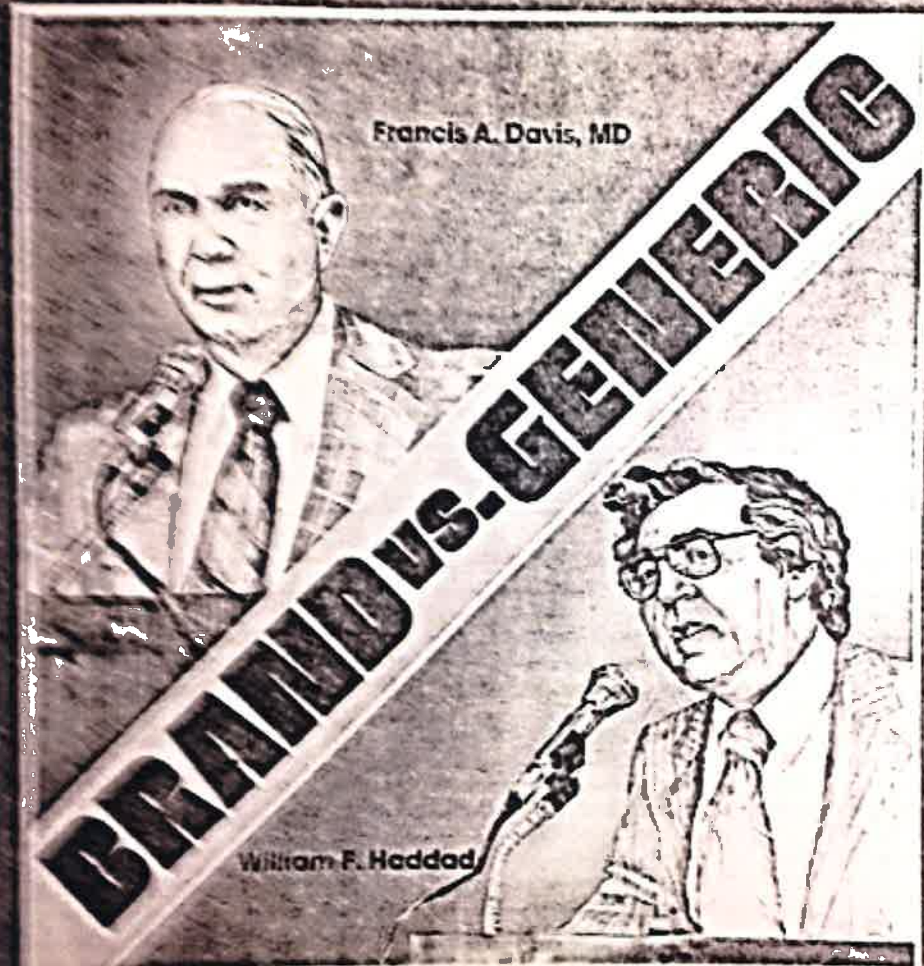
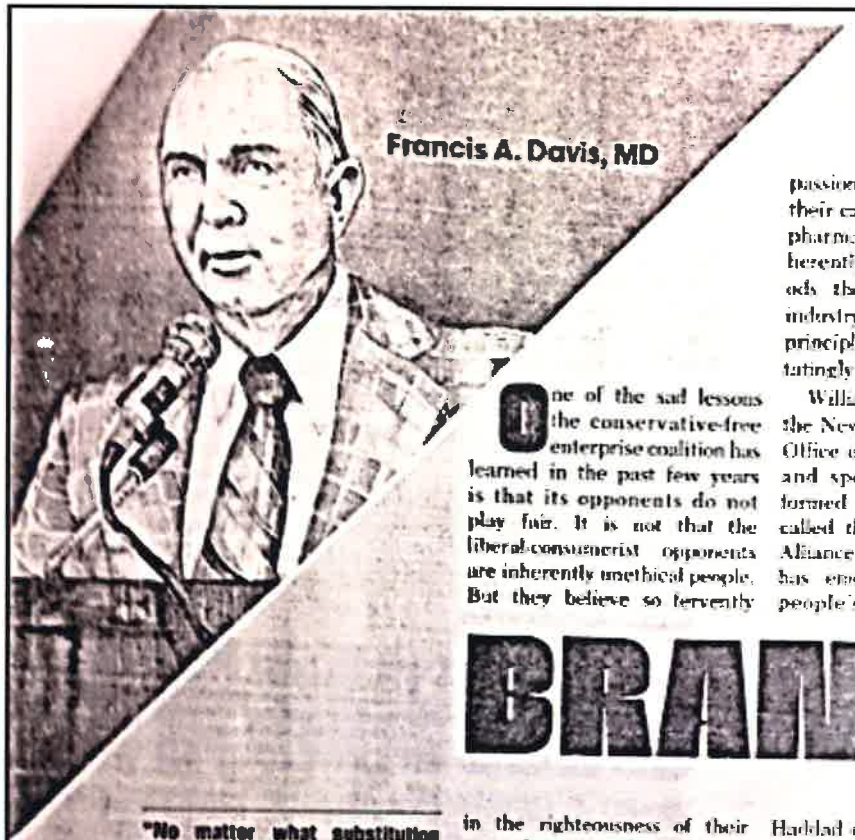
PRIVATE PRACTICE



Wheels of the Past!

of General Practice
Eurodollar Flood
of Health Planning



Francis A. Davis, MD

BRAND VS

One of the sad lessons the conservative-free enterprise coalition has learned in the past few years is that its opponents do not play fair. It is not that the liberal-consumerist opponents are inherently unethical people. But they believe so fervently in the righteousness of their cause that any methods they use to further that cause must be, by very definition, virtuous. And of course this philosophy is not a modern phenomenon. It is an ethical problem which has plagued mankind throughout civilization – the conviction that a benign end bestows virtue on otherwise unvirtuous means employed to achieve that end.

"No matter what substitution laws are passed, we will not abandon our patients and the brandname drugs that we know will help them."

This sort of philosophy permeates the generic drug movement. The consumerists waging the battle to assure that the nation's prescriptions will be filled with generic drugs manufactured by small non-research firms rather than with brand-name drugs manufactured by large innovative firms believe passionately in the rightness of their cause. They *know* that the pharmaceutical industry is inherently wicked. And the methods they employ against the industry are methods which, in principle, they would unhesitatingly deplore.

William Haddad, director of the New York State Assembly's Office of Legislative Oversight, and spokesman for a newly formed lobbying organization called the National Consumer Alliance on Prescription Drugs, has emerged as the generic people's chief spokesman. Haddad can be low-keyed and relatively reasonable when he is in front of an audience that is not totally sympathetic to his cause or when he debates the issues with a knowledgable opponent. This was certainly the case last August when he discussed the generic drug issue with Dr. Francis Davis, practicing physician and publisher of PRIVATE PRACTICE magazine, at the Midwest Pharmaceutical Advertisers Club's Summer Seminar.

But Haddad's tactics, before other kinds of audiences, consist largely of unsubstantiated accusations and raucous name calling. In fact if "hatemongering" were not a term applied exclusively to the American

right wing, then Haddad would surely be a hatemonger.

He continuously repeats, if the audience is right, that the pharmaceutical industry lies and cheats and steals. But when he gets down to specifics, his case is not overwhelming. One of Haddad's examples is that the industry circulates published scientific studies (Haddad without documentation insists the studies are "phoney") favorable to brandname drugs. In some circles such behavior would not be seen as particularly nefarious. Haddad cites it as an example of criminal conduct and generalizes from there. "The 'big lie,' heavily promoted, has been the technique of this industry. Their multi-billion dollar advertising budget, and all that implies, hangs as a heavy hammer over the heads of anyone challenging the industry."

Another example Haddad uses as proof of pharmaceutical industry wickedness, is that it works with state legislatures for its own self interest — that is, it lobbies. He uses the following as positive proof of this kind of legislative "abuse": "They *(the pharmaceutical industry)* are about to surreptitiously push for 'consumer legislation' which will allow Joe Citizen to come into a pharmacy and say 'Don't give me any of those inferior generics, give me (trade name) tetracycline!'" Again, a movement to allow the sick patient to chose the quality of drugs he takes would hardly seem like a wicked one, but Haddad seems capable of convincing his audience that indeed, such activities ought not to be allowed to exist. Nor should any other lobby effort on the part of the pharmaceutical industry.

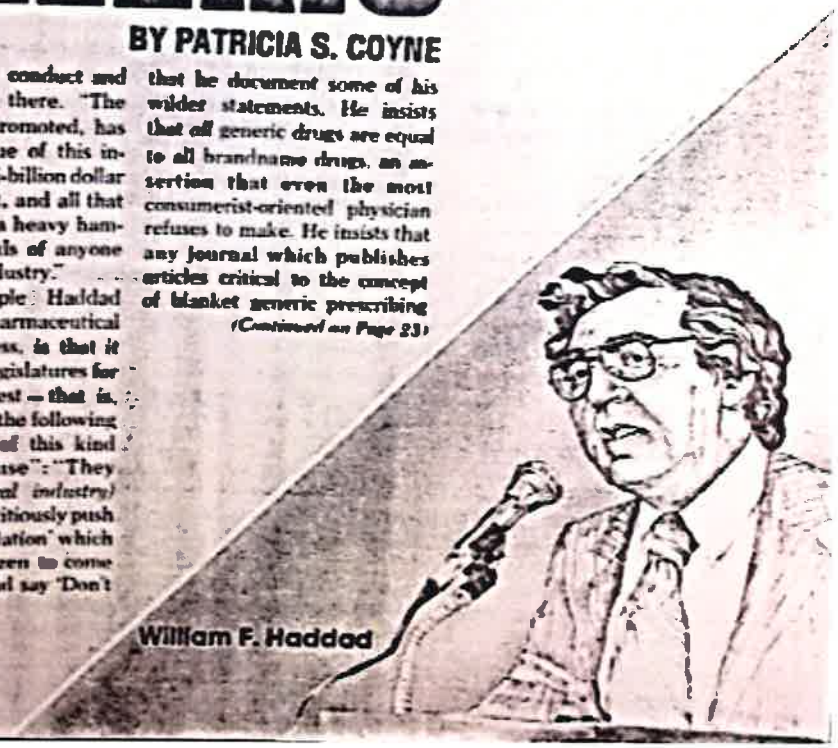
It is difficult to understand why Haddad is allowed to get away with this kind of rhetoric and why the media do not insist that he document some of his wilder statements. He insists that *all* generic drugs are equal to all brandname drugs, an assertion that even the most consumerist-oriented physician refuses to make. He insists that any journal which publishes articles critical to the concept of blanket generic prescribing

(Continued on Page 23)

The federal government has "failed miserably to protect the states and the consumer from the last of the Robber Barons, the prescription drug industry."

GENERIC

BY PATRICIA S. COYNE



William F. Haddad

(Continued from Page 17)

has been bought by the drug industry. If the journal in question does not accept advertising, then the article's *author* has been bought.

Physicians according to Haddad, continue to prescribe brandname drugs, either because they are dolts or because they are bribed. "Detailmen," Haddad charges, "often buy their access to busy doctors by offering unlimited free samples, gifts, trips, conventions, and, in the past, cash." Never does it occur to him that physicians might simply be attempting to do the best they can for their patients. In fact his charges of criminal conduct spill over onto the physician who works within the law to prescribe by brandname. In New York the substitution law says that when physicians sign prescriptions on the right (as they have been in the habit of doing), a generic drug may be substituted. If they switch over to the left, then their patients are treated with the brandname specified. He is outraged that so many physicians insist on signing the left hand side of the prescription, and he charges that such practice is an evasion of the law. "In New York," he threatens, "physicians have already been warned...that unless they shape up and follow the intent of our law, they are in for stricter regulation."

Nor does Haddad tone down his prose style before Congress. "The bottom line," Haddad testified before the monopoly subcommittee of the Senate Small Business Committee, "is that the federal government and the Congress (over the past twenty years) have failed – and failed miserably – to protect the states and the consumer from the last of the Robber Barons, the prescription drug industry. The federal government and the Congress, to use a Southern expression, have had 'round heels.' You were – and to some extent, still are – a pushover for the drug industry..."

None of the Congressmen pointed out to Haddad that the Robber Barons, to which Haddad referred, have increased the price of their product only 25% in the last eleven years while everything else has gone up 86.1%. If the rest of American industry had managed such a feat, despite federal inflation, then some of the nation's economic woes would be less pressing.

Again, why is Haddad allowed to get away with it? In fact, if Haddad's opponents were to use anything like the same rhetorical methods that Haddad himself employs, the harangue would go:

"Is Haddad a demagogue? It seems to matter not to him that patients will suffer and die through his efforts. Haddad would be content only at seeing the pharmaceutical industry grovel at his feet, even if by doing so he must step over the bodies of the victims of shoddy, dangerous drugs. In fact it has been charged that Haddad is power-drunk, a man who will not rest until all American industry has bowed to government control.

"Haddad, in his youth, served as assistant to Senator Kefauver during his investigation of the drug industry. He tells about the time that he stood over the Senator's grave and vowed to break the industry. In fact he seems to have convinced himself that that industry was somehow responsible for Kefauver's death. In that he surely has deluded himself, for, as the rest of Washington is aware, Kefauver drank himself to death, and in so doing he left his bereaved family a portfolio that included a comfortable number of pharmaceutical company stocks.

Why is Haddad allowed to get away with it?

"Is Haddad talking the public? He retains his taxpayer-financed job as New York's director of legislative oversight while at the same time he acts as spokesman for a lobby called the National Consumer Alliance of Prescription Drugs. And although Haddad insists that he does not lobby on the taxpay-

(Continued on Page 24)

BRAND vs. GENERIC

(Continued from Page 23)

er's time, that lobby's letterhead address matches the address of Haddad's state office, and anyone who wishes to do business with Haddad's lobbying organization can do so by calling Haddad at his state office.

"It might be interesting to inquire as to the extent that Haddad's public and personal jobs overlap. It might be interesting as well to inquire into the extent that Haddad is personally compensated for his lobbying efforts."

Of course Haddad's opponents do not use that kind of personal attack upon Haddad, even though the tenor of his own attacks invite it. They continue simply to ask in vain that he document his charges. They continue to battle him on the issues alone. Pharmaceutical Manufacturer Association President Joseph Stetler sent Haddad a list of some of his more blatantly false charges, asking for documentation, and closed by saying, "I look forward to your reactions to these questions, Mr. Haddad. You and I are far apart on many things, but I would like to make a stab, at least, at keeping our arguments on a rational plane. It is probably to my advantage for you to continue making distorted and false and malicious statements, but I'd rather win against people who don't give me that advantage."

And in last August's debate Dr. Davis stuck to the issues well. He cited specific on-record studies, proving that certain generic drugs, although previously approved by the FDA, cannot be trusted. He mentioned the generic chloramphenicols which the FDA finally admitted, in the wake of adverse studies, were not effective. He reminded the audience that the FDA had admitted, again only after a private study had proved the point, that some generic digoxins varied in absorption rate to the extent that they were actually dangerous for the patient. He told the story of how American airmen in Thailand, suffering a penicillin-resistant gonorrhea epidemic, were treated with a governmentally purchased, ineffective, tetracycline and, as a consequence, suffered chronic, intractable, urethritis and hepatitis. He cited as well, his own experiences when his patients had refused to respond to substituted generic drugs and subsequently responded to their brandname counterparts.

"This malpractice business is getting beyond a joke."

Davis scoffed at the idea that physicians are duped by detailmen into prescribing brandname products. "Doctors tend to be strongwilled individualists. Often the same people who say MDs can be brainwashed, call us arrogant and opinionated, unwilling to listen to new ideas. They can't have it both ways. Well-educated professionals cannot be gulled for long. If a drug works consistently and well, we use it. If not, we do not use it. No matter how much salesmanship. No matter how many plastic pens."

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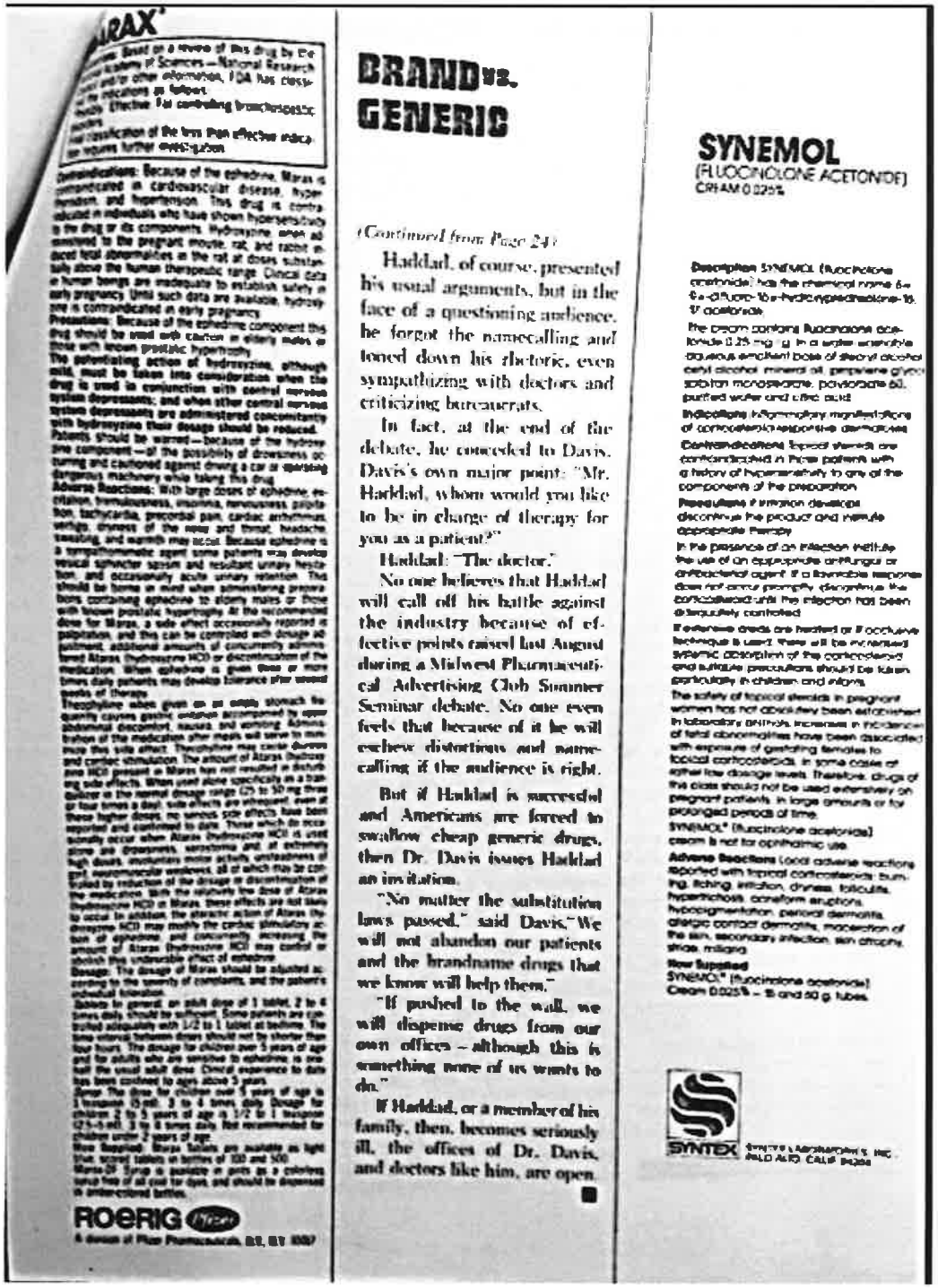

ARAX®

Based on a review of this drug by the Academy of Sciences—National Research and/or other information, FDA has classified the indications as follows:

Effective: For combating bronchospastic disorders

Lack of classification of the less than effective indications requires further investigation.

Contraindications: Because of the ephedrine, Marax is contraindicated in cardiovascular disease, hyperthyroidism, and hypertension. This drug is contraindicated in individuals who have shown hypersensitivity to the drug or its components. Hydroxyzine when administered to the pregnant mouse, rat, and rabbit induced fetal abnormalities in the rat at doses substantially above the human therapeutic range. Clinical data in human beings are inadequate to establish safety in early pregnancy. Until such data are available, hydroxyzine is contraindicated in early pregnancy.

Precautions: Because of the ephedrine component this drug should be used with caution in elderly males or those with known prostatic hypertrophy.

The potentiating action of hydroxyzine, although mild, must be taken into consideration when the drug is used in conjunction with central nervous system depressants; and when other central nervous system depressants are administered concomitantly with hydroxyzine their dosage should be reduced.

Patients should be warned—because of the hydroxyzine component—of the possibility of drowsiness occurring and cautioned against driving a car or operating dangerous machinery while taking this drug.

Adverse Reactions: With large doses of ephedrine, excitation, tremulousness, insomnia, nervousness, palpitation, tachycardia, precordial pain, cardiac arrhythmias, vertigo, dryness of the nose and throat, headache, sweating, and warmth may occur. Because ephedrine is a sympathomimetic agent some patients may develop vesical sphincter spasm and resultant urinary hesitation, and occasionally acute urinary retention. This should be borne in mind when administering preparations containing ephedrine to elderly males or those with known prostatic hypertrophy. At the recommended dose for Marax, a side effect occasionally reported is palpitation, and this can be controlled with dosage adjustment; additional amounts of concurrently administered Ataraxoids (hydroxyzine HCl) or discontinuation of the medication. When ephedrine is given three or more times daily patients may develop tolerance after several weeks of therapy.

Theophylline when given on an empty stomach frequently causes gastric irritation accompanied by upper abdominal discomfort, nausea, and vomiting. Administration of the medication after meals will serve to minimize this side effect. Theophylline may cause diuresis and cardiac stimulation. The amount of Ataraxoids (hydroxyzine HCl) present in Marax has not resulted in disturbing side effects. When used alone specifically as a tranquilizer in the normal dosage range (25 to 50 mg three or four times a day), side effects are infrequent, even at these higher doses; no serious side effects have been reported and confirmed to date. Those which do occasionally occur when Ataraxoids (hydroxyzine HCl) is used alone are drowsiness, sometimes oral, at extremely high doses, involuntary motor activity, unsteadiness of gait, neuromuscular incoordination, all of which may be controlled by reduction of the dosage or discontinuation of the medication. With the relatively low dose of Ataraxoids (hydroxyzine HCl) in Marax, these effects are not likely to occur. In addition, the ataractic action of Ataraxoids (hydroxyzine HCl) may modify the cardiac stimulatory action of ephedrine and concomitantly increasing the amount of Ataraxoids (hydroxyzine HCl) may control or abolish this undesirable effect of ephedrine.

Dosage: The dosage of Marax should be adjusted according to the severity of complaints, and the patient's individual toleration.

Tablets: In general, an adult dose of 1 tablet, 2 to 4 times daily, should be sufficient. Some patients are controlled adequately with 1/2 to 1 tablet at bedtime. The time-interval between doses should not be shorter than four hours. The dosage for children over 5 years of age and for adults who are sensitive to ephedrine is one-half the usual adult dose. Clinical experience to date has been confined to ages above 5 years.

Syrup: The dose for children over 5 years of age is 1 teaspoon (5 cc), 3 to 4 times daily. Dosage for children 2 to 5 years of age is 1/2 to 1 teaspoon (2.5–5 cc), 3 to 4 times daily. Not recommended for children under 2 years of age.

How Supplied: Marax Tablets are available as light blue, scored tablets in bottles of 100 and 500.

Marax DF Syrup is available in pints as a colorless syrup free of all coal tar dyes, and should be dispensed in amber-colored bottles.

ROERIG Pfizer

A division of Pfizer Pharmaceuticals, NY, NY 10017

BRAND vs. GENERIC

(Continued from Page 24)

Haddad, of course, presented his usual arguments, but in the face of a questioning audience, he forgot the namecalling and toned down his rhetoric, even sympathizing with doctors and criticizing bureaucrats.

In fact, at the end of the debate, he conceded to Davis. Davis's own major point: "Mr. Haddad, whom would you like to be in charge of therapy for you as a patient?"

Haddad: "The doctor."

No one believes that Haddad will call off his battle against the industry because of effective points raised last August during a Midwest Pharmaceutical Advertising Club Summer Seminar debate. No one even feels that because of it he will eschew distortions and namecalling if the audience is right.

But if Haddad is successful and Americans are forced to swallow cheap generic drugs, then Dr. Davis issues Haddad an invitation.

"No matter the substitution laws passed," said Davis, "We will not abandon our patients and the brandname drugs that we know will help them."

"If pushed to the wall, we will dispense drugs from our own offices – although this is something none of us wants to do."

If Haddad, or a member of his family, then, becomes seriously ill, the offices of Dr. Davis, and doctors like him, are open. ■

SYNEMOL
(FLUOCINOLONE ACETONIDE)
CREAM 0.025%

Description SYNEMOL (fluocinolone acetonide) has the chemical name 6α-9-difluoro-16α-hydroxyprednisolone-16, 17-acetonide.

The cream contains fluocinolone acetonide 0.25 mg/g in a water washable, aqueous emollient base of stearyl alcohol, cetyl alcohol, mineral oil, propylene glycol, sorbitan monostearate, polysorbate 60, purified water and citric acid.

Indications Inflammatory manifestations of corticosteroid-responsive dermatoses.

Contraindications Topical steroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

Precautions If irritation develops, discontinue the product and institute appropriate therapy.

In the presence of an infection institute the use of an appropriate antifungus or antibacterial agent. If a favorable response does not occur promptly, discontinue the corticosteroid until the infection has been adequately controlled.

If extensive areas are treated or if occlusive technique is used, there will be increased systemic absorption of the corticosteroid and suitable precautions should be taken, particularly in children and infants.

The safety of topical steroids in pregnant women has not absolutely been established. In laboratory animals, increases in incidences of fetal abnormalities have been associated with exposure of gestating females to topical corticosteroids, in some cases of either low dosage levels. Therefore, drugs of this class should not be used extensively on pregnant patients, in large amounts or for prolonged periods of time.

SYNEMOL® (fluocinolone acetonide) cream is not for ophthalmic use.

Adverse Reactions Local adverse reactions reported with topical corticosteroids: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, miliaria.

How Supplied
SYNEMOL® (fluocinolone acetonide)
Cream 0.025% – 15 and 60 g. tubes.

SYNTEX

SYNTEX LABORATORIES, INC.
PALO ALTO, CALIF. 94304

...itorial

by Llewellyn H. Rockwell, Jr.

The Generic Scam

Were it not for the vested interests of politicians and generic groupies, drug substitution would be in intellectual receivership. Study after scientific study, as well as extensive clinical experience, have shown that the whole notion is pharmaceutical nonsense.

Yet in early 1978, FDA Commissioner Donald Kennedy told a morning TV audience: "As far as our records are concerned, large and small firms, brand-name firms and generic firms, have indistinguishable records of performance." Although he was only echoing similar statements by his four predecessors, this and related Congressional testimony has for the first time been subjected to a thorough examination.

Using the FDA's own published figures, Eli Lilly and Company did an extensive computer analysis, under the direction of Mrs. Lynne Pauls. The study, "FDA Enforcement Activities Within the Pharmaceutical Industry: Analysis of Relative Incidence," shows the following, for 1974-1977:

1. FDA took court action against non-research drug companies 43 times as often as against research-intensive firms.
2. Non-research companies had almost seven times as many drug recalls as research firms.
3. The small, non-research firms had over one and a half times as many drug product problem reports as the large companies.

Since these are ranked according to severity, the companies that supply most of the cheap drugs used for substitution are shown to have more frequent *and* more serious problems, by the FDA's own reckoning.

Critics, including Mr. William Haddad (see page 16), immediately responded that the study was useless, because the research-intensive companies would have much larger recalls, since their output is so much greater than the cheapie houses.

Mrs. Pauls reran all the data for the past year through the computer, asking for the number of dosage units recalled by FDA.

In 1977, with about 25% of the total output, the non-research companies accounted for 15 million dosage-unit recalls; the research firms for one million.

Commissioner Kennedy then complained that one major company with a bad recall record was left out of the study. He was asked to name the company, which was unknown to Lilly researchers. He has not done so.

Last month, a DPT vaccine being administered to West Virginia school children turned out to be defective. It caused unusual swelling and inflammation, pain, fever, and several days of sickness. Manufactured in Italy, the vaccine was purchased from a small non-research generic company on a low bid.

Cheap drugs and biologicals may seem to save money, but they can exact a high cost, as West Virginia school children know.