POLICY STATEMENT

NATIONAL CONSUMER ALLIANCE ON PRESCRIPTION DRUGS

July 12, 1978

Pressures have been building to revamp the methods by which drugs are approved, marketed and monitored. For over two decades the pharmaceutical industry, and its ally, organized medicine, have systematically and effectively lobbied and unduly influenced the policy decisions of Congress and the Food and Drug Administration. In those years, consumers have been over-prescribed, under-protected and over-charged. The Drug Reform Act of 1978, may provide a vehicle to address these problems.

There are some excellent improvements proposed in the new legislation: information labeling for patients, limited distribution of certain drugs which could present dangers if not properly used, procedures for removing a suspect drug from the marketplace, post marketing surveillance, availability for independent scientific review of raw data resulting from safety and efficacy testing, and provisions for enabling the public to participate in the FDA administrative process by reimbursing attorney's fees and other costs.

Unfortunately, while the legislation reaches several vital issues, it effectively avoids others. In some instances, key provisions of the current law--such as those pertaining to personal criminal liability, testing procedures and export of unapproved drug products--are removed or weakened.

Two of the most offensive provisions of the proposed law--bypassing the Park* decision and permitting overseas sale of

*U.S. v. Park, 421 U.S. 658.

products banned in this country--were the result of eleventh hour changes, introduced after industry representatives obtained an advance copy of the carefully guarded legislation. Consumer groups did not obtain an advance copy.

The proposed legislation, however, fails to address what many consider the critical issue of prescription drugs: the extraordinary price differences between drugs prescribed under their trade names and products dispensed under their generic names. The FDA can undermine the deceptive claims of the industry about the safety and effectiveness of generic drugs by publishing a list of interchangeable drugs. The FDA also has the authority to inform the medical profession and the public that there is no difference between the two products.

Moreover, the history of the pharmaceutical industry offers us little comfort as we examine the proposed legislation. If anything, we must examine each clause of each section with particular care. When an entire act is changed, rather than amended, a wealth of important case law can be set aside. Consumer victories of the past can now be subjected to the drug industry's technique of prolonged and persistent litigation.

Against this background, we are faced with a potential weakening of the restraints against industry. This proposed legislation, to be successful, must move us ahead, not backwards.

The proposed legislation, with the changes suggested below, enjoys the conditional support of the participating organizations.

What follows are the highlights of the strengths and the weaknesses of the proposed legislation.

Positive Aspects

(1) The requirement for patient information inserts in most prescription drugs will enumerate side effects and give consumers other information now provided only to doctors.

(2) The provision for independent scientific access to raw data resulting from safety and efficacy testing will provide long-needed safeguards for the public. However, it should not be limited to data submitted in connection with a monograph application but should apply to pertinent data submitted both before and after the monograph hearing, such as post market surveillance data.

The suggestion that detailed summaries might replace this scientific access is not acceptable. In the past, failure to make such information available for careful monitoring has resulted in dangerous drugs reaching the market place, remaining in the marketplace too long or causing needless deaths or illnesses during the investigational use of the drug.

(3) The limited distribution of certain drugs provides a control framework which does not exist under current law. However, we would like assurances that, in the limited distribution of drugs, provision be made for proper access to these drugs by low income consumers and the elderly.

(4) The authority to remove suspect drugs from the market-place and keep them off the market pending a final decision provides the FDA with added flexibility to quickly protect the public interest.

(5) The establishment of an independent Center for Clinical Pharmacology to conduct research, testing and pre-clinical investigations of drugs widens FDA's ability to monitor drug products. It is suggested that one of the first priorities of this Center be the testing of products for their clinical effect on the young and the old. Current testing covers only a narrow spectrum of human development.

(6) Post market surveillance of drug products provides the consumer with a degree of protection not available under the current legislation, but this should not be considered a substitute for good pre-marketing testing. We also believe the five year post-surveillance is too short.

(7) Price posting will enable the consumer to pre-determine the cost of medicine.

(8) Stricter control of the activities of detailmen is long overdue, as are standards for industry's marketing practices. Physicians have become dependent on the entrepreneurial sales pitches of detailmen and advertisements in medical journals as a source for drug information.

(9) The requirement that "an informed consent" of a patient be obtained before certain drugs that present potential dangers are used.

(10) Publication of a compendium of drug information for use by physicians and the public.

(11) Public participation in the FDA administrative process and the provision for the award of attorney's fees and costs will provide consumer groups the opportunity to develop independent expertise on drug issues.

Negative Aspects

(1) Under the current practice, the senior corporate officers of drug companies bear strict responsibility for the improper manufacture or distribution of drugs. The proposed legislation would reverse a decision of the Supreme Court upholding this sanction. We believe that this fixing of responsibility at the top has forced executives to monitor carefully the activities of subordinates. Replacing this sanction with weaker laws provides another white collar loophole through which executives can escape liability.

(2) Under current practice, drugs not approved for sale in the United States cannot be shipped abroad. The new law removes this limitation and provides a means for "dumping" unsafe products overseas on the theory that unless we change this practice, U.S. companies will establish plants overseas to manufacture the products outside the U.S. jurisdiction. The deterrent of "non approval" in this country is a proper safeguard and should be maintained.

(3) The new law would relax present requirements for testing the safety and effectiveness of the so-called "breakthrough drugs". The new law would allow the Secretary of HEW to grant permission for marketing without a demonstration of efficacy through adequately controlled studies. We have not been able to discover any specific and concrete evidence that a relaxation of the present requirements is warranted. The present IND process provides ample opportunity

for non-commercial distribution, testing and use while at the same time providing more protection for the public.

(4) The relaxation of safeguards for human testing is also unwarranted.

(5) The proposed legislation is silent on the generic-trade name controversy. Confusion over the interchangeability of drug products enables the industry to sell its higher priced brand name products where lower priced generics are safely and readily available. FDA has developed, but not published, a list of interchangeable drugs which could end that controversy. A provision mandating the publication of this list should be included in this legislation.

What We Would Like FDA and the Congress to Further Consider:

(1) Currently, drug information is provided to physicians by salesmen (detailmen) or through trade publications dependent upon drug advertisements. This practice has led to higher priced drugs, irrational prescribing and the overuse and misuse of drugs. To counter industry's multi-billion dollar propaganda program, FDA must become the public defender against this incomplete information. FDA should serve as the source of drug information and as the aggressive disseminator of this information.

(2) HEW should develop a "Formulary of the United States" which would include only those drug products which medical experts consider necessary for good medical practice. Medicaid reimbursements should be pegged to this Formulary.

(3) A requirement that the official, or generic, name be used in labeling and advertising of drugs and that trade names for drugs be eliminated.