the studies were cited and quoted. The general problem of comunicating with the physician was discussed, as there seemed to be disagreement concerning the effectiveness of "Dear Doctor" letters.

Dr. Ley noted that a periodical to physicians has been suggested and is under consideration. Dr. Dowling urged more signed articles in Journals such as the *JAMA* or the *New England Journal of Medicine.*

Dr. Richardson also supported some form of regular communication.

The "Dear Doctor" letter itself was not discussed further except for Dr. Spink's comment that penicillin itself does not prevent the development of rheumatic fever, as implied in the letter.

The next three speakers discussed the desirability of uniform labeling.

Dr. Edwin Ortiz first described the steps leading up to the uniform labeling of oral contraceptives. The most recent revision of oral contraceptive labeling was in June 1967. Several meetings have been held with the oral contraceptives manufacturers concerning labeling and also one concerning the manner in which effectiveness may be expressed.

Dr. Alan Smith described problems with uniform labeling for tetracyclines. The FDA proposes two package inserts; one for pediatric dosage (liquid), and the other for adults (tablet/capsule dosage forms). The manufacturers of tetracyclines, however, vigorously resist generic labeling and oppose the concept of uniform labeling. They raise various objections, including differences of opinion about the age for the tooth staining warning. Dr. Kirby, who is on the NAS efficacy review committee which is considering tetracyclines, pointed out that physicians are *disease* oriented, not bacteria oriented and recommended the phrase "Diseased, due to ——— organisms" rather than a list of organisms, in the labeling of tetracyclines. Dr. Alan Smith noted that Lederle's Acromycin lists 50 different diseases. Drs. Spink and Morrison concurred that diseases should be listed. Dr. Dowling pointed out that the tooth warning would not be needed in parenteral products and Dr. Kirby agreed.

It appeared to be the consensus of the Board that pediatric and adult labeling inserts should be different, and that one should accompany the liquid and the other the tablet/capsule preparations.

(Dr. Morrison left the meeting)

Dr. Ley noted that on about August 1, the need for developing a recommended format for the package insert was discussed. The Bureau felt that it would be better to develop a set of *guidelines* for package inserts. This would later be useful for a compendium. A Bureau of Medicine committee has deliberated and has set down a tentative suggested outline of labeling guidelines.

Dr. Jennings continued the discussion of the labeling guidelines, reminding the Board that at their previous meeting some of these questions had been described: the wording of pediatric dosages, pregnancy warnings, and the need for detailed pharmacology discussion and bibliographic references. He supported the concept of uniform labeling in that it would convey information and provide education as well as avoid promotional aspects. Dr. Jennings also distributed an example of a package insert (Indocin) as well as revision suggestions for the same drug insert. "The package insert is our principle product," said Dr. Jennings.

Dr. Dowling suggested that under the Adverse Reactions heading a distinction be made between reactions *definitely* established and those *not definitely* established, as was done with the oral contraceptives. He also noted that a long list of reactions to drugs loses its effect, if it is so lengthy.

Dr. Jennings favored a package insert in two parts, the first part having simple directions for use and the second part containing a fuller explanation.

Dr. Ralph Smith noted that there are two different types of uniform labeling: (1) for related drugs (like oral contraceptives, phenothiazides and phenothiazines) and (2) for the same drug put out by a number of firms. The latter is a simpler problem, some of the panels at the National Academy of Science are talking about developing model package inserts for drugs of the latter type. Dr. Smith noted that the format for a package insert is already pretty much standard and has been fairly well accepted by the firms without need for any regulation. Both Dr. Smith and Dr. Ley pointed out that the guidelines for labeling were still in a draft form and did not represent established policy. Dr. Ley solicited the comments of the Board members in the next several weeks, both on the guidelines and on the "Abbreviated" package insert which Dr. Jennings had written for Indocin.