Commentary: Need for Uniform Application of Technology on an International Scale

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In his paper, Dr. Petricciani and colleagues have ably reviewed many recent changes in the technology of vaccine research, development and control.

Were I to restrict my commentary to the contents of their paper, I could simply say "Amen" and sit down. The Bureau of Biologics has indeed, as Dr. Petricciani says, learned from the past. One must commend the Bureau for the creative and enlightened way it seeks to discharge its duty of protecting the public.

Are all problems in this area of vaccines related to technology?

Lewis Thomas, the head of the Memorial Sloan-Kettering Cancer Center in New York City recently put the question of the technology of medicine into perspective (*1*)..

He described three distinctly different levels of technology in medicine. The first, which he terms a "non-technology," includes a great deal of clinical medicine—the bedside practice of medicine with much of its hospitalization, nursing and paramedical support. It is very expensive and increasingly so.

The next level Dr. Thomas refers to as "halfway technology." These are the techniques designed to compensate for disease or to delay death. He sees organ transplants and artificial organs in this category, although the public (with the media representing each procedure as a breakthrough rather than a makeshift) view these inventions as high technologies. Much of the complicated treatment associated with the management of coronary artery disease, electric gadgetry, special units and ambulances and of cancer therapy by surgery, irradiation and chemotherapy, Thomas sees as halfway technology.

Thomas regrets that the public takes for granted the third kind of technology—the real, high technology of medicine which includes immunization against many of the childhood virus diseases, the modern immunization methods against pertussis and diphtheria for example. This third technology is so effective that it fails to attract much public notice. Thomas emphasizes that there are far fewer examples of high technology of medicine than the public has been led to believe. High technology results from a true understanding of disease mechanisms and is comparatively simple, relatively inexpensive in the long term and surprisingly easy to deliver.

It is good to recall occasionally what Thomas refers to as the halfway technology for poliomyelitis in the early 1950's: Sister Kenney and "the ceremoniously applied hot fomentations," the painful (in patient terms) acquisition of data on total immobility or passive mobility to support one or another theory of the day. It does us good to recall this, for it draws our attention to the cost-effectiveness of this halfway technology versus that of vaccine.

So I take no major issue with Dr. Petricciani's paper. Those aspects of the high technology of vaccination are in good hands. One must be impressed with international cooperation to date in seeking to achieve uniform quality of products and prompt dissemination of information on biologicals. One cannot but be

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impressed that the recent illness of six young soldiers (and the death of one) in my own home state of New Jersey can result in the instant alerting of public health resources around the world and the instant mobilization of appropriate government, academic, and industry scientists in the area of research and development to make plans to combat a possible influenza pandemic due to swine influenza virus.

I believe it would be an exercise in futility to get bogged down in a morass of historic examples of those simultaneous attempts to develop biologicals against a single disease, which, for better or for worse, did not result in equivalent products. We could fill a book with the failures in any area of research and development.

The title of this brief commentary refers to the need for uniformity in the application of technology on an international scale. In certain measure, that need is self-evident. In some areas of this technology, uniformity is important. Dr. Petricciani's report suggests that the necessary uniformity exists and will continue to exist.

Let us remember, however, that uniformity is an average—nothing more nor less than an average. Absolute pursuit of a code of uniformity can lead to lack of opportunity both for initiative and for serendipitous discovery.

Indeed, a good case can be made for the need for *non*-uniformity in certain areas that we will be discussing in the next few days. Jenner waited 20 years before he had the courage to depart from the uniformity of his peers and experiment on eight-year-old James Phipps (*2*), while Pasteur was led serendipitously to his method of immunization (*3*).

Dr. Williams has ably highlighted his concern for problems related to the costs of developing present-day vaccines. My principal concern today relates to something that endangers the application of this high technology field of vaccination to clinical investigation and ultimately to clinical use.

How can we ensure that it will be possible to develop new and needed vaccines?

As Dr. Hilleman pointed out, the critical problem is not how to control the testing. We have the mechanisms. The critical problem is "Who shall be subjects?"

If it is very difficult, if not impossible, to undertake research in children, how can we develop a vaccine for children against diseases which are serious in childhood but for which adults develop an immunity later? And how can an industry be encouraged to develop new modalities for treatment or prevention of crippling diseases when the legal and legislative spotlight turns on the rare child injured by a new vaccine and virtually ignores the millions saved from injury and death?

It is important that no group should be deprived of the opportunity to be subjects of ethical research. This is especially true for vaccine research. I have touched on children, but we must also consider institutionalized subjects, be they children or adults, as long as there is some potential for benefit. Further, we must not prevent the possible use of prisoner volunteers, as some well-meaning people appear to be attempting to do.

My purpose in touching upon this sensitive question of volunteerism and research subjects is to focus upon the serious need for this conference to be constructive, to be positive. Let us concentrate on the goal of how to ensure our ability to develop new and needed vaccines to protect the public. Let us not emphasize what should be stopped, but what should be started.

And to achieve that goal let us, as suggested by Dr. Williams, agree that government, industry and the private sector have a role to play. To that let us add the academic world, ethicists, and lawyers, all of whom have a role to play.

But let us play our roles constructively and in concert.

References

1. Thomas, L.: The Lives of a Cell. The Viking Press, New York, 1974.
2. Guthrie, D.: A History of Medicine. Thomas Nelson & Sons Ltd., London, 1945.
3. Cannon, W.B.: The Way of an Investigator. Hafner Publishing Co., New York 1968.