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Governmental Regulation of the Drug Industry

J. Mark Hiebert*

IN TODAY'S WORLD of increased government participation in business, certain industries are frequently spotlighted for particular attention. The communications industry is one, the drug industry is another. In both cases the special attention is fitting, for the communications industry, like the drug industry, each in its own way, reaches the very fiber of American life. Each has the inherent capability of changing our political and social order.

The drug industry has played a key role in prolonging the life expectancy of man, and in lowering the death rate at birth. It has thus helped to create large and growing populations of those over sixty-five and of those under twenty-five. Just consider for a moment the impact of these groups on our politics, on our internal affairs, and on our foreign problems. Only eleven years from now—in 1980—there will be 35 million new voters. In many ways, this group will determine the future of our country.

Look at the famous “pill.” On the one hand we in the drug industry have been praised for liberating women, and for providing a possible solution to the nightmare problems of overpopulation. But, simultaneously we are accused of lowering the moral standards of our society. Of course, blaming the pill for immorality is like saying that central heating is responsible for nudity in the theatre.

At any rate two points are basic: first, the drug industry directly affects the foundations of our society and therefore is a reasonable concern of government. Secondly, the drug industry has a legitimate and productive function and those who administer it should not abdicate their responsibility to regulatory agencies.

To expand on the second point: the major purpose of the medical profession is the creation of new products for the improvement of health, the development of which must be communicated to the public at large. There is no such thing as a “market” for a product, until someone creates that market. The needs that we in the drug industry satisfy, whether it is for Bayer Aspirin to alleviate a headache, or penicillin to cure an infection, are purely theoretical until the product is made and distributed. Simply stated, people's needs, even for something as basic as food, are abstract. Until the businessman creates, makes, distributes and

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[*Editor's Note:* This is a paper presented at the American College of Legal Medicine's 1969 convocation. See Editor's Note, above, at the beginning of this Symposium.]

communicates to the public the value of his product to satisfy those needs, there is no such thing as a real market.

You will note that this function of business is not defined in terms of profits alone, and perhaps we had better deal with that point before we proceed.

Peter Drucker, the eminent business writer, has said it best: "Profit is not the explanation, cause or rationale of business behavior and business decisions, but the test of their validity . . . for the problem of any business is not the maximization of profit, but the achievement of sufficient profit to cover the risks of economic activity, and thus to avoid loss."

In short, we in business must produce a profit to stay in business, and to keep ourselves alive and growing. In the drug industry, we seek to operate profitably so that we can increase our capacity to satisfy our customers, and by so doing improve the health of our nation. This is not a rationalization, but the very essence of our existence.

I said earlier that it is my belief that the drug industry is a reasonable concern of government. Under insistent public prodding, government is adding more and more terms and conditions under which our industry must operate. Further, they are undertaking to deliver services which the public thinks it needs, and which in retrospect we realize we should have provided. That doesn't mean, however, that we in business can let government take on our job.

The businessman is uniquely equipped to create change, to guide change, to wield change as a business and social weapon. Thus, it would be a real tragedy if business were to allow consumer problems to become a main concern of government. Business must retain its leadership in this area.

We are in the middle of a social rebellion, whether we like it or not. The upheavals on college campuses, the urban crises, the apparent alienation of our youth and the bewilderment of their elders, are symptomatic of our growing pains—of the costs we must pay for change.

Sometimes social rebellion may be carried too far, or too fast. Then, if man does not discipline himself, government has no alternative but to do it for him. In this day of permissive social behavior, those of us in business and the professions have a very special concern, for our freedom and liberty may be the first to be imperiled by the lack of self-discipline.

Rebellion is no longer limited to youth. It is, of course, a natural state for the young. Now, I do not mean to disparage our wonderful emerging generation . . . but, in its criticism of business and free enterprise, youth is often idealistic to the extreme, and I cannot help but remember a comment made by an English statesman. He said something to the effect, "You cannot trust young people in public affairs . . . not

because of their vices, but because of their virtues." As an aside, I might modernize this phrase by adding these words: in emphasizing their virtues, they sometimes resort to vices!

My point here is that government, like youth, is sometimes idealistic to the extreme in its approach to business, and government might better serve society by a more practical approach.

Let me tell you a little story.

At a gathering of businessmen and government people in Washington, I was approached by a lady active in consumer affairs. She said: "I know that you are interested in the problems of safety . . . why in heaven's name are you against the Blank safety closure?" She referred to a safety closure for medicines which has been heavily promoted in Washington.

I replied: "Well, it's simple enough. The Blank closure doesn't always protect the medicines in the bottle—many of them break down. We in the drug industry cannot compromise the ultimate quality of our products. In addition, there is another problem—while children probably cannot open the safety closure, neither can the elderly nor the infirm!"

She said: "Why didn't you say this in the first place?"

I said: "I did, but no one was listening!"

This misunderstanding points up one of the areas where government could be more practical in its approach to business—it could listen!

Let's look at a few of the realities.

Since I graduated from Medical School, man's life expectancy has increased to over 70 years, and at least one major curse of mankind—infection—has been largely overcome. Somebody has been responsible for all of our medical advances, and I respectfully submit that the medical profession and the pharmaceutical industry have done at least as much as the government to bring this about. I do not discount the tremendous financial contribution that government makes to the health fields, especially in the area of fundamental research on disease.

Nevertheless, since 1940, it is the United States drug industry which has been responsible for the introduction of 525 new ethical drugs—many more in number than all of the rest of the world combined.

I stress this point, because we seem to be at a place in time where it has become popular to belittle the research efforts of the drug industry—to cloud the facts with sophomoric opinion, with pseudo-statistics, and with faulty conclusions. Here we are dealing again with a few people—in and out of government—who mean well, but simply do not know the realities of the situation. They are not listening.

Another facet of the problem is this: our government is not constituted to run a business—any business—successfully, let alone the very complicated drug industry.

I am not making moral judgments—talking about right or wrong. I am talking about business techniques and business efficiency. Let me emphasize this by asking some questions.

1. Does the government show the ability to handle its own budget and make money work for it?

2. Have we seen evidence of the government's ability to distribute welfare and poverty money on a creative, fruitful and equitable basis?

3. How effectively has our money been spent during the long, long war in Vietnam? Art Buchwald pointed out that when you consider the money we spend to inflict a single casualty, it might be more economic to hire the Mafia to do the job for us.

4. How well does the government run the Post Office?

Granted my concept may have been overstated. I don't think it is necessary for me to dwell on the inability of our government to run a business—that's not its job. We should not be irresponsible in judging government activity by business standards. Those are often, and rightfully, a secondary consideration. The people in government are just as dedicated and just as competent as the people in business, but we must recognize that their roles are essentially different. Bureaucracy does not mean mediocrity, but neither does it equate with business enterprise.

Consider this point carefully, because it is at the core of the problem. Business is capable of making great strides with new developments that benefit mankind because it is willing to take risks with money, time, and resources.

Because these risks are so great, no new product can survive unless it is supported by the help of old products. It takes years to recover the development costs of any major new invention.

Take our new pain reliever *Talwin*. We all agree it is a tremendous development. But just like a potential young genius still in the cradle, the product has to be nursed and supported into maturity. No new product survives without the help of the old. If it weren't for Bayer Aspirin there would be no *Talwin*.

That is why the companies that produce "me-too" drugs and sell them under generic labels at cut-rates do not develop life-saving medicines, and make little or no contribution to the historic advances made by the health industries.

I think I have outlined some of the very real problems involved in the relationship between government and the drug manufacturers. Perhaps I can also offer a few thoughts on the directions we might take to solve them.

First of all, it's obvious to me that no problems can be solved during the pitch of battle, when antagonisms run high. Similarly they cannot be solved when emotional headlines have become a daily media weapon.

Secondly, all real fruitful exchanges must take place in an atmosphere of cooperation and understanding. I don't believe that the House or Senate Hearing Room always meets those requirements. The lawmakers who participate in these hearings are experts in their jobs, brilliant in cross-examination and often devastating.

The businessman, on the other hand, is neither lawyer, lecturer, nor public speaker. He meets the trial examiner in an alien atmosphere, and is easily chopped up—even when he is right. Certainly this is not the ideal environment in which to achieve real medical progress.

Third, government and business should begin to deal with each other on a long range basis . . . to plan, and to establish guidelines for progress. And they must be mutually sensitive to each other's needs and, most important, to the health needs of our nation. We might begin with the establishment of three-part committees, composed of representatives of the medical profession, the drug industry and government. These committees, with specific goals, could start working towards a better relationship.

Please note that I do not ask government to drop its "watchdog" function, nor business to abandon its militant attitude against over-control. Both concepts are necessary parts of the system of checks and balances—but remember too, that both are essentially negative functions, and that health advances are made only through positive effort.

Fourth, within the already existing framework, both government and the drug industry should re-examine their present postures, with an eye towards the real issue: what more can be done to improve the health of America?

The practices of both medicine and law are essential to a truly workable alliance between government and the drug industry. The American College of Legal Medicine is certainly well equipped to offer solutions to many of the intricate problems besetting industry and government. There can be no question of its experience and judgment in this area—and I suggest now that it also has a responsibility in this direction.

Fifth, anyone who attempts to reconcile the problems between government and the drug industry will quickly recognize that the situation is not entirely bleak. A great many steps—positive, productive steps—already have been taken to improve the relationship.

The method of bringing together representatives of government, the medical profession and the drug industry is not a flight of fancy. It has already been emphasized on several occasions by my own company. It was in just such a cooperative atmosphere that basic labeling and dosage forms were established for several of our principal products, as early as 1955.

I am also referring to the working relationship that exists between the government and the Pharmaceutical Manufacturers Association in

the areas of manufacturing and quality control. These joint seminars are not the kind that make headlines, but they are important in providing practical, workable solutions to our mutual problems.

For example, there are the recent proprietary advertising regulations, worked out after a year and a half of consultations. The drug industry is still not convinced that these new regulations are perfect, yet they are so much better than they were before the joint consultations began. And, we are at least at the stage where we can now attempt to live with them.

There are projects like the Council on Family Health. Leaders in the drug industry, recognizing that responsibility for their products did not end at the loading platform, founded this non-profit public service organization. For three years the Council has been educating American mothers on how to promote home safety and protect the health of their families. Senator Magnuson said, sometime ago, with reference to the Council: "You cannot legislate carelessness out of existence." With the whole-hearted support of many units of federal and state governments, the Council has been highly successful in educating mothers away from carelessness.

In fact, a few months ago, Senator Magnuson was prompted to say: "If the people in Detroit had been doing over the years what the Council has been doing, there would not be a Ralph Nader."

The people working in the drug industry and in government are equally sincere, dedicated and talented; their problem is mainly one of communication.

We in both industry and government must communicate with honesty, which insures its own credibility. We must learn to communicate more effectively, more clearly, more rapidly—for the stakes are high—the health of your family and mine.

When put in these terms, perhaps even the most biased, the most stubborn, can agree on a common goal, the achievement of freedom from disease and freedom from pain for everyone.