Consumer Perspective: Position Paper

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Preventive medicine is of vital concern to all consumers, and it is generally accepted that immunization has been the key tool which has resulted in dramatically reducing both the incidence and severity of communicable diseases in many parts of the world.

Nevertheless, there is some apathy, and even some resistance to immunization programs among the American public, largely because of confusion and uncertainty about the effectiveness as well as about the risks in the programs.

The recent swine flu program merely exacerbated the already-existing consumer concern. Obviously, there is not adequate public acceptance and involvement in immunization as is shown by the very low levels of immunization among American children. In 1977, there were some 20 million, almost 40% of our children, who were not immunized against one or more of the childhood diseases for which vaccines are available.

This is not due to the fact that consumers are complacent. Not all of us have, and I quote, "forgotten the spectacle of the iron lung, the generation of deaf children, the babies with birth defects because their mothers contracted German measles," end quote, as Secretary Califano has stated. It is more likely due to the fact that consumers have heard more about some of the major side effects of vaccinations—the convulsions from DPT vaccine which occur in one case in 5-7000, sometimes with abnormal screaming due to the pertussis, the encephalitis that occurs from measles vaccine occasionally, the temporary arthritis, or nerve damage, or brain damage from rubella vaccine, the Cutter incident when more than 100 contracted polio from supposedly killed virus, the cases of Guillain-Barre syndrome from swine flu vaccine, about which we have heard so much in recent years.

In England, several hundred families have formed the Association of Parents of Vaccine Damaged Children after 182 of their youngsters suffered severe disorders, including deafness, blindness, and paralysis after whooping cough vaccinations.

In our own country just a few weeks ago, it was reported that 24 cases of abscesses occurred in children who received DTP vaccines in six different states.

Another cause for consumer resistance may be the lack of agreement within the medical profession as to the effectiveness of some vaccines, and also as to the need for better targeting of the population for specific vaccination.

When some doctors recommend flu shots, while others recommend against them, when the World Health Organization in 1967 reported the ineffectiveness of flu shots, and when tests to evaluate the potency of flu vaccine were so unreliable as to be called, quote, "completely worthless," end quote, by the official responsible for regulation of the vaccine, it is no wonder that the public confusion and lack of confidence merely increases, and spreads to all immunization programs.

But consumers are not saying that all vaccination programs should stop. What they are saying is, we have not really been leveled with. We have not been given all the information we should have had to make an informed rational decision. We are not sure enough work has been done on all the vaccines to make them as safe as possible.

The Ribicoff hearings brought out a number of instances indicating that the Division of Biologics Standards was not as vigorous

as they might have been in pursuing investigations into possible contaminants; for instance, herpes virus in dog kidney cells in which it was proposed to produce rubella vaccine, or viruses in monkey cells used for growing vaccines, as they might have been.

Consumers also question whether there is adequate continuing active surveillance of vaccines in general use, not just during periods of epidemics, but over constant years of use.

The danger of hypersensitivity from killed measles vaccine was not discovered until 4 years after licensing. It is known that mumps vaccine can also hypersensitize some people to subsequent exposure.

We would like to be reassured that the mechanism exists to pick up something that may occur at a relatively low rate over a long span of years, and that mechanisms to find ways to avoid hypersensitization are being developed.

We are also concerned about the preservatives in vaccines when we read that a Federal District judge awarded a plaintiff \$650 thousand for damages caused by a preservative added to a vaccine in a way that caused very serious brain damage.

We are not sure that vaccines are effective when we read of measles outbreaks among adolescents who had previously been vaccinated against measles.

Our confidence is further shattered when we discover that the DBS had allowed at least 32 biologicals or vaccines to remain on the market for at least 10 years, even though they were not effective in use, and even though some of them could have serious side effects.

We wonder if vaccines are being given to the right people. Take, for instance, rubella, about which you have heard so much today. Apparently rubella is a relatively harmless disease in young people. The danger is that pregnant women who get the disease in the early months of pregnancy are highly likely, and there's some question about how likely, to give birth to malformed, blind, deaf, or heart-affected offspring.

Since rubella vaccines are all live, they cannot be given to pregnant women safely. But the children who are given the vaccine, and are then later exposed to German measles, while they do not develop rubella, may still transmit the infection to a pregnant mother.

We are not sure enough is being done to improve existing vaccines, especially influenza and pertussis. Some vaccines already in use, but not subjected during development to currently recommended methods of field testing, obviously need to be evaluated on the basis of data obtained, in most instances, during regular use. We have a right to know what means are used to assess vaccines. Are they as good as they possibly can be? Are standards for vaccine safety and potency being updated, and are they being made available to the public?

We feel that there is a need to find new ways to enhance the immune response to weak vaccines to make these products more effective. More information is needed on the mechanisms of immunologic adjuvants, and how they can be used more effectively and more safely.

Perhaps more emphasis should be placed on basic research to develop strategies for modulating the immune response of the body so as to increase resistance to pathogens.

If the pneumonia which flu patients get is the real danger, maybe we should be concentrating on how to prevent pneumonia instead of influenza. I was interested to hear about the pneumococci vaccine which has just been accepted.

If public understanding and support of immunization programs are to be achieved, the questions which are raised by these uncertainties among consumers must be answered, even if the problems they indicate are not immediately resolvable.

Consumers must be represented at the earliest planning stage of immunization programming. As Dr. Harvey Wiley said back in 1906 when the Food and Drug Administration was first established, and I quote, "The principle that the right of the consumer is the first thing to be considered would be worth more to this country than the actual protection to health," end of quote.

Consumers must know how carefully the need for a vaccine has been established; what are the possible adverse effects; what are the possible choices; what is the best target, so that they can participate as informed partners in an immunization program.

It is true that decisions with respect to the uses of technology must be based on sound technologic information developed by experts. But these experts are not necessarily the best equipped to make judgments on acceptable public risks and benefits. Such judgments should be made by a broader-based group in which consumers must have significant participation. Immunization has

become a public concern, and the public has declared its right to know and to participate in the decision making.

For that reason, and because we agree that there is, at present, no formal mechanism to bring the concerned parties together in the decision-making process, organized consumers support the recommendation made by a number of the National Immunization Work Groups that a National Immunization Commission be established by the Congress of the United States.

As proposed, the Commission would include representatives from those who administer and those who receive the vaccines, as well as from many others involved in the manufacture and distribution, and the Commission would provide the Secretary of HEW, and the Congress with advice and assistance in formulating an effective National Immunization Policy.

Unfortunately, Secretary Califano has taken no steps to implement this recommendation so far, and, instead, embarked on a stepped-up immunization program without any apparent recognition of the many consumer concerns outlined above.

It is doubtful that the necessary consumer acceptance and support will be achieved by this cavalier ignoring of the recommendation of the Work Groups, either for the childhood immunizations or for the talked-about flu inoculation program.

I hope that these deliberations during this symposium will give the consumer concerns much more serious attention.