

EDITOR'S PAGE

OTC or not OTC—That Is the Question

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One of the quiet revolutions occurring in the pharmaceutical industry has been the transformation of prescription drugs to over-the-counter (OTC) medications. I remember when the H₂ blockers were first introduced OTC; I was amazed that such a class of drugs could make that transformation. Many of the NSAIDs followed suit, and now it seems that many others are poised to do the same thing. The potential for long-term pharmaceutical company profit is staggering.

A few years ago, while talking to pharmaceutical company leaders, I was informed that they had made corporate decisions to spend more and more of their advertising budget on ads that went directly to the consumer, including television, magazines, etc. At the time, I was concerned about the decrease in advertising revenue for *JACC*, which, by the way, has occurred. Although companies still advertise new drugs in the medical journals, they have shifted their advertising for established drugs to the general public. The appearance on television of noted people such as Bob Dole and Dan Reeves has enhanced the anecdotal power of this advertising. The closing statement of these ads, which used to say, "See your doctor," may soon say, "Available in your neighborhood drugstore."

Current examples of this transformation are the statin drugs. A recent FDA hearing heard testimony pro and con about proposed OTC drugs in general, and especially the statins. There are interesting arguments for making the statins available OTC. They have been extremely beneficial drugs for both primary and secondary prevention of coronary artery disease. They have reduced morbidity and mortality while, at the same time, they have been remarkably free from side effects and serious adverse reactions. The public is very interested in taking charge of their own health these days. The wave of "dot coms" that provide medical information and advice urges individuals to take charge of their own well-being. The billions spent each year in this country on vitamins, minerals, herbs, and other alternative therapies attest to the almost insatiable desire of many Americans to prevent disease and to treat themselves. Of course, the statins would be offered in low dose (equivalent to 10 mg lovastatin), as are all OTC medications, but this still might help in lowering LDL cholesterol. Instructions would be included about lifestyle changes (especially diet and exercise) and the need for lab measurements and physician input into the process.

Arguments against OTC use can also be persuasive.

Although they are remarkably side effect-free, the statins do have an occasional downside, including liver and skeletal muscle toxicity. These can generally be discovered only by blood tests, and it is unclear how many patients will actually get their blood drawn. Previous OTC medicines (e.g., H₂ blockers and NSAIDs) frequently had measurable symptomatic end points that allowed OTC users to judge dosing and efficacy, making them easier to use appropriately. No such clinical feedback is available with the statins, which are meant to prevent disease in asymptomatic individuals. A similar FDA review is underway to consider providing certain antihypertensive drugs OTC to control blood pressure, another asymptomatic syndrome. The side effect profile of certain antihypertensive agents may make this decision more problematic. Will patients buy blood-pressure measuring devices, or will they get their blood pressure checked regularly in their local drugstore or mall? Will patients regularly get their blood measured (up to a year) for liver enzymes and lipids if they are on statin drugs?

Another issue with OTC statins is whether or not some individuals will be falsely reassured by being on a statin drug, when they really need far higher doses. An equivalent dose of 10 mg lovastatin pales next to doses of 80 mg, which have been used in some clinical trials. If patients elected to use multiple 10 mg doses, they might pay much more than the equivalent prescription dose because some manufacturers have flat pricing across all their prescription doses. Furthermore, depending on their insurance coverage, consumers may get prescription drugs for a copayment that is much less than the price of OTC drugs, for which they must pay out of their pockets. This may result in consumers paying too much for ineffective dose levels. This is exactly the circumstance decried for the natural herbs and supplements—too little "bang for the buck." Although OTC instructions would include advice about the necessity of physician monitoring, this is no different from current practice, wherein patients receive prescriptions from their physicians and are followed in the office. Our current practice seems to avoid the pitfalls outlined above for OTC medications.

Our primary responsibility as physicians is to put our patients' health and well-being above all other considerations. Protection of the patient is implicit in that responsibility, as is optimum care. At the present time, I believe that a caring and informed physician can provide an edge in optimum care and safety that even the best intentioned and

well-informed patient cannot match. It seems self-evident that not all drugs should reach OTC status. The real question, therefore, is where to draw the line. That is the current FDA challenge. Hopefully, physicians and medical societies will offer appropriate input into this quiet revolution. There are no black or white answers, but the gray zone has the capacity to dramatically transform medical care

forever. We have the opportunity to make sure that the risk/benefit ratio markedly favors patient well-being.

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