

by generic names, to be authorized for use in Federally supported programs (SN 3/4). Under Sen. Long's proposal a nine-man Formulary Committee of physicians and Government officials would select those drugs to be included in the listing and would establish a "reasonable charge" for each. Federal representatives on the Committee would probably be the Commissioner of the Food and Drug Administration, Director of the National Institutes of Health and Surgeon General of the U.S. Public Health Service.

Although the Long amendment drew only lukewarm response from the Senate and fire from the brand conscious pharmaceutical industry, it won approval last week by a 43 to 37 vote, adding it to the legislation the House had enacted earlier. It goes to Senate-House conference within days. The vote in the Senate was close, and the amendment's acceptance by the House is not assured, but members of the Senate Finance Committee, which guided the bill through the Senate and will represent the Senate in conference, say the handwriting is on the drugstore wall: If economies aren't forced this year, they will be next.

The point of Sen. Long's amendment is to save Government money by avoiding expensive brands when low-cost counterparts are available. It also would be likely to lead to price-slashing on drugs across the board as consumer demand and industry competition followed Medicare-Medicaid purchases to force costs down. But broad as its economic ramifications are, its impact on the scientific world could be even more significant. The scientific implications of the amendment may present challenges of such magnitude they cannot be met for several years.

The crux of the matter is quality and therapeutic equivalency (SN:4/22). The Formulary Committee would first have to evaluate drugs, approving only those of acceptable quality. In handling two or more products with the same ingredients, designed to do the same thing, it would have to establish therapeutic equivalency in clinical tests to be sure they really behaved identically in the body. Both these requirements demand a large supply of qualified experts not readily available. Food and Drug Commissioner James L. Goddard says, "If all drugs were reliable, there would be a concrete basis for price comparison, and drugs could be included in a formulary solely on a cost criteria. Unfortunately, the FDA is not currently in a position to guarantee the purity and quality of every drug on the market." Estimating that it will be three or four more years before it can make that guarantee, Dr. Goddard says he would be "extremely reluctant" to see

any action on the Long proposal at this time. It will be even longer before FDA could evaluate all apparently equivalent drugs for their actual identity of effect.

Health, Education, and Welfare Secretary John W. Gardner concurs. In his January 1967 "Aid for the Aged" message, President Johnson instructed Secretary Gardner to "undertake immediately a comprehensive study of the problems of including the cost of prescription drugs under Medicare." Jointly with the FDA, Gardner's Task Force on Prescription Drugs launched the Government's first study of therapeutic equivalency. They are trying to determine whether drugs from different companies approved and marketed for the same purpose actually behave the same way in a patient's body. For the study, which is being conducted at Georgetown University, they selected 50 of the 200 most commonly prescribed products which are sold under both generic and brand names.

The Task Force says it will be next June at the earliest before it has information on these 50 drugs. In answer to the argument that any drug in the marketplace is therapeutically equivalent to others sold under the same generic name, Dr. Goddard says simply, "we do not have controlled clinical studies to decide the issue in all cases."

Coming to the defense of brand names, a Parke, Davis scientist last week informed a Senate hearing of studies showing that copies of a Parke, Davis antibiotic are not as effective as the company's original version. The antibiotic is chloramphenicol (brand name, Chloromycetin), a highly potent drug used only for serious infections.

Since the Parke, Davis patent ran out last February, several drug houses have been selling versions of this antibiotic, all of which are certified, batch by batch, by the FDA. Dr. Leslie M. Lueck, quality control director for Parke, Davis, testified that in tests of competitors' products, he found they did not dissolve as rapidly as package labels said they should and that, in clinical tests, persons taking the competing companies' chloramphenicol had so little of the active ingredient in their blood that it could not have done them any good at all. As a result, the FDA has launched its own clinical studies of the chloramphenicols. Results may be available by mid-December.

Questions of equivalency and quality will inevitably come up before a Formulary Committee if one is set up. Dr. Goddard points out that the cost, in manpower, time and dollars, will be staggering. Legal challenges to Formulary Committee decisions are also anticipated, he says. The Committee would have to evaluate each of the 5,000 drugs available in the United States.

AILING DIVORCEES

A New Public Health Problem

Divorced persons suffer emotionally and they suffer financially, as has long been known. Now it seems they suffer physically as well.

Dr. Lester Breslow, director of the California State Department of Public Health, last week revealed his findings about disease and divorce. Divorced persons, especially men, are prime candidates for suicide, alcoholism, mental breakdown and an early death. All the chronic diseases which plague the population, including cancer, show higher incidence in divorced men, he finds, from study of records going back to 1900.

Divorced men had more than twice the death rate of married men, and were significantly higher in almost all other forms of disease.

Dr. Breslow is at a loss to explain why, but the parallel even extends to cancer; divorced people develop more tumors than their married friends.

Nor could he explain why divorced women fare better than the men, unless it is the natural physical superiority of women in resisting all kinds of disease.

"All of our health data indicate that women are better able to withstand the problems of life than men," he said.

Dr. Breslow says the department will now devote considerable effort toward finding special methods of treatment for divorced persons who become ill.

California is a logical state to pioneer in this direction. The divorce rate is almost twice the national average. In 1966, there were 62,648 final divorce decrees in California and 6,480 annulments as against 144,000 marriages.

DR. MURRAY'S MILESTONE

Doubt Cast in Toronto

Toronto General Hospital last week was engaged in searching its surgical records and X-ray library to determine whether it had on its hands a surgical milestone or something considerably less.

It was at a fund-raising dinner for the hospital that Dr. Gordon Murray claimed to have rejoined a severed human spinal cord (SN: 12/2). But the hospital's chief of surgery, Dr. William Drucker, now says that the records on patient Bernard Proulx show no such operation. In the midst of a battle carried by press conference and television interview, the hospital appointed a special committee to review the Proulx case and six others Dr. Murray claims.