Journal of Pharmaceutical Sciences

JUNE 1976

VOLUME 65 NUMBER 6

The *Journal of Pharmaceutical Sciences* is published monthly by the American Pharmaceutical Association at 2215 Constitution Ave., N.W., Washington, DC 20037. Second-class postage paid at Washington, D.C., and at additional mailing office.

All expressions of opinion and statements of supposed fact appearing in articles or editorials carried in this journal are published on the authority of the writer over whose name they appear and are not to be regarded as necessarily expressing the policies or views of the American Pharmaceutical Association.

Offices—Editorial, Advertising, and Subscription Offices: 2215 Constitution Ave., N.W., Washington, DC 20037. Printing Offices: 20th & Northampton Streets, Easton, PA 18042

Annual Subscriptions—United States and foreign, industrial and government institutions $50, educational institutions $50, individuals *for personal use only* $30; single copies $5. All foreign subscriptions add $5 for postage. Subscription rates are subject to change without notice. Members of the American Pharmaceutical Association may elect to receive the *Journal of Pharmaceutical Sciences* as a part of their annual $60 (foreign $65) APhA membership dues.

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A CHALLENGE TO THE DRUG INDUSTRY

For years we have been hearing about the so-called "drug lag," in which critics—predominately from the drug industry—have charged the federal government and, specifically, the Food and Drug Administration with being ultracautious and unduly conservative in granting approvals for the marketing of new drugs. It has been claimed that too much data are required, that the review process is too meticulous, and that the levels of demonstrated effectiveness and safety for new drug approval have been set too high. It is claimed that, as a consequence, drugs become available abroad many years before they are permitted to appear on the U.S. market.

Overnight, a situation has developed that has had the ironic effect of completely reversing these respective traditional stances. The government is now prodding, pushing, and exerting pressure on the drug industry to move quickly to mass produce and mass market a new pharmaceutical product. And the industry is in the position of being reluctant and hesitant because it has legitimate uncertainties about the safety and effectiveness of the drug preparation involved.

We refer, of course, to the swine flu vaccine and the goal of producing sufficient vaccine to immunize virtually the entire U.S. population by early winter of this year.

Testimony of knowledgeable witnesses at Congressional hearings in early April indicates that there are some legitimate questions as to the probable effectiveness of the vaccine—what percent of the immunized population will achieve positive protection—as well as concerns about the safety of the product. The latter presumably might be attributable either to individual allergic reactions, since egg cultures will be used in its production, or to faulty manufacturing procedures which could result in an entire batch being defective.

On the other hand, the predictions of the magnitude of the threat posed by a 1918-type epidemic make it clear that the nation must be prepared to accept certain risks in order to head off the possibility of a national health calamity.

Steps must be taken by the government agencies involved—the Food and Drug Administration for control and regulation, the Center for Disease Control for overseeing the program nationally, the National Institutes of Health for influenza research, and state and local governments as a pipeline for bringing the program to the community level—as well as the pharmaceutical industry to see that the hazards are minimized, while maximizing the hoped-for benefits.

Reportedly, the drug industry has been reluctant to undertake production of the vaccine in the absence of Congressional action granting immunity on grounds of either antitrust violations or product liability. Such concerns are understandable; the request for such immunity represents sound business practice.

However, as to product liability, whether due to anaphylactic reactions or the possibility of a faulty batch, such risks constitute the normal occupational hazards associated with the pharmaceutical manufacturing business. The only significant difference here is the brief timetable involved, which limits the amount of testing and study that can be conducted before the product goes into general distribution.

Such testing is important and its value must not be downplayed. However, it would seem to be a manageable problem—one that can be largely resolved by properly reallocating resources and personnel, even though this may mean disrupting the research timetables and production schedules for other drug products. Granting product liability immunity would establish a bad precedent and is fraught with other hazards.

As this column is being written, the vaccine program is still not completely resolved. However, all indications are that the pharmaceutical industry will respond positively and responsibly, with the result that adequate supplies of the vaccine will be available in time to undertake the nationwide immunization program, thereby heading off the epidemic threat. We commend those involved for accepting this challenge.