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Position Paper

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The prevention of infectious disease through vaccines has become an issue of public policy, with society expecting an equal voice to that of medical scientists, or even the power of veto. The forces which have led to this posture are very real.

Not many years ago, the decision-making process was different and simple. The individual physician decided which vaccines should be given to individual patients in his/her practice. More recently, with introduction of new vaccines and more discerning inspection of old vaccines, the scientific information base became increasingly formidable. Expert panels were assembled to weigh the complex data concerning the microbe and its immunology and the disease process to be prevented. The panel was asked to arrive at a best judgement concerning the need, relative safety and effectiveness of the vaccine, the optimal product, and schedule of use. Representing all disciplines and wisdoms, microbiologists, epidemiologists, immunologists, federal and local public health officers, and practicing physicians have debated, attained agreement, and made recommendations.

This decision-making process has been challenged by serious concerns of an increasingly aware public. I accept society's demand for participation in public policy for a number of sound philosophical reasons. I shall list six. These include: 1) the fact that immunization decisions typically involve large numbers, often millions, of individuals, *e.g.,* the recommendation for universal immunization of children for prevention of the basic childhood diseases. There are few medical products administered wherein a single decision affects so many. Because a vaccine reaches so many, any complication though uncommon or even very rare, becomes conspicuous.

2) Vaccines are given to prevent possible future diseases, not as therapy to cure present illness. Because vaccines are given to essentially healthy people, any adverse effects become less understandable and less acceptable. 3) Many vaccines are not simply recommended, they are urged and even mandated, *e.g.,* requirement for school entry. Vaccines so mandated carry an implied responsibility for the wisdom of such public health policy with special attention to safety and efficacy. 4) Public funds are requested for vaccine programs. A recommendation for vaccine use, if valid, should apply to all designated recipients. Surveys show that inequity in distribution regularly occurs when no measures are taken to reach certain segments of the population. Requests for special funds reach the congressional forum, resulting in high visibility and sharpening of issues. 5) The knowledgeable participation of the public is necessary in any overall national immunization policy. To attain the 90% or greater level of immunization necessary to control the spread of disease, each household becomes an active participant. 6) There is presently in our society a strong current of privacy of the individual and the right of self determination. This has taken many forms in terms of "rights", but in the health field has included individual or societal determination of the freedom to accept or reject traditional wisdom of the medical establishment. The public response to laetrile is an example.

Let us then accept joint participation of the biomedical and public health communities with the consumer in arriving at public policy and move forward to look at the consequences of such an arrangement.

I identify major issues which are difficult in their solution. I have guarded optimism about their outcome. Here are five issues, constituting the body of my comments, which I believe will stress the system and will require new levels of diligence and understanding in order to best serve our national goals.

I would like to discuss first the issue of decision-making in the face of technologic complexity. The enormity of making decisions about vaccines has always awed me. A recommendation of yes or no, a detail of product, dosage, and timing will set in motion a staggering number of shots given, or not given. How accurately can these decisions be made? They can be made with reasonable, but not finite, accuracy. Vaccines are prepared from the actual virus or bacterium presumably rendered harmless. By their nature, these materials are less readily purified, controlled, and potency tested than simpler medicinals. Examination of toxicity in the laboratory is limited to test tubes, tissue culture, or animals and none of these in an absolute sense approximates the human host. This creates the need for testing the final product in man, often in children.

How useful are field trials in man? They are very useful and essential, but I would like to discuss their limitations, which in turn bear on the decision-making process. Such prelicensure trials cannot detect all contingencies. In testing, say 5 or 10 thousand children, those very rare adverse effects which occur only once in 100 thousand or once in a million individuals cannot be detected. Also, trials cannot anticipate delayed adverse effects, *e.g.,* years later. Then too, in most trials, the protective effect against actual illness can only be inferred from studies of antibodies acquired in the bloodstream. The exact percent of protection and its duration can only be documented when the immunized population later undergoes natural challenge in an epidemic situation. Thus, there is certain information which is not all in until the vaccine has been used for some years and in millions of people. How long should we wait before releasing a given new vaccine for general use? Should we wait until every single possible question is answered and every unknown known? What of those individuals who become ill or who die each year with a potentially preventable disease while the vaccine is withheld and being perfected?

The general point to be made from these details is that the decision-making process is deeply embedded in technology and one is called upon to make social choices based upon interpretation of a technology which may at the time be studded with uncertainties, probabilities, and unknowns. Despite good faith, money, research, and effort, nature does not yield up all its useful secrets readily. The addition of consumers to the decision-making process will not altogether alter these technologic limitations, but it can provide a broader base of value judgement for addressing society's appropriate response.

The second issue is the interaction of the biomedical scientist and the public. The joint involvement of consumer and scientist in one body will be an interesting experience. The scientist is used to full, critical, and no-holds-barred debate, but only amongst those with equivalent information, background, and motives. The scientist is concerned that in the essential process of open discussion and information exchange, that the public may be dismayed by lack of certainty, variables, and unknowns in the scientific data base, and, furthermore, that differences of opinion among scientists could be misinterpreted and invite public indecision or indifference.

The consumer can provide new leadership in fostering the

appropriate use of established vaccines through education and local enabling procedures. The provision of apolitical federal leadership and funding when necessary to support broader vaccine use and support research to improve and develop new vaccines, can be greatly assisted by public awareness. The biomedical scientist, the social scientist, and the consumer have a period of learning ahead, involving reciprocal education and recognition of multiple views. We will hopefully see a shift in emphasis from confrontation to problem-solving.

The third issue concerns the concept of risk/benefit ratio. The risk/benefit ratio involves value judgements that every practicing physician and public health officer confronts daily. Is the cure safer or more dangerous than the disease we are trying to prevent? If we knew with exquisite accuracy all the consequences, the answer would be relatively simple. It becomes difficult, however, where we deal with probability, rather than absolute certainty and we are often trying to balance the probable risk to a few against the probable benefit to many. Benefit can be measured in terms of saving lives, avoiding chronic disease, or sick days or in terms of saving health dollars. Also, the question of benefit could be asked in terms of two different sociologic settings. The first occurs when the end effect of immunization is protection only of the individual. An example is tetanus immunization, where only the recipient is protected and the issue of weighing risk and benefit is, thus, a personal one. But what about the second situation, typified by rubella, measles, or polio vaccines, where the actual number of people immunized determines the spread of virus? In this case, it is a community concern. Immunization of one's neighbor, classmate, or the inner city, or suburb increases the benefit to others in the community as well.

The ability to place rare adverse effects of vaccines in perspective makes assessment of risk extraordinarily difficult. Psychology and emotion clash with the arithmetic in the equation. I would like to call on some analogies made by Dr. DeWitt Stetten in a recent article entitled "What Men Fear" (1). This year, 45–55 thousand people will be killed by automobiles, yet fear of automobiles is relatively rare. Seventy-five thousand deaths will be caused by or contributed to by cigarette smoking, yet the population seems remarkably indifferent. "I can smoke or not, as I wish, I can ride in a car or not ride . . . as I wish. Therefore, I have trouble being afraid of cigarettes and automobiles." In these instances, fulfillment of need, or benefit, is immediate and tangible; the risk seems remote. In contrast, the individual baring his arm for a vaccine, informed of a risk in that syringe and knowing of an unpredictable protection against illness in the future, seems to have a sharper dilemma than in his decision to drive or smoke, although the vaccine risks may be negligible by comparison. This same dilemma is also faced, but on a mass scale, by those who make vaccine recommendations nationally. In a new vaccine under consideration, does the benefit have to be 10 times, 1000 times, or 100,000 times greater than risk to be acceptable, or does any risk rule out embarking on the vaccine program? Will society say that it is better for the community to face the disease that nature may or may not have in store than risk harm to the individual at the hand of the physician?

The concept is singularly important because absolutely risk-free medicines of any kind, no less vaccines, are only theoretical. Even the commonplace aspirin, bought and used with little thought, is now known to have important side effects.

The fourth issue addresses the role of the media. The public perception of vaccines is shaped by cultural tradition and, of course, by their physicians, but to a large extent by the mass media. With what fidelity does the media mirror the facts and pros and cons of immunization? There are many instances of good reporting which are objective and which place current events in context and perspective. There also appears to be a natural attraction to the reporting of the exceptional, the dramatic, the confrontational. This can overshadow even an overwhelming weight of scientific opinion which often lacks sparkle in its effort to be judicious. Can we have a knowledgeable public and a sound and reasoned basis for an immunization policy given our national penchant for trial by public ordeal?

The successful, quiet war against preventable infectious diseases has been less well reported to the public than the plateaus and setbacks. I do not underestimate the persuasive power of the media in this new joint enterprise on which we embark.

The fifth issue, that of liability, is an important and disturbing one, which has not yet been adequately addressed. The national goal of full immunization with established childhood vaccines and also the development of much needed new vaccines is handicapped by the compelling need for some sort of indemnification. With increasing awareness the problem of liability has emerged as a public issue. Vaccines do carry inherent risks as we have seen. Add to this, furthermore, all adverse events that appear to be linked to vaccination because they occur close to the time of injection. Even when no causal relationships may exist, the vaccine may be suspect, with resulting unfavorable publicity and litigation.

A responsible policy would recognize that liability presently exists at several levels. The health department, school system, or physician who recommends immunization may be asked to accept liability for any real or alleged adverse consequence. The pharmaceutical manufacturer is similarly vulnerable. This liability threat has, at times, dampened the ardor of the provider in urging appropriate immunization and also contributes to the dwindling number of pharmaceutical companies producing vaccines. Neither of these effects is in the public interest.

Informed consent may decrease our moral burden, but it does not respond to the central issue. At the moment, litigation is the only avenue of remedy for an injured vaccine recipient immunized by a physician who in good faith follows recommended procedure and with a product properly prepared by a manufacturer following the best state-of-the-art guidelines.

Because of the absolute need for testing in the human, a special liability problem exists in the development of new or improved vaccines. Vaccines against hepatitis, gonorrhea, bacterial meningitis, viral pneumonia, and croup and gastroenteritis in infants, and a new living influenza vaccine as well as other products are in various stages of research and development. In terms of liability, those who volunteer for experimental trials may undergo special risks. The scientists testing the new vaccines, although under extensive local and national surveillance, may be at unique personal liability risk. The volunteer may be benefited personally by the protection of a new vaccine. However, unforeseen vaccine-associated injury may leave him with no recourse at present other than to commence a law suit.

Because society as a whole benefits from a high level of community participation in the vaccination program, and continued advances depend upon broad-based experimental trials, it is fitting that a fair extrajudicial, nonadversary compensation system be instituted for recipients of established licensed vaccines as well as for study volunteers.

The partnership which we are entering between the scientific community and the public is enormously complex. I see problems to be solved which are historically new. At what point in the process of scientific development, testing, and distributing vaccine, is it socially useful for the public to become involved? When are the consequences of wide dissemination of scientific debate and uncertainties about vaccine products productive or counterproductive for our goal of full vaccine use? How can the public discriminate between instances of apparent scientific complacency, ineptitude, or bureaucracy as compared with the very real limits of current scientific capability? How can corrective forces be applied without loss of public confidence? If we are to solve these problems, the public, the scientific community, the media, the law, and the government must set aside any political and parochial views and address the issues with responsibility and wisdom.

REFERENCE

1. Stetten, D., Jr.: What Men Fear. Perspectives in Biology and Medicine, p. 515–523 (Summer, 1978).

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