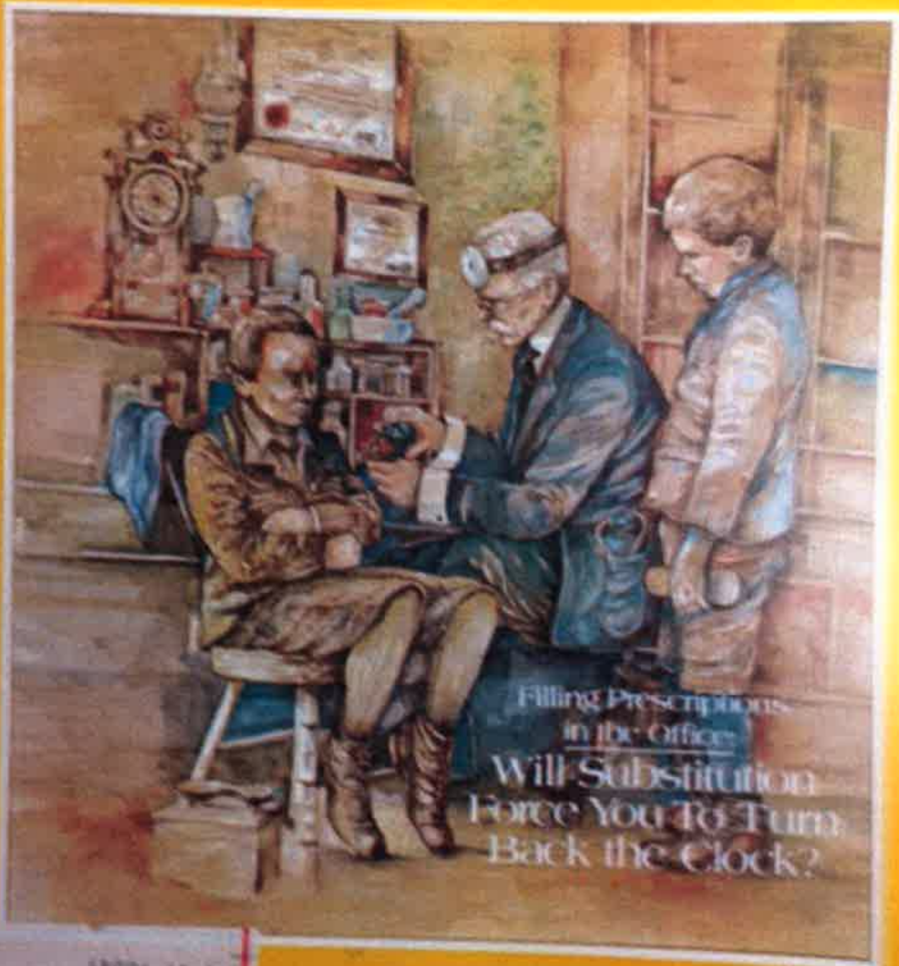
PRIVATE PRACTICE

September 1978



Publisher's Report

Will You Be Forced To Turn Back the Clock?

I wonder if doctors realize what happens to many of the prescriptions they write for their patients. In 33 states, laws have been passed permitting substitution, and now the House Subcommittee on Consumer Protection and Finance is considering a bill to permit national generic substitution. Called the Murphy bill (HR1963), it would authorize a pharmacist to override a doctor's prescription for a trademarked drug product, unless the physician specifically designated otherwise on the prescription. This legislation would require the pharmacist to dispense the least expensive drug.

In most states the law says that if the doctor doesn't write on each prescription blank "DAW" (Dispense As Written), the pharmacist may substitute a like drug for the one prescribed by the doctor. The laws are similar in that they do not specify that the substituted drug must have the same therapeutic effect as the one requested by the doctor. The outcome of these laws is that the doctor is no longer in charge of the therapy of his patients. Patients are simply being cheated. They are not getting the benefit of the expert opinion of their physician, for which they have paid. These patients not only get a second-class drug, but they get second-class medical care because of bad legislation.

Most doctors believe that the drugs they prescribed are being dispensed to their patients. A recent check, however, reveals that this is not true in many instances. Throughout the nation there is massive substituting of drugs going on, whether the law permits it or not. The time is gone when doctors can just write a prescription and know the patient is getting what was prescribed. It is essential, if patients are to get good medical care, that physicians continually check to see what is being done to their prescriptions. One of the ways many physicians cut down on the proliferation of substitution is by asking patients to bring their bottles of medicine to each appointment. Substitution has stopped on these patients. A casual description to the patient of what he should receive also helps in stopping substitution [illegible] scriptions.

This is an [illegible] but there is no [illegible] assure that patients [illegible] medicine, unless physi[illegible] prescriptions in their [illegible]. This is legal in the [illegible] states, but most of us [illegible] such a procedure, although [illegible] may have to be done.

Most doctors want their patients to get the medicine they prescribe. To make sure this is done, doctors are going to have to stay alert and watch what is happening to the prescriptions they write. ■

Francis A. Davis, MD.

FEAR AND LOATHING AND GENERIC DRUGS

by Patricia S. Coyne

The first National Conference on Generic Drugs was not the sort of summer event in Washington that draws crowds in off the street. The purpose of the conference, held at the Mayflower hotel, was to provide aid and comfort to those who toil to promote drug substitution. In attendance were a smattering of state legislators, a rather large crowd of generic manufacturing representatives, a warily inquisitive delegation from the brand-name companies, members of the consumerist oriented press corps, and, of course, the consumerists themselves.

The consumerists set the tone for the meeting, and that tone was one of relentless fear and loathing. Perhaps a somewhat similar atmosphere prevails in the meeting halls of the Ku Klux Klan or the Weatherpeople. But even groups such as these would be hard put to outdo the consumerists in terms of sheer suspicion and hostility.

The wrath of the consumerists, as we all know by now, is directed at big American business in general. And among the members of the genericist wing of the consumerist movement, the particular cause of fear and loathing is the large research-oriented pharmaceutical company, which has the temerity not only to manufacture a quality product but also to make a profit.

"The pharmaceutical industry," a consumerist speaker explained thoughtfully to the audience, "is really about the sleaziest industry you can come across. They don't hesitate to lie, to cheat, to deceive.... To give you an idea of the kind of people you're dealing with, when they go overseas, they never tell the truth.... They withhold information.... They promote drugs for indications they could never get away with here.... It might be possible, however remote, that *something* they say is true but I doubt it.... A truth squad on the part of the PMA [Pharmaceutical Manufacturers Association] is contradictory. You say you have an ethical drug industry. I can't imagine an industry that's less ethical."

The proximate cause of this high consumerist dudgeon boils down to the fact that the large research pharmaceutical houses manufacture a drug and assign to it a brand name. A physician, in the same way that a man chooses a Buick LeSabre rather than simply a car, then chooses one of these brand name drug products for his patient. And that's what drives the genericists wild. They are intent upon removing this choice from the physician and forcing drugs selected, not on the basis of the reputation of the company which manufactures them, but on the basis of price alone. If a small company can manufacture a drug product more cheaply than a large company, then the genericists intend to see that America is dosed with it.

The major problem here – aside, of course, from the very chancy quality of the cheaper drug, a problem that the generic people chose quite blithely to ignore – is that by working to promote the use of generic drugs they are also working to stymie drug research. Their ultimate objective is to mandate the exclusive use of drugs produced by companies which do not engage in research for new products. It is the price

THE PROBLEM

"The Three Fears"
The Greatest of These Will Be Banished by Universal Health Insurance

by Llewellyn H. Rockwell, Jr.

A Near Thing

While Senator Kennedy and Secretary Califano argue about the timetable for nationalizing medicine, it's useful to remember an earlier battle.

Shortly before World War I, after compulsory health insurance had been enacted in much of Western Europe, it seemed unstoppable in the United States. High officials of the AMA praised it. *JAMA* editorialists called it "pregnant with benefit to the public." Even those who doubted the legitimacy of the pregnancy seemed to agree with the *Medical Record* of New York: "Whether one likes it or not, social health insurance is bound to come. . . ."

In an America as yet unaffected by New Deal centralization, proponents focused on state governments. The influential American Association for Labor Legislation (AALL) drew up a model bill, and the New York state legislature seemed ready to pass it, to be followed quickly by Massachusetts, Illinois, and other states where Progressivism was powerful.

Under compulsory health insurance, as proposed by the AALL and seconded by most of the AMA leadership, the state government would pay 20% of the cost, employees from 20% to zero, depending on their earnings, and employers from 40% to 80%. All medical, surgical, nursing, and hospital costs would be covered, and all necessary drugs and medical supplies. Disabled workers would get cash payments, and private insurance companies were barred from participating in any part of the plan.

Physician compensation was not covered in the initial draft of the law, but most everyone—medical leaders included—thought capitation and closed panels fair methods.

A few years later, compulsory health insurance, which had seemed certain to sweep the

Continued on page 40 ▶

"The Three Fears"
The Greatest of These Will Be Banished by Universal Health Insurance

of the brand-name product which finances the research done by the brand-name houses, however, and without this price there would be no new drugs.

The world still suffers from a host of minor diseases and a considerable number of major diseases which are unlikely to be eradicated without significant pharmaceutical research financed by the sale of brand-name drugs. And since the stated aim of the consumerist-genericist is to improve the health and well-being of his fellow citizens, logic suggests that the drug research problem should play at least some small role in his considerations. But if it did at the genericist gathering at the Mayflower, it was a very silent role indeed.

Instead, the speakers at the conference devoted their time and efforts to whipping up emotions. And with good reason, for the consumerists face a very basic problem. They have found, much to their distress, that no one – neither the physician nor the pharmacist nor the consumer – is particularly interested in changing the nation's medication habits. The physician sticks stubbornly to the products he has used an[d] trusted, the pharmacist con[tinues] to dispense them, and th[e] consumer, who could in 197[?] have saved himself an averag[e] of $1.90 a year, if only he ha[d] insisted upon using a generi[c] product, continues to remain un[-]enthusiastic at the prospect of [a] generic future.

The problem, therefore, i[s] how to explain away this na[tional] indifference. It can't be because of defects in the genericist vision, for obvious reasons, nor can it be the result of shortcomings in the consumerist philosophy. The fault, therefore, must lie with the major companies themselves, and it was to this theme that the genericists addressed themselves.

The companies, we were told by Stanley Steingut, a long-time New York State politico whose reputation is considerably less than savory, issue insidious lies, "massaging doctors' fears." To illustrate his point, he held up a copy of PRIVATE PRACTICE, which he labelled industry propaganda. There was, to be sure, a considerable amount of

Continued on page 23 ▶

The world still suffers from a host of minor diseases and a considerable number of major diseases which are unlikely to be eradicated without significant pharmaceutical research financed by the sale of brandname drugs.

pleasure to be derived from being singled out as Public Enemy Number One at such a gathering. But the connection was somewhat less than clear. PRIVATE PRACTICE is neither owned by nor accepts its marching orders from the drug industry. True, we accept drug company ads, but the *New York Times* runs lingerie ads, and I have yet to hear it referred to as an organ controlled by underwear interests. In fact, Steingut's demagoguery was just a bit irritating, for those who write for *PP* can write rings around a regiment of drug-industry flacks.

But no matter. The audience lapped it up, and seemed quite thrilled at the suggestion that the industry does undercover work as well to thwart the mandatory prescribing of generics.

"I don't want to scare you," Steingut told the state legislators in the audience, "but they can get guys out of office....they can be everywhere." Just why it was so unethical of the pharmaceutical industry to work to combat legislation calculated to insure its own demise was never adequately explained. But the assumption hovered in the air and the audience accepted it without question.

Senators Gaylord Nelson and Edward Kennedy were the two main speakers on the first morning of the conference, and they lent a certain amount of authority to what would otherwise have been a rather ragtail affair. Nelson, in his querulous fashion, detailed a long list of drug industry perfidies. His assumption, apparently, was that any kind of drug promotion is an act of deception and distortion, per se, and that any attempt on the part of the major pharmaceuticals to combat the generic movement and assure their own survival was by definition inherently evil.

Kennedy, however, set out to do more than merely raise the indignation level of a highly select audience. He has been working for years on various pieces of health care legislation; yet he has produced almost nothing to show for it, and he is getting impatient. Thus, he was there at the conference to push his Drug Regulation Reform Act, still at this writing undergoing mark-up. His speech was delivered with the kind of passion statesmen usually reserve for the subjects of war and dire economic peril, and those in the front few rows found themselves leaning back under the barrage. This is Kennedy's way of convincing an audience that he is a man of deep sympathy and concern, and this audience positively glowed.

But the content of Kennedy's pitch was highly selective. It stressed, with a hang-my-heart-on-a-cross-of-gold sort of fervor, the minor, consumerist points of the bill - elimination of detail men, control of drug promotion, a drug usage reporting system, postmarketing surveillance. To other audiences, and in fact in the written introduction to his bill, Kennedy insists that the Drug Regulation Reform Act is written to combat the drug lag — to get new drugs to sick kids. He was strangely silent on that inherently emotional issue however and confined himself to waxing passionate on detailmen who bribe doctors with trips to the Caribbean.

When Kennedy, the high point of the conference, swept out, he took with him television cameras and a good portion of the press. The audience, still radiant from the Kennedy mystique, split into panels which could only have been letdowns. The panel on the safety and effectiveness of generics became bogged down in the kind of scientific haggling which served, if nothing else, to demonstrate to laymen in the audience that there was a wealth of information concerning the production and

Continued on page 26 ▶

Continued from page 23

manufacture of pharmaceuticals of which they were ignorant.

Perhaps the most interesting panel was the one on Kennedy's Drug Regulation Reform Act, which pitted the consumerists against an FDA spokesman who, within that context, came off as a dyed-in-the-wool conservative. The underlying assumption by the majority of these panelists, the most prominent of whom was Dr. Sidney Wolfe, director of Nader's Health Research Group, was that no new drug is a good drug, nor for that matter is any old drug. The consumerists felt that the bill made too many concessions to the industry, although the FDA attempted to assure the consumerists that it would assume more control than before. Afterward one of the consumerists remarked that what she did not like about the bill was that it was *political* – as though she expected a piece of legislation to be something else – intellectual? religious?

The next day's session concerned itself with the nuts and bolts of legislatively mandating that pharmacists fill presciptions with the generic equivalent of the brand name the physician prescribes. And it was in these sessions that the dismal facts were dragged out. Although over forty states have passed some kind of substitution laws, "fully two-thirds of the laws enacted by the states have yet to produce significant consumer savings." Substitution laws are not working, in other words. A few concrete suggestions were offered in drawing up alternative legislation that would change all that. Legislation which allows the physician to sign on one side of the prescription for the brand name drug, and on the other side for a generic substitution, is bad. Even legislation which requires that the physician write in "no substitution" is bad because the word "substitution" has "psychological overtones." Doctors should be required to write "medically necessary" in order to prescribe brand-name drugs.

Legislation which mandates that all substitution savings be passed on to the consumer is also bad. It doesn't sufficiently motivate the pharmacists, and consumers who press the consumer-saving issue are playing into the hands of the pharmaceutical industry. Also, pharmacists ought to stop being so worried about opening themselves to malpractice suits if substituted drugs harm patients. "Just don't worry about it," they were enjoined. And something, no one knew quite what, had to be done about the lack of consumer interest. Giant Pharmacies had initiated a costly generic campaign – but they were quietly dropping it because of consumer response. Drug Fair and Peoples' had studied the generic issue and agreed to ignore it. Some way had to be found to "educate" the public and "educate" the physician.

One of the most bizarre suggestions for physician "education" was to send Jehovah's Wit-

new-style teams of students around to doctors' offices to counter industry propaganda. (If the pharmaceutical industry is truly interested in rallying doctors to its cause, it might take note of this idea. There is nothing better calculated to turn the average American physician against generics than to have a bunch of kids lecturing him on his prescribing habits.)

But government representatives at the conference assured the concerned audience that help was on the way. The FDA plans to expand and publish its list of medically interchangeable drugs. (A question asking why, if all generics are equivalent to brand-name drugs, such a list was necessary, was met with hostile silence and a quick rhetorical cover-up.) HEW has decided to publish a "Guide to Drug Prices" comparing generic and brand-name cost and plans to mail the list to every physician and pharmacist in the country. The FDA and the Federal Trade Commission (FTC) promised to get together to draw up model substitution laws for the various state legislators to use. The FTC will help the states by "monitoring vigilantly any attempts by pharmaceutical manufacturers and their allies to undermine substitution efforts."

Thus, the conference ended on a note of optimism. The federal government was stepping in to aid them in the cause. And with the power of government working for them, the mandatory generic substitution cause could not fail. Nor was their optimism unfounded. One industry representative that I talked to at the conference admitted that the report he would send back to his company would be unequivocal: Go generic. In other words, phase out research, phase out quality control, and make sure ours is the cheapest drug to hit the market.

The economic imperatives for this are obvious, and come from the office of the coordinator of the conference, William Haddad, director of the New York State Assembly's Office of Legislative Oversight and Analysis. His own investigation revealed that "eighty percent of the drugs sold by the brand-name manufacturers were multi-source products and could be manufactured by any company, and a minimum of 52% of their profits came from the multisource line. Add to that the facts that 70% of all major drugs will be off patent shortly, the states are changing their laws, the federal government is beginning to move, and both European and Canadian companies are buying into the generic market, and you have the outline of a major challenge to an inflexible industry which, for historic reasons, won't compete."

Haddad's conclusions are, of course, ridiculous. The 80-odd research oriented drug houses have competed so effectively that in the past ten years the price of prescription medicine has gone up 27.8% as compared to 86.1% on all other items. But they have competed by researching, developing, and then establishing on the market the results of their research and development. This is the foundation upon which innovative

Continued on page 45 ▶

Mrs. Schwartz wants to arm wrestle you for a prescription refill . . .

FEAR AND LOATHING AND GENERIC DRUGS

Continued from page 27

American industry, from Kleenex to Xerox, has been established. And it has produced remarkable results, nowhere more so than in the field of pharmaceuticals.

But if Haddad's figures are correct, if the generic movement does indeed threaten the profits and subsequent ability of the pharmaceutical industry to conduct meaningful research, then the movement is a dangerous one indeed. There are still diseases which threaten the health and lives of the world's population, and physicians cling stubbornly to brand-name drugs, not only because they trust those drugs' effectiveness, but also because by so doing, they encourage and support the eradication of disease. Rather than being dupes of the pharmaceutical industry, as the generic enthusiasts charge, they are simply, in an indirect way, fulfilling their Hippocractic Oath.

"The PMA," it was repeated with dreary frequency at the conference, "is in bed with the AMA," thereby conjuring up the picture of a nefarious and slightly kinky relationship between the American drug manufacturers and the American physician. In fact the two are joined in a legitimate marriage, the purpose of which is to rid the world of disease. The only rati[onal] response is to trust the m[arriage] and hope that it is fruitful.

But the consumerists' conc[ern] for the health of their fell[ow] man seems not to center in [is]sues like sickness and the er[adi]cation of crippling disease. [No]where in my hearing was th[e] subject even mentioned. T[he] ruling passion of the consum[er]ists at the First National Co[n]ference on Generic Drugs w[as] the fear or loathing of the pha[r]maceutical industry. Someho[w] if that industry could be broug[ht] to its knees, then the worl[d's] medical care problems wou[ld] take care of themselves. An[d] that's the way it is, in th[e] never-never land of generic consumerism.