

in continuous prolonged therapy for 6 months, whereas the article reported in fact that Esidrix-K was not administered continuously over that period, but was given intermittently, two weeks on and two weeks off during the first 3 months and thereafter only as required.

2. The advertisement in the September 21, 1964 edition of the Journal of the American Medical Association failed to present a brief summary relating to side effects, contraindications and effectiveness of the drug Esidrix-K as follows:

(a) The advertisement omits the following essential information:

(1) That the drug potentiates the antihypertensive effect of other agents, that additions of such agents should be gradual, and that dosages of ganglionic blockers, in particular, should be halved.

(2) That some of the factors predisposing to hypokalemia (hypopotassemia) are intensive and prolonged diuretic therapy, restricted sodium chloride intake, and corticosteroid therapy.

(3) That "In severe hypokalemia, large oral doses of potassium may be necessary to correct the deficit" and "Since these tablets may not provide all the potassium required by some patients, a diet rich in this element will help obviate depletion."

(b) In the statement "Important . . . for doctors who want to be sure their patients on diuretic antihypertensive therapy have potassium protection: Be sure to prescribe Esidrix-K . . ." the advertisement does not fairly show the effectiveness of the drug and lacks fair balance in presenting information as to such effectiveness, since it implies that the drug, in recommended dosage, can prevent or correct potassium electrolyte imbalance in all patients, while in fact there are some patients who may not be protected at all from potassium imbalance by the highest recommended daily dose of Esidrix-K.

(c) The advertisement claims that Esidrix-K "dissolves consistently and completely in intestinal juices within 17 to 20 minutes . . .", accompanied by a sketch of part of the gastrointestinal tract, thereby implying, unfairly and falsely, that this dissolution occurs in intestinal fluid within the intestines of patients, contrary to results of investigations made by defendant which report that the earliest complete disintegration time of Esidrix-K observed in the actual intestines of a patient was two hours.

COUNT 2

1. The mailing piece was not substantially the same as the labeling authorized by the approved new drug application effective with respect to the drug Esidrix in the following respects:

(a) The combined therapy warning set out above in Count 1, g1(b) is omitted.

(b) The mailing piece distorts scientific reports to an extent that they appear to say something that was not in fact reported, as follows:

(1) The findings reported in the 1959 article by Hejtmancik, Hapmann and Kroetz (Reference No. 4) are misrepresented so as to exaggerate efficacy, in part by failing to mention that 7 of the 19 patients referred to were given a daily maintenance dose of 50 mg. three times daily, contrary to the claim that "Effective maintenance dosage was 50 mg. twice daily," and further, that these 7 patients were given an initial dose of 300 mg. rather than the recommended initial dose of 50-100 mg.; and the mailing piece further fails to mention that the authors' patients suffered such side effects as depression of serum potassium levels below normal, including one case of clinical hypopotassemia with marked weakness, and elevation of blood urea nitrogen levels, which prompted the authors to warn that "the rise in the values of blood urea nitrogen observed in some indicate a need for caution in the administration of this drug."

(2) The mailing piece reports only the satisfactory clinical responses noted in the 1959 article by Zuspan, Barnes and Bell (Reference No. 5), but fails to mention the unsatisfactory effects reported by the authors, including the fact that 18% of the group of patients treated with the drug experienced adverse reactions, as compared to no adverse reactions among a group receiving a placebo.

(3) The mailing piece quotes the 1959 article of Kemp and Findley (Reference No. 7) to show that Esidrix is "completely effective" in treat-