APPENDIX 1
STUDIES ON THE PREDICTABILITY OF OTC HEARTBURN

Consumer Research Diary Study on Heartburn Prediction Accuracy

A 14-day consumer research study was performed: the objective of this study was to assess the accuracy of the predictions of adult male and female heartburn sufferers who claimed to be able to predict their heartburn in advance at least some of the time. The results indicated that consumers are highly accurate on days when they predict heartburn. Therefore, a low projected rate of "needless dosing" would be expected on days consumers take medication because they predict heartburn will occur.

Methods

Subjects were heartburn sufferers who claimed to be able to predict their heartburn at least some of the time. Out of 227 subjects who provided diary information, 213 provided demographic information. Half (50%) of the subjects were male and half were female. Age ranged from 18–65 or over and 95% were Caucasian. The subjects came from a range of geographic locations in the US.

Subjects were not allowed heartburn prevention medication, but they were permitted to treat heartburn symptoms with the product of their choice after symptoms started. Over the course of 14 days, subjects recorded information on predicted and actual heartburn episodes in a diary.

For each day, subjects were asked to predict within 1 hour of waking whether or not they would experience heartburn, and also to predict the factors that might be associated with it (i.e., food/beverage, exercise/physical activity, stress, overeating/overindulgence, smoking, medication, lying down soon after eating, hectic lifestyle, fatigue/lack of sleep, or an unlisted cause). They were permitted to revise their judgment later, providing they noted the time of revision and the new associated factor of prediction. Subjects were instructed to record the time heartburn symptoms started and the factors that contributed to each episode.

The diary data were analyzed by diary day for the following:[237]

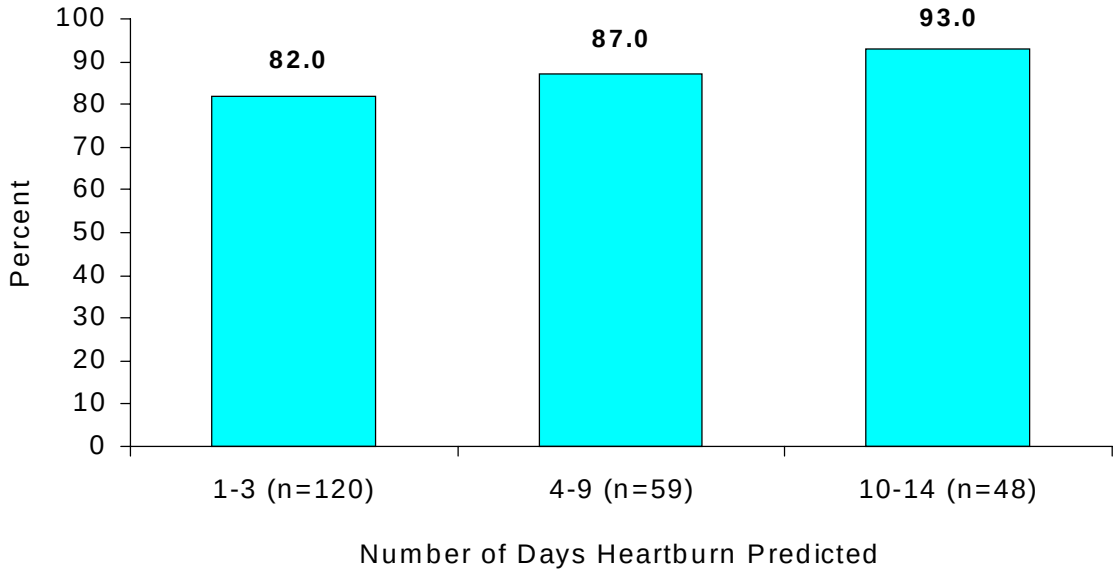
- sensitivity (% of subjects with heartburn who correctly predicted the episode)
- specificity (% of subjects without heartburn who correctly predicted they would not experience heartburn)
- positive predictive value (% of subjects who predicted and actually experienced heartburn)
- negative predictive value (% of subjects who did not predict and did not experience heartburn)
- total percentage correct
- prevalence (% subjects who experienced heartburn)

Results

A primary finding of this study was the generally high accuracy when subjects predicted that they would have heartburn. The key parameter for establishing this trend was positive predictive value. This measure (the percentage of those predicting heartburn who actually experienced symptoms) is significant because it suggests the rate at which those who would likely have prevented heartburn would be correct to do so.

As Figure A1 indicates, subjects had high positive predictive value scores regardless of how many days on which they predicted heartburn during the 2-week period.

FIGURE A1
POSITIVE PREDICTIVE VALUE SCORES FOR SUBJECTS BY NUMBER OF DAYS PREDICTING HEARTBURN (AVERAGE ACROSS ALL DAYS)



In-House Research Study on Heartburn Prediction Accuracy

Concurrent to the above study, a 10-day study conducted among P&G employees further tested consumers' accuracy at predicting heartburn. Twenty-two (22) subjects who claimed to be able to predict heartburn were entered into the study, which had a similar design, except that diary data were confirmed with a daily telephone call to the study site's voice message system. Calls were made within 1 hour of the prediction and noted the factors associated with the anticipated heartburn. A later call noted whether the heartburn occurred.

Study results for this telephone-recorded study corroborate those of the larger, diary-based trial. The average positive predictive value for the study was 83%.

Conclusions

The results of these two studies indicate clearly that consumers are accurate when they predict heartburn. In the consumer study, the subjects predicted heartburn on average of 4.9 days over the 14-day study and were correct 90% of the time. In the in-house study, subjects predicted 4.2 days of heartburn on average over the 10-day study and were correct 83% of the time. Overall, the accuracy of these predictions in both studies suggests that there would be a low rate of "needless dosing" when consumers take steps to prevent heartburn.