WILLIAM F. HADDAD
Office of Legislative Oversight
and Analysis
World Trade Center Two
Room 5075
New York, New York 10047

THE ASSEMBLY
STATE OF NEW YORK
ALBANY

Press
(Press Release)

May 30, 1978
FOR FRIDAY A.M. RELEASE

MEMO TO: Editors
FROM: Bill Haddad
RE: New York's Drug Law Undermined by Physicians

A review of 50,000 prescriptions prepared since the New York State Law mandating substitution of lower priced drugs went into effect reveals that physicians stand as the major impediment to reduced drug prices for the consumer.

Under the bi-partisan state law, which passed both houses with almost a unanimous vote, the physician was provided with the opportunity to sign his prescription either to the left or to the right. If he signed to the right, he set in motion a process under which the pharmacist was mandated to substitute a lower priced generic drug from a New York Formulary of interchangeable drugs. If he signed to the left, it was "prescribed as written."

Seventy-five percent of the doctors are signing to the left, forcing consumers to pay the higher prices.

One-third of the doctors are not using the proper forms for prescribing, creating confusion in the marketplace.

As part of its legislation, the Assembly prepared, and the Food and Drug Administration validated, a list of medically interchangeable drugs. That list was revalidated and sent to every pharmacist by the State Department of Health. A generically substituted drug would be identical with the trade name counterpart. The only difference would be price which, earlier Assembly surveys indicated, could range as high as one thousand percent, but usually fell into the 300-700 percent range. In other words, three out of every four consumers are being prevented from obtaining identical lower priced drugs by the failure of the doctor to set in motion the new legislation. They are paying, on the average, three to seven times more for a drug.

Commissioner Don Kennedy, head of the FDA, has repeatedly stated that drugs on the New York drug list are medically interchangeable and that the FDA information on which it is based encompasses not only the drug itself but the manufacturer.

During the legislative process, representatives of doctor's organizations stated they needed the "FDA stamp of approval" because the industry's detailmen have, for decades, told them that generics were unsafe and ineffective. The New York formulary proved these statements inaccurate and fraudulent.

Early inquiries by this office have indicated an active campaign by the several thousand industry detailmen in New York to (1)urge doctors to tell pharmacists to use a trade name product whenever a prescription is phoned in; a fourth to a third of prescriptions are called in; (2)sign to the left. Trade publications, who live off drug industry advertisements, have editorialized against the legislation and printed pictures showing a physician how he can sign to the left and get a brand name product. After the second year in medical school, doctors learn about drugs from detailmen, the traveling salesmen of the industry who visit doctors offices with information and free samples, and the trade press, which is, we believe, all but co-opted by the industry advertisements.*

In other states, physicians have gone along with the changed substitution laws. In Florida, one drug chain reported an average saving of $3.49 per prescription. Similar savings are being denied New Yorkers.

In the legislative process, great consideration was given to the issue of protecting the physicians right to select drug products and to avoid government intrusion on that all-but-sacred right. Current results, if they hold constant, bring into question whether the physician, either through ignorance or arrogance, is abusing that right. Certainly three out of four brand name prescriptions is far out of line with physicians elsewhere in the nation.

Today, most private and public hospitals, most governments (state, city and federal) and most reimbursement plans require generic prescribing. New York's law was designed to provide lower drug prices for the family earning over $5,000 a year, the family which pays medical bills without subsidy. The failure of the physician to take note of the new law is posing an undue burden on this hard-pressed, middle income family.

* (In the classic case, the Journal of the American Medical Association hired a Chicago consultant to tell them how to get drug ads. He said for them to abolish their distinguished Council on Drugs and to change their prescribe generic policy. They did. Ads, at one time, provided the entire AMA with 70-odd percent of their operational costs; now it is down to forty-odd percent. Just this month, the Journal editorialized against generic prescribing).

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NOTE TO FILES

FROM: DEE

DATE: AUGUST 25, 1978

CC: BILL

Met with Dan Badia, President of Pharma-Tek, on Aug. 21st. who wanted to alert us to some of the problems small companies have getting state contracts. He wrote to all of the states, requesting bidder applications and general information. Fifteen states responding. Of these, he says that Mass., Louisiana and Texas are the best to deal with. Some of the typical problems he runs into.

1. Bureaucratic gobbleygook that serves to block small firm participation. See attached letters from Georgia as an example of this. The first letter from Georgia says that "many purchases are made from a certified brands list." When Badia inquired about the certification procedure, the response was that Georgia does "not have "Certified Brands Lists..." See also the third paragraph of the New York letter as another example of administrative blocks to small manufacturers.

2. Before letting a contract with Badia, the low bidder on a particular purchase, Ohio wanted samples of the product. This wasn't easy because Badia had to get Copanos to make up the drugs on a rush basis and send back to Ohio. It was made clear that the sample drugs met specifications in every way except for not being scored on the top. Ohio agreed to accept unscored drugs, but then later refused to give Badia the contract because the samples weren't scored. Referred Badia to Bill Heitsman.

3. Florida takes bids, then publishes a list of the bidders with prices (highest as well as lowest). State institutions purchase

separately rather than centrally through the state. The big manufacturers have the money and sales force to detail the separate state institutions. Badia, and the other smaller manufacturers obviously don't so it becomes very difficult to get contracts in a state like Florida.

4. States sometimes require a performance bond which is particularly hard to get for the smaller company. The bond must specify that if the manufacturer does not fulfill his contra he must then pay the difference between the bid price and the final open market price that the State contracts for.

5. Product liability requirements are also a big problem for the small companies. Badia says he just can't get coverage from the insurance companies. The latter want to write policies for ½million dollars for a single occurence and $1 million in the aggregate. Copanos' coverage (Badia buys antibiotics from Copanos) is really not sufficient since he reduced it to $300,00 in order to reduce his annual premiums to $36,000.

EDITORIAL

BY STANLEY SIEGELMAN

"Pharmacy And The Law"—A Film Every Pharmacist Should See

Film makers know that when a movie is touted as being "naughty," more people will rush to see it.

I reacted in just that predictable way, when I learned that Pfizer had produced a film that an arch critic of the industry characterized as meretricious. The critic was William Haddad, N.Y. State Assembly Office of Legislative Oversight & Analysis, champion of the state's new generic substitution law. Speaking at St. John University's annual Pharmacy Congress (see story, page 69), Mr. Haddad openly charged that the Pfizer film was "full of lies" and that it told "only half the story". He has complained to the FTC.

As a one-time theatre reviewer, I could not resist this kind of buildup. I scampered to see the offending film.

What I found was a provocative exploration of the pitfalls of product liability as they relate to pharmacists. Three eminent lawyers were shown participating in a symposium. Clearly, what they said was not dictated by Pfizer or by any other drug company. They simply gave their honest professional opinions as practicing attorneys.

What, then, did Mr. Haddad find so disturbing? Well, he evidently regards the film as an attempt to scare pharmacists about certain alleged dangers of generic dispensing. I, on the other hand, found the premise of the film to be sensible and pragmatic.

Each attorney advocated prudence on the part of a pharmacist who engages in product selection. In no sense could such advice be construed as "anti-generic". In fact, any reputable manufacturer of generic drugs would, I believe, happily endorse this basic point of view.

New York State is now operating under a substitution law that is based on a list of products deemed therapeutically equivalent by the FDA. There is still some question, however, about whether the FDA would assume liability on the pharmacist's behalf if necessary. Another point of dispute is whether the FDA could truly guarantee equivalency of the various products.

Mr. Haddad insists that all the drugs listed in the N.Y. formulary are indeed therapeutically equivalent, and invokes the authority of FDA in making this assertion.

According to one attorney in the film, the pharmacist's dilemma is considerably strengthened when the law compels him to substitute. But experts say that this entire area of litigation is unexplored. There has not yet been a case in which a pharmacist has been sued for faulty product-selection.

In the fullness of time, such a case will undoubtedly come to pass. Meanwhile, a circumspect pharmacist would do well to acquaint himself with the possibilities that do exist. The Pfizer-sponsored film does a fine job in delineating precisely those potential trouble-spots.

In stating that the film is worth seeing, I am not plugging Pfizer, or brand manufacturers, or attorneys. Neither am I attacking Mr. Haddad or the many fine generic manufacturers now operating in the industry.

I mean only to state that the film is helpful to the pharmacist. To borrow a print for showing to your local pharmaceutical group, write to Roerig division of Pfizer, 235 East 42nd St., New York, N.Y. 10017. There is no charge.

WABC TV REBUTTAL NO. 11 – 1977

REBUTTAL: FELTON DAVIS, JR., NEW YORK STATE HEALTH PRODUCTS MANUFACTURERS ASSOCIATION

When it comes to your prescription medications, quality and therapeutic effectiveness must be guaranteed. Before generic substitution is permitted in New York State, you must be assured of two conditions. First, the standard for the copies and the original must be the same. And, second, the copies and the originals must be proven to be interchangeable in actual medical practice.

You do not have these guarantees now because the Food and Drug Administration does not assure the interchangeability of drug products. The proponents of this legislation would like you to believe that gigantic savings would occur if substitution were allowed. This simply isn't true.

Price, of course, should be a consideration in all product selection. But, in the case of medicines, price must yield to quality. Medication that doesn't work is too costly at any price. Substitution should not be allowed in New York State until equivalent quality and therapeutic effectiveness are guaranteed by the Food and Drug Administration.

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CANDACE CARUTHERS – EDITORIAL DIRECTOR

KENNETH H. MACQUEEN VICE PRESIDENT AND GENERAL MANAGER
WABC-TV 7 WEST 66 STREET NEW YORK, NEW YORK 10023 212 LT 7-7777

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