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THE MacNEIL/LEHRER REPORT

"Generic Drugs"

In New York

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Transcript of "Generic Drugs"

ROBERT MacNEIL: These are four pairs of commonly used prescription drugs. In each pair, one is the trade name, or proprietary, drug; the other is its generic equivalent. One is usually more expensive than the other, but are they the same otherwise, and can they be used interchangeably?

Good evening. Everyone who has to get a prescription filled knows how much drugs cost these days. Would we save a lot of money if doctors prescribed, and pharmacists made up, prescriptions using generic drugs instead of the brand names? And if they did, would the effect on the patient be any different? Those are the questions we examine tonight.

Just on the question of price, let's take a closer look at the four commonly prescribed drugs we saw a moment ago. All these drugs were bought today in New York. The prices may vary elsewhere in the country. For the same quantity of pills, the antibiotic Erythrocin cost six dollars. Its generic version, erythromycin, cost $4.80. Hydrodiuril, used for high blood pressure, cost $8.50; the generic, hydrochlorothiazide, $5.00. Serpasil, the hypertension medicine, cost $2.50; but under the generic name reserpine, $1.25. Lanoxin, a pill heart patients use, cost $1.95, while its generic counterpart, digoxin, cost $1.75.

Since the turn of the century, it was illegal in most states for pharmacists to substitute a generic drug for a brand name unless the doctor specifically called for it. In recent years twenty-two states and the District of Columbia have passed laws permitting pharmacists to substitute generic drugs at their discretion. Today the issue came up in the Legislative Oversight Committee of the New York State Assembly. The hearings were organized in part by William Haddad, who first became involved in the generic drug question when he worked with the late Senator Estes Kefauver in the 1950's. Haddad is Director of the Office of Legislative Oversight in the New York Assembly.

Mr. Haddad, at your hearings today you produced a list of generic and brand name drugs. What is the significance of that list?

WILLIAM HADDAD: The significance of that list is that that list has been available for a number of years bottled up in the bureaucracy and lost in the computers of the Food and Drug Administration. That is a list of trade and generic drugs that are equivalent, that have the same therapeutic effect, that have been checked out to the manufacturers' level. In effect, any name on that list is a safe and effective drug. And as we heard at the hearing today, there is no higher authority in the United States than the Food and Drug Administration; and it's the Food and Drug Administration who conducted the tests and helped put together the various lists which we compiled into a single list. It's not been made public before. The importance: it is now in the public domain.

MacNEIL: How many drugs are on that list?

HADDAD: Approximately 2,500, without counting various dosage forms.

MacNEIL: I see. Twenty-five hundred brand names plus 2,500 generics?

HADDAD: No, together -- total.

MacNEIL: So 1,250, roughly, effective drugs.

HADDAD: Yes.

MacNEIL: What is the goal of the legislation your committee is considering?

HADDAD: Well, the Standing Committee on Consumer Affairs -- we're the investigative arm of the legislature -- in the Assembly is considering legislation that would require doctors to prescribe generically. However, it would give the doctor the override; if he wants a trade name, he can always have it. The doctor is always right. That's not one of our arguments. It's that the doctor would be required to prescribe generically unless he indicates otherwise; second, that that list would become institutionalized as a state formulary so everybody would know what is safe and effective. Most of the doctors we questioned said, "Sure, we'd be price-conscious if we knew there was such a list." There is such a list.

MacNEIL: Is that why generic drugs are not more commonly prescribed by doctors, because they do not have access to this list?

HADDAD: That's one of the reasons. The other reason is advertising -- specialized advertising, and techniques of the drug company that border on illegality.

MacNEIL: Would your bill, or the bill that will eventually go before that committee, therefore be rather stronger than those substitution laws in the twenty-two states and the District of Columbia in that the doctor would <u>have</u> to prescribe a generic drug?

HADDAD: Well, in those twenty-two states it varies. Some are mandated substitution, which puts the weight on the pharmacist to substitute a generic for a trade name; some are generic requiring the doctor to sign generically. I think the significance -- and we are going to repeal the substitution law if it gets through the Senate as well -- the significance, I think, personally, is that list; that list has never been made available for at least a decade or two decades. The doctors have been told that generics are unsafe. There is no higher authority in the United States; that list is a list of safe and effective drugs down to the manufacturer level. There can be no more debate at this time unless they want to take on the technology of the Food and Drug Administration.

MacNEIL: You said during the hearings today that the drug industry was, to quote you, "lying through its teeth" about this matter. What did you mean by that?

HADDAD: It was a strained statement on my part. For about twenty years now, the drug companies have fed false, misleading, decep-

tive information to doctors and others about the safety of generic drugs. The company Eli Lilly, from which we'll hear tonight, has a saturation television campaign now under way which says that generics are unsafe. That is absolutely untrue. And the information being provided the doctors by the system which spends $600 million a year on detailing -- or having salesmen visit doctors personally and providing them information on drugs and saying drugs -- generic drugs -- are unsafe. That's untrue; it's blatantly untrue.

MacNEIL: There are more than 1,200 drug manufacturers in the United States. One of the three largest is Eli Lilly of Indianapolis, which Mr. Haddad just mentioned. Its Vice President for Medical Affairs is Dr. Robert Furman, who is with us in Washington. Dr. Furman, first of all, how do you respond to the charge Mr. Haddad made specifically about your company?

Dr. ROBERT FURMAN: I would categorically deny that Eli Lilly & Company has carried out a saturation campaign alleging that generic, non-branded drugs are unsafe. We have always maintained that the quality of drugs manufactured by Eli Lilly & Company are of the highest order possible for us to make them. We are a heavily research-oriented, technologically highly developed company, an innovative company that brings new drugs to the marketplace along with other giants in this field. We are at the same time manufacturers and marketers of probably as many, if not more, generic drugs than any other company.

MacNEIL: Could I stop you there, sir, and ask you: are there differences, in your company's view, between brand name drugs and generic drugs -- the generic equivalent?

FURMAN: Yes, there are differences, of course. The problem is to discern where those differences reside and their significance. Let me point out that two drugs can be identical from the point of view of their chemical composition, the binding agents that hold the ingredient together, the shelf life, the presence or absence of impurities, the weight constancy -- all of these could be identical chemically, and from a point of view of medicinal chemistry they would be of high quality. And yet, if we're talking about a few extra pounds pressure in compressing one tablet over another, manufacturers may make the difference between the drug or tablet dissolving in the GI tract and the other passing through to reside, ultimately, in the bed pan.

MacNEIL: Does the advantage in that difference always reside with the brand name drug over the generic drug?

FURMAN: Let's get away from talking about brand name drugs and generic drugs. Let's talk about chemical entities, some of which bear a patented label which identifies it as Lilly's or Merck's or somebody else's. The point that we're trying to make is that the research know-how, the quality assurance, the quality control that goes into our products is what makes us think that generic drugs marketed by companies with this know-how and with a tradition, if I may quote one of our ads which says "We've been making medicines for four generations as if your life depended on it." Eli Lilly & Company believes this. This is inherent in the company's products, it reflects the integrity of the company; and I take strong exception to a state-

ment by Mr. Haddad that we are saying that generic, or non-branded drugs, are unsafe. We've never said that, Mr. Haddad. I challenge you to show me that we've said that.

MacNEIL: We'll have Mr. Haddad back in a minute. I just wanted to get back to this question: if there is a difference between generic and brand name drugs, does the medical advantage, in your view, in that difference always reside with the brand name drug?

FURMAN: Not always, no. I can't categorically state that 100 percent of the time without exception that a brand name drug is superior to a non-brand name drug. It isn't the question of whether the drug is marketed under its generic label or a branded label; it is what's gone into its production, it's what's gone into evaluation of the ingredients that ultimately are used to synthesize the end product, how it's formulated, pressures, pH, color, taste. If you have an antibiotic to treat a child with strep pharyngitis and it tastes terrible or its consistency is awful and the mother can't get the child to take it, it doesn't make any difference whether it's equivalent biologically or therapeutically. If the child won't take it you've got therapeutic failure. If you've got an elderly geriatric patient who's taking some of those drugs you showed us earlier -- a reserpine to lower blood pressure, a diuretic to increase urine excretion and water excretion and salt excretion, and a digitalis preparation to stimulate the contracting power of the heart -- and the physician has titrated her with drugs of a given manufacture and she is responding well, she then gets a prescription for refill and goes to the druggist and she gets three new manufacturers' preparations which have modest differences in their rate of absorption and efficacy and she may be in a therapeutic catastrophe.

MacNEIL: I see.

FURMAN: These are subtle differences that transcend simple laboratory analysis. These are differences that are part of the physician's background and his evaluation. The FDA, or no other agency or laboratory, can determine these factors by dissolution, et cetera.

MacNEIL: Okay. Well, thank you. We'll come back in a moment. Before a prescription drug can be sold in the United States it must first be approved by the federal Food and Drug Administration -- the FDA. Dr. Marvin Seife, Director of the FDA's Division of Generic Drug Monographs, is the man who issues the FDA's "safe and effective" approvals for generic drugs. Dr. Seife, your job is to approve these drugs. What differences between generic and brand name drugs do you see?

Dr. MARVIN SEIFE: I see none if a drug has been precleared by the FDA and arrives on my desk for approval. Each drug undergoes the same -- there is no differences; I take pride in the fact that our office treats both the largest firms and the smallest firms in the same manner. They each have to undergo the same rigorous tests, tablet validation, current good manufacturing procedures, adequate and safe labeling to the physician, whatever goes into the package that we must clear. Before this drug is approved, each manufacturer must meet what we consider our standard; they must conform to the United States Pharmocopoeia monograph, dissolution studies, bioavailability studies and many other things.

MacNEIL: In your work I'm sure you must hear this a great deal, but do you recognize, as scientists, the differences that we've just heard from the gentleman from Lilly's in their perception of the efficacy of various drugs?

SEIFE: Yes, I understand what was said. Pharmaceutical elegance was addressed in the recent statement by Lilly, and this certainly enters into the acceptability of any drug by a patient and I can well understand what was alluded to. However, we understand fully -- now, let's get to antibiotics. Antibiotics in this country are checked batch-by-batch certification. This service is paid for by the pharmaceutical company; every pharmaceutical company pays for this service. As far as the FDA is concerned, each batch is similar to the other batch. All antibiotics are interchangeable, as are all biologics, insulin and these sorts of drugs. In recent years we are now with the drug efficacy study implementation whereby the National Academy of Science, the National Research Council has evaluated all drugs from 1938 to 1962; as a result of the Kefauver-Harris amendments' post-thalidomide tragedy, drugs were called "safe and effective." Prior to '62 drugs were only approved for safety. Following the amendments drugs had to show effectiveness. And so since the contract with the NASNRC we have published in the Federal Register a series of notices stating that various drugs were safe and effective, and called for either a full or an abbreviated New Drug Application. In my mind, the FDA precleared these drugs prior to marketing. This has not been carried out to the fullest until recently, upon the order of Judge Green; in the summer of 1965 he said, "FDA, do your duty; comply with the law. Preclear all marketed drugs." As a result of her ruling, 117 drugs with supposed or actual bioavailability problems have been policed 99.9 percent, I would say, as to their being approved by the agency.

MacNEIL: Okay. Let me ask you this: is there any reason, in your view, why generic drugs should not be prescribed and used in the great majority of cases?

SEIFE: If the drug is approved by the Food and Drug Agency as safe and effective and the preclearance process is followed, I see no reason why generic drugs cannot be used in lieu of a brand name.

MacNEIL: Thank you. Let's talk to someone who has to make these decisions every day. Dr. Michael Halberstam has to decide every day whether to prescribe generic or proprietary drugs. He's a practicing physician in Washington, D.C. and the author of several books and numerous articles on health and medicine. He's also a nationally syndicated columnist on health. Dr. Halberstam, how do you decide, as a physician, between prescribing a generic or a brand name drug for a patient?

Dr. MICHAEL HALBERSTAM: I frequently prescribe generically, and also, of course, by brand name. Sometimes a generic equivalent is not available because a drug is a new one and the patent still exists, so in that case there's no choice. Sometimes I prescribe by brand name because I don't remember the generic name. As you yourself noted at the beginning of the discussion, the generic names are the chemical names and sometimes they're quite complex and occasionally they may slip the physician's memory. But more frequently, I think, the decision to prescribe generically -- which I do, I think, more than

half the time -- is because I personally do not feel that the slight differences that Dr. Furman of Lilly alluded to earlier are of clinical significance to my patients. That is, there are some clinincal situations where the degree of bioavailability -- the fact that the capsule does not dissolve as rapidly or so easily -- is not terribly important, because dosage is rather crude in many aspects of medicine. But for the very same reason there are many instances where I will prescribe by brand name -- by the company's name -- because it is an instance where a very slight variation in the availability of the actual chemical can make a genuine difference in how the patient feels. For example, the two heart pills that you showed earlier, digoxin and Lanoxin; Lanoxin being the brand manufacturer's name, has been shown to be very consistent in its quality, whereas digoxin has not been. And when we are dealing with a drug like digoxin, where a very slight variation in the rate at which it dissolves can cause a medical catastrophe, I very much prefer to stick to a brand name drug which has a quality behind it and which also has consistency behind it.

MacNEIL: Do you feel pressure from the drug industry yourself, and do doctors feel that pressure, to prescribe the brand name drug?

HALBERSTAM: No. I have to point out that, among other things, I also edit a magazine which gets a great deal of advertising from drug companies, so I'm both -- in a sense -- a consumer of advertising and in one sense removed a producer of this advertising. I resent advertising which insults my intelligence or which is clearly not true. I feel at times bombarded by advertising -- other people's magazines, not my own -- and I think that physicians in general have a certain skeptical attitude towards drug advertising. I think the allegation that they are brainwashed by drug companies is completely untrue. Actually, if you do look at the patterns of sales of drugs, you'll find that great advertising campaigns are not very effective in getting drugs prescribed in large amounts. What is effective in making a drug popular among physicians is, in fact, the effectiveness of that drug. Among the five most commonly prescribed drugs in New York State are two generic drugs, but of the brand name drugs the drugs are ones which have been shown to have been effective and are shown to have quality behind them.

MacNEIL: If what you say is true -- you in your own case prescribe perhaps fifty percent generic drugs -- why, proportionately, are generic drugs so little prescribed? I've read figures as low as ten percent of all the drug use in the country.

HALBERSTAM: Right, I think in general it's about ten to fifteen percent. Again, part of that is because many of the newer drugs are not available in generic formulation. They are still protected by patent. That goes, for example, for some of the common tranquilizers, which are very highly prescribed. Another reason is that I think in general older doctors tend to prescribe more by brand name because in the past generic drugs were made by almost anybody who could get together a garage and some chemicals, and the consistency of them and their reliability was very uncertain. And indeed, I think the FDA itself, every year when it comes time to ask for appropriations for the FDA's budget for next year, complains that they don't have enough money to send inspectors around to all the plants, but then in between times they tell you that yes, they are doing a fine job and getting to every one of these little plants. I think doctors

tend to feel that when it's a matter of marginality they would rather stick with a company that they know to have very high standards and to have a long-established reputation.

MacNEIL: Let me ask all of you this question: who should decide, the doctor or the pharmacist or the consumer, which drug is used in a particular case? Let me go back to Mr. Haddad, who's been sitting here for a while.

HADDAD: Mike was my doctor in the Peace Corps, and he prescribed generically for me.

MacNEIL: You're still alive.

HADDAD: (Laughing.) I'm still alive. I'll answer very succinctly, but I have to put a caveat on it: the doctor should have the final right at all times, but the doctor does not possess, as even Mike indicated a few minutes ago, and I'll go on and explain that later, sources of information that are completely independent of the industry. Digoxin, which he talked about, had problems, but they're over with. But the sources of information for the doctor are limited, many controlled by the drug companies.

MacNEIL: Would the pharmacist be a better person to decide this?

SEIFE: No, I feel the practitioner, whether he be physician, dentist, podiatrist or osteopath, should be final judge as to a prescription, regardless of whether generic or brand.

MacNEIL: Dr. Furman, I presume you don't disagree with that.

FURMAN: No. I would just like to comment that the information provided the physician by industry and its representatives has to conform with FDA-approved statements. This is regarded as "labeling," and even our drug representatives -- the vast majority of whom are trained, registered pharmacists -- are constrained to limit their remarks to those consistent with what the FDA has approved based on the extensive clinical trials submitted to the FDA by the company in support of its New Drug Application.

MacNEIL: Let me ask you all this question: twenty-two states now have some form of substitution law, and the District of Columbia as well. Are you all generally in favor of repealing the anti-substitution laws around the country? Dr. Halberstam, are you in favor of that?

HALBERSTAM: Well, I am to the extent that I think that the physician should have the option of checking off and saying on a prescription, "Generic may be substituted." And the physician can put his or her check mark on that and allow on that particular prescription generic medication to be dispensed. That, by the way, would obviate the problem of physicians forgetting the generic name.

MacNEIL: (Laughing.) I see. The pharmacist would then remember it.

HALBERSTAM: That gives the choice to the physician; it assumes that the prescription will stay as written unless the physician spe-

cifically says you may substitute. Apparently, there are other bills in the hopper, including the one which Mr. Haddad described, which put the emphasis the other way, and which I think many physicians, including myself, would resent.

MacNEIL: I see. Dr. Furman, is Eli Lilly in favor of repealing these anti-substitution laws?

FURMAN: No, we're not. You know, I must remind you that generic prescribing has been something that physicians have had the prerogative to engage in for years. I was taught generic prescribing by two of the most famous clinical pharmacologists in the business, Goodman and Gilman. I think a physician, when he specifies a chemical entity of a particular manufacturer, whether he gives the chemical name and it's "--Merck," "--Lilly;" or "--(whoever)," or he identifies the product by its brand name, he should be able to rely on the pharmacist dispensing what he has ordered unless the pharmacist -- for reasons which are substantial and substantive in his mind -- communicates his thoughts to the physician. And I think this relationship which brings the pharmacist into the therapeutic situation as a member of the team is what we need to encourage, and not to insert some legislative fiat between the pharmacist and the physician, which I really think would be counter-productive.

MacNEIL: I see. But just looking at it from the consumer's point of view -- the chap who actually pays the bill in the drug store, Dr. Furman -- would there be any pressure to get these costs down if there weren't legislation repealing these anti-substitution laws?

FURMAN: Well, let me just say that surveys have been taken of consumers in a number of areas in which they've had an opportunity to express an opinion as to whether they think the pharmacist should have the right or the obligation to change the physician's prescription in terms of product selection, and the vast majority say no, they want to have the physician have the confidence that what he has ordered will indeed be dispensed. Now, I think you should realize that the drugs in the marketplace that represent those drugs for which the vast bulk of money is spent are really highly competitive; and the drug industry, despite what many people think, is a highly competitive industry and when we're talking about generic drugs -- high-volume drugs, such as some of the antibiotics, for example -- the competition has honed the price down to levels which I doubt very much generic substitution's going to alter.

MacNEIL: Thank you. I just wanted to get a final few-second answer; is the federal government, as part of its cost-consciousness in medicine, trying to push the idea of the use of generics?

SEIFE: In the past, we were committed -- we <u>are</u> committed to cut the price or help cut the price of drugs across the board through the MAC program.

MacNEIL: Thank you. That is the Maximum Allowable Cost in federal institutions.

SEIFE: Yes.

MacNEIL: Thank you, gentlemen, both in Washington, very much,

and thank you here. Jim Lehrer is away on vacation this week. I'm Robert MacNeil, I'll be back tomorrow night. Good night.