A. Attitude of the Firm

The poor attitude of Merck regarding the advertising regulations has persisted since their promulgation. This is clearly shown in the following passage from attorney Coburn's letter:

> "Regulations 1.105(a)–(e) to the extent they purport to regulate or specify the contents or form of an advertisement for a prescription drug in other respect [except as provided in the statutory langugae of section 502(n)] are, we submit, unauthorized by law and do not constitute an independent basis for determination of whether or not a violation of Section 502(n) has occurred."

In effect, Merck challenges all of the principles of fair balance provided in the existing regulations, and even challenges the Government's authority in respect to requiring ingredient information in advertisements except as specified in 502(n).

We believe that Merck's challenges present a basis for trying the validity of the promulgated-regulations 1.105(a) through (e). Because revisions of the regulations are in process, however, the time may not be advantageous to the Government to proceed toward a Federal Court determination of the validity of the existing regulations, particularly 1.105(e). We are omitting, for the present, comments in rebuttal of Merck's position in respect to the charges on the promotional copy of the ad. We have to say, however, that the Merck position in respect to each of the charges against the promotional message is, in our view, extremely weak should such issues come to trial. We would anticipate reframing charges in relation to the promotional message within the statutory language.

B. Examples of Issues Available Under Section 502(n) Relating to Omissions

1. The statute provides that the advertisement alleged to misbrand the sample must include a true statement of information in brief summary relating to side effects and contraindications.

(a) A charge was that the ad omitted the warning (side effect) information that "As with other anti-inflammatory agents, INDOCIN may mask the signs and symtoms of peptic ulcer."

The respondent implies evasively and erroneously that the contraindication in the ad applying to "active peptic ulcer" satisfied the test of a true statement in relation to the quoted side effect.

The issue is whether that side effect information is in brief summary or otherwise in the ad. We contend that it is not.

(b) A charge was that the ad omitted the warning (side effect) information that "indomethacin itself may cause peptic ulceration or irritation of the gastrointestinal tract."

The respondent claims that the information "is clearly set forth in the advertisement." The claim is untrue.

The issue is whether any information in the ad meets the tests of a true statement with respect to the quoted side effect. We contend that it does not.

A charge was that the ad omitted the precaution (relative contraindication) that "a possible potentiation of the ulcerogenic effect of these drugs [steroids, salicylates, phenylbutazone] cannot be ruled out at present."

The respondent does not deny the omission but uses somewhat unintelligible language to reconcile the omission by stating that the omission "strengthened the specific warning against *any* use of INDOCIN in the presence of the conditions stated, with or without other agents."

The issue is whether the quoted precaution is omitted from the ad. We contend that it is.

(d) A charge was that the ad omitted side effect information concerning a list of specific side effects which included, among others:

> (1) nausea, anorexia, vomiting, epigastrict distress, abdominal pain, diarrhea, gastritis; and
>
> (2) angioneurotic edema, rashes, acute respiratory distress, purpura, thrombocytopenia.

The respondent does not deny the specific omissions but attempts to reconcile the omissions by stating that the side effects (1) were included under the "general side effect of 'G.I. disturbances'" and that the side effects (2) were included under the "general side effect of 'hypersensitivity reactions.'"