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FDA Is Probing Merck Division

FIRM COULD FACE CRIMINAL PROSECUTION OVER AD FOR ARTHRITIS DRUG

(By Morton Mintz)

The maker of Indocin, a drug widely prescribed for arthritic disorders, has appeared at a closed hearing to show cause why the company should not be criminally prosecuted for an Indocin advertisement.

The firm, Merck, Sharp & Dohme, a division of Merck & Co., Inc., confirmed that an informal hearing was held recently by the Food and Drug Administration's district office in Philadelphia. The company said comment on the substance of the discussion would be inappropriate.

The advertisement appeared several times last year in the Journal of the American Medical Association. Its headline said Indocin (indomethacin) "extends the margin of safety in long-term management of arthritic disorders."

CITED BY FDA COUNSEL

That headline was cited last October by William W. Goodrich, FDA's chief counsel, in a speech in Manhattan.

"There is not yet enough experience to support the claim for greater long-term safety," he told the Pharmaceutical Advertising Club. "To the contrary, the longer the drug is used, the more side-effect information appears."

Goodrich mentioned Indocin in the course of criticizing promotions of the "Big Eight" prescription drugs—a group of drugs and antibiotics, including indomethacin, that entered the market in 1965 and within 12 months had become among the 200 drugs most frequently prescribed.

Like most new drugs, the official said, Indocin was asserted to be safer and more effective than existing products in the same therapeutic group. But as experience has accumulated, he said, "more side effects have been noted and more warning information has been required."

In response to an inquiry, FDA said it knows of 16 deaths and 303 side reactions among Indocin patients.

ASSOCIATION WITH DRUG

Seven of the dead were children, the agency said. Only one of these deaths was said to have had a clear-cut association with Indocin. In another, the association was regarded as questionable. In the remainder, it was regarded as dubious, because the children had had severe illnesses and had been treated with other medicines.

The nine adults had had long-standing rheumatoid arthritis and were, FDA said, in an age group over 50. The deaths of three of them were said by FDA to have had a "possibly clear-cut" relation with Indocin. Such a relation was doubted in the others, all of whom had had major, pre-existing complications.

In another complaint about the AMA Journal ad for Indocin, Goodrich told the Advertising Club that the ad quoted "authoritative sources, without the full impact of the actual articles."

He pointed to a claim of usefulness for Indocin in arthritis of the spine ("anklosing spondylitis"). The claim is supported by a reference. A physician who checked it out. Goodrich said, would find that the reference was to a 2-inch abstract of a speech made in 1964.

In addition, Goodrich said, the ad failed to cite this statement in the abstract: "Excellent results have also been obtained in some cases of rheumatoid arthritis . . . there have been some striking failures as well."

A third complaint made by the agency counsel was that the ad "omits some very important warning information that is required" in the authorized prescribing instruction—the brochure enclosed with every package of a drug.

In West Point, Pa., a Merck, Sharp & Dohme spokesman said:

"It is our judgment, based on the facts of Indocin use, that this new anti-arthritic agent does not suffer from certain disadvantages such as the production of hormonal side effects and certain blood dyscracias which do occur with some of the other agents previously available. In this way it has extended the margin of safety in the long-term management of arthritic disorders."

Since the Goodrich speech FDA has refused to comment on the closed hearing or on the possibility of prosecution. Except where data are requested by Congress,