My own beliefs + Not Necessarily reflecting those of OMB or the Administration.

As you probably know, the Administration Bill S1217 on regulation of recombinant DNA research left to existing law all issues involving the publication of information submitted to the Government by prospective licensees as required by the Bill. I understand that this was based on an OMB decision that DNA activities required no special rules for the handling of proprietary information. This decision was made in the face of a number of different studies and opinions that the Freedom of Information Act (FOIA) and the Federal Advisory Committee Act (FACA) do not sufficiently protect the proprietary information submitted to the Government whether to comply with law, aid in satisfying the needs of the Government, or obtain from the Government funding to support research and development efforts. The unpredictability of protection afforded by FOIA and FACA and the recommendation or need for statutory relief has been clearly pointed out in (1) a report by the President's Commission on Biomedical Research, (2) a report by the National Commission for the Protection of Human Subjects (both generated on the basis of a charge from the House Committee on Interstate and Foreign Commerce and the Senate Committee on Labor and Public Welfare), (3) the December 11, 1975 agreement between Congressman Moss, the father of the FOIA, and Congressman Goldwater, (4) A November 18, 1975 letter from the Energy Research and

Development Agency, (5) a November 18, 1975 letter from the Department of Justice, and (6) a January 28, 1977 letter from Philip Handler, the President of the National Academy of Sciences. ~~(All of these materials are attached.)~~ one also sent to commission on human subjects.

Of course, there are many others who have expressed similar views, including the Department of HEW, the drafter of S. 1217, in testimony before the President's Commission, and the National Commission for Protection of Human Subjects. The first version of Section 1817 of Senator Kennedy's proposed "Recombinant DNA Regulation Act" appears to take these recommendations into consideration by providing a special section which enhances protection of proprietary information required to be submitted to the Government under the proposed Act.

Although I am in agreement with OMB that FOIA and FACA would be the more appropriate place to correct the near universal belief that these acts do not provide adequate protection for proprietary information submitted to the Government, I am of the opinion that correction of this problem should not await such action. I believe the detrimental effects that delay will have on new research programs that may emerge prior to the time that amendment to FOIA and FACA can be made outweigh awaiting such amendment. It seems clear that Congress by Senate passage of S37, which includes a special provision for the treatment of

value from those of no value. In fact, the experiment itself is conducted to answer these questions. Dr. Handler's letter is eloquent testimony to this fact. Section 1817 eliminates the need to make this consideration.

- Section 1817 recognizes the fact that the owner of information is in the best position to decide what is or is not proprietary. Furthermore, the owner's interest in protecting his property is immediate and primary, while the Government's interest is derivative and secondary.

- When functioning under FOIA and FACA the definition of "proprietary information" becomes definitive of disclosure, but this definition is embodied in the common law and, therefore, must await case-by-case enumciation. Section 1817 eliminates the uncertainty and cost of such case-by-case review.

- Section 1817 eliminates the injustice of compelling an individual to jeopardize his proprietary rights on the one hand and to pay for the cost of his vindication on the other as would be required by FOIA and FACA.