Putting an End to Secret Formulations

"Secret nostrums" were a scourge of the past that pharmacy, medicine, and the general public had to deal with in their collective efforts to advance rational therapy. From the medical scientist's viewpoint, it is basic, elementary, and essential that, if at all possible, one knows exactly what it is that is being used as an agent of treatment. Without complete composition information, how else is it possible to practice either good medicine or good pharmacy?

We recently attended a scientific conference at which University of California Pharmacy School Dean—and former Food and Drug Commissioner—Jere E. Goyan was a featured speaker. During his presentation, he observed that in the former dark days of science, "magic was medicine"; but in the present, enlightened period of science, "medicine is magic."

It is wonderful if medicine is able to produce results that can be described as "magical." However, it is in no one's best interest—and certainly not in the patient's nor in the practitioners' who are treating that patient—for the product used in treatment to be a secret formula: a sort of "magic potion," if you will.

But yet, that is still what prevails to a large degree even today.

Granted, drug manufacturers are required by law and regulation to make known the identity and quantity of the medicinally active ingredients in their products. However, they are not required to do so with respect to the so-called "inactive" ingredients. This despite the fact that these "inactive" ingredients may pose a serious health hazard to many patients. For reasons of safety, patients either may need to avoid, or may wish to avoid, such ingredients as lactose, tartrazine, cyclamates, saccharin, monosodium glutamate, sulfites, nitrites, as well as miscellaneous other preservatives, colors, or flavoring agents.

Yet, most drug manufacturers not only are unwilling to list such inactive ingredients in the labeling or advertising of their products, but adamantly refuse to divulge the information in response to specific requests.

When queried as to the basis for this policy, the usual response is "trade secrets." To which we can only retort: "Baloney!"

Every manufacturer must surely realize that the sophistication of trained laboratory personnel and the instruments and advanced equipment available today would enable any competition to "crack" a product's formula, both qualitatively and quantitatively with relative ease and speed. Competent pharmaceutical analysts would find such a task to be only a moderate challenge at most. And when we have stated this view to our industrial scientist colleagues, they have generally admitted—although usually "off the record"—that such is indeed the case.

So what is the real reason for this carefully maintained cloak of secrecy?

In our opinion, it has virtually nothing to do directly with competitors—any real trade secrets are much more likely to be involved in how the product is put together, than what is in it. No, we believe that the underlying reason for this policy on the part of so many drug firms is simply due to their desire to maintain an aura of the unknown, of magic, and of mystique surrounding their products. And this is not done out of concern about competing firms, but rather for the effect they believe it has on physicians, pharmacists, and patients.

As early as 1970, the American Pharmaceutical Association, by formal action of its House of Delegates, adopted a policy statement that "the Association seek legislation or regulations to require a full disclosure of therapeutically inactive as well as active ingredients of all drug products."

Subsequently, this official APhA policy position was broadened and strengthened on several occasions: most notably in 1980, when it was explicitly clarified that the policy was intended to cover both prescription and nonprescription drugs, and that disclosure included not only a passive willingness to reveal the information, but also an active listing of the information in product labeling and advertising.

Regrettably, however, the "proponents of magic" prevailed in the policy-making offices of corporate drugdom, and few companies have been willing to break with the operating policy of composition secrecy.

In recent months, however, the issue has heated up considerably. *First*, Ralph Nader's Health Research Group filed a "citizens' petition" with the Food and Drug Administration seeking new regulations to require that inactive ingredient information be listed on labels, in package inserts, and in the *Physician's Desk Reference*. *Second*, Jeffrey L. Brown, chairman of pediatrics at United Hospital in New York, filed suit in Washington, DC, federal court to force FDA to divulge the names of all approved drug products containing lactose as an ingredient. *Third*, Congressman Richard L. Ottinger (D.-NY) introduced legislation (H.R. 4126) to require disclosure of both active and inactive drug ingredients.

FDA initially refused freedom-of-information and similar efforts to get it to reveal the requested composition information. But then the agency notified the industry that, in effect, it would no longer serve as the industry's guardian angel; it would not defend against trade secret lawsuits unless the companies themselves defended against those suits.

How each individual drug company decides to act remains to be seen. But for the prescription drug industry's major trade group, the Pharmaceutical Manufacturers Association, this clearly presented a serious dilemma: is their primary concern to protect patients' lives or company dollars?

In rapid succession, the PMA first jumped in, and then scrambled out. Indeed, PMA's retreat was so hasty that the trade press was still carrying reports about PMA's February 27 decision to intervene in the case even after PMA actually withdrew from the lawsuit on March 14.

But, embodied in PMA's announcement to the press that it decided to withdraw from the case was an explanatory statement that, in our view, was most gratifying: "PMA withdrew . . . because it concluded that, while the identity of inactive ingredients is legally a trade secret, the medical justification for disclosure of the presence of lactose nevertheless warrants release of that information . . . . PMA recognizes the concerns of those who favor disclosure of inactive ingredients generally and intends to work with all interested parties toward a fair and equitable solution to the overall problem."

It appears that a new day has dawned, and that human lives rather than dollars may yet prevail as the subject of principal industry concern. Welcome aboard, PMA!

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