"Are Generics Safe"
Office of Legislature Oversight and Analysis
April 28, 1977

APPENDIX A

THE ANTI-GENERIC CAMPAIGN

Over the last ten years, major brand name drug companies have waged a continuous, highly sophisticated campaign to discredit generic drugs. Unable to compete on the basis of price, these companies have used Madison Avenue to shift the argument to one of safety.

In the last two years the anti-generic campaign has intensified. Twenty-four states have by now passed legislation to allow generic substitution; the public has become better informed; the generic cause has gained ground. What were once oblique "product image" ads have become outright attacks on the generic manufacturers.

The New York Area is currently experiencing a media saturation campaign, sponsored by a major drug company. The money invested is an indication of the millions of dollars at stake for the brand name manufacturers.

The state of Oklahoma experienced a similar campaign in 1975-76. At that time a generic drug substitution bill was before their state legislature as well. (The legislation eventually passed.)

The assertions made during that campaign were subjected to an indepth review by the Illinois Consumer Affairs Office. Their report tabulated, and refuted, forty-five separate incidences of false statements.

Copies of a small portion of those campaign materials are attached. Note that the sponsoring agent, the Congress of County Medical Societies (Washington, D.C.) offers to make all campaign materials available, free of charge, to any county medical society.

'Deception' Charged in Campaign To Kill Oklahoma Generic Drug Bill

CHICAGO—Charging that 76 percent of the claims in an advertising campaign used last year to defeat drug substitution legislation in Oklahoma were "totally false," the Illinois Consumer Advocate Office (CAO) warned last month that material in a massive media blitz by an Oklahoma City ad agency is being offered free of charge to opponents of drug substitution laws in other sections of the nation.

Celia A. Maloney, Illinois consumer advocate, said a detailed analysis of the Oklahoma campaign undertaken by CAO disclosed that only three percent of the statements in printed material could be construed as completely truthful. "There seems to be a consistent and possibly intentional pattern of deception" that has taken on national importance, Mrs. Maloney said.

At issue is a proposal by about 20 state legislatures this year to permit dispensing of cheaper, generic drugs instead of more expensive brandname prescriptions. Twenty-two states already have passed some form of drug substitution legislation, one of the primary objectives of the joint NRTA-AARP state legislative committees.

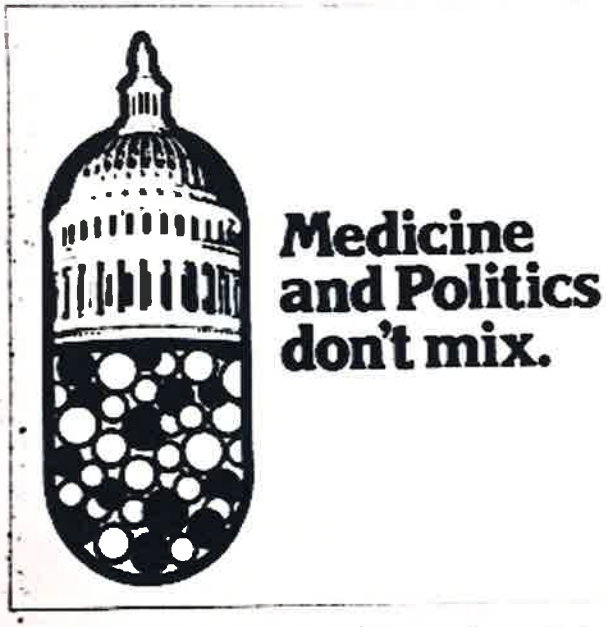
The Oklahoma campaign, which consists of radio-TV commercials, newspaper ads and displays in drug stores and doctor's offices, was put together by Adsociates, an Oklahoma City agency retained by two county medical societies and pharmacists' associations.

Mrs. Maloney pointed out that in states and also Canadian provinces which have laws that allow drug substitution, there has been a consistent pattern of significant savings at no additional risk to consumer health; increased competition in the industry, accompanied by stabilization of previously fast-rising prices, and improved standards of prescription quality, all of which contradict claims made by the Oklahoma group.

The Illinois consumer advocate said that a price survey made by her office in April, 1975, found that brand name drugs in Illinois

County Medical Societies Campaign to Beat Drug Substitution

by the editors of PRIVATE PRACTICE



Increasing pressure on the Oklahoma State Legislature to repeal Oklahoma's strong anti-substitution law had doctors worried. "When I write a prescription for one of my patients," Dr. Orange Welborn of Ada, Oklahoma, told PRIVATE PRACTICE, "I want him to get the exact drug I prescribe,—not a cheap generic some bureaucrat in Washington claims is equivalent to the brandname I have used and trust."

But lobbying by labor unions, consumerists, and retired people's groups — using the chimera of reduced prescription drug costs — was getting close to success. Soon, Oklahoma doctors might have their prescriptions changed and generic drugs substituted without their or their patients' knowledge.

So instead of wringing their hands, the Pottawatomie and Pontotoc County Medical Societies and Pharmacists Associations decided to do something about it. With the help of the Congress of County Medical Societies, they launched a massive media campaign in their Oklahoma counties — using TV, radio and newspapers — to stop the repeal of the anti-substitution law. So far as PRIVATE PRACTICE has been able to discover, this campaign is unique in American medicine. "We know constituent pressure does sway legislators as nothing else does," Dr. Welborn explained, "and we are mobilizing the voters — our patients — through advertising explaining that drug substitution can hurt their health. Believe me, the results already show that the politicians listen, and listen very carefully."

THE RISKS OF SUBSTITUTION

Dr. Frances A. Davis, chairman of the Pottawatomie County Medical Society's legislative committee, noted: "If all the chemically identical medicines available for substitution were really the same, there would be no danger to our patients at all. But just as a diamond and a chunk of coal start with the same chemical composition, and wind up completely different, so do medicines.

"Those differences are enough to kill our patients or to cure them or to make them sicker or to make no difference at all. Substitution plays Russian roulette with our patients' health, and we just aren't willing to sit back and let it happen."

"One of the most serious instances," added Dr. Welborn, head of the campaign for the Pontotoc County Society, "concerned digoxin. In tests, equal dosages of different manufacturers' digoxin were absorbed at startlingly different rates. In some cases, myocardial infarctions and deaths resulted. Lanoxin avoids these troubles. And if I prescribe Lanoxin, I don't want a generic digoxin substituted. If drug substitution becomes law, I'll have no way of knowing what my patients eventually get."

"The quality of medical care is certain to decrease," says Dr. Davis, "if the physician's choice of therapy is subject to economic considerations over purely medical ones. In fact, the Judicial Council of the AMA has held that 'the physician has an ethical responsibility to assure that high-quality products will be dispensed to his patients. Obviously, the benefits of the physician's skill are diminished if the patient receives drugs . . . of inferior quality.' If a doctor cares about his patients and cares about the quality of medicine he practices, he must work to stop drug substitution."

DOES SUBSTITUTION SAVE MONEY?

Proponents of drug substitution say it would save substantial sums of money for patients, but Roy Kelly, MD, of Shawnee, Oklahoma, disagrees: "Studies have shown that generic substitution would save patients 1.7¢ on the dollar at most. And, in fact, in Saskatchewan, Canada, prescription prices rose an average 13% after substitution was enacted, probably because pharmacists' malpractice premiums went up so much. In Kane County, Illinois, doctors and pharmacists tried substitution. The experiment was ended after three months, because patients didn't save any money."

The anti-substitution campaign ended with a two-hour movie, and the commercial breaks were used to answer viewers' questions on substitution. During a segment of the movie, moderator Orange Welborn, MD (third from left), confers with Frances A. Davis, MD, president of the Congress of County Medical Societies (fourth from left). The other panel members are J. B. Wallace, MD (far left), William Bryan, RPh (second from left), and Gordon Richards, RPh (far right). In the background, members of Dr. Welborn's office staff have telephoned questions from viewers. 135 were received.

Gordon Richards, RPh, of Shawnee, told PRIVATE PRACTICE: "I tell my customers that they've got to remember that today's medications are more powerful than they used to be. So while individual tablets or capsules may cost more, it takes fewer to treat them. Because of this, the average dosage price has gone down, not up, since 1960."

PHARMACISTS ALSO OPPOSED TO SUBSTITUTION

The American Pharmaceutical Association has been pushing hard for substitution since 1970, even though it was instrumental in getting anti-substitution laws passed in the early 1950s. Because of the APhA, many think that all pharmacists want substitution. But ethical pharmacists do not, and the Pottawatomie and Pontotoc County Pharmacists Associations joined their medical colleagues in fighting it. Adds pharmacist Richards: "Drug substitution is bad for the prescriber, for the pharmacist, and, most of all, for the patient. I am completely opposed to it." The pharmacist's scientific training makes him realize all the factors that can make chemically equal drugs act differently in the body. "In my day-to-day dispensing, I have seen the unsatisfactory results of one drug, as compared to a similar drug, in the experience of my customers," said another pharmacist.

"Drug substitution severs the lines of communication between the pharmacist and physician," said Mr. Richards. "It eliminates the 'teamwork' from the health-care team by taking the physician out of the final choice of the drug to be used. When the pharmacist and physician work independently rather than together it is the patient who suffers most. It is in the best interest of the patient for the pharmacist to consult the physician before making any changes in the prescription. If drug substitution were legalized, neither the physician nor the patient could be certain that a prescription was dispensed exactly as written. It is important that the doctor and patient have confidence that the medicine dispensed was what the doctor intended."

ADVERTISING

In the Autumn of 1975, representatives of the two county medical societies met in Oklahoma City with the Congress of County (continued on page 5-d)

A doctor's office (above) and a pharmacy during the anti-substitution campaign

continued from page 8-3 Medical Societies and a well-known local advertising agency, Associates Out of the meeting grew the indepth TV, radio, and newspaper effort to stop substitution in its tracks.

Working closely with physicians in private practice, Berry Wheeler, president of Associates, and his staff, crafted six full-page newspaper advertisements, three TV spots, and two radio spots (see Appendix). During the five weeks, the full-page newspaper ads appeared regularly in the daily newspapers of the two counties, accompanied by good editorial support. The 60-second radio and 30-second TV spots were used sparingly at first, and built to a crescendo during the last week. All told, the advertisements appeared on radio 700 times, on TV 60 times, and in newspapers, 29 times.

Each ad was designed to create interest and action. People were given a local phone number in each county, manned 24-hours a day, seven days a week, to call for information. Everyone who wanted more information was sent a pamphlet, "Why Prescription Drug Substitution is Bad Medicine for Oklahoma," written for lay people by Francis A. Davis, MD, and Gordon Richards, RPh (see Appendix), which contained a card to fill in and send to local representatives. Some people wanted to protest immediately to their legislators, and wecards were sent in their names by the two county medical societies.

As a backup, every doctor's office and pharmacy in the two counties had a large counter card on prominent display, headlined, "Oklahomans, Help Yourselves! Stop Prescription Drug Substitution Before It Becomes Law!" In two pockets at the bottom of the card were the Davis-Richards pamphlets and pre-stamped protest cards.

The last night of the campaign, Saturday, February 24th, two hours of TV time were purchased for a movie — *The Boston*, starring George Peppard — and the 20 minutes of commercial breaks were used to take phone calls from patients about the issue, a panel of doctors and pharmacists answered their questions, telephone-to-tv.

POLITICS AND MEDICINE DON'T MIX

Since the March issue of PRIVATE PRACTICE had to be at the printer before the final results were in, they will be reported in our April issue. But there is enough evidence to support Shawnee's Dr. Leon Combs, who called the effort a "real success." Other county societies in Oklahoma are gearing up to repeat the campaign in their areas, if necessary. But there is no doubt that in the population of Pottawatomie and Pontotoc Counties, some 70,000, thousands of people have become militant substitution-fighters. Many protest cards and letters hit the State Capitol, causing quite a stir, and probably killing drug substitution in Oklahoma for the foreseeable future. The people agreed with the campaign's slogan, "Politics and Medicine Don't Mix." Interestingly, older people led in number of protests, giving the lie to lobbyists who claim that retired people support substitution.

One letter from a woman in Shawnee to her state legislator read: "I am gravely concerned about the bill before the legislature which will permit drug substitution for the person preceding a prescription from his or her physician to a drug store.

"I feel this is a very dangerous bill and could have far reaching effects on the individual patient. I have a chronic eye condition and the particular drug prescribed by my physician is quite effective in giving relief. If I should have this drug substituted it could increase the infection or even might cause loss of hearing. In fact, this particular bill seems to be the most dangerous legislation which has been presented to the legislature.

"Please exert every effort to defeat this particular bill and you will certainly have contributed a great service to all the people in your district."

THE FUTURE

"Now that we know this kind of approach works — and works well," notes Dr. Combs, "we're ready to share it with all the other county medical societies in America. Any county society wanting to run a similar campaign will have to pay only for the media time — the Pottawatomie and Pontotoc County Societies will supply video tapes, audio tapes, and newspaper mats for free. Any county society that wants more information can write to the Congress of County Medical Societies [2007 Northwest 63rd Street, Oklahoma City, Oklahoma 73116] or Associates [5929 North May Avenue, Oklahoma City, Oklahoma 73112].

"Right now our societies and the CCMS are working to design a media campaign against the disaster of National Health Insurance for use in selected Congressional districts. The socialists haven't won this battle yet." PRIVATE PRACTICE will be reporting on this soon. ☐

Three Myths of Prescription Drug Substitution

Twenty years later, a minority of pharmacists, some politicians, and groups claiming to speak for consumers and older Americans, are pushing for the repeal of anti-substitution laws.

The repeal effort is based on three myths.

ONE, that pharmacists are more knowledgeable than physicians about prescription drug products;

TWO, that patients would reap large savings if "generically equivalent" drugs were substituted for brandname products;

THREE, that prescription drugs with the same chemical ingredients will have the same therapeutic effect.

Myth One

Pharmacists are very important, indeed indispensable, members of the patient-care team. But when it comes to knowing how drugs work in *people*, rather than in the abstract, physicians have more training and experience.

Your doctor has listened to you, questioned you, examined you, and made a diagnosis of your condition. The drug he prescribes is based on the therapeutic results he has witnessed in previous cases. Only the physician knows the particular diagnosis for each case, and only the physician should have the final choice of drug to be used for it.

The pharmacist is qualified to give you valuable advice concerning the usage, side effects, contraindications, and usual dosage of your prescription; however, deciding what drug would work best for you is the right and responsibility of the physician. Without the final authority to choose the drug, the physician cannot effectively control the patient's therapy.

Myth Two

Then there is the claim that substitution will save you money. An independent research firm did an extensive survey to determine what the savings would be if all drugs were prescribed generically — essentially the same as permitting pharmacists to substitute. The savings of prescribing by chemical rather than brandname (using more cheaply made drugs) would average only 1.7% (or 1.7¢ on the dollar). Companies that cut corners in manufacturing and quality control can sell more cheaply than the national firms that do not, but not by a wide margin. In fact, America's pharmaceutical industry has an enviable record in holding down costs. On the whole, the average tablet or dose costs less today than in 1960. There aren't many other products you can say that about.

But the study above is only a projection. What about the places where substitution has actually been implemented?

It's legal in Saskatchewan, Canada, and instead of prices going down, they went up — 19% on the average. Some think the culprit was the increased cost of malpractice insurance for pharmacists. When they started substituting, their liability increased.

In this country, fifteen months of substitution in Kane County, Illinois, ended when no savings to patients could be shown. In Massachusetts, Maryland, and Kentucky — where substitution has been implemented — no savings has resulted.

Myth Three: The Critical Issue

Myths Numbers One and Two are not the critical issues, however. Myth Three, and the risk it can pose to your health, is.

Drug expert William H. Havener, MD, gives seven reasons — and he says there are many more — why chemically equivalent drugs may not have the same effect.

1) *Purity.* Purity can vary greatly. Generic (non-brandname) penicillins can contain up to 15% impurities, says the Food and Drug Administration, and still be sold. Granted, penicillin impurities are very hard to remove, but reputable brandname penicillin is 98% pure. In fact, people with "penicillin allergies" are often allergic to the impurities rather than the penicillin.

2) *Stability.* A product's package doesn't seem very important, but ill-packaged drugs can quickly deteriorate and become unusable . . . but by then, you've already paid for them.

3) *Taste, smell, color, consistency.* If you have children, you know how important these are in medicines. They're also vital in long-term adult therapy.

4) *pH.* What is the degree of acidity or alkalinity?

5) *Coating.* The right kind of coating protects sensitive medicines against destruction by stomach acids. The wrong kind can permit a pill

or capsule to pass through the body undissolved, with no medical effect whatsoever;

6) *Deterioration.* Some drugs, if improperly produced, can deteriorate to ineffective or toxic substances. The widely used antibiotic tetracycline, if dispensed in relatively acidic capsules, slowly transforms into a deadly kidney poison. Without appropriate — and costly — safeguards, this kind of problem can occur.

7) *Absorption.* How well a medicine is absorbed into the body depends on many factors, including how rapidly it dissolves, the nonactive ingredients used, stability in digestive juices, and how it reacts with food in the stomach.

The Dangerous Effects of These Differences

Here are some specific examples from medical journals that also received some attention in newspapers.

A few years ago, it was discovered that while Chloromycetin (brandname) is a very powerful and effective antibiotic for certain infections, all the generic equivalents of chloramphenicol (chemical name) would not do the job, no matter how much was given to patients.

Digoxin (generic name) is used by millions of Americans to help their hearts beat more forcefully. In 1974 the Food and Drug Administration discovered that some manufacturers' digoxin varied so much in absorption rate from batch to batch, that patients could get dangerously high or low amounts from the same dosage. The FDA also noted that Lanoxin (brandname) had no such problem. It was a little more expensive, but it worked, unlike its cheaper counterparts.

Alan Tasoff, MD, writes of his experiences as an Air Force doctor in Thailand in 1972: "Struggling to overcome a penicillin-resistant gonorrhea epidemic among airmen — of the magnitude of twenty new cases per day — we were armed with an Italian-manufactured tetracycline, purchased in massive quantities by Congress. The drug was chemically equivalent — in the judgment of consumer groups — to brandname drugs. The failure of this drug to dissolve in the alimentary tract was known to all physicians prescribing it, but supplies had to be consumed before a replacement could be made available. The ultimate cost to the airmen involved was chronic, intractable urethritis and prostatitis."

Two Branches of the Government Say All Drugs Aren't Equal

With all the controversy surrounding this question, the United States Senate Health Subcommittee asked the Office of Technology Assessment (OTA), an agency of Congress, to study the whole problem of prescription drug bioequivalence (whether chemically equal drugs will be equally available in the body, therefore allowing them to have an equal effect).

The OTA set up a Drug Bioequivalence Study Panel and asked Dr. Robert M. Berne, dean of the Yale University Medical School, to be its chairman. After months of intensive study, the panel released its report in July 1974. Among its findings were:

"Current standards and regulatory practices do not assure drug bioequivalence for drug products."

"Present . . . guidelines do not insure quality and uniform bioavailability for drug products. Not only may the products of different manufacturers vary, but the product of a single manufacturer may vary from batch to batch or may change during storage."

"The problem of bioinequivalency in chemically equivalent products is a real one."

The Food and Drug Administration has so far identified 193 categories of drugs, including thousands of different products, as having known or strongly suspected equivalence problems.

The People Say They Don't Want Prescription Drug Substitution

In a democracy, what the people think counts. So it is important to know the findings of the national and two state surveys on the relative importance of drug cost, quality, effectiveness, safety, and bioequivalence. 2,537 people were surveyed all across America, and 1,149 people were questioned in California and Wisconsin.

Seventy-one percent of the people questioned nationally believe the physician, not the pharmacist, should determine which drug product a patient takes. (In the state surveys, the percentage was 75.)

In the state surveys, people placed far greater importance on effectiveness and safety of prescription drugs than on their cost or speed of relief. In fact, cost was last by a decisive margin.

Over 70% in the national poll said they didn't want substitution of generic drugs for those prescribed.

(continued on page 5-8)