3. Inadequate Opportunity for Interested Parties to Participate in MAC Determinations

Under the proposed regulations, the only opportunity for interested persons to participate in MAC determinations, and, if so, at what level, occurs in accordance with Section 19.5(e) after the Board has published its recommendations in the Federal Register. While qualified representatives of the patient, the professions and the industry are promised involvement in the overall program development through participation on the Pharmaceutical Reimbursement Committee, it is not at all clear that the Committee's views will carry any significant weight in the Board's determinations. Indeed, at the November 14, 1974 press conference announcing the MAC proposal, one HEW official reportedly commented that the Committee "will not be officially involved in the decision-making chain".

The generalized representation of broad interests on the Advisory Committee certainly is no substitute for the opportunity of particular parties to take part in specific MAC determinations. Yet, as noted above, such participation, even on an informal basis, would not occur under Section 19.5(e) until after the proposed MAC determination has been published in the Federal Register. But, by that time, the Board, pursuant to Section 19.5(b) and (d), will already have solicited and received the comments of FDA and the Committee. Thus neither FDA nor the Committee will have had the benefit of the views of interested persons at the time that they must render their advice to the Board.

The opportunity for comment by interested persons is inadequate not only in its timing but in its nature as well. Section 19.5(e) directs the Board to invite the submission of written comments, while Section 19.5(f) holds out the possibility of an informal hearing