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FDA Public Forum Meeting
June 28-29, 2000

Testimony of Lorie Rice, MPH

Thank you for the opportunity to speak with you today. My name is Lorie Rice and I am here to convey my perspective of key issues in the consideration of cholesterol lowering drugs for OTC status.

It has been a while since I participated in an FDA hearing. I can tell you now that it is much easier to participate on the other side of the microphone. Before I begin, I want to disclose that I serve as a consultant to Bristol Myers Squibb. My full time job is the Associate Dean of External Affairs and Assistant Clinical Professor at the University of California, San Francisco School of Pharmacy. I teach pharmacy law and ethics. My comments today, however, are my own - neither those of Bristol Myers Squibb nor UCSF.

I served as a consumer representative on the initial NDAC for four years. It was both an honor and a marvelous learning experience. Representing consumers, however, was not a new experience for me. In California, I was the Executive Officer of the State Board of Pharmacy for 7 years, and then served as a consumer representative on the State Board of Behavioral Sciences. In May, I was appointed by the Governor to serve on the State Medical Board - again as a consumer representative. I take these responsibilities with utmost seriousness.

This is an excellent time to be a consumer representative. Consumers themselves are becoming more vocal and more engaged. This is particularly true in the area of health care or "self care" as it has become referred to commonly. The reasons for their involvement come as no surprise.

First, the rise of managed care has, to a large extent, depersonalized health care and made it challenging for patients to get quick responses to their health care needs. Also, every day consumers find more products and more information at their fingertips, or, at the

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click of their mouse. Many adults rely on multiple sources for their health information – such as television, magazines and journals.

The explosive use of the Internet also has provided a readily accessible method of disseminating and retrieving information on everything from herbal “cures” for hair loss to the molecular structure of antidepressants. It is no wonder then that consumers are making personal decisions about their health care after gathering information from a variety of sources – some that are reputable and some that are not. The simple fact is that consumers are seizing these opportunities of involvement and all indications are that this trend is unstoppable.

For example, consumer use and interest in alternative medicine is at an all time high. A recent survey in JAMA found that 42 percent of Americans used some form of alternative therapy in 1997 at a cost of nearly \$30 billion in unreimbursed expenses. Between 1990 and 1997, patient visits to primary care physicians remained constant, but their decision to visit complementary and alternative medical practitioners increased by almost 50 percent. This same study noted that almost one in five adults taking prescription medicine also was taking herbal products and/or high dose vitamins. Consumers pursue these options because they perceive them to be effective and because they are congruent with their values and beliefs about health.

In recognition of this consumer demand for information and newer and better ways of participation in their own care, the University of California, San Francisco has recently established the Center for Responsible Self Care.

We all are familiar with and appreciative of the options now afforded the consumer with the many switches over the last several years of prescription drugs to the non-prescription category. When I was a committee member, we evaluated data on safety and efficacy and weighed the benefit/risk for products proposed for OTC status to fill unmet needs. Some of these expanded the definitions of “OTC-ness”. As a result, the consumer has

been given even more choices of self-care remedies; and these, to our benefit, have all met the standards required by the FDA.

Today, and in July, it will be up to you, as well, to help consumers as they continue their effort to help themselves. Along with many others, I look forward to your next meeting when you will have a unique and, indeed, historic opportunity to consider, case by case, whether an approved cholesterol lowering drug should be made more accessible to an eagerly awaiting consumer population.

During those deliberations, there are specific issues, which I ask you to give special consideration. These are the points that I would be thinking about if I were sitting on the other side of the table. I was educated on these points during my tenure on the NDAC and, in fact the committee's diligent application of these criteria were critical for each and every OTC switch.

First, please remember that consumers want to become involved in their own health care and once they decide to do so, they will begin to try a variety of different options; they should be given this choice with products that clearly demonstrate predictable safety and efficacy.

Second, it is imperative that labeling directions provide all the information a consumer needs in order to decide whether the product is appropriate, and certainly when and how to initiate and continue administration. I think that you can feel confident if you are provided with data reflecting a high level of label comprehension in a study of a broad based population.

Third, and equally as important, you must be assured that consumers can not only read and understand the directions for use, but that they also will follow the label message. This must be illustrated by consumer use trials.

Fourth, especially in cases such as cholesterol lowering drugs, you must be convinced that the doctor-patient dialogue is maintained. A sponsor must present research that provides convincing evidence of minimal interference in that relationship.

Lastly, please be prepared to consider the related and significant benefits that a switch could afford the target population. This was always an important issue for me. Examples include: the facilitation of entrance into the health care system, the enhancement of the doctor-patient relationship, and the full array of otherwise unavailable consumer education programs, which increase health education for the individual and the population at large.

If, upon reflection, a candidate meets these criteria, in a data driven manner, you should be persuaded that that drug is suitable for OTC availability as a contribution and compliment to their total health care.

Thank you.