DRUG REGULATION

Crackdown on Drug Ads

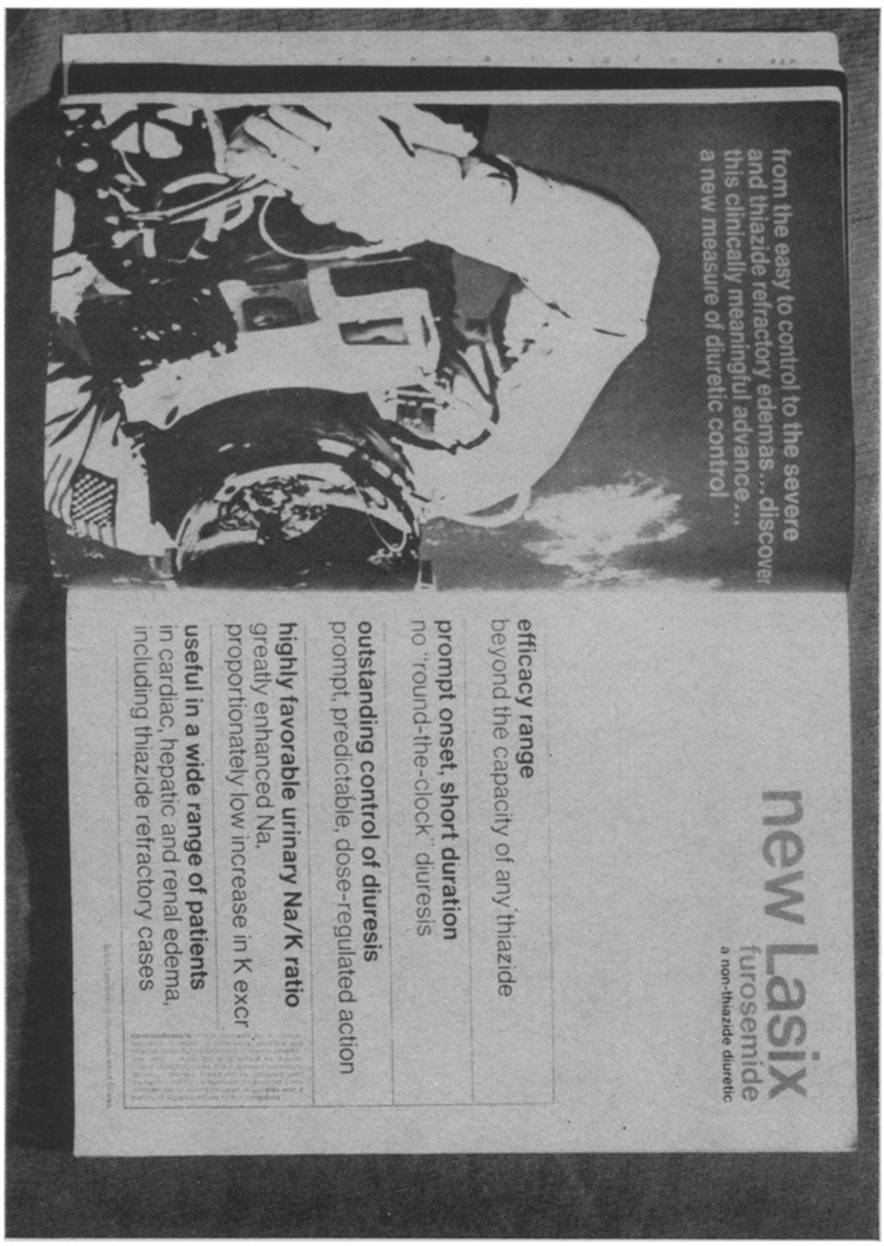
by Barbara J. Culliton

The Food and Drug Administration outlined the ground rules in its war against splashy drug advertising, and expects to publish binding regulations for ads—content and layout—by the first of the year.

Regulations requiring ads to tell the whole truth and be realistic in their claims have been around at least since 1962. But complaints from the drug industry that the guidelines were not clear enough, as well as some highly exaggerated ads, have forced an FDA decision to issue new regulations that will spell out in precise detail what can and cannot be done.

The Federal Trade Commission, under its authority to curb unfair and deceptive advertising, will assist FDA in its policing. FTC chairman Paul Rand Dixon thinks that the government's position is already clear, and with FTC and FDA ready to advise at any point, there should not be any problem if business is willing to cooperate voluntarily. "Go and sin no more," Dixon warned industry.

FDA sees drug ads as labels and is using its authority in that area to cut out the "high hysteria" ads that "come screaming off the page" of professional journals. It objects to ads proclaiming that a single tranquilizer cannot only relieve tension but also cure sadness or that one birth control pill is the safest, surest, most effective pill going, even though there is no scientific evidence to support the assertion that one is significantly better than another. All this, as FDA sees it, comes under the category of unfair and deceptive advertising, and from here on in, ad makers will have to present the whole story of a drug in their pleas for doctors' attention, listing contraindications as clearly as they list merits.



FREMONT DAVIS

FDA acted against this ad. Contraindications are in insert, lower left.

Lasix Seized

In a recent move along these lines, FDA siezed a small sample of Lasix, a new diuretic agent, and took action against its manufacturer, Hoechst Pharmaceuticals, Inc., for running an ad that did not present the facts in fair balance. The ad opened with a two page color spread of an astronaut floating outside his capsule (a NASA picture) and said "In an age of discovery step beyond the thiazides." Page four boldly hailed Lasix as a "non-thiazide diuretic" and then, in small print six pages later, listed its contraindications, including anuria (a lack of urine excretion from the body) and states of electrolyte depletion which may manifest themselves by weakness, dizziness, lethargy, leg cramps, vomiting, and/or mental confusion. The company has stopped publishing the ad.

A spokesman for Hoechst said the manufacturers were "surprised" at FDA's action because discussions between company officials and FDA authorities were underway before the seizure. Hoechst is more than willing to comply with FDA regulations and changes the ad, he said.

No one has challenged the safety of effiacacy of Lasix. Only the advertisement was called into question.

Advertising by its very nature is meant to be attention-getting, a representative of the drug industry told the tenth annual educational conference of FDA and the Food and Drug Law Institute, Inc. where the new rules were outlined and discussed. Irving H. Jurow, vice-president and general counsel of Schering Corporation, countered FDA's position, saying that drug advertising that made broad, emphatic statements was not necessarily deceptive because of the highly selective nature of its audience. He contended that advertising and labeling were not,

in fact, the same thing. The law, he said, provides that ad information relating to effectiveness and contraindications be included in a "brief summary"—and that does not mean a full and detailed explanation.

Any physician who wants full information about a drug can get it from the folder in the package, from the company's detail man, or from the company directly, a representative of industry said. However, William W. Goodrich, FDA's general counsel retorted that busy doctors haven't time to go through all that and what we need is "better performance by those who advertise and by those who create advertisements." Better performance is needed, he said, not just to meet the demands of government regulators as some have suggested, but "to improve the quality of patient care and meet the needs of the sick and the distressed at the end of the long line of drug distribution."

Drug Recalls on Rise

Drug safety is the other area in which FDA has stepped up its vigilance.

The incidence of drug recalls has risen sharply in the last few years, the conference was told. Prior to the 1962 Kefauver-Harris drug amendments there were about 70 a year. Fiscal 1966 saw the number rise to 449, Douglas C. Hansen of FDA reported, and this in spite of efforts by the drug industry to produce safe and legal products. "There are too many instances where unsafe drugs are finding their way to the market place," Hansen commented.

The answer, according to Hansen, is "GMP," otherwise known as good manufacturing practices. About 78 percent of the costly recalls can be blamed on poor manufacturing processes that allow labeling errors, contamination and potency variation, among other problems, to creep in. If manufacturers followed the rules of GMP, the sources of error could be eliminated, he said. Among the rules spelled out in the Federal Register in 1963 are requirements for the design of buildings, the qualifications of key personnel, the proper storage of materials, the keeping of records, the cleaning of processing equipment to prevent cross contamination of products and for control of packaging and labeling.

More stringent requirements under the 1962 admendments and a larger staff of trained people at FDA who devote their time to seeking out defective drugs accounts in part for the upward surge of drug recalls. The trend can be expected to continue, he said.

INTERNATIONAL TECHNOLOGY

U.S. Answers Allies' Plea

While one arm of the federal government—the Department of Commerce—is seeking to exploit the U. S. technological capability to expand exports, the White House is yielding to pressure from Europe to help close the "technology gap."

Nobody in Washington knows yet if the gap between U. S. and Western European technology exists outside of the Europeans' minds.

But in response to complaints from abroad, President Johnson has created a committee to investigate. Dr. Donald F. Hornig, his assistant for science and technology, will be chairman.

"The basic principle here," Dr. Hornig said, "is finding ways of keeping both America and Western Europe progressing at a rapid rate."

European representatives at a meeting of the science committee of the Organization for Economic Cooperation and Development last January decried the "technology gap," saying that this country, because of heavy government investment in computer and space technology, enjoyed an industrial advantage over theirs.

If this gap is closed, however, it will be from both sides, Dr. Hornig said, since Western European countries are ahead in some areas, particularly metallurgy. Other Washington sources said that although the U.S. may lead in electronics and aircraft techniques, it lags in other fields, including plastics, cryogenics and shipbuilding.

Serving with Dr. Hornig on the committee will be representatives of the Departments of State, Defense and Commerce; the National Aeronautics and Space Administration, the Atomic Energy Commission and the Council of Economic Advisers.

Dr. Hornig has been consulting on technological matters with such countries as Great Britain, Belgium, France, West Germany and Italy.

"We don't know exactly what they want," a State Department science aide said. "It's difficult to find this gap. But that is what the committee will do: study to see if there is a gap, and if so what to do about it."

The goal, Dr. Hornig stated, is to find ways of speeding up the progress of European friends, without slowing down our own.