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Testimony of Sidney M.Wolfe, M.D.

Director, Public Citizen's Health Research Group at

FDA Hearing on Direct-to-Consumer Advertising of Prescription Drugs

October 19.1995

As will be discussed in the accompanying charts, the primary purpose of advertising, either to physicians or to consumers, is to sell drugs and the history of both kinds of advertising demonstrates that such ads are designed to be as misleading and, sometimes, false as they can get away with. In the area of physician drug advertising, the study by Wilkes and colleagues three years ago demonstrated that a substantial proportion of clearly regulated physician ads--not previously cleared by FDA and going to an audience more knowledgeable than patients--were false or misleading.

There is little question that, as exemplified in the tragic case of direct-to-consumer promotion of Lilly's arthritis drug, Oraflex, patients, armed with misleading information, can greatly influence their physicians' decision to prescribe a drug. The recent ad from Medical Marketing and Media, shows how eager the media are to convince drug companies that by taking out direct-to-consumer ads in their publications, they can reach--and influence--not only patients but also their physicians. The ad for Virazole, not "voluntarily" sent to FDA for pre-approval, demonstrates how dangerous it can be to rely on a voluntary approach to regulating such ads.

We favor a moratorium on DTC prescription drug advertising until FDA has in place a set of regulations aimed specifically at such ads, rather than using regulations intended to cover physician and other health professional advertising. In the alternative, while such regulations are being promulgated and finalized, FDA should be much more aggressive in insisting on prior clearance of all such ads and taking appropriate enforcement actions whenever serious violations occur.

DTC DRUG ADS THE PUBLIC PAYS TWICE

- The reason for drug ad regulation is drug ads.
- Drug ads to doctors are false and misleading.
- The only purpose of drug ads is to sell drugs--not to educate the public.
- The public will pay twice for false and misleading drug ads--in higher drug costs and in health.

THE ACCURACY OF DRUG ADS

Wilkes et al. Ann Intern Med. 1992;116:912-919.

• Review of 109 Drug Ads in 10 Leading Medical Journals

Among the Conclusions:

- 38% of the ads potentially violated 5 or more FDA regulations
- 40% did not present a fair balance between effectiveness and side effects
- 47% did not highlight problems in special patient groups such as the elderly

THE "QUALITY" OF DRUG ADS

- "One of the worst ads I've ever seen.
 It promotes the use of a dangerous medicine for trivial indications."
 (Phenergan, by Wyeth-Ayerst)
- Misleading through omission."
 (Dilantin, by Parke-Davis)
- "Advertisements, like this one, are reasons why something must be done to avoid such terribly misleading information about a drug." (Noroxin, by Merck Sharp & Dohme)
- "These ads are fundamentally lacking in integrity." (Unasyn, by Roerig)

"Dangerous Virus Strikes 274 Babies"

armory 29, 1994, The Orange County Register

"Pneumonia Spreads Among Infants"

January 20, 1994, Lox Angeles Times

Important message to Parents

Looks like a cold. Is it RSV?

Symptoms:

* Nasal stuffiness

* Runny nose

* Cough

* Wheezing

*Rapid or labored breathing

It could be RSV.

Call your doctor, ask about RSV, or 1-800-572-7400 for more information.

Hospitalized children with RSV - the only available therapy:

Virazole®

(ribavirin)

Ask your doctor.

Pharmaceuticals, Inc.
Costa Mesa, CA. 92626

(See full prescribing information below)

Manuface (relative production) (relative pro

.een taken, emesis should be encouraged. The would be kept in a darkened room for eight hours ineous reactions subside. The treatment for seas resulting from overdosage or over-exposure w accepted procedures for treatment of severe e have not been any clinical reports or tests to nore severe reactions may result from the concestion of furocoumarin-containing food while on N (TRIOXSALEN) therapy; but the physician the patient that taking limes, figs, parsley, parsd, carrots and celery, might be dangerous.

REACTIONS AND SIDE EFFECTS

can result from excessive sunlight or sun lamp cosure. Occasionally, there may occur gastric minimize this gastric effect, the tablets may be ilk or after a meal. Some patients who are unte 10 mg. will tolerate 5 mg. This dosage prone therapeutic effect but more slowly.

children over 12 years of age)

wo tablets daily, taken two to four hours before riods of ultraviolet exposure or fluorescent 0). (See suggested sun exposure guide.)

plerance to sunlight and/or enhance pigmentaolets daily, taken two hours before measured posure to sun or ultraviolet irradiation. Not to or longer than 14 days. The dosage should **NOT** as severe burning may occur. (See suggested guide.)

GGESTED SUN EXPOSURE GUIDE

time to sunlight should be limited according to plan: Basic Skin Color

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sure	20 min.	25 min.	
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and tenderne	988.	,	

ould be worn during exposure and the lips pro-

light-screening lipstick (10).

EXPOSURE: Should be initiated according to the sun-lamp manufacturer.

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I.A.: Feliman, J.H.: and Kaufman,

14. El Mofty, A.M., Vitiligo and Psoralens, PERGAMON PRESS INC., Long Island City, New York, 1st Edition.

ICN PHARMACEUTICALS, INC. 3300 Hyland Ave. Costa Mesa, CA 92626 USA

Revised August, 1993 Shown in Product Identification Guide, page 312

VIRAZOLE®

[vira 'zahl']

(Ribavirin for Inhalation Solution)

WARNINGS:

USE OF AEROSOLIZED VIRAZOLE IN PATIENTS REQUIRING MECHANICAL VENTILATOR ASSIS TANCE SHOULD BE UNDERTAKEN ONLY BY PHY. SICIANS AND SUPPORT STAFF FAMILIAR WITH THE SPECIFIC VENTILATOR BEING USED AND THIS MODE OF ADMINISTRATION OF THE DRUG. STRICT ATTENTION MUST BE PAID TO PROCE DURES THAT HAVE BEEN SHOWN TO MINIMIZE THE ACCUMULATION OF DRUG PRECIPITATE, WHICH CAN RESULT IN MECHANICAL VENTILA-DYSFUNCTION AND ASSOCIATED IN CREASED PULMONARY PRESSURES (SEE WARN-LNGS).

SUDDEN DETERIORATION OF RESPIRATORY FUNCTION HAS BEEN ASSOCIATED WITH INITIA. TION OF AEROSOLIZED VIRAZOLE USE IN IN. FANTS. RESPIRATORY FUNCTION SHOULD BE CAREFULLY MONITORED DURING TREATMENT. IF INITIATION OF AEROSOLIZED VIRAZOLE TREATMENT APPEARS TO PRODUCE SUDDEN DETERIORATION OF RESPIRATORY FUNCTION, TREATMENT SHOULD BE STOPPED AND REINSTI-TUTED ONLY WITH EXTREME CAUTION, CONTIN-UOUS MONITORING AND CONSIDERATION OF CONCOMITANT ADMINISTRATION OF BRONCHO-DILATORS (SEE WARNINGS)

VIRAZOLE IS NOT INDICATED FOR USE IN ADULTS. PHYSICIANS AND PATIENTS SHOULD BE AWARE THAT RIBAVIRIN HAS BEEN SHOWN TO PRODUCE TESTICULAR LESIONS IN RODENTS AND TO BE TERATOGENIC IN ALL ANIMAL SPE CHES IN WHICH ADEQUATE STUDIES HAVE BEEN CONDUCTED (RODENTS AND RABBITS) (SEE

CONTRAINDICATIONS).

DESCRIPTION TO THE TRANSPORT OF A STRAIGHT AND Virastle® is a brand mame for relativistin, a synthe side with antiviral activity. VIRAZOKE for in the line tion is a steelle, puphilised powder to be received accord Administration. But 100 mi glass within grains of the state and when the state of the sta contain 20 mg of etherstein our wal pill Aerosolization is to be carried out in a Small

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RAZOLE is in

Well Informed

Very Important

Prescription Drug Issues

and safety Efficacy

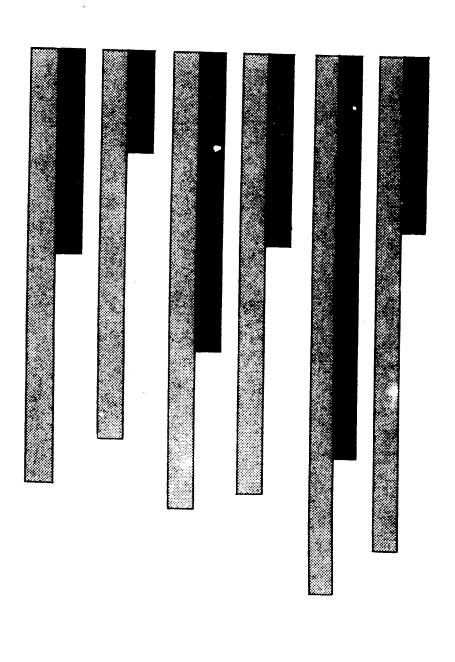
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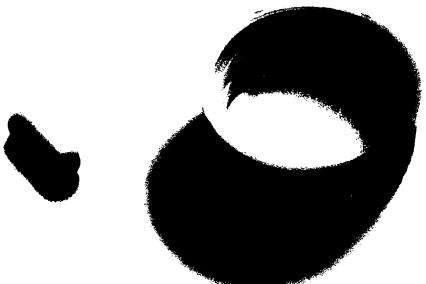
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MEDICAL MARKETING & MEDIA Vol. 30 No. 5 May 1995



84% of doctors consider prescribing a remedy if a patient asks for it by name.*

We get your name to 38 million adults overnight.

USA WEEKEND's weekend delivery in 430

newspapers lets you educate consumers so they ask for your brand by name. It's the power of a broadcast buy in print. That's why many phar-

maceutical companies use USA WEEKEND

to launch new remedies, target seasonal needs and garner market share. For more information, call Beth Lawrence at (212) 715-2137.



The magazine America responds to.