

Response

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Under the heading "Vaccines Are Not Perfect", Dr. Mortimer mentioned the risks associated with the measles, polio, and other vaccines in current use. In the July 1978 issue of the *American Journal of Clinical Pathology*, I analyzed the available data on the so-called risks of the measles and polio vaccines and pointed out the inaccuracies and confusing language in the present "information and consent" forms published by the Center for Disease Control (1). Such inaccurate statements are harmful because they imply certainty where there is at best grave doubt and, thus, contribute to the many unjustified litigations against vaccine manufacturers; litigations that have led many of them to discontinue production of vaccines, as Dr. Mortimer has already mentioned. Speaking of the risk of measles vaccine, Dr. Hinman used the words "may be if it truly exists." Yet his organization, the Center for Disease Control, is responsible for the following statement:

Subacute sclerosing panencephalitis (SSPE) is a slow virus infection of the brain caused by a measles-like virus. A recently published study [Modlin and associates] has revealed that SSPE follows measles at a rate of approximately 5-10 cases for every million children developing measles. Live measles vaccine may be associated with SSPE at a rate of 0.5-1.1 cases per million doses of measles vaccine distributed. Thus, the risk following natural measles is 5-20 times greater than following measles vaccination."

"However one may argue that 'may be associated with' does not mean 'caused by'. The final sentence attributes a risk of SSPE to live measles virus vaccine and defines that risk at 0.5-1.1 cases per million doses. Such an assumption of definite risk by parents and even by sophisticated pediatricians is reflected in the following recent comment by Sydney Gellis: 'The risk figures are no consolation for the child who develops SSPE after measles vaccination, but there appears to be nothing that can be done at present to lessen the small risk of SSPE which accompanies the vaccine.'"

My own analysis of the published data, referred to above, led me to the following conclusion:

Is it correct and proper to say or imply that a small risk of SSPE accompanies the use of measles vaccine, when in effect there is no evidence for such a risk and a very high probability that the rare postvaccinal cases result from natural infection with special strains of measles or measles-related viruses before vaccination? Would it not be more correct to say that available data provide no evidence that the measles vaccine virus can cause SSPE, but show that the immunity provided by the vaccine can protect against SSPE?

What I have just said about the so-called small risk of vaccine-associated SSPE also applies for different reasons to the risk of vaccine-associated encephalitis, which has been the basis of many litigations against manufacturers of measles vaccine, of whom

only one is now left in the US. Accordingly, I believe that it would be more correct to say that available data provide no evidence that a variety of neurologic disturbances that may be seen within 1-30 days after vaccination in one child of every million vaccinated are caused by the measles virus vaccine, but they do show that the immunity provided by the vaccine can protect against the neurologic complications that occur in one of every 1000 reported cases of natural measles.

In discussing the beneficial effects of oral polio vaccine, Dr. Mortimer, like the Center for Disease Control, equated vaccine-associated cases of poliomyelitis-like paralysis with "vaccine-induced", and said that there can be no such complications after killed polio vaccine "because the virus is killed." The data presented in my July 1978 article indicate the inaccuracy of both of these statements as well as of other statements in the information and consent forms published by the Center for Disease Control. The so-called risk of oral polio vaccine-associated paralysis is so small that during the 8-year period of 1969-1976 inclusive, 18 states and the District of Columbia with a population of over 36 million did not report a single case of paralytic poliomyelitis of any kind. In 1978, thus far, only one case of paralytic poliomyelitis has been reported in the entire USA and this case, I have been told, originated outside the USA. In the pre-polio-vaccine era, it was established that a small proportion of clinically and even pathologically characteristic paralytic poliomyelitis was not caused by the three types of poliovirus. In addition, a variety of other conditions have in the past been mistaken for paralytic poliomyelitis, and all of these relatively uncommon diseases cannot be expected to disappear even when complete prevention of paralytic disease caused by the three types of poliovirus has been achieved.

About 18 months ago, an extensive study and conference on immunization problems, commissioned by the Department of Health, Education and Welfare, recommended legislation that would free manufacturers from liability for claims of alleged injury arising from the use of vaccines that are prepared and controlled in accord with federal regulations and are used in accord with recommendations of the Public Health Service and professional societies. Such a law would provide an alternative legal mechanism for investigation and, when indicated, compensation for vaccine-associated injuries, but no such law has been enacted.

The inaccurate statements about vaccine risks, the irrationality of the present consent forms, and the failure of Congress to pass the recommended vaccine-associated claims act are all impediments to an expanded public supplementation of the current routine immunization of children.

REFERENCES

1. Sabin, A. B.: *Am. J. Clin. Pathol.*, 70: 114, (1978).