Dispatch Tells Why Administration Wants New Drug Legislation

Editor's Note: Stirred by the thalidomide tragedy, Congress is taking a close look at America's drug control laws. President Kennedy says new legislation is needed to protect the public from "unsafe and worthless drug products." Pharmaceutical manufacturers warn that "unnecessarily extreme" controls may delay introduction of life-saving medications. The following dispatch tells why the administration thinks specific proposals now in Congress are necessary and why, in some instances, the drug industry is opposed to them.

By LOUIS CASSELS

Washington — (UPI) — America has the strictest drug control laws of any nation on earth.

But the agency which enforces these laws, the U.S. Food & Drug Administration (FDA), has been warning for years that they are strict only by comparison with the relatively lax requirements of other countries. It has said repeatedly there are dangerous loopholes which ought to be plugged.

The FDA's pleas for new legislation have met with considerable resistance from the $3.5 billion pharmaceutical industry, which contends that too much government regulation will do more harm than good by stifling progress in drug development.

The drug manufacturers seemed to be winning the argument, so far as Congress was concerned, until the recent thalidomide scare. This country's close call with the baby-deforming drug put Congress in the mood to pass a bill. Legislative proposals which President Kennedy made on behalf of the FDA last March have been retrieved from committee pigeonholes in the House and Senate. Early action seems likely.

The major administration proposals around which congressional debate will center are:

LICENSING NEW DRUGS

Under present law, a new drug may be placed on the market 60 days after the manufacturer has submitted a licensing application unless the FDA intervenes to block it.

If the FDA is dubious about a new drug, but lacks evidence to supress it outright, it may stall for months or years by demanding further information or raising successive objections to the details of the application. That's how FDA medical officer Frances O. Kelsey spared Americans from a thalidomide disaster. But as the law is now worded, FDA scientists feel they are under pressure to let a drug go on the market unless they can demonstrate it's unsafe.

Under the proposed legislation, the "affirmative approval" of the FDA would be required before any new drug could be marketed. If the FDA failed to clear an application within a reasonable time, the manufacturer could demand a hearing. But the burden of proving the drug safe would clearly rest upon the manufacturer.

Drug manufacturers contend the FDA already has adequate powers to require complete proof of a drug's safety before letting it reach the market. They say animal tests, clinical trials and other evidence demanded by FDA in a new drug application often fill a six-foot shelf of volumes. The new procedures, they say, would permit bureaucratic inertia to delay the introduction of valuable new medicines.

EFFECTIVENESS OF NEW DRUGS

Present law does not require a manufacturer to prove a new drug is effective as well as safe. Even if the FDA has a good reason to doubt the efficacy of a product, it has no choice but to let it go on the market. Once it is on sale, the FDA can seize it as a "misbranded" drug, but it must be prepared to offer proof in court that the drug won't do what the manufacturer has claimed for it.

John L. Harvey, deputy commissioner of the FDA, refers to this procedure as a "cat-and-mouse game which allows a manufacturer to fool the public with a worthless product until the government catches up with him."

The new legislation would put the shoe on the other foot. The manufacturer would be required to prove his product is effective, as well as safe, before it is licensed for commercial sale.

The Pharmaceutical Manufacturers association (PMA), which represents leading ethical drug houses, agreed "in principle" with this proposal. But it is anxious to have the law so worded that "substantial evidence" of a drug's effectiveness will be enough to get it the placed in the hands of physicians for trial. The administration's bill calls for "preponderant evidence" and the drug manufacturers fear that this language could block drugs whose efficacy is questioned by some authorities, though others may consider them of tremendous life-saving value.

REPORTS ON EXPERIENCE WITH NEW DRUGS

In 1961, the FDA learned belatedly that a muscle-relaxing drug, which had been on the market since 1956, has been implicated in 54 cases of hepatitis, including 15 deaths. After recalling the drug from the market, it discovered that the manufacturer had been accumulating reports of these adverse reactions for five years without saying anything about them.

The new legislation would require drug companies to make regular reports to the FDA on clinical experience with the new drugs.

WITHDRAWAL OF DRUGS

Serious side effects of a new drug may not become apparent until it has been in use for some time. That happened with thalidomide. It also happened in this country with MER/29, which was widely used for lowering blood cholesterol levels.

By last November, FDA had learned of four cases in which patients taking MER/29 had developed eye cataracts. Government scientists wanted to suspend the drug but were told they had no legal power to do so under present law unless they could prove that MER/29 was unsafe when used in the dosage recommended on the label. Since the recommended dosage had been exceeded in three of the four cataract cases, MER/29 stayed on the market.

Five months later, in mid-April of this year, the FDA had accumulated evidence of enough injuries at the recommended dosage to require the withdrawal of MER/29.

The new legislation would permit immediate suspension of any drug when the FDA believes that it presents an "imminent hazard" to public health.

Drug manufacturers hope some safeguards will be provided to insure that FDA's withdrawal powers are not used "capriciously."

"It would be a shame to have a good drug snatched off the market because some government official panicked over a single complaint," said the head of one big pharmaceutical company.

MANUFACTURING CONTROLS

Last fall, complaints began to pour into FDA about a dietary supplement. Male patients using it were developing enlarged breasts. Female patients had abnormal uterine bleeding. Investigation showed careless manufacturing processes had permitted the product to become contaminated with synthetic sex hormones produced in the same plant.

Present law does not give the FDA the power to inspect drug manufacturing processes, or to set minimum requirements for manufacturing controls that will insure security. Most good drug houses are scrupulously careful on their own initiative. But there have been enough incidents like the sex hormones to show some of the nation's 1,300 drug manufacturers are not above cutting corners and taking chances with public health.

The proposed legislation would empower the government to set quality control standards for drug manufacture and enforce them through plant inspection.

The provision is viewed with considerable concern by an industry in which trade secrets are jealously guarded. Although the PMA has not taken a stand against inspection as such, it wants the FDA's investigating powers limited to matters directly affecting drug safety.

OTHER PROVISIONS

Other provisions of the legislation would: require advance government safety certification for all types of antibiotics (only five of the 35 types in wide use are now subject to certification).

Require that drugs be identified on their labels by their standard pharmacological names as well as by the manufacturer's brand name.

Tighten federal controls over barbituates and stimulant drugs such as amphetamines which now are being sold illegally in many areas.

Require that medical advertisements for new drugs advise doctors about their bad as well as their good effects.

German Doctor Discusses Phocomelia and Its Treatment

(Editor's note—Thousands of babies were born with arm and leg deformities in Europe during the last two or three years. In most cases, the mothers had taken the drug thalidomide during pregnancy. Germany, hard hit by deformities, is taking the lead in treating the handicapped children. A German doctor discusses the problem in the following dispatch.)

By ZANDER HOLLANDER

Frankfurt, Germany — (UPI) — "When the nurse told me about our baby, it was like a blow from God.

"But now I know he is a person, a human spirit. We love him even more than our other normal children. We believe he can have a decent life if we do the right things for him now."

Dr. Ekkehard Stoerig, senior physician of the Frankfurt University Orthopedic clinic, nodded warm agreement as Hans Schmidt—let us call him that—described his feelings about the son born to his wife two years ago with badly deformed arms and legs.

Schmidt's son is one of an estimated 3,000 to 5,000 children born in Germany with such phocomelia—or seal-like—deformities during the past three years. In almost all cases the mothers had taken "Contergan" pills. Contergan is the German trade name for the tranquilizer drug thalidomide.

More Advanced

Because the drug tragedy hit Germany so hard, Dr. Stoerig ruefully says German doctors and therapists probably are further advanced in caring for the tiny phocomelia victims than those of other countries.

"We have made great strides in developing therapy techniques and prosthetic artificial limbs. We had to," Stoerig says. "But most important we have learned you must begin right away to treat the babies. We used to think there was little point to prosthetic limbs until the patient was ready to start work. Now we know to wait is disastrous."

The Frankfurt clinic received one or two phocomelia cases a year before the wave of birth deformities. Suddenly in 1960 there were 10 deformed babies; in 1961 there were 22, and in the first five months of 1962 there were five.

Phocomelia is no respecter of classes. Parents of deformed babies included an interior decorator, an automobile mechanic, a tool factory worker, a doctor on the Frankfurt clinic staff and thousands of others from all walks of life.

"Your first reaction is panic — you ask yourself over and over, why us?" said the doctor. It was 18 months ago that the wife, who took Contergan to counter sleeplessness, gave birth to a son with clubbed and crippled arms.

"Then comes reconciliation as you learn to know and love the child, and you realize you and he must make the best of it.

"That is when you must listen to your heart."

The doctor and his wife accept the fact that their son will always be physically handicapped.

"But he could become a good doctor," the father said. "We hope for him just as for any other 18-month-old, and we try to treat him the same. Of course there are differences if he reached for something — he is learning to grab with his pinkie. We do have hope that we can help him to have a good life."

Now Loves Him

A pretty, brown - haired young mother whose deformed baby is only six months old, said, "At first I hoped he would die — he's my first. But now I love him."

Dr. Stoerig began therapy on this woman's son a few days ago.

"First we must prevent any further damage," he explains. "Deformed limbs can lead to deformed spines without speedy corrective treatment.

"Then twisted arms or legs must be straightened. A twisted stump is a shaky base for an artificial leg.

"Those little fingers in the shoulders are valuable — they must not be allowed to atrophy. We strengthen them by special exercises. When the time comes those fingers will operate the controls of a mechanically - powered artificial arm."

Dr. Stoerig has graphic proof that rehabilitation is possible. One picture shows a smiling two-year-old girl without arms. Others show the same little girl two years older, building with blocks, wheeling a doll carriage and playing a toy xylophone — all with artifical arms.

Therapy Costly

The therapy is costly. Dr. Stoerig estimates a child's prosthetic limb costs from 2,000 to 3,000 marks ($500 to $750). The child probably will need perhaps three or four sets of artificial limbs before he is ready for final adult-size limbs capable of refined adult movements.

The West German federal health ministry is now devising ways to help families of such babies shoulder the economic burden.

"The child must have these things," says Stoerig. "When the time comes for normal children to play patty-cake, these infants must have limbs capable of patty-cake. When they enter school and must learn to write they must already have mastered prosthetic arms capable of holding pencils, and writing.

"These children are physically one down from the moment of birth," Stoerig puts it. "They must be made equal or even one up on normal people mentally."

Equally Capable

Stoerig and his colleagues agree phocomelia babies are as intelligent as normal babies and equally capable of learning.

"It's more than a medical job," Stoerig tells phocomelia parents. "Our job is to build the child's confidence, to surround him with love and understanding, to make sure he never loses contact with the real world in which he will have to make his way."

"There is a moment I dread," the interior decorator said. "One day my child will be playing in a sand pile with other children and someone will say, look at that cripple.

"But we are too fast to throw a life away nowadays. We will not throw away this one. It will be hard, but he deserves a chance. He gives me and my wife much joy."

Butterfly's Love Life Discussed at Science Meeting

Corvallis — (UPI) — The short, happy love life of the butterfly provided a light interlude here today for thousands of scientists gathered to discuss the wide aspects of biology.

The report on butterfly romancing was delivered by Dr. Lincoln P. Brower and Dr. Florence Cranston of Amherst college at the American Institute of Biological Sciences convention.

The male of the beautiful Queen butterfly uses perfumed "hair pencils" to entice his lady, they said.

Pursues Female

The male pursues the female, overtakes her in the air, and induces her to alight by brushing her with the scented sticks, they told the American Society of Zoologists.

Then the courtship proceeds. If the lady is willing she folds her wings, while the male rubs her head with his antennae.

Then, in an age-old tradition, they say, "he carries her to an inconspicious spot," where the happy pair rest motionless for hours. The courtship often ends without mating, the scientists added.

The report was one of many delivered today, covering topics ranging from bats and crabs to the unity of biological science.

Dr. Curt Stern, president of the American Society of Zoologists, said in spite of its separate approaches, the unity of biological science is becoming more apparent.

Unifying Factors

He said separate animal and plant sciences are being re-evaluated in terms of their place in the overall structure of learning. And, he said, there is a need for emphasis on unifying factors.

Dr. Asher Treat of City College, New York, reported on a clever mite that lives in the ear of a moth.

The moth needs its hearing to avoid being eaten by bats, he said. The mites avoid their own destruction, he said, by never infesting but one ear of any moth.

Other reports covered habits of hermit crabs that live in empty snail shells, hereditary mongolism, and "how much nucleus is enough for one cell."

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