.*

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* For omission of, or unsatisfactory, ingredients statements, see No. 4656.

**SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS
REPORTED IN D. D. N. J. NOS. 4641-4660**

Adulteration, Section 501 (b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium, and its strength differed from, or its quality or purity fell below, the standard set forth in such compendium; and, Section 501 (c), the article was not subject to the provisions of Section 501 (b), and its strength differed from, or its purity or quality fell below, that which it purported or was represented to possess.

Misbranding, Section 502 (a), the labeling of the article was false and misleading; Section 502 (e) (2), the article was not designated solely by a name recognized in an official compendium and was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use; and, Section 502 (j), the article was dangerous to health when used in the dosage, or with the frequency or duration, prescribed, recommended, or suggested in its labeling.

**DRUGS AND DEVICES ACTIONABLE BECAUSE OF POTENTIAL DANGER
WHEN USED ACCORDING TO DIRECTIONS**

4641. Dr. Reilly's Applicator and Dilator Assembly (a device) and Dr. Reilly's Rectal Remedy Pile-Aid (a drug). (Inj. No. 272.)

COMPLAINT FOR INJUNCTION FILED: 1-7-54, E. Dist. Wis., against Dr. Reilly's, Inc., Milwaukee, Wis., and its president, Dr. John F. Reilly; and Hunter Enterprises, Inc., Milwaukee, Wis., and its president, Robert S. Hunter, to enjoin the interstate shipment of the above-mentioned drug and device, which were misbranded.

ACCOMPANYING LABELING: Testimonial letters dated 4-15-52 and 6-30-52 signed by Evelyn Donner and Edward R. Hoffmann, a form letter addressed to "Dear Friend" and beginning with the words "I am not only sending," a leaflet entitled "Important Information Direct from Dr. Reilly," a leaflet entitled "Dr. Reilly's Medicating Applicator," a leaflet headed "This Concerns Your Health," a form letter addressed to "Dear Friend" and beginning with the words "Until now no easy, convenient, inexpensive home treatment has been available," a form letter addressed to "Dear Friend" and beginning with the words "You will find enclosed answers to questions sometimes asked," a pamphlet entitled "Comfort for all the family," and a leaflet containing "Instructions for Use."

RESULTS OF INVESTIGATION: The device consisted essentially of a small metal pump, plastic tubing, a plastic applicator, and rectal dilators, and was designed to be attached to a bottle of the drug and to inject the drug into the rectum.

The drug consisted of a solution of camphor-phenol in mineral oil, together with a small amount of a certified coal-tar color. The drug was packaged in 8-ounce bottles suitable for attachment to the device.

CHARGE: The complaint alleged that the defendants had been and still were engaged in the business of distributing, selling, and introducing into interstate commerce the above-mentioned drug and device, which were misbranded as follows:

502 (a)—the labeling contained false and misleading representations that the articles, when used in combination, constituted an adequate and effective remedy for piles, hemorrhoids, rectal irritations, inflamed tissue,