June p. 423) have been incompletely under-
stood, Sir Hedley accuses us of misreading the description of his life-table analyses. The original article merely states that life-table analyses were carried out, and displays graphs to show the outcomes of these analyses. As no details of the analyses are given it is difficult to see how we could have misconstrued them. From the criteria suggested by Lionel and Herzheimer 1 for assessing the reports of therapeutic trials we must conclude that the report of the trial by Sir Hedley and his colleagues is unsatisfactory, as the statistical tests are not described nor are important results of the analyses given.

Sir Hedley Atkins also glosses over our criticism of the small numbers on which he and his colleagues based their conclusions. It is well known that the effect size in a life-table analysis is greater than the number of patients actually followed up for the maximum length of time, but obviously cannot be greater than the total number of patients studied. We clearly pointed out how unsatisfactory the numbers studied by Sir Hedley and colleagues are even if all the 370 patients had been followed up for the full 10 years.

Now, the valid sequential analysis, by the sign method 2 would have provided a statistical basis for the decision to continue or stop the trial.

Liquor Bilirubin Levels in Rhesus Haemolytic Disease

Sir,—In the interesting paper by Dr. B. R. Pridmore and others (15 July, p. 136) the authors state that "samples contaminated with blood should be discarded and not sent for analysis." However, in our experience valuable information may be obtained from

the examination of red cells containing amniotic fluid. Where the husband is hetero-
ygous for the D-antigen it is important to carry out the Kihlauher-Betke method of staining on these red cells. If significant numbers of fetal cells are present these should then be grouped. The demonstration of a D-negative fetus may prevent further unnecessary investigations, including a repeat of the amniocentesis.

Finally, Sir Hedley seems to have missed both the points in the penultimate paragraph of our earlier letter. Firstly, we pointed out that both the operation and the radiotherapy differed in the two cases, not only the producing confounding of main effects in the trial. Any difference found could be due to the difference in surgery, or in radiotherapy, or to the interaction of the surgery and radiotherapy. The trial carried out by Sir Hedley and his colleagues cannot distinguish among these alternatives, and yet these authors attribute the differences seen to the difference in surgery. The second point made in this paragraph concerned the immunological effects of radiotherapy. The fact that the radiotherapy may have been sub-optimal for tumour destruction does not, as Sir Hedley mistakenly implies, mean that the radiation will have no effect on the immune response. Indeed, a suboptimal dose of radiation may well be the most harmful in that it may damage the immune response more than it damages the tumour.

Now, it would be churlish to suggest that the trial by Sir Hedley and colleagues is of no value, but we remain fully convinced that the accolade awarded to this paper in your leading article may be less undeserved. The unfortunate effects of this high praise on practising surgeons who choose not to read the full trial report can hardly be overemphasized, and it is hoped that a retrogressive drift back to radical mastectomy will not take place.—We are, etc.,

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Was it a Drug?

Sir,—I have for some years now and with scant success been trying to follow Ministerial reasoning as expressed by his appointed referees in cases of "Was it a drug?" as reported in the B.M.J. The latest concerns Allergic prescribed for an infant apparently allergic to ordinary cow's milk, but not to this preparation (Supplement, 29 July, p. 108).

I can remember the days when the general position in such matters was fairly clear. If, outside a hospital, a patient of yours had acquired some special diet or food, however vital, this ranked with warm clothing, and housing as something that could not be prescribed on an E.C.10. Then along came Proplis, whose notions had, I hope, a better effect and apparently still linger on in the minds of the referees. This publication therefore needs close retrospective examination.

It was edited by a distinguished committee, the Joint Standing Committee on the Classification of Proprietary Preparations, and, without any logic that I or anyone I have spoken to can expound, it decided to suggest that the dispensary advice that might be made in the case of substances that otherwise would be considered foods. The only basis I could postulate for these exceptions lay in whether the substance was one of the kind which if seen by a doctor in the conditions when ordered in hospital Proplis made the extraordinary recommendation that Casilin might be considered a drug in cases of biochemically proved hypoprothrombinaemia. One was more than thought that the said Joint Standing committee would have been the first to recognize that such a requirement was nonsense. Hypoprothrombinaemia, broadly speaking, occurs in two conditions. Firstly, when there is excessive loss, as in nephritic syndrome or carcinoma, and, secondly, when there is deficient manufacture, as in liver disease. It does not occur in ordinary starvation. Whatever the cause of hypoprothrombinaemia no amount of prophylactic treatment by mouth can raise it unless the cause can be remedied. It follows that any suggestion that Casilin is given only to raise the blood proteins and is not really a food is absurd.

Proplis and, I have said, I had thought of reasoning has now very rightly been withdrawn. Local medical committees are once more required to make a decision in each case on what seems to them logical and reasonable grounds—above all, one hopes, on principles that are consistent and will give the prescribing practitioner an idea of what to expect. This particular case of Allergic was only briefly mentioned by you. Neither the reasoning of the local medical commit-

TEE nor of the referees was given. Since, however, the local medical committee decided it was a food one must assume that it decided its effect was to promote nutrition, and even if it was specially modified and vitally necessary food it was still a food.

I now challenge the referees to state their thinking in writing. If, as I expect, they fail to do so then we have the right to ask whether they intend to continue making invidious distinctions, as did Proplis, or whether they will allow salt-free butter and bread for patients on a low salt diet, fat-free or fat-substituted milk powder for those on low cholesterol diets, and starch-free and sugar-free foods for diabetics.

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The details of two pregnancies in which this examination has proved valuable are given in the Table. At delivery neither infant was affected by haemolytic disease of the newborn. We consider therefore that it is very important to study some blood-stained

liquors, in particular when the father is heterozygous for the D-antigen.—We are, etc.,

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