Generic Drugs— Tomorrow's Market

By WILLIAM F. HADDAD

Mr. Haddad is the Director of the Office of Legislative Oversight and Analysis in the New York State Assembly.

I WOULD LIKE TO SHARE with you succinctly, precisely and candidly my views of the state of the art of the ethical drug industry. From a business point of view, I don't like what I see. The classic inflexibility of some of the major companies is creating a domestic vacuum which must attract foreign investment. Competition will be restored to the industry either by the decision of the major companies to abandon the techniques of the past which have kept drug prices unreasonably and unconscionably high, or by the intervention of skillful entrepreneurs who will scoop up a market made ripe by state and federal legislation.

As you may know, I've spent a great deal of my professional life dealing with controversial subjects, from political corruption and organized crime in New York, to anti-trust and poverty in Washington. But, in all that time, the prescription drug industry has remained unique. It is the only industry I know that believes its own deceptions.

Just this month, an in-house attorney for a major pharmaceutical house, in a private conference called to negotiate the necessity of their appearance under subpoena at a public hearing, told me his company had not had a recall for over twenty years, in sharp contrast to the smaller generic houses which, he said, have repeated recalls. The professionals know there is little difference, today, between generic and trade company recalls or adjustments, so I found his statement hard to believe, but he insisted. I checked. His company had over twenty-five recalls and many minor confrontations with the Food and Drug Administration (FDA) since 1970 alone. Yet he so believed the industry's propaganda that he raised the issue in a professional conference.

At a pharmacy convention last month, called in part to examine New York's tough new law mandating substitution, I ran into a solid wall of opposition when I tried to explain that the pharmacists self-interest, due to changing state laws, no longer lies with the manufacturer.

However, the audience was not, as I had expected, composed of pharmacists, but of detailmen and company marketing personnel who greatly outnumbered the pharmacists present.

Protecting the Consumer's Rights

Today, without even batting an eyelash, the drug industry, which mounted and sustained a political campaign in all fifty states to prohibit the pharmacist from exercising his professional judgment on substitution, and to keep the consumer out of the selection process, now, having lost that victory, is telling state legislators they must protect the consumer's right to select his product. We both know that industry has secretly decided to fight a rear guard action against generics, buying time to convert to "branded generics". But to insure the success of this rear guard action, they need to create new state laws, following the successful route of the fifties when they used state legislatures to prevent substitution and advertising. Their new law would allow a consumer to specify a brand name in states where substitution is permitted or mandated. The consumer could walk up to the pharmacist and say "give me Parke Davis tetracycline, not that cheap, unsafe, low priced generic." Documents I have seen indicate that the industry has contingency plans to shift a substantial portion of its $1.3 billion promotion budget into mass media. What they did to the doctor, they now plan to do to the consumer. Now that state and federal legislatures have caught up with the physician and are using reimbursement practices to compel generic substitution, the drug industry in the very near future will begin to market to the mass audience, an audience, ironically which the industry desperately tried to keep out of the process for twenty years. But, industry faces one major hurdle. State legislatures, which, in past years, rolled over and played dead for the drug industry lobbyists who could call on the corner pharmacist and the local American Medical Association doctor for help, are no longer as vulnerable as they once were. Many legislators had learned to fear the skill and the power of the Pharmaceutical Manufacturers Association but I doubt they will find the going easy this time around although, I must confess to you, the ploy that the

consumer must have the right of final selection is one fine public relations argument.

Basis of Industry Profits

Underneath all of these plans, of course, is the quicksand on which drug industry profits are based: the mass deception that generics are not as safe or as effective as trade name products. When that argument goes, the house-of-cards will topple into the quicksand. Two major companies from whom we took public session testimony last year told us that seventy to eighty percent of their brand name products were available generically.

Publication of the New York formulary, and its subsequent verification by the FDA, was the first nail in the coffin. Now industry's attack must be escalated from the relatively defenseless generic company, to the scientifically powerful FDA.

Shortly, either the Congress or the FDA itself may initiate a similar list. The drugs on that list will either be called "interchangeable" or, at the very worst, they will be labeled "medically interchangeable," with the only differences between products limited to shape, color and taste. Publication of that list will be followed by state legislation designed to mandate the reduction of prices for consumers. When the federal government bites the political bullet and finally issues its list, it will be extremely difficult for the Maximum Allowable Cost (MAC) program to continue to drag its feet. The government will have issued its list of bioequivalent drugs, and MAC is mandated to set price ceilings.

Next, either the feds or the New York Assembly will add one additional column to the list: a price comparison. There, in one simple document will be the full story: interchangeable drugs, approved manufacturers and comparative prices. It will be exceedingly difficult for any politician to fight the inevitability of that list when the comparison will reveal a range of one dollar for the lowest priced safe effective interchangeable drug to $10 for the most widely used brand name product.

In the past, the drug industry developed successful techniques for staving off the inevitable. As Senator Kefauver once said, "the person who orders doesn't buy, and the person who buys doesn't order." Within that unique framework the obvious target was the physician who, after the second year in medical school, learned about prescription drugs from detailmen or from ads in scientific journals. The detailmen were and are salesmen and the scientific journals often were not much better.

"Prescribe Generically" Policy

How many of you remember how the AMA came to change its "prescribe generically" policy? In those days, back in the fifties, the AMA's distinguished Council on Drugs approved all advertisements for the AMA Journal and would only allow the innovator to use a brand name. It came down hard on useless drug combinations. And, like the AMA itself, advocated generic prescribing.

The AMA hired a Chicago consulting firm to tell them how to increase the revenues of the Journal. The answer was obvious: get rid of the Council and change your generic policy. AMA did both and the Journal flourished, furnishing, at one point, as much as two-thirds of the AMA's entire budget.

The Journal hasn't changed much in all those years. In the current issue, there is an article which reports that even batch testing of tetracycline doesn't insure interchangeability and an editorial condemning generic prescribing. In the past, the Journal has been able to reach doctors with this information without fear of rebuttal. It remains to be seen if the change of air in Washington includes the willingness to challenge this thinly disguised industry propaganda.

Deceptive Marketing

There are some hard facts which the industry must face in the months directly ahead. You and I know that the drugs on the New York list are safely interchangeable and that the difference in their use comes from a style of marketing which I classify as deceptive and which is increasingly coming under governmental restraints.

You and I also know that many branded generics are made for the large companies by generic houses who sell the same products for a third to a fourth of the trade name price. How long do you think such a deception can be maintained? The large companies cannot easily claim these products are not manufactured safely; they cannot say their branded generics are more effective. They can only hide the fact that their high priced product is made for them by the smaller generic company. In short, the "cover-up" will create more publicity than the act, a la Watergate.

Today some twelve percent of the market is generic. The other eighty-eight per cent of the potential generic market is being sold trade name products. To that equation, factor in this information: three-fourths of the states have repealed substitution laws, the Su-

preme Court has ended the ban on advertising, and increasingly, government reimbursement plans are pegged to generic prices. Add this information: the FDA—at long last—is taking a strong stand on the medical interchangeability of products and cutting through the haze of bioavailability and bioequivalency. With that cold blooded business equation, how long do you think it will be before foreign investors seek out this attractive market? Eighteen months ago I warned that we were creating a vacuum for foreign take-over, much as the Japanese and the Germans took over the small car business when General Motors failed to heed the warning of some of its executives that it was worth the risk to cut profits from eight percent return on investment to six percent return to keep the competition out. These executives argued, as I argue now, that if you let this attractive market go, foreign-owned generic conglomerates will begin to challenge all your drug products, prescription and over-the-counter. Serious business, but I don't see too many drug companies treating it as serious business. Two take-overs are already in the offing, one new owner with tremendous capital to invest.

Foreign Competition

If I were an overseas investor, you know what I would do? I would find one or two American houses, buy them out, increase production from foreign source material—thus further cutting costs—and establish a Foremost-McKesson distribution system, provide liability coverage, deliver in the middle-of-the-night using the new air-freight distribution systems, create an eight hundred line for orders, provide good credit, run contests and, in general, do what a good old fashioned American entrepreneur would have done before the drug industry became addicted to monopolistic marketing practices.

Will anyone heed this warning? I doubt it. The rear guard action of branded generics is a short term policy that will face stiff opposition from government, leaving the field wide open to foreign competition.

The salvation of the drug industry is to go back to basics. Spend some of the promotion budget on finding new drugs and providing methods for better systems to deliver drugs into the body.

The salvation of this industry is to face up to the political realities of the nineteen seventies—these are not the fifties where opposition politicians could be run out of town.

The salvation of this industry is to become competitive and the first companies to break the line and enter the true generic market,

will profit from that experience and will restore Wall Street investor confidence.

This is a new ball game, the industry no longer owns the ball-park or even the concessions. If the ethical drug industry is to survive the coming crisis in investor confidence it must open its ears to its critics and, as my father used to say to me, learn from your enemies.

[The End]