

Editorial

Patentable vs. Non-patentable Treatment

Last year I sent a letter to *Therapeutics Initiative*, University of British Columbia, Department of Pharmacology and Therapeutics in response to their report on "Lipid Lowering Therapy." So far they have not deigned to respond to me. Niacin is not patentable for lowering cholesterol. It could have been patented in 1954 but the Government of Saskatchewan, for whom I was working, would not permit me to do so. Had I been wiser and more experienced I would have done so anyway. The commercial drugs are all patented, owned by a drug company and are fiercely and fearlessly promoted and defended. I felt that the text of this letter would be of interest to JOM readers.

Comments on Therapeutics Letter

The recent report "Lipid Lowering Therapy" published in *Therapeutics Initiative* for April/May 1998 is biased against niacin and for the xenobiotic drugs so highly touted in the medical literature by their owners. There is no patent on the use of niacin and therefore no one really takes any great interest in presenting its therapeutic efficacy and side effects fairly.

Efficacy

In presenting the evidence that one of the statins has value in helping to control heart disease, the authors combine myocardial infarction and cardiovascular disease to yield 13.5% in patients on the drug, and 21.5% for patients on placebo. For total mortality in women, there was little difference between the two groups (6.9% for the statin and 6.0% for placebo). Where is the corresponding figure for the men? With the second statin, total mortality was again similar for both groups. Therefore the major difference was in the incidence of myocardial infarction. Surely the mortality figure is much more relevant and should have been listed for all the groups.

Niacin reduced total mortality by nearly

11% while none of the other substances were better than placebo. Both MI and CV are again lumped together. Also the authors failed to report that the niacin group lived on average two years longer, even though for most of these patients the niacin had been discontinued some years previously. No mention is made of the fact that niacin, being a B vitamin, has virtues far above what one would expect from drugs.

Side Effects

The overall incidence of side effects from the statins was about the same as it was for the placebo group. These are compared as if the side effects commonly seen with placebo are identical with the side effects produced by drugs. It is extremely unlikely that the side effects commonly found in placebo studies which are short lived, innocuous and of little consequence can be equated with the side effects of drugs. With niacin they listed several effects. The vasodilatation (flushing) is not a side effect. It is an essential effect of the niacin as a general vasodilator. Cutaneous reactions include browning of the skin, especially in the flexor surfaces. It occurs most often in schizophrenic patients. This is totally safe and usually is gone within a matter of months or years, leaving normal, even healthier skin behind. Gastrointestinal problems are uncommon and minimized by taking the niacin immediately after eating. Gout is listed as a side effect. I have used niacin, since we first discovered it lowered cholesterol levels in 1955¹ and have given it to well over 4,000 patients. I have not seen a single case of gout. In fact I have given it to patients with gout who are no better nor worse while on niacin and respond to the usual medication for gout. I have not seen cases of atrial fibrillation.

It is a general rule that physicians comfortable with niacin and who appreciate its therapeutic properties have very little problem with it and their patients have very few side effects. When they occur, they are eas-

ily dealt with. Physicians who know little about niacin, mistrust it, and their patients have much more trouble with it. Their mistrust will be further reinforced by this biased report.

For the few who can not tolerate niacin, one can use inositol hexaniacinate. This preparation has all the therapeutic advantages of niacin and none of the side effects. It is available in health food stores as No Flush Niacin. It costs three times as much as niacin, i.e. \$15 per month, but this is still much better than the cheapest statins which cost \$45 per month and the most expensive which costs \$150 per month. Drug coverage plans would be wise to achieve some of this saving and, even more important, improve the health of the patients. Drug plans should cover inositol hexaniacinate as they now cover niacin.

Statins have no beneficial side effects. They lower cholesterol, but have little effect on the other lipids, do not enhance health, decrease MI and perhaps extend life.

Niacin, the vitamin, has an enormous number of beneficial side effects. These are discussed in McCracken's book,² which should have been read before issuing the report.

In avoiding a detailed outline of the side effect of the statins you omitted one that may be most serious and will appear with continued use. It inhibits the synthesis of coenzyme Q10. Since most elderly people and most sick people tend to be short in this vitamin substance, the statins will add to the burden.

Taking all these factors into account and considering the tremendous savings in money for individuals and health plans, all physicians should be encouraged to use niacin. In the United States, patients who do not have drug coverage are encouraged to use niacin. In Canada where physicians do not think about drug costs and where they are almost totally unfamiliar with niacin they prefer to use the statins. Of course, niacin is not conveyed to doctors via expensive and beautiful advertisements

and by enthusiastic detail people.

Since writing this letter I received William B. Parsons, Jr. book *Cholesterol Control Without Diet. The Niacin Solution.*³ This is the best book ever written which describes the relationship between niacin and blood fats. Dr. Parsons was the first physician outside of Saskatchewan to use niacin for lowering cholesterol and is one of the foremost authorities in the world, having studied and used it since 1955. In contrast to the statins, which are expensive, do not have the same wide therapeutic properties compared to niacin and have no the track record or decades of observation, niacin is hardly known to the average physician, especially in Canada where drug plans carry some of the costs. In sharp contrast niacin lowers total cholesterol, lowers the low density lipoproteins, lowers triglycerides, and elevates the high density lipoproteins, has been used for decades and is the only compound that decreases mortality and increases life span of people who already suffered their first coronary. Dr Parsons describes the techniques used by drug companies to promote their own products and the techniques used by medical journals to assist them.

Obviously there are two main classes of compounds (1) the patented drugs and (2) the non-patented compounds. With few exceptions, non-patentable drugs have extreme difficulty become generally accepted. This applies to all the nutrients and very few drugs. Lithium is an example of one that was promoted by the NIH and which achieved its present status because of their interest in treating manic depressive psychotics. In sharp contrast, patented drugs, even the ones that have hardly any therapeutic value and have serious long term side effects, can, with proper advertising, become very common and will replace any previous, even better, non-patentable compound. Thus the synthetic thyroid preparation replaced desiccated thyroid.

I have no solution to this quandary. If

the patent system did not exist we would have not the synthetic drugs we have today. A few are essential but most should never have been brought to market. If every compound could be patented, the nutrients and the beneficial herbs could compete with the synthetic drugs but this would make the nutrients much more expensive. Surely modern society should have the wit to develop systems which would allow the widespread use of all therapeutic compounds whether or not they are patented. Perhaps with the present system there should be a independent health agency with no ties to the

industry, to the profession or to Universities to properly evaluate and then promoted the compounds that are safe, effective and cheap.

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References

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2. McCracken, Robert D: *Niacin and Human Health Disorders*. Fort Collins, CO. Hygea Publishing Co. 1994.
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