W Cuberson VI 3/2 UDB There is no doubt at all that free Zuchersmins used on classic denived vorcine has been overtaken by events - (i) development out of neost derived vorcines (ii) accurace of Filds in blevelopment Dr Harris products. His miselling technique will be of volue in Mr Alcock developing other vorcides. GRO. HEPATITIS B VACCINE

1. A submission to MS(H) of 26 May 1982 on the availability in this country of the American vaccine against Hepatitis B referred to research in this country and elsewhere into producing other Hepatitis B vaccines and to the financial support being given by the Department, totalling £130,000 to date, to developmental work on a new British vaccine, pioneered by Professor Arie Zuckerman, to the Public Health Laboratory Service Centre at Porton Down.

American vaccine, MS(H) said "The positive policy must be to press on to produce a British product at a more realistic price.". Ministers will wish to be aware of the present situation concerning the development of a vaccine against Hepatitis B with British sponsorship.

3. For some years the Department has been supporting research at the London School of Hygiene and Tropical Medicine, under the direction of Professor Zuckerman, on the development of a plasmaderived hepatitis vaccine. This work has given rise to a technique of presenting a vaccine to the body's immune system known as "micelling". Development of the micelle technology has been money well spent, and the technique is likely to have a valuable and widespread application to a number of vaccine products in the future.

The Department had, however, become concerned about the wisdom #f continuing to encourage work directed towards the production of A British plasma-derived micelled hepatitis B vaccine and sought the Fiews of an expert group of advisers. The advice given by this group reflected the view that the work so far on the Zuckerman project in relation to hepatitis plasma-derived vaccine had been overtaken by events. In particular, mention was made of (i) the unwillingness of British manufacturers to be involved with a plasmaderived product (especially due to the emergence of the Acquired Immune Deficiency Syndrome) and (ii) that, simultaneously, developments have occurred in recombinant DNA technology enabling the Hepatitis B surface antigen to be expressed in yeast and other cells. On a realistic forecast of the time necessary to complete the remaining research, development and safety testing of a plasma-derived micelled vaccine (4-5 years), it was clear that in the same period a clinically acceptable and more desirable yeast-derived recombinant DNA vaccine could well become available. There are already British links with companies overseas in developing a synthetic Hepatitis B vaccine and it is now for the British Pharmaceutical Industry to take the initiative. The British Technology Group are funding a collaborative venture between the London School of Hygiene and a Research Institute in Sweden.

5. Officials have concluded that the Department should no longer support the development of a plasma-derived Hepatitis B vaccine for routine use and that no further encouragement or finances should be directed to this end. Professor Zuckerman's basic research in hepatitis generally and in micelling will continue to be encouraged and considered for further research funding. While no guarantee can be given that there will be a British Hepatitis B vaccine in the foreseeable future, it is a distinct possibility. But the pace of such a development will be governed by the interest of the British Pharmaceutical Industry.

6. If Ministers agree, Professor Zuckerman will be informed of the intention to withdraw funding.

	GRO-C
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Ext GRO-C

2 December 1983

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