PUBLIC POLICY

Generic Drugs Favored

Generic, rather than brand prescriptions, get new support as Washington prepares for drug-expansion of Medicare.

by Barbara J. Culliton

Ever since the Kefauver-Harris Drug Amendments shook the drug industry in 1962, the big name companies have successfully fended off proponents of generic rather than brand name prescribing.

Now, on Capitol Hill where pressure is mounting to include prescription drugs in Medicare benefits, there is a movement afoot to cut the Government's drug bill, which already hits close to $300 million a year, by encouraging the use of inexpensive generic drugs instead of their high price brand name counterparts. (In referring to drugs, the generic name indicates the active chemical ingredient in a specific medicine, not a class or type of compound.)

- Aspirin is always and only aspirin, whether it cost 39 cents or $1.39; the difference is a matter of semantics. Call it aspirin, and the price is low. Attach a brand name and the cost more than triples.
- Price discrepancy is even greater when it comes to prescription drugs, an area in which the consumer-patient is usually in no position to choose among various brands; but his doctor is. Chances are that when the patient pays almost $25 for Achromycin, a widely used antibiotic, he doesn't even know he could get the same thing for about $4.50 by simply calling it tetracycline—its generic or established name.
- Serpasil, a brand name antihypertensive and calming agent, is really reserpine. A druggist pays about $40 for 1,000 Serpasil tablets which he retails at a mark up of 66⅔ percent. Call it reserpine, and he pays only 69 cents for the 1,000 pills, also with a 66⅔ percent mark up.

Most physicians prescribe by brand name not because they are trying to burden their patients but because they still think brand name products are better or because they are familiar with a compound's brand name and have no idea what its generic name is. Pharmaceutical houses spend hundreds of millions of dollars every year to send "detail men" out to the field to sell their wares to practicing doctors, and as a result, the doctors do know more about brand name than generic products.

The major drug houses justify high prices for their brands by claiming first and foremost that a brand name is a guarantee of quality. Their less powerful opponents say it has nothing to do with quality, only with profit. That profit is poured into basic research on new and better drugs, the companies retort, and they also point out they have a right to make money, particularly on products they themselves discovered or perfected. It's all part of the free enterprise system, so to speak.

There is no doubt that research carried out by wealthy drug houses has led to the discovery of many new drugs. Whether or not a brand name insures a high quality product, however, is a matter of considerable debate. In fact, a recently reported analysis by the Food and Drug Administration revealed that 8.2 percent of 4,573 drug samples did not meet potency standards. Breaking this down into products marketed under brand names versus those sold under generic names, 8.8 percent of 1,991 brand name samples were deficient compared to 7.7 percent of 2,582 generics. "Nobody came out of this survey looking good," an FDA official commented.

Winton B. Rankin, deputy commissioner of FDA said the real issue is one of quality, not generics versus brands. "If a drug manufacturer cannot put out good drugs, then he will have to get out of the drug business," he said, adding that FDA will apply this yardstick to the full extent of the law. The 1962 drug amendments made the extent of the law far reaching.

It is too early to say whether or not this will be the year of truth for generics, but three pieces of legislation are pending in Congress that, if passed, would give non-brand products a fighting chance on the competitive market by educating the public and medical profession about their existence, their safety and efficacy and their comparatively low cost.

In January, Senator Joseph M. Montoya (D—N. Mex.) introduced legislation to bring prescripton drugs under Medicare. His bill has strong Senate support with 21 co-sponsors but may travel a rocky road in the House, in part because long-promised White House backing for such an extension of health coverage is not likely to materialize.

Some $600 million—about 20% of

Senate backing of low cost generics could cut retail prices and open new competition between drugs.

the drug industry's sales—would be affected; that's the size of the drug purchases by persons over 65, those covered by Medicare.

The Montoya bill mandates use of generic pricing in filling Government paid prescriptions under Medicare as long as the generic version of a drug is deemed to be of a reasonable quality. It also establishes an independent "Formulary Committee" to decide which products meet quality standards, which brand name drugs should be allowed, how much the Government will pay for each one, and what flat professional fee (rather than mark up percentage) will be allowed to cover pharmacists' services. The bill places these powers in the hands of Surgeon General William Stewart, Commissioner of the Food and Drug Administration James L. Goddard, and Director James Shannon of the National Institutes of Health, to be advised by seven representatives of the academic, business and professional communities.

Theoretically, there should be no question of quality in approved drugs, be they brand name products or generics. If FDA is doing its job and keeping up with advances in medicine's understanding of drug action in the body, it ought to be able to guarantee that every drug on the market is safe and effective; in other words that it does what its manufacturer says it will.

FDA pharmacologist Dr. Stephen Krop says that if two products meet the same standards for identity, purity and physical state (tablet, liquid, etc.), those products should be interchangeable therapeutically. Dr. Daniel Baines, special assistant on new drugs at FDA, says that if a manufacturer can demonstrate that his drug works better and is more effective than his competitor's product, FDA will make every effort to learn the reason why. Then one of two things can happen. Either the less effective drug improves, thus becoming the equivalent of the other, or it will be taken off the market for failing to meet FDA's efficacy standards.

A second and complementary piece of drug legislation may be introduced within the next few weeks by Senator Russell Long (D-La.), chairman of the powerful Senate Finance Committee to which the Montoya bill has already been referred. The Long bill, as does the Montoya proposal, will generally require the use of generics, but applies to Federal drug spending in all welfare and social security programs, not just spending under Medicare. Last year Senator Long introduced similar legislation that drew fire for demanding Government funds be limited strictly to generic version drugs. This year's proposal, seen as a much more reasonable bill, will take into account the fact that there are situations in which brand name products must be used, one case being a drug having only one supplier.

The drug industry, not unexpectedly, opposes any moves to require doctors to write and druggists to fill prescriptions with generics. They condemn it as an invasion of physicians' right and obligation to determine the precise medication patients shall receive.

Both bills, however, do have the support of the prestigious American Pharmaceutical Association which has long encouraged pharmacists to adopt the use of professional fees rather than the mark up system and also endorses greater use of generic drugs. If druggists charged a standard fee, of $2.00 for example, for filling any prescription, the consumer cost of some medicines would go up but the price of high priced drugs would drop significantly. According to Robert Steeves, general counsel to the APhA, druggists who have experimented with the fee system have reported no loss of profit and have enjoyed cutting economic ties to big name companies.

The third piece of relevant legislation, introduced on the floor of the Senate a few weeks ago, will take on added importance if the Montoya and Long bills become law. Senator Gaylord Nelson (D-Wis.) proposed that the Food and Drug Administration be authorized to publish yearly a compendium of all approved drugs, listing clearly both generic or official and brand names and giving comparative data on drug composition, uses and possible side effects. Such a compendium would be the first to put this kind of information into doctors' hands in a usable, convenient form.

Although the FDA has no official comment on Senator Nelson's bill, it is understood the idea originated within the drug agency.

PLANETARY ASTRONOMY

Pole-sitting Spacecraft Is Venus-bound

There's a spacecraft perched on a pole in Pasadena, Calif., 24 feet in the air, turning slowly and intermittently round and round. It looks like a rather woebegone windmill, but in about four months it's going to leave on a trip to Venus that may take it closer to the mystery planet than any man-made object has ever gone before.

The present record-holder is Mariner 2, which passed within 21,648 miles of Venus on Dec. 14, 1962. That's about the length of a trip around the world with a couple of short cuts. Before that the trophy belonged to the Russians, who launched Sputnik 8 into orbit around the earth, then used that as a flying launch pad for a probe called Venus 3, which got to within 62,500 miles but with its radio dead.

JPL

The pole-sitting newcomer is Mariner 5, first of its kind to be launched since Mariner 4 was sent outward on its successful photo-mission to Mars more than two years ago. Though the Venus probe will not have its predecessor's elaborate camera system, it will carry a brace of newly-designed low-frequency antennas for the same kind of "occultation" experiment that was on the Mars mission.

Mariner 5 will swing around behind Venus so that the planet passes between the spacecraft and earth, while its low-frequency transmitters send out a continuous broadcast. Just before and after the signals are completely cut off by the planet, they will be reduced in varying degrees by the layers of Venus' atmosphere. Decoding the signals will provide a thickness "profile" of the atmosphere at different altitudes.

The pole on which the spacecraft now resides is an antenna test rack, which turns slowly around so that the efficiency of the antennas can be measured from every conceivable angle. Mariner 5 comes off its pole in six to eight weeks, is then set for launch in June, and should pass within 3,000 miles of Venus on Oct. 19 of this year.