Perspective

The Wright Stuff

by Stephen J. Hellebusch, PhD

At the recent Nonprescription Drug Manufacturers Association conference on "The Future of OTCness: A Data Driven Process," Curtis Wright, MD, MPH, formerly of FDA, pointed out that the requirement FDA has for approving a prescription-to-nonprescription switch is "S3" — safety, safety, safety.

He noted that consumers regularly purchase very dangerous products in other areas of life. Most telling was his point that your local gas station will cheerfully sell you a powerful explosive inexpensively and with no identification required.

Dr. Wright also discussed FDA's decision to switch nicotine replacement therapy (NRT) products. He said research has demonstrated that physicians have not performed as one would hope or expect, relative to these products. The net impact of several studies strongly suggested that the over-the-counter (OTC) package worked at least as well as, perhaps better than, the prescription product plus doctor involvement. Given the increased access among the large group of smokers (more than half[1]) who said they were "very" or "somewhat unlikely" to go to a doctor for smoking cessation, the logic for approving these switches was compelling.

I was very involved in the switches of Nicorette and Nicoderm from prescription to OTC. As an agent of SmithKline Beecham Consumer Healthcare, I was in charge of executing and reporting four Phase IV prescription quit-rate studies (the studies to which Dr. Wright referred).

Using a database of a national pharmacy retailer, we contacted those who had received a first prescription for the NRT product. Subjects were mailed letters that did not mention the topic of the study, and they could call us or not, as they chose. Only the retailer, who already had the information, knew the names of those receiving letters. These pivotal studies were accepted by FDA as supporting the rationale for switching Nicorette and Nicoderm.

This design, used to estimate quit rates at six weeks and at six months, with carbon monoxide verification, was chosen as much more realistic than the alternative - having a doctor available and randomly assigning subjects to a prescription or OTC cell. That design was considered unrealistic, because it would not leverage the doctor-patient relationship.

Dr. Wright was correct in his assessment that physicians were not performing as one would hope in this important area of preventative medicine. We took the opportunity, while these prescription users were on the telephone, to ask them about how their doctor had counseled them in their quit attempts. Let me cite a few facts from one of the studies.[2]

Seven in 10 of the 142 subjects in this study claimed it was their idea to get a prescription for Nicorette. More than a fourth did not see the doctor in person, but requested the prescription over the phone. Excluding the 16% who say the doctor never spoke with them about their attempt to quit smoking, the average time the doctor spent was about 10 minutes. All were asked if they had follow-up conversations with the doctor; 81% said "no."

I believe each switch is unique. It may be, as Dr. Robert Temple implied in disagreeing with Dr. Wright, that sometimes a bad doctor is better than a good OTC package. But, as these NRT data show, there also are cases in which it is hard to imagine a good OTC package being worse than an uninvolved physician.

Notes

1 Smoker Domain Study. On file at Hellebusch Research & Consulting

2 Six-Week "Average Rx" Smoking Cessation Rates for Persons Filling Nicorette Prescriptions Study (October 1994). On file at Q2.

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