calls The Project on the Predicament of Mankind. As an afterword in *Limits to Growth* explains, "The project was not intended to be a piece of futurology. It was intended to be, and is, an analysis of current trends, of their influence on each other, and of their possible outcomes." Club members say that their organization represents no particular ideology and merely wants to bring mankind's predicament to the attention of those in a position to avert global calamity.

Carroll Wilson, a member of the club and a professor of management at M.I.T., says that after several months of talent-scouting the club settled on Jay Forrester as the best man for the job. He committed himself tentatively to the project after a club meeting in Bern on 29 June 1970, "that momentous date when it all began," Wilson says. Forrester had the project roughed out in his mind within a day or so. A 2-week meeting at Cambridge, Massachusetts, followed later that summer, and after that it was left to Meadows and his group to produce a report during the next 18 months. Meanwhile, Eduard Pestel, a director of the Volkswagen Foundation and also a member of the Club of Rome, convinced his foundation to grant a quick quarter-million for the project.

The resulting book was actually written by Meadows' wife Donella. Encouraged by Peccei and Wilson, she and her husband signed over the rights to it late last year to a little-known public policy think tank in Washington called Potomac Associates. Then the hoopla began.

Fully cognizant that, to borrow a phrase from a press release, an "intellectual bombshell" had fallen into its lap, to say nothing of a potential best-seller, Potomac Associates president William Watts passed a copy of it along to Benjamin H. Read, director of the Woodrow Wilson International Center for Scholars in Washington. Read quickly agreed to organize a symposium on the book, and the Xerox Corporation promised its financial support of the meeting.

Then came the publicity. To spread the word, Potomac Associates hired Calvin Kytle Associates, an energetic local public relations firm. Kytle churned out some zingy press releases and background material, embargoed it all for Sunday 27 February, and promptly struck a PR man's idea of gold. The *New York Times*, the Washington *Post*, the Boston *Globe*, and others picked up the story and splashed

DBS: Officials Confused over Powers

A notable state of confusion prevailing over federal authority to regulate biological products such as vaccines has finally been resolved. The point at issue is no less central than the government's authority to require that biological products be of proven effectiveness. Attorneys in the Department of Health, Education, and Welfare have now discovered that the department was entrusted by Congress with such authority 10 years ago but neglected to delegate it to the relevant regulatory agency, the Division of Biologics Standards (DBS).

This bureaucratic oversight was first noticed by James S. Turner, a public interest attorney who has been investigating the DBS following his representation of DBS scientist J. Anthony Morris in a Civil Service grievance procedure held last year (*Science*, 25 February and 3 March 1972). Officials of DBS, Turner noted in a legal memorandum shown to Senator Abraham Ribicoff (D–Conn.), believed they possessed authority to require safety, purity, and potency in the products they licensed, but not effectiveness. But authority to require effectiveness, Turner argued, was granted by Congress in the 1962 amendments (Kefauver amendments) to the federal Food, Drug, and Cosmetic Act.

"DBS apparently believes that it has no legal authority to test vaccines for effectiveness," Senator Ribicoff repeated to the floor of the Senate on 15 October last year. "If this legal interpretation is correct, Congress should act to give the Division the duty to do so; if the interpretation is incorrect, the Division should begin to fulfill its responsibilities."

In a memorandum of 23 November, Wilmot R. Hastings, general counsel of HEW, advised the Secretary that in his opinion the Department had indeed been invested with the authority to regulate biological products for effectiveness by the 1962 amendments to the act, but had never "formally delegated" such authority to the DBS. Following Hastings' discovery, this omission was remedied last month by official order.

How did this 10-year misunderstanding come about? As far as concerns the Secretary's office, it seems that in between the coming and going of secretaries, the efficacy of vaccines was a matter sufficiently trivial to get overlooked. Officials in the DBS were concerned about the problem, but believed that the 1962 amendments did not apply to biological products, in part because of a regulation drawn up by the Food and Drug Administration excluding biologics from a section of the federal Food, Drug, and Cosmetic Act. (Turner's comment on this position: "During investigation into the subject of biologics efficacy, some attempt might be made to discover how widespread the notion is that an Act of Congress can be nullified by a regulatory agency's announced regulation.")

Each year since 1964, the DBS has included in its legislative proposals a request that the division be given the authority to require effectiveness, a request that HEW officials have repeatedly ignored. Nevertheless, the DBS believes it has, in practice, ensured efficacy in all products licensed since 1962 by requesting manufacturers to provide efficacy data on a voluntary basis when applying for permission to test out a new biological product.

The new authority delegated to the DBS will primarily affect products licensed before 1962. These include rickettsial vaccines and many of the bacterial vaccines, for which proof of efficacy has never been demonstrated. All of these vaccines were believed to be effective at the time of licensing, DBS officials say, but some may not meet today's more stringent standards.

If the DBS has ensured efficacy in practice, at least for products licensed since 1962, what difference has the lack of formal authority made? Turner contends that the division has not moved as vigorously as possible in ensuring the efficacy of such vaccines as influenza and that, with formal authority to require efficacy, the DBS would have had to be more active in improving and developing this and other vaccines.—N.W.