The New York Times

Founded in 1851
ADOLPH S. OCHS, Publisher 1896-1935
ARTHUR HAYS SULZBERGER, Publisher 1935-1961
ORVIL E. DRYFOOS, Publisher 1961-1963

The New York Times

February 23, 1978

A Choice of Drugs

A New York State law that requires pharmacists to fill many prescriptions with relatively inexpensive drugs continues to meet intense opposition from the drug industry and local pharmacists. The industry contends that consumers risk getting drugs that are neither safe nor effective. The pharmacists want to keep the law from going into effect on April 1—at least until malpractice liability questions are resolved. These issues were considered during a protracted legislative battle. They should not be allowed to weaken or postpone a long-overdue effort to bring consumers some relief from drug costs.

The new law requires that all prescription forms contain two signature lines for the physician. If he signs on the right, the usual spot, the pharmacist must fill the prescription with a low-priced "generic" drug even if the doctor has written in a higher-priced brand name. If the doctor signs on the left, the pharmacist must fill the prescription as written. The wholly admirable goal is to break the cycle by which drug companies heavily promote certain brand names, doctors routinely prescribe the familiar names, and patients end up paying far more. The tranquilizer meprobamate, for example, costs $10.99 per 100 units when sold as Equanil, the Wyeth brand name, but as little as $2.99 when sold generically.

The centerpiece of the new procedure is a list of interchangeable drugs, compiled by the State Assembly and maintained by the State Department of Health. It is the first such list ever put together—a model on which other states are patterning their own drug regulations. It has been validated by the Federal Food and Drug Administration as "an accurate guide" to drugs that are "safe, effective and equivalent in therapeutic performance."

The pharmaceutical industry contends that though products on the list may be chemically equivalent, it cannot be assumed that they will produce the same therapeutic effects. Subtle differences in manufacturing processes, for example, can change the rate at which a drug dissolves in the body. The industry also questions the competence of many manufacturers on the New York list. It claims never to have heard of some and notes that others have been cited for poor manufacturing practices.

But in fact, the F.D.A. says there is no significant difference between large and small firms or between brand-name and generic products. Virtually all companies are inspected at least once every two years. And while there is indeed doubt that all drugs with the same chemical formulation produce the same therapeutic effects, that doubt hangs over even the best-known products and companies. New York's list has been scrubbed clean of drugs that must be precisely equivalent—unless there is positive evidence that they are so. The remaining drugs are assumed to be therapeutically equivalent. If there is evidence to the contrary, it can be addressed without invalidating the whole effort.

•

The complaints of the pharmacists stem in large part from their fear of malpractice liability. Until now, pharmacists have been little more than robots carrying out "doctors' orders," and they have been covered for liability by the major drug companies. They now will be required to pick lower-priced generics whose manufacturers offer less liability protection. The pharmacists would like the state to assume the liability. That issue, too, can be addressed in hearings without blocking implementation of the law.

The new law will place a greater burden on the consumer—to question his doctor as to why a particular brand is prescribed, and his pharmacist as to why a particular substitution is made. The major drug companies are moving rapidly into the manufacture and distribution of generic drugs, asserting that their generics are superior to those marketed by some lesser-known companies. But the price of these "branded generics" can be two or three times higher than the lesser-known kind. "We can't see any quality reason for that difference in price," asserts the F.D.A. Commissioner, Donald Kennedy. In sum, the prudent consumer will still have to shop around for savings at the drug counter.

Companies' Packaging of Generic Drugs Is Called a Threat to Substitution Law

By RALPH BLUMENTHAL

Major pharmaceutical companies are [illegible] moving into the marketing of generic drugs, [illegible] fears among New York State legislative and consumer representatives that the state's new cheaper-drugs law is about to be undermined and the public deprived of expected cost savings.

Industry leaders acknowledge what one called "a big push" toward generic, or nonpatent, standard formula drugs. But they deny that the growing marketing of generic drugs in trade-name packages amounts to any attempt to circumvent the law that goes into effect April 1. Rather, they maintain, the advent of such so-called "branded generics" represents the best of both worlds for the consumer—trade-name products at cheaper prices.

The conflicting positions are producing a new furor over an issue that appeared to have been settled with enactment of the generic-drug law last Aug. 11.

[illegible]

At stake is a hefty share of the estimated $[illegible] billion that Americans spend on pharmaceuticals each year—a market in which generics now account for about $2.7 billion, up an estimated 20 percent between 1972 and 1976, according to legislative testimony.

The law requires the 12,000 pharmacists in the state to fill prescriptions starting April 1 with cheaper counterparts of patented trade-name drugs—that is, with generics in most cases—unless the physician specifically directs otherwise. He does this by signing his name on a special part of the prescription blank.

For example, a doctor may prescribe Terramycin, a trade-name antibiotic made by Pfizer. Under the new law, unless the doctor made it clear that he specifically wanted that trade-name drug, the pharmacist is required to substitute any cheaper counterpart that is certified as equivalent by the Food and Drug Administration. That could be oxytetracycline, the generic counterpart of Terramycin.

In this case, according to data collected by the state's Office of Legislative Oversight and Analysis, the savings to the consumer would be considerable.

A bottle of 100 capsules of 250 mg. oxytetracycline was priced at $5.49. The same quantity of Pfizer's Terramycin was selling for $29.99.

But the advent of branded generics has injected a new element. Now oxytetracycline is sold packaged by Parke Davis & Company. It was selling for $14.99, the legislative office found.

Ordinarily, the study noted, the pharmacist might still select the cheapest counterpart. But since the law requires only the substitution of a cheaper equivalent—and partly because of what the study called an industry campaign of "lies" and "deception" about the safety of unbranded generics—the pharmacist could turn to the growing lines of medium-price branded generics rather than the cheaper alternative.

In recent hearings, interviews and memos, the legislative office, directed by William F. Haddad, and the chairman of the Assembly's Consumer Committee, Harvey Strelzin, Democrat of Brooklyn, have raised an alarm over what they depict as an effort to "subvert" the law with such branded generic drugs.

Assemblyman Strelzin said at a legislative hearing on Jan. 12: "Branded generics are nothing more or less than generic drugs in a trade-name bottle. In many if not most instances they are produced by a generic house for the trade-name company. The only difference is price.

"If this attempt to evade the New York State law is not met head-on, gains to the consumer forecast under our law will all but be wiped out."

What it amounts to, said Robert Egan, until recently acting Commissioner of New York City's Department of Consumer Affairs, "is an attempt on the part of the major drug companies to have their cake and eat it too."

Reached in Washington, the industry's leading national representative, C. Joseph Stetler, president of the Pharmaceutical Manufacturers Association, said in response, "There's no doubt a big push toward generics in the drug business. But I can't see how the consumer is being disadvantaged, when he's getting a quality product with a brand name at a lower price."

Pharmacists' Objections

What a purchaser and pharmacist buying of a branded generic gets, Mr. Stetler added, is greater quality assurance and protection against liability.

Such claims are disputed by the legislative critics, who say their research has disclosed no difference in general quality between generic and trade-named drugs. Nor, they said, have they come up with any case in which a generic manufacturer has been sued for a flaw in his product.

Other objections to the new law were raised in an interview by Sol J. Rubino, executive director of the Pharmacists Society of the State of New York, representing about 3,500 of the 12,000 druggists in the state.

He said: "Does the consumer have the right to override—to select a trade name if he or she wants? No. If a pharmacist doesn't stock the generic, what is he going to do, send the customer elsewhere? Do I have to duplicate my entire stock?"

Assemblyman Strelzin at the Jan. 12 hearing in Albany was equally firm. "I serve warning to the drug companies and to the heavy-handed Pharmaceutical Manufacturers Association that we intend to play hard ball," he said. He added that as long as he was committee chairman, "attempts to weaken the impact of our law on the consumer will be exposed and resisted."

How Drug Prices Compara

According to Assembly Office of Legislative Oversight and Analysis

(Manufacturers' names in parentheses)

Source: William F. Haddad, Director, Office of Legislative Oversight and Analysis

Yonkers Herald Statesman
7/6/78

'Last angry man' is still fighting drug companies

By JUDITH RANDAL

WASHINGTON — If awards were given for sustained righteous indignation, William F. Haddad should easily qualify.

He has been battling the deceptions of the drug industry for almost a quarter century. Although nearing 58, as head of the New York State Assembly's director of legislative oversight he shows no signs of quitting now.

It all began in 1954-57 when he worked for the late Sen. Estes Kefauver, who then was just beginning his probe of the giant pharmaceutical firms. In 1965, when Kefauver died of a heart attack, Haddad vowed to take up where the Tennessean had left off.

While holding down a variety of jobs, he managed to dragoon New York City into instigating anti trust action against five major firms for price fixing and overcharging on antibiotics and to persuade 42 states to join in the suit. The out-of-court settlement for $128 million was, in 1969, the largest in history.

IT PARTICULARLY riles Haddad that with 1,200 drug firms in the United States, the 126 companies that belong to the Pharmaceutical Manufacturers Association sell about 95 percent of the prescription medicines and that, as a corollary, the prices for their products remain the highest in the world.

Yes, drugs are cheaper when sold by chemical or generic name. Yes, they are subject to the same safety and effectiveness requirements of the Food and Drug Administration as their far more costly brand-name counterparts. And yes, brand-name medications have been as often subject to FDA recalls for quality shortcomings as the others.

Until recently, laws enacted in the 1960s by every state legitimized the ruse by making it illegal for a pharmacist to fill a prescription generically if the doctor had called for a brand-name drug. Forty of these laws have been repealed since 1976. But except in Florida, where one chain of druggstores alone has saved consumers $2.4 million and, to some extent in California, the expected savings have not been realized.

For one thing, the new laws, of necessity, permit brand-name prescribing for the minority of patients for whom this has a crucial psychological benefit and physicians in some states and pharmacists in others (depending on how the law is worded) have used this loophole to defy the change.

FOR ANOTHER, the vast propaganda machine of the PMA and its members grinds on. Although no such thing has ever happened, for example, company salesmen are telling pharmacists that they may be sued if they dispense generically.

In addition, the ever-resourceful industry has further muddied the waters by the introduction of "branded generics." These drugs are somewhat cheaper than those with catchy trade-names, but still are typically four times more costly than those now prescribed by the likes of an Eli Lilly or Smith, Kline and French.

Time must eventually run out on the PMA. Already it is not too soon to assign considerable credit to Haddad, a real life version of "The Last Angry Man."

Judith Randall is a freelance writer who specializes in medical affairs.

Newsday July 19

Firms Criticized On Generic Law

By Adrian Peracchio

A legislative report scheduled for release today by Assembly Speaker Stanley Steingut condemns the prescription drug industry for conducting a "malicious and cleverly designed" propaganda campaign to frighten physicians and pharmacists away from generic drugs.

Steingut ordered a study of the legal implications of the generic-drug issue after state surveys showed that doctors and druggists were largely ignoring the new state law allowing generic equivalents to be substituted for more expensive brand-name drugs.

The report, prepared by William F. Haddad, head of the Office of Legislative Oversight and Analysis, accuses the drug industry of using film strips and tapes disguised as educational materials to reduce generic substitution.

The charges were labeled "absolute nonsense" by Richard Hamilton, a spokesman for the Washington-based Pharmaceutical Manufacturers Association, the lobbying arm of the drug industry. "Stating our position on generic substitution is no more a propaganda campaign any more than what Steingut and Haddad are conducting is propaganda," Hamilton insisted.

After the statewide circulation of drug manufacturers' educational materials, Haddad said, 70 per cent of pharmacists and doctors surveyed by the state cited the fear of increased legal liability as the reason for refusing to go along voluntarily with the intent of the generic drug law. Others did not believe that generics were in every case equivalent to trade-name drugs in therapeutic value despite the state's reassurances.

Haddad concludes in his report that "there is not a single case on record involving a liability lawsuit over the proper substitution of a generic product for its trade-name counterpart." The report also quotes insurance company executives as saying that generic drug substitution would not affect rates.

Steingut said drug companies released tapes and films suggesting that doctors' and pharmacists' liability would increase dramatically if they substituted generic drugs for brand-name products.

Hamilton said the association and its members, among whom are generic drug makers, never claimed that generic products were inferior to trade-name drugs. "What we have said is that the capabilities of manufacturers vary, their products vary and this can cause differences in the therapeutic value of their drugs, whether they are labeled as generics or not."

A drug industry-produced educational tape cassette obtained by Newsday addressed in ominous tones the issue of legal liability in connection with generic substitution. But the tape, produced for Eli Lilly and Co., never states that druggists could be legally liable in malpractice suits for proper generic drug substitutions. The tape concludes: "Dispensing only quality products therefore is the pharmacist's surest means of protecting both the patient and himself."

Wall Street Journal — August 9, 1978

REVIEW & OUTLOOK

Drug Wars

The latest skirmish between drug manufacturers and drug regulators is over drug substitution laws. Since 1970 there has been a broad-front push to change state laws to encourage the filling of prescriptions "generically"—by type of drug—rather than by the traditional specifying of the manufacturer's trade name. This policy is supported by "consumer advocates," politicians and bureaucrats to promote substitution of cheaper alternatives and thus bring down retail drug prices, saving taxpayers money for Medicare and Medicaid payments for prescription drugs.

Needless to say, the major drug manufacturers are unhappy with this development and are resisting it. Among other things, they maintain that generic drugs are not the same and that their trade name products differ in important qualities such as density, coating and care in manufacture. Conversely, the regulators (and, of course, the generic drug producers) claim that generic drugs are "medically interchangeable," so buying a brand name is a waste of money.

Both sides display voluminous evidence which laymen cannot hope to understand, but the gap is not as wide as press releases indicate. When pressed, drug manufacturers' spokesmen will grant that some drugs are the same, if only because they are manufactured in the same plant and sold by several companies under different labels. On the other side, FDA grants that "biochemical equivalence" is within a range of plus or minus 20%. Furthermore, batches of the same drug will vary somewhat, and the relationship between chemical levels and the effect of drugs on patients is less than exact.

Since generic drugs might have sufficient variability to have different effects on a patient, drug substitution laws specify that the prescribing physician may designate a particular brand of drug. Nevertheless, the doctors' organizations have become active against generic drug laws—the Journal of the American Medical Association recently made a blistering attack on them. For their part, the regulators claim that the physicians have been "brainwashed" by the drug companies, especially by the "detailers," the drug salesmen who are so important in the drug marketing and information system.

Still, physicians are a fiercely proud and independent lot, unlikely to be so susceptible to wooing by mere salesmen. The pharmacists seem to have resisted the brainwashing of the drug companies, since they endorse the substitution of drug [illegible] [illegible]

costs, like everyone else in the medical business, are frustrated physicians, and like the idea of having more "professional" responsibility. Also, they are changing their pricing practice from the traditional percentage mark-up on wholesale price to a fixed "professional fee" for filling a prescription with the wholesale price passed through to the consumer, so they don't care if a cheaper drug is sold.

But the druggists have gone to court in New York to try to overthrow the new law, which provides among other things that a pharmacist must substitute the lowest priced generic, even when the patient wants another. If no substitute is available, the patient must be sent out on the street empty-handed. This contrasts with, for example, the Illinois law, where pharmacist and consumer retain choice.

Another peculiarity is that New York's "formulary" (catalog) of drugs includes at least one drug that is under injunction for violation of patent. The Food and Drug Administration, which reviewed the New York formulary, also takes the position that patent fights are none of its business. So the pharmacist must either violate the patent law or the New York State drug substitution law. Illinois sensibly does not include patent breakers in its formulary. The New York formulary also fails to make it clear that the listed drugs are not necessarily equivalent if they are packaged in different forms, such as capsules or tablets.

Oddest of all is a politician's press release saying that three-quarters of doctors are "forcing consumers to pay the higher prices" by prescribing by trade name, when—apparently through an error by the same politician in writing the legislation—two-thirds of the drugs listed in the New York formulary are single-source, so it doesn't matter if the doctor prescribes generically or by name.

The responsible party seems to be one William F. Haddad, a lieutenant of the assembly speaker, who derives his expertise in the area from being a self-appointed "consumer advocate."

This incident makes us suspicious of the federal drug substitution bill now before the House. Forty states now permit drug substitution, most of them without hassle, because they relied on doctors, pharmacists and professional public health officials, not headline hunters.

By the way, according to the Bureau of Labor Statistics, retail drug prices are up [illegible] since [illegible], compared with [illegible] for the overall Consumer Price Index.