

investigation into the immunopathology of children with chronic enterocolitis and regressive developmental disorder¹ brings into sharp relief the inappropriate intervention of politics into what should be an apolitical scientific examination.² It is perhaps understandable that health officials are tempted to discredit innovative clinical research into the biological mechanism of vaccine-associated health problems when they have steadfastly refused to conduct this kind of basic science research themselves. However, it should not be accepted without protest.

Condemning research of the kind undertaken by Wakefield et al will only ensure that no scientific progress is made toward identifying children genetically or otherwise at high risk of immune and neurological dysfunction after vaccination. Such children could be screened out of the vaccination programme. And there will be no scientific progress made toward developing therapies to restore children who have been injured to good health.

In their commentary, US Centers for Disease Control employees Robert Chen and Frank DeStafano² take a cheap shot at the intellectual integrity of British physicians, the British public and *The Lancet* when they imply that reports in British medical journals and in the British media in the 1970's concerning pertussis-vaccine associated neurological damage were unfounded and led to a "painful history" that could be repeated if Wakefield's report is taken seriously "because passion would then conquer reason and the facts again in the UK". US public health officials will not accept any independent thinking or scientific investigation into vaccine-associated health problems that does not carry their imprimatur. In the words of Herbert Spencer, "There is a principle which is a bar against all information; which is proof against all argument; and which cannot fail to keep a man in everlasting ignorance. That principle is contempt prior to investigation."

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- 1 Wakefield AJ, Murch SH, Anthony A, et al. Ileal-lymphoid-nodular hyperplasia, non-specific colitis and pervasive-developmental disorder in children. *Lancet* 1998; **351**: 637-42.
- 2 Chen RT, DeStefano F. Vaccine adverse effects: Causal or coincidental? *Lancet* 1998; **351**: 611-12.

Sir—I am surprised that Andrew Wakefield and colleagues¹ and your correspondents² have not pointed out that an MMR vaccine that we were

using in the early 1990s has already been withdrawn from the market. This followed reports by general practitioners of adverse reactions that seemed to be related to that vaccine. Since that time, I have not seen or heard about any child having a reaction to MMR vaccine, whereas before then I was aware of several children having adverse events after MMR vaccination.

Looking at the ages of the children in Wakefield's study,¹ it seems that most of them would have been at an age when they could well have been vaccinated with the vaccine that has since been withdrawn.

In some cases the parents associated MMR vaccination with autism, and there seems nothing in Wakefield's report, or in the subsequent correspondence that gives any firm evidence to reject these views of the parents. The only sensible suggestion about a solution comes from Payne and Mason²—to look at primary-care computer held records—which has also been suggested by the chairman of the Primary Care Virology Group. However, such a method is unlikely to be able to detect an association, if it arises from a vaccine that had been taken off the market 4-5 years earlier.

The most important task now falls (as usually seems to be the case in such situations) on those working in primary care: it is to get the message across to parents that MMR vaccination carries a much lower risk than their children not having the vaccine. This message is especially pertinent because the media and public interpretation of the safety of MMR vaccine was probably the complete opposite of what it should have been. Wakefield and colleagues' report did not show an established link between MMR vaccine and autism. The very strict standards demanded for vaccine safety had already caused the removal of one MMR vaccine because of reported possible adverse events. Knowing this, we and parents should have even more, not less, confidence in the safety of present MMR vaccine and the benefits of vaccination.

One cannot really blame the public and media for their interpretation of the recent MMR concerns, because if we do not provide all the information, how can we expect the media to produce balanced articles, and more importantly, how can we expect parents to make a sensible fully informed choice?

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- 1 Wakefield AJ, Murch SH, Antony A, et al. Ileal-lymphoid nodular hyperplasia, non-

specific colitis, and pervasive-developmental disorder in children. *Lancet* 1998; **351**: 637-41.

- 2 Payne C, Mason B. Autism, inflammatory bowel disease, and MMR vaccine. *Lancet* 1998; **351**: 907.

Questions on breast-implants study

Sir—In 1991 the Committee on Appropriations of the US Congress was sufficiently concerned about the risk of breast cancer in women having breast implants to fund the National Cancer Institute "to develop a strategy for conducting longitudinal studies on women on the various types of silicone breast implants, with particular attention to those used for breast reconstruction after mastectomy or injury."¹

The result was the Follow-up Study of Women with Augmentation Mammoplasty, an intramural project of the National Cancer Institute. The initial protocol was released in November, 1993. Findings will be reported soon. We do not know what the results will be, but we have some questions about the methods, the fieldwork, and the questions this study will be able to answer.

(1) Why was reconstructive surgery an exclusion criterion in the protocol if the intent of Congress was "particular attention to [implants] used for breast reconstruction after mastectomy or injury"?

(2) What are the key hypotheses of the NCI study?

(3) Given the large number of questions about arthritic and rheumatic symptoms and conditions in the study questionnaire, has the emphasis of the study changed? Are arthritic and rheumatic conditions and symptoms now a primary endpoint?

(4) What statistical power can be expected for arthritic and rheumatic conditions and symptoms?

(5) Why were women having breast reduction surgery not used as the "unexposed" controls?

(6) How will the investigators deal with response rates among women screened and deemed eligible to participate if they are below 85% as specified in the protocol? Is a difference in response rate expected between the group of women exposed to breast implants and the control group? How are denominators used to calculate response rates defined?

(7) Women who had plastic procedures other than breast augmentation may be considerably younger or much older than those who had breast implants. Does the necessary