

INDUSTRY PRACTICES REVIEW COMMITTEE

Report on Infractions #55 – November 1, 2004 to December 31, 2004

1 Company and issue: Fujisawa Canada Inc. Invitation to a health sciences centre transplant team to view a baseball game from a Skybox on June 8, 2004.

Discussion: The company advised that the total number of individuals who attended was 12 and that number included five healthcare professionals, two coordinators, one corporate representative, and four children. In discussing the matter, members of the Committee noted that, as provided for in the Code: *“The purpose of any social interaction between Rx&D members and healthcare practitioners must be building and enhancing the business relationship in an ethical and professional manner.”* In that regard, Committee members affirmed that children cannot be considered as individuals with whom the industry would build a *“business relationship.”*

Decision: Contravention of Section 7B.1.3 which states that in providing hospitality, companies must convene groupings no larger than three customers to one pharmaceutical representative. The company was also advised of the inappropriateness of including children in such social interactions.

2. Company and issue: Lundbeck Canada Inc. Event entitled *“Market Research Focus Group on Progression in SSRI Therapy”* held June 2, 2004 at Ruth Chris’ Steakhouse, Mississauga, Ontario.

Discussion: The invitation to the event described it as consisting *“of one to one and one-half hours of interactive discussions, presentations, and workshops geared to gain market research information on a new anti-depressant therapy,”* and it offered an honorarium of \$250. to each participant *“for their consultative services during the session.”* The agenda read as follows: *“Welcome, introductions and pre-meeting profiling 6:15 – 7:00, Escitalopram Clinical Presentation 7:00 – 7:45, break 7:45 – 8:00, Discussion: Treatment Goals and Successful Outcomes in Depression 8:00 – 8:30, Breakout session: Building a SWOT for Escitalopram, and Post-meeting Evaluation 8:45- 9:00.”* A third party healthcare communications company handled *“the research and consultative session content, facilitation, participant management and compilation of results.”* As the product in question was not, at the time, on the Canadian market, a corporate representative presented *“a brief clinical overview of the core clinical trials and mode of action so that the participants would have a basic understanding of the product profile.”*

The company confirmed that *“participants were asked for their feedback on the ideal messaging and positioning for Escitalopram, based on its clinical profile and the current treatment gaps in the antidepressant market. “Information was collected through group discussion, as well as a pre and post meeting written feedback form.”* The Pre-meeting Profile form asked for comment on the following statement: *“It is my hope that the information provided today will demonstrate that Escitalopram, a new treatment option, will offer benefits to my patients above traditional therapy.”* The final question on the Feedback form asked participants to *“rank the following products (Celexa, Escitalopram, Effexor, and Paxil) in terms of their benefit to patients in your practice: 1 – Most Beneficial, 2-Beneficial, 3-Slightly beneficial, and 4-Least Beneficial.”*

Members of the Committee found that while the event was designated “*market research*”, it actually combined two types of activity – market research and an advisory board. They also noted that one-half of the meeting was devoted to discussion of Lundbeck’s product Escitalopram, a medicine not yet granted a Notice of Compliance by Health Canada. While ruling that some overview of the product was warranted in order to provide a framework for discussion, the Committee felt the lengthy discussion of Escitalopram constituted promotion of a medicine before the issuance of an NOC when, in fact, the information could have been obtained by simply identifying the product as a new antidepressant in development by Lundbeck. They also felt that the same rationale applied to the company’s use of the product’s name in the statement (quoted above) “*It is my hope that the information provided today will demonstrate that Escitalopram...*”

Decision: Contravention of Section 12.2.3 which states that “*market research must not deliberately sway the opinion(s) of the participant(s).*”

3. Company and issue: Pfizer Canada Inc. Activity entitled “*Dyslipidemia Practice-Based Learning Program – Focus on the Diabetic Patient.*”

Discussion: According to the company’s documentation the program was “*designed to allow primary care physicians to review patients’ charts and optimally implement the Canadian Working Group Guidelines (Recommendations for the management and treatment of dyslipidemia) towards achieving optimal levels of blood lipids including LDL-Cholesterol, Triglycerides and the ratio of Total Cholesterol to HDL-Cholesterol in as many patients as possible.*” The covering “*Dear Doctor*” letter in the documentation kit stated that “*the program is a unique educational experience and a valuable component to your continuing professional development.*” It also stated that “*the primary objective of the Practice-Based Learning Program is to examine the day-to-day practice patterns of physicians, specifically the optimal management of patients with dyslipidemia.*”

As part of the Program, physicians agreed to review 25 of their charts, for those male patients aged forty years or older, and those female patients aged 50 years or older over the course of eight weeks. On completion, the forms were to be forwarded to a third party organization “*for compilation, analysis and the production of a report for you containing individual data collected from your practice and aggregate data collected from all participants in Canada.*” On receipt of 25 “*fully and properly completed forms,*” participants were paid an honorarium of \$375.00. The Honoraria Form also included the following statement: “*I would like to lead a peer discussion to share my experience. Upon completion of my presentation, I would receive an additional honorarium of \$250.00.*”

The Evaluation Form asked participants to “*strongly disagree*” or “*strongly agree*” with the following statements, among others: “*Has been a useful learning exercise*”, “*Met my learning objectives.*” It also asked participants to “*identify two modifications to your practice that you intend to implement*” as a consequence of the workshop.

Committee members noted that on the one hand, documentation on the program spoke to a “*market research*” activity and on the other, to a “*learning*” activity. Despite the company’s position that the activity was market research, not education, the Committee found that in effect the program combined two areas of the Code, namely market research and continuing health education. In addition, members felt that the completion of patient profiles raised elements of a post registration clinical study. Members also noted that while the Code permits payment of a

honorarium to participants in market research, it does not permit the payment of an honorarium to individuals who participate in market research and, in turn, share their learnings from the market research activity.

Decision: Contravention of Section 12.2.1 which states that *“the purpose of an individual or group interview must be made clear to the participant(s).”*

SUMMARY – REPORT #55

Company	Category and number of Infractions	Number of Infractions 12-month period
Fujisawa	Hospitality – 1	2
Lundbeck	Market Research – 1	1
Pfizer	Market Research – 1	1

(R&D)