

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13423

PRESENTATION OF
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to the
FDA HEARINGS ON PROPOSED LABELLING FOR DIABETES DRUGS

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It is now more than 5 years since the findings of the University Group Diabetes Program (UGDP) were presented at the American Diabetes Association annual meeting. Despite the findings of increased cardiovascular mortality in patients taking oral diabetes drugs and their lack of efficacy, their use has continued. Over the last 5 years, however, several of the largest diabetes treatment centers have swung strongly away from using these agents.

The question is, why are 1 1/2 million American adult onset diabetics being given drugs costing more than 100 million dollars per year, killing an estimated 10-15,000 patients per year and not having any demonstrable benefits in treating diabetes?

There are three reasons which appear to explain this irrational state of affairs:

1. The pride of physicians
2. The inadequacy of most diet programs for diabetics
3. The profits of the drug industry

1) Pride

As candidly stated this year by Dr. Frank Davidoff -- Professor of Medicine and diabetes specialist for the University of Connecticut Medical School -- and probably unspoken but thought by thousands of other physicians, pride plays a major role in the continued prescribing of these drugs by doctors in the face of evidence to the contrary. (Testimony - Sept. 19, 1974, Senate Small Business Subcommittee).

"It is one thing to challenge the safety of a drug . . . But to be told that the drugs we had been giving to diabetics for 12 years were unnecessary, beside the point, in a word ineffective, was, as I see it, a more serious blow to our professional pride." We submit that the pride of doctors is standing in the way of giving the best treatment to their patients and that this is irresponsible medicine if not malpractice.

2) Inadequate Diet Programs for Diabetics

According to Dr. Ethan Sims, diabetes specialist and Professor of Medicine at the University of Vermont Medical School,

"If we grant that there are 1 1/2 million patients reportedly taking oral agents and that 50% are grossly overweight, we have 750,000 patients with diabetes and obesity who are probably also less physically active than they should be. If we assume that 90% of them are not exposed to any vigorous and comprehensive regimen such as that at the Grady Hospital, 675,000 are left with their obesity essentially untreated and 4 out of 5 are taking an agent which increases their obesity. The taking of oral medication lulls both physician and patient into believing that something worthwhile is being accomplished, while the options which could