WILLIAM F. HADDAD
Office of Legislative Oversight
and Analysis
World Trade Center Two
Room 5026
New York, New York 10047

THE ASSEMBLY
STATE OF NEW YORK
ALBANY

M E M O R A N D U M

TO: Harvey Strelzin

FROM: Bill Haddad

RE: FDA

DATE: May 5, 1977

Dave and I met with Commissioner Kennedy of the FDA and he agreed to validate our list for "safety, effectiveness and interchangeability". We ran into some bureaucratic problems, but, I think, by putting down our head and running, we have moved them to the side. We said we wanted the validation within ten days. I asked Senator Kennedy to call Commissioner Kennedy to let him know how important that list was to him and us; we also saw Senator Nelson and the top staff aide, Ben Cordon, also called the FDA to let them know of Nelson's interest. Nelson said he will hold hearings on our information. I still have to get Senator Long involved.

I talked to Ben Bradlee at the Washington Post and later to Larry Stern (national editor) and Mort Mintz, their correspondent on these issues. They will do a story for us and want to publish the list. The Times also wants to print the list. We have some control of the timing. That story is designed to provide a national forum for the list and to increase its significance.

Actually, the FDA people who will have to check the list for us, worked with us all week and have already done most of the work. They said we had "erred on the side of caution".

Over the weekend we must recopy the list in a form that makes it easier for the FDA to process quickly. Dave will take it to Washington and work with them.

I am thinking about a hearing in Albany called "Are Trade Name Drugs Safe?" We have the Carlin type evidence, and some interesting examples of drug company pressures on the AMA and on the National Academy of Science (we met the former director of their drug study while I was in Washington). I will be thinking through these ideas and be in a position to make some suggestions to you next week.

I also think if we are to help the pharmacists on their fee (which I think we should do after a quick and fair cost review) we should put that increase in your current legislation because that will give us a powerful, vocal ally and some more clout in the Senate. As you may recall, our repeated requests to the Governor's office for an impartial study were rejected because they feared an increase might result and they didn't want to spend any more money. At that time we politically separated ourselves from that decision, indicating that we were more subject to pressure from the pharmacists and indicated we might do a study of our own. They seemed to understand and approve that action. Sandy followed through on this.

cc: Mike DelGiudice
Pete Grannis

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WILLIAM F. HADDAD
Office of Legislative Oversight
and Analysis
World Trade Center Two
Room 6020
New York, New York 10047

June 3, 1977

Mr. Edward Kosner
Newsweek Magazine
444 Madison Avenue
New York, New York 10022

Dear Ed:

I need your help.

For about twenty years the drug manufacturers have successfully---and I believe fraudulently---maintained that drugs produced under their generic names were unsafe, ineffective and did not react in the body in the same manner as drugs produced under their brand names. The key to their success was the doctor who believed this to be true. The doctor, we knew, was in a structured information situation, being provided with material from the detailman (the route salesman for the drug companies) and medical journals which were co-opted by drug advertising (the AMA actually abolished its distinguished Council on Drugs and changed its policy favoring generic prescribing on the advice of a management consultant hired to tell them how to increase their drug advertisements).

For at least ten years, the Food and Drug Administration has been in a position to end that controversy but, for a combination of internal bureaucratic reasons and external pressure, nothing happened.

New York State decided to go for the eye of the dragon and produce the list of safe, effective and interchangeable drugs, and either through legislation or executive order establish that list as a formulary for the state and the nation. As we have done on other issues (notably natural gas and the Arab boycott) we have done for ourselves what the federal government failed to do.

There is a story in how the list was produced, hidden from view of the political level of the agency, working with courageous bureaucrats who risked their jobs to help, using Freedom of Information requests to protect them (and disguising our interest because the drug companies monitor, on a daily basis, the Freedom of Information requests) and then compiling the list and coming in the front door with a "fait accompli" and asking the FDA to verify what we had done from their records.

My main interest, in this note, is to get the substance of the Times story into the magazine so doctors and state politicians can learn there is such a list available.

Thanks for listening.

Sincerely,

William F. Haddad

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NY TIMES Editorial

June 9, 1977

Rx Against Brand-Name Medicine

You are ill or otherwise in need of medication and the doctor prescribes a drug, say a tranquilizer. He has read some or much literature; he has heard the testimony of patients; he has been inundated with the claims and samples of detail men representing dozens of drug manufacturers. Thoughtfully, or instinctively, he pulls out his prescription pad and, instead of "chlordiazepoxide," he writes "Librium." In choosing the more familiar trade name, he lightens the burden on his memory, invokes well-advertised distinctions to avoid error, simplifies the task of the pharmacist and allows the patient to ingest a pronounceable medicine. And he makes millions more for the successful manufacturer, whose product has won out over dozens of similar drugs. The chances are that the drug with the easy trade name costs two or three or six times more than the same dose known only by its scientific, or generic, name.

Those who are interested in saving patients money have long argued for the right, if not the duty, of doctors to prescribe by generic name instead of the higher-cost brand name. But until recent years, for reasons of commerce and politics, most states required trade-name prescription. The drug manufacturers had persuaded legislators—and many doctors—that generic versions of a drug were less safe or effective and that in any case they were not identical or "therapeutically interchangeable."

Echoes of these arguments persist, but even if valid in some cases and to some degree, they have been largely discredited as self-serving to the industry. Government regulators maintain the same careful watch over generic drugs as they do over trade-name drugs. Many physicians have learned to substitute the less expensive versions on their patients' behalf, where the law permits. The Government itself now buys generically for its own uses, at great saving to taxpayers. More than 25 states have already repealed laws that require prescription by trade name, but doctors have not had much help from drug manufacturers in learning the generic names they might substitute for the advertised brands.

It was not until this year that any state tried to compile its own list of equivalents. Now the New York State Assembly has done just that and the Food and Drug Administration has been persuaded to validate the list; it covers all but a few of the 1,600 approved drugs on the market. We can only imagine why the F.D.A. refused for years to produce such a guide for the benefit of both doctors and patients. But the heroic efforts of Albany legislators and their staffs have now removed the last excuse for the legal requirement that doctors prescribe only the more expensive trade names.

That is not yet the end of the story, however. For New York State is confronted by two different legislative approaches to reform. The Assembly has passed a bill that would require every physician to write the generic name of a drug on his prescription; he could also specify a brand name if he thought it made a difference, but he would not have to do so. Once again, for reasons of commerce and politics that we can only imagine, this bill has blocked in committee in the Senate behind a more cumbersome alternative. It would permit—but not require—a physician to prescribe either generically or by brand name and then allow him a choice of instructions to the pharmacist: to "dispense as written" or to regard "substitution (as) permissible." The alert patient, if he lobbies his physician and his pharmacist, could obtain a generic drug under either bill; the unwary would have to yield to the convenience of the doctor and druggist if the Senate prevails.

The Assembly version of this long-overdue reform ought to become law. The New York list of equivalents ought to be available to the nation. The consumer, at last, ought to be able to get good drugs at the lowest possible cost.

Date: 1977. current.
Co. invoved: Ciba Geigy, Bolar, Zenith
Drugs involved: Hydrochlorthiazide

Sources: Bob Shulman pres of Bolar, Marvin Seife, US Dept of Justice

CIBA GEIGY (NJ): ANTITRUST VIOLATION

Ciba Geigy claims to hold a valid patent on HYDROCHLORTHIAZIDE.

(Normal patent life is 17 years; Hydrochlorthiazide has been on the market since at least 1959; this patent will not expire till December 1981.) 22 yrs ?

Ciba Geigy's habit has been to license other companies for the manufacturer of Hydrochlorthiazide, but under conditional and restrictive arrangements. The arrangements insure that they continue to control the commerce.

The Justice Department has sued Ciba Geigy several times for antitrust violations and unfair trade practices regarding Hydrochlorthiazide.

One case was settled out of court in 1976, with Ciba Geigy agreeing to discontinue several practices.

Ciba Geigy is on a second round of trying to control the market: this time in an attempt to preserve the market for their big seller Ser-Ap-Es.

Ser-Ap-Es is Hydrochlorthiazide in combination with Hydralazine and Reserpine. It ranked as the 40th largest seller in 1976; it figures high in Ciba Geigy's product line.

Ciba Geigy is in the process of eliminating competition for Ser-Ap-Es. They have pressured each company presently manufacturing the drug to sign an agreement which

a) allows them to mfr Hydrochlorthiazide, but
b) restricts them from mfrg it in combination with Reserpine.

Ciba Geigy has gotten Barr Labs and Zenith Labs (both of NJ) to sign the aggreement.

Bolar Pharmaceuticals (Long Island, NY) is the only remaining company manufacturing a Ser-Ap-Es equivalent. Enclosed is a letter and agreement which Bolar received after one brief, noncommittal conversation with Ciba Geigy officials.

Bob Shulman, president of Bolar, intends to fight it, on basis of unfair restriction of trade and the legal precedent.