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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"

January 20, 1994, The Orange County Register

"Pneumonia Spreads Among Infants"

January 20, 1994, Los 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.

This message provided to families by:

ICM Pharmaceuticals, Inc.
Costa Mesa, CA. 92626

(See full prescribing information below)

Vitamin E

Background: Development of antibodies to the *Haemophilus influenzae* type B (Hib) capsular polysaccharide (CPS) is the most important component of the Hib vaccine. The CPS is a repeating disaccharide unit, and the vaccine is composed of a purified CPS conjugated to a protein carrier. The vaccine is administered to children at 2, 4, and 6 months of age, and a booster dose is given at 12-15 months of age. The vaccine is highly effective in preventing Hib disease, and the incidence of Hib disease has declined significantly since its introduction.

Methods: The vaccine is composed of a purified CPS conjugated to a protein carrier. The vaccine is administered to children at 2, 4, and 6 months of age, and a booster dose is given at 12-15 months of age. The vaccine is highly effective in preventing Hib disease, and the incidence of Hib disease has declined significantly since its introduction.

Results: The vaccine is highly effective in preventing Hib disease, and the incidence of Hib disease has declined significantly since its introduction. The vaccine is composed of a purified CPS conjugated to a protein carrier. The vaccine is administered to children at 2, 4, and 6 months of age, and a booster dose is given at 12-15 months of age.

Conclusion: The vaccine is highly effective in preventing Hib disease, and the incidence of Hib disease has declined significantly since its introduction. The vaccine is composed of a purified CPS conjugated to a protein carrier. The vaccine is administered to children at 2, 4, and 6 months of age, and a booster dose is given at 12-15 months of age.

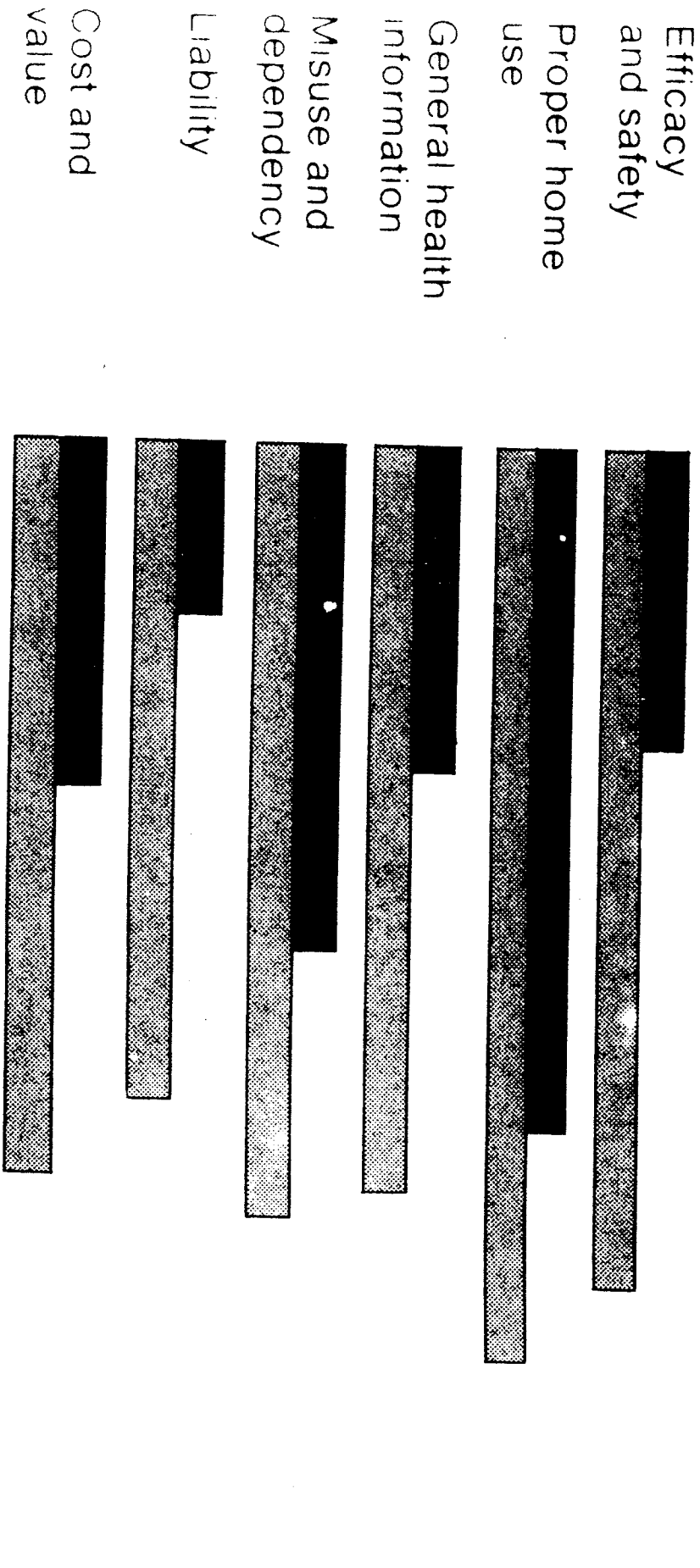
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INDICATIONS
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Knowledge and informational needs

Well Informed Very Important

Prescription Drug Issues



% Households Responding

**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-



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