Institution: University of Bristol

Unit of Assessment: 4 – Psychology, Psychiatry and Neuroscience

Title of case study: Consumer protection and commercial impact of proven ineffectiveness of a food ingredient designed to aid appetite control

1. Summary of the impact

Research conducted at the University of Bristol between 2002 and 2006 directly influenced a significant commercial decision about use of a food additive to aid appetite control, which protected consumers from an ineffective product. Concerns about increasing levels of obesity worldwide and the toll this takes not only on human health but on health care costs, have led to the development of food ingredients that satisfy hunger for longer (enhance satiety). One such major new ingredient, Fabuless, which is owned by DSM (Dutch State Mines), a leading global manufacturer of food ingredients, was being considered by Unilever for inclusion in its range of diet foods. DSM and Unilever contacted Professor Peter Rogers, who is known for his novel methods for the experimental study of appetite control, to test the effectiveness of Fabuless. Rogers demonstrated no satiety effect of Fabuless when consumed in realistic products, which caused Unilever to abandon Fabuless as a potential food ingredient in 2009. Publication of the research also meant that other food manufacturing companies and regulatory authorities were informed about the ineffectiveness of Fabuless.

2. Underpinning research

In 2002, Unilever and DSM sought the expertise of Peter Rogers, Professor of Biological Psychology (2003-present; previously Senior Lecturer (1999-2003)), and his University of Bristol colleagues in human appetite control, to test the potential satiety-enhancing effects of Fabuless. Originally named Olibra, this is a vegetable oil emulsion, which influences gastrointestinal peptides in the small intestine that are involved in signalling satiety in order to increase feelings of fullness after eating.

The Bristol-based testing of Fabuless was done between 2002 and 2006, and followed very promising results from earlier studies conducted by another research group. The new studies used methods that Rogers was instrumental in developing when he was a PhD student (Rogers and Blundell, 1979, *Psychopharmacology 66,* 156-165) and which have been widely adopted in experimental studies of human appetite control. These methods include scales for self-rating of appetitive states, and a technique, known as the 'test meal,' for measuring spontaneous food (calorie) intake under highly-controlled conditions.

Research findings

Rogers and his colleagues conducted a total of five studies of the effects of different doses of Fabuless in various prototype food products. Key outcome measures were how much food was consumed in subsequent meals and perception of hunger and satiety (fullness). The results showed that Fabuless had little or no efficacy once subjected to common food-manufacturing processes [1-3], including mild processing such as inclusion in a yoghurt-based meal replacement [2]. Further work was then undertaken to review systematically all the available (published and unpublished) evidence on the short-term appetite effects of Fabuless, and investigate inconsistencies in the study findings based on variations in methodology [4]. The results of this meta-analysis showed a small but inconsistent appetite suppressing effect of Fabuless. One, although not the only, factor found to contribute to this variability in efficacy was the extent to which the product underwent processing after Fabuless had been added. This is crucial, as such processing would occur in almost all realistic applications of the ingredients (i.e., in retail products available to consumers).

Key researchers

Rogers led the 2002-2006 research programme, while satiety studies were carried out by Dr

Hendrik Smit (University of Bristol Research Associate 1992-2003) and Mrs Emma Keenan (University of Bristol Research Assistant, 1999-2008). Unilever and DSM supplied the foods containing Fabuless and its placebo, and their scientists worked with the Bristol team in developing the study designs. Professor Rogers carried out the meta-analysis in 2008 and 2009 with Katherine Appleton (University of Bristol Research Associate 2003-2005, subsequently at Queen's University, Belfast) and Hendrik Smit (University of Bristol Research Associate as above, subsequently at Oxford Brookes University).

The Bristol findings have since been independently corroborated (Chan et al., 2012, *Physiology and Behavior 105,* 742-748).

3. References to the research

[1] Smit, H. J., Keenan, E., Kovacs, E. M. R., Wiseman, S. A., Peters, H. P. F., Mela, D. J. & Rogers, P. J. (2011). No efficacy of processed Fabuless™ (Olibra™) in suppressing appetite or food intake. *European Journal of Clinical Nutrition, 65,* 81-86. DOI: 10.1038/ejcn.2010.187

[2] Smit, H. J., Keenan, E., Kovacs E. M. R., Wiseman, S. A., Mela, D. J. & Rogers, P. J. (2012). No appetite efficacy of a commercial structured lipid emulsion in minimally processed drinks. *International Journal of Obesity, 36,* 1222-1228. DOI: 10.1038/ijo.2011.237

[3] Smit, H. J., Keenan, E., Kovacs, E. M. R., Wiseman, S. A., Peters, H. P. F., Mela, D. J. & Rogers, P. J. (2011). No appetite or food intake functionality of Fabuless™ (Olibra™) in processed food products. *Appetite, 57,* 545. DOI: 10.1016/j.appet.2011.05.032

[4] Appleton, K. M., Smit H. J. & Rogers, P. J. (2011). Review and meta-analysis of the short term effects of a vegetable oil emulsion on food intake. *Obesity Reviews*, 12, e560-e572. DOI: 10.1111/j.1467-789X.2011.00861.x

4. Details of the impact

'It is clear that this research has had a commercial impact already, and will likely have continuing implications for future applications of this technology in consumer products. We also see this as an example where by publishing their evaluation of the efficacy of commercialised food technologies, including 'negative' data, academics can play a role in the protection of the consumers.' [a] Unilever Senior Scientist, commenting on the impact of this research.

Evidence proving no efficacy leads to commercial decision to abandon Fabuless and opinions of misleading advertising

In 2000, Unilever acquired diet foods and drinks manufacturer *Slim-Fast* for $2.4billion [b]. In the early 2000s Unilever made plans to use Fabuless as a food ingredient, including in new products for the Slim-Fast range. As a direct result of the research carried out by Rogers, Unilever abandoned its plans to use Fabuless in 2009. This will have led to a significant decrease in projected sales of Fabuless and its value to its owner and manufacturer DSM (Dutch State Mines, a leading global manufacturer of food ingredients).

The concerns raised by the research over Fabuless resulted in a dispute between Unilever and DSM. Attempts to resolve this dispute lead to a high level meeting between Unilever and DSM in Geneva, Switzerland in 2008 at which the disputed efficacy of Fabuless was discussed. Both Rogers and Appleton were called as 'expert witnesses' to that meeting. Three of the outcomes from the meeting were an agreement that the results of the research, including the meta-analysis of studies, should be submitted for publication, the later final decision by Unilever not to use Fabuless, and subsequently pressure from Unilever on other companies that they should not use this ingredient with satiety claims.

Although Fabuless is still used in some products for appetite and weight control by other manufacturers, its use is likely far less widespread than it would have been without the Bristol research bringing into question its efficacy. It is clearly challenging to provide evidence of products that would have otherwise used Fabuless, however, the fate of some products that were using it are evidence that the research impacted commercial use of the product. For example, in 2008, Candia launched its Silhouette Active slimming milk product with Fabuless as its active ingredient. In 2012, the District Court of Paris made the decision that the company's advertising of the product was misleading consumers following a complaint by the National Association for the Defence of Consumers and Users (CLCV) [c]. Candia did not appeal the decision as they had effectively stopped marketing Silhouette Active in France after sales plummeted and it had lost its health claims following an opinion by the French food safety agency (AFSSA) [c].

DSM sought to secure a ruling from the European Food Safety Authority (EFSA) in support of their claim for efficacy of Fabuless, but this was found to be unsubstantiated and the claim has been disallowed in the EU since December 2012 [d]. Since this ruling, the Bristol research has been published in the public domain, and has been independently confirmed (Chan *et al*., 2012, *Physiology and Behavior 105,* 742-748).

The most recent clinical findings referred to in the DSM website [e] are from 2002 and recent consumer-style reports are conspicuously absent from the DSM site and from the other domains globally. Together, this strongly indicates that Fabuless sales are reducing, presumably as a consequence of loss of sales to Unilever and the EFSA ruling, both of which rest largely on the Bristol research.

It is difficult to quantify exactly the commercial consequences of not using a product of this kind. It is certain, however, that Unilever has not invested any more in developing products containing Fabuless; has not assigned a marketing budget for the projects and has not purchased Fabuless to add to products. This has clearly resulted in a reduced demand for Fabuless and a cost saving for Unilever. Unilever had planned to use Fabuless in their Slim-Fast range that has a major market share (US Slim-Fast sales are currently almost $200 million p.a. and in the UK Slim-Fast remains the dominant meal replacement product with a 71% share of the £59 million p.a. market [f and g]) so their cost-saving is substantial. It is likely that their abandonment of plans to adopt Fabuless will lead to similar actions from other producers of slimming products. Unilever and many of its competitors are multinational corporations and therefore the reach of this impact is significant.

Consumers protected from purchasing and consuming ineffective product

As a result of this change of policy based on the Bristol research, consumers are protected from purchasing and consuming an ineffective product, which otherwise would have been strongly marketed by major global companies in a sector that is worth $13billion globally [f]. Although the ingredient is not harmful to consumers, it was proven ineffective, so the impact of the research does have considerable reach, ostensibly in Europe, covered by the EFSA decision, but also globally. It is clear that availability of Fabuless has decreased worldwide.

5. Sources to corroborate the impact

[a] Letter from Dr David Mela, Unilever Senior Scientist, corroborating the background, results and impacts of the research.

[b] http://www.businessweek.com/articles/2013-01-24/how-slim-fast-lost-out-to-weight-loss-rivals accessed 14 June 2013

[c] 'Painful end for active shape' (29 November 2012) *LSA.fr* <http://www.lsa-conso.fr/fin-douloureuse-pour-silhouette-active.135788>

[d] European Food Safety Authority (2011) SCIENTIFIC OPINION: Scientific Opinion on the

substantiation of health claims related to formulated palm and oat oil emulsion and contribution to the maintenance or achievement of a normal body weight (ID 577) and maintenance of body weight after weight loss (ID 1553) pursuant to Article 13(1) of Regulation (EC) No 1924/20061EFSA Journal 2011;9(6):2252 Parma, Italy.

[e] 'Fabuless' (9 Nov 2011) *DSM* [website] <http://www.dsm.com/markets/foodandbeverages/en_US/products/nutraceuticals/fabuless.html#> accessed 16October 2013.

[f] Boyle, M. (15 Jan 2013) 'Unilever's Slim-fast goes from juggernaut to after-thought', *Bloomberg* <http://www.bloomberg.com/news/2013-01-14/unilever-s-slim-fast-goes-from-juggernaut-to-afterthought.html> accessed 16 October 2013

[g] United Kingdom Food Replacement market: Unilever foods UK dominates http://www.companiesandmarkets.com/Market/Food-and-Drink/Market-Research/Meal-Replacement-in-the-United-Kingdom/RPT1032407?aCode=b665b089-afc2-4102-9abd-a47c38e3ae3c accessed 23 October 2013