some 24 firms to discuss bad advertising practices. These had been followed by "remedial" letters, the published details of which are well known to the industry.

Expanding on this, Dr. Goddard read excerpts from the Dynapen promotional letter, one being the claim "notable lack of side effects." He said when the firm exercises the option of calling attention to side effects, it incurs the obligation of presenting a balanced view of side effects. In this case, a few of the more serious side effects should have been named.

Mr. Weeden suggested that the package insert with the letter listing side effects should overcome the fair balance problem. But Dr. Goddard said this was not a replacement for balancing "promotional" side effect information in the subject letter. Dr. McCleery said that the limited experience with the drug at lower dosage levels provides no valid basis for the general claim of lower side effects for the drug.

Messrs. Weeden and Simonton and Dr. Peltier joined in commenting on the concept used in the promotion. They said physicians had been consulted and the result was that they promoted for sites rather than organisms—sites associated with "staph" infections. They said they thought the approved indications had not been exceeded.

Dr. McCleery pointed out that some examples of infections recited in the letter are not typically staphylococus-associated but streptococcus-associated—"impetigo," "cellulitis," "lymphangitis" and "lymphadenitis"—and that some other listed things like "infected skin ulcer," "postoperative infections," "infected wounds, burns and lacerations" could be due to many organisms other than staphylococcus. He referred to the May 1968 issue of the *American Journal of Diseases of Children* in which there was reported a group of 214 patients with impetigo of which 74% was due to Group A streptococcus.

Dr. McCleery emphasized that there is no legal basis within the approved indications for the slogan "specific for skin and soft tissue infections." He indicated that the letter was replete with non sequitur statements, that there were ample opportunities to be clear, but that this was avoided in a well-tailored misleading message. He said the firm even chose to include a dangerous dose recommendation, in that it emphasized a 125 mg dose without stating it was limited for use only for mild-to-moderate (and localized) infections.

An exchange followed between Messrs Simonton and Goodrich in which the latter advised that the letter should have stood on its own, and while the package insert was included, it did not offset the side effect imbalance and, in any event, the letter was inconsistent with the package insert.

Mr. Goodrich then said that when it was learned how much of the drug had been certified (apparently enough for 44,000,000 units), it was apparent that there was a desire to get into the general penicillin market. Mr. Simonton took the opposite position and said an attempt had been made to limit marketing for approved indications.

Dr. Goddard said that the alternate indication seemed to be presenting problems. He said if it became necessary, that the package insert may be revised to delete the second indication, which permits the physician to start the drug without first knowing the identity of the causative organism. He added that the letter did not provide proper guidance and then asked what was the thrust of the journal advertising.

Mr. Weeden said all Dynapen advertising had been stopped but admitted that at least one ad will appear in the Medical World News issue of May 31.

Dr. McCleery reminded the visitors of the continuing disagreement over many months regarding the package insert reference to "strep" and "pneumo," and to the latest FDA move of that paragraph to the end of the indications section. He said that the information was intended not to expand indications but to assist the physician in knowing when it might be safe to prescribe it for the second indication.

The discussion turned to the development of resistance in relation to the letter sentence, "Resistance has not developed during therapy." Dr. McCleery said that the problem of resistance had been handled in a misleading way and called attention to various reports of resistance. When Dr. Peltier stated that "no patient has developed resistance during therapy," Dr. McCleery said this was not true. Dr. Peltier stated that he was not saying there are no resistant strains [which was a reversal of what he had said previously].

Dr. Goddard then said the problem under discussion primarily concerned violation of agreement regarding indications for Dynapen. He requested reports from the visitors as to what the firm is saying to its detail men. He requested