PUBLIC HEALTH

FDA: Consumer Guardian

Sleuthing to rival that portrayed in any "Who-Done-It" fiction is done by the Food and Drug Administration to protect you, the consumer, Lillian Levy reports.

➤ SINCE the turn of the century, the Food and Drug Administration has been fighting against tremendous pressures, political and technological, to maintain the purity of foods, drugs and cosmetics in the United States.

The annual cost of this inspection and detection to provide consumer protection is fantastically low—12 cents per person. The scope and importance of FDA's work largely goes unnoticed. However, the recent tragedies resulting from the use of thalidomide, a tranquilizer pill which causes birth defects, have focused public attention on the Food and Drug Administration and some of the life and death aspects of its daily work.

Broaden Regulations

The dread pills also have bolstered support for legislation to broaden FDA regulatory powers over the development, experimental testing and licensing of drugs. Prior to the discovery of the effects of thalidomide on unborn children, drug reform legislation, as proposed by Sen. Estes Kefauver (D.-Tenn.) earlier this year, was virtually dead as a consequence of public indifference and a Congress highly sensitive to private industry.

Now haunted by the specter of more than 7,000 misshapen children, some limbless and others with horribly deformed limbs—innocent victims of a tranquilizer—the public and Congress are willing to give increased economic and legislative support to the FDA. Unhappily, from the earliest beginnings, it has required tragedy to spur the strengthening of the FDA.

In 1906, a series of illustrated articles in newspapers and magazines revealed the dangerously filthy conditions in commercial food plants, with rats and vermin crawling over ingredients upon which U. S. citizens were feeding. A shocked public learned of candies colored with poisonous dyes, baby syrups doped with narcotics, and of the terrible—often fatal—consequences of reliance on the cure-all promises of "patent" medicines.

These exposes led Congress to pass the original Pure Food and Drug Law of 1906, vesting responsibility for enforcement in the Bureau of Chemistry of the U. S. Department of Agriculture. Headed by Dr. Harvey Wiley, who led the nationwide crusade for the law, scientists in the Bureau became the first food and drug "detectives," establishing a program of exposure and disclosure to insure that foods set on American tables are pure and wholesome and that drugs consumed are safe and effective.

In 1927, the Food and Drug Administration was established as a separate unit of the Department of Agriculture; but no legislative changes occurred until 1938 when the danger from cosmetics manufactured without any controls aroused the public and stirred Congress into action.

Following World War I, as a result of technological advances, a flood of new consumer products for external uses, such as cosmetics, appeared. It soon became evident that "the play of the market place" was not enough to insure the purity or safety of these products.

For example, thallium, an ingredient now considered too hazardous for consumer usage even in rat poison, was used in a depilatory. Ointments with high mercury content were sold as bleach creams. Cosmetics to color eyebrows and lashes contained chemicals capable of causing blindness.

The 1906 law provided no consumer protection against these dangerous products, but Congress took no action to amend or revise the law until, in 1938, public outrage, prompted by tragedy—this time blindness from an eyelash cosmetic and deaths from an elixir containing dangerous amounts of sulfa—precipitated the complete revision of the law.

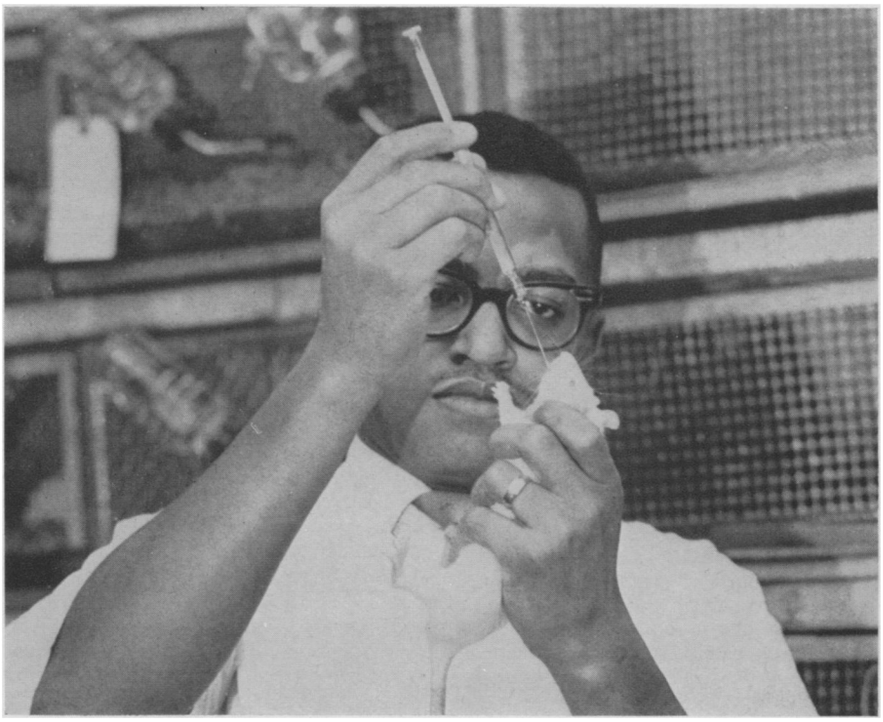
For the first time, FDA was given responsibility for the safety and purity of cosmetics. In addition, the new law declared a food to be adulterated if it contained any added poisonous or deleterious ingredients unless these were deemed necessary in its production or could not be avoided under good manufacturing practices. The law authorized FDA to set tolerances in such cases.

Evidence of Safety

However, the burden of proof was placed on the FDA to show that a substance was toxic or harmful. Amended legislation since 1958 has transferred the burden of proof to the manufacturer who must submit evidence that additives and new drugs are safe.

Tremendous pressures are placed on FDA by industry, often with political support, to approve a product which the manufacturer wishes to market. This was clearly illustrated in the case of thalidomide. Merrell Company of Cincinnati, Ohio, had asked FDA to license the drug, originally developed in West Germany, for commercial U. S. sale. In spite of more than 50 calls by Merrell Company representatives, Dr. Frances O. Kelsey, FDA physician, refused to issue the license, although the drug was widely used in Europe. The drug was limited to investigative use only in the U. S. and only a few hundred expectant mothers in the U. S. may have been exposed to it.

Similar pressure is currently being applied



FDA "DETECTIVE" WORK—FDA scientist is examining a laboratory animal for the effects of an additive which a manufacturer wishes to use to enrich a food product for human consumption.

to FDA by drug industry officials to support their request to ease a restriction in the 1958 Food Additive Amendment which prevents using cancer-producing additives in animal feed. Drug officials contend that the restriction seriously obstructs research to produce more and cheaper meat, eggs and dairy products. However, the American Veterinary Medical Association has urged passage of legislation "to strengthen Food and Drug Administration control over animal feed additives and drugs."

New regulations have been proposed by Anthony J. Celebrezze, newly appointed Secretary of Health, Education and Welfare, "strengthening control over testing of new drugs." However, these regulations set no specific standards for selecting clinical investigators or for testing.

Under the new proposals, all the drug companies have to do is inform the FDA that a new drug is to be tested and supply details concerning its distribution of drugs for human testing, following pre-clinical testing on animals. This would mean more reports for FDA physicians to study but not more authority. Will it take another drug tragedy of the dimensions of thalidomide to strengthen the regulatory authority of the FDA?

Understaffed and Underfunded

While there still appears to be a reluctance on the part of Congress to increase FDA regulatory powers, the thalidomide tragedy has focused attention on the fact that the FDA is woefully under-funded and understaffed. This makes its achievements even more remarkable. The FDA New Drug Section, for example, has 12 full-time doctors, 12 chemists and two part-time doctors. It has no laboratories for testing and research on the more than 40 applications for new drugs it receives almost daily. In addition to the inspection of new drugs, FDA specialists daily inspect and analyze foods for pesticide residues and other contaminants, study the effects of additives used to enrich or preserve foods, check cosmetics to make certain they contain nothing to destroy or maim those who use them as beauty aids.

For less than $22,000,000 annually and with 2,412 employees, FDA administers laws covering products valued at over $110 billion and protects the priceless health and lives of more than 180,000,000 Americans.

Congress has voted appropriations to provide a 25% increase in the present staff, less than the cost of a superjet airplane.

The work of the FDA staff often is routine, prosaic and unexciting because fortunately the great majority of food, drug and cosmetic producers are honest and maintain high production standards. A typical day of one of the 637 inspectors in any one of the 18 FDA districts scattered through the United States might include sanitary inspections of food factories and warehouses; a "control" inspection of a drug factory's processing program; investigation of an injury complaint associated with a food, drug or cosmetic; collection of samples of products under FDA regulations for laboratory analysis; attempts to buy prescription drugs without a prescription in a drug store reported to be selling such drugs illegally; seizure of filthy, spoiled or harmful products; and testifying as a Government witness in Federal court against an FDA violator.

Occasionally, however, as in the case of thalidomide, the FDA undertakes an investigation that has all the elements of suspense, drama and tragedy of a first-rate mystery story.

During the season of Lent, three years ago, FDA chemists investigated the death of a small boy in New Jersey which occurred after the child had eaten fish. They discovered his death was due to sodium nitrate which was on the fish in excessive amounts. Fast work by FDA teams located the plant which originally distributed the fish, recalled all the deliveries and thereby prevented other similar tragedies.

Several years ago, when children at a Halloween party became seriously ill, FDA sleuths traced the illness to candy colored with a red coal tar dye banned by FDA regulations. The candy manufacturer was found, his deadly sweets recalled and destroyed.

In one month alone, FDA investigators gathered evidence to convict fake health food promoters, to ban a fraudulent diagnostic device which prevented thousands of hoodwinked patients from getting proper treatment and which convinced similar numbers they suffered from diseases they did not really have, and to prevent sales of a fake arthritis "cure." In addition, the FDA seized shipments of cherries and canned tomatoes contaminated with fruit flies and maggots and other products which failed to carry labels warning against hazardous substances; banned unsafe therapeutic devices; and removed from sale air purifiers which the manufacturers falsely claimed provided relief from asthma and hayfever. Its inspectors also prevented the sale and distribution of bottled cherries containing harmful coloring, wheat bran containing DDT, bulk wheat found to have a poisonous mercury compound, and peanuts, pecans, potato chips, rice and flour that were filthy and unfit for human consumption. The FDA also prosecuted drug companies for illegal sales of prescription drugs and for shipping for commercial sale drugs not approved by FDA.

All this, for 12 cents per person per year, is part of the vital daily work of FDA as the nation's "Consumer Guardian!"

• Science News Letter, 82:146 September 1, 1962

VITAL STATISTICS

Population Growth in Small U.S. Cities Fastest

➤ POPULATION growth in the United States between 1950 and 1960 was fastest in small cities, statisticians of Metropolitan Life Insurance Company reported in New York.

Cities with 10,000 to 15,000 residents in 1950, as a group, increased their population more than 35% in the decade, while cities with 100,000 or more residents gained only 7%. In each group of cities, however, population growth varied widely from one geographic area to another. Relative gains were largest in the West and Southwest, and smallest in the Northeast.

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