
The role of FDA enforcement in misleading product labelling claims in hospitality

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Abstract: Chronic diseases are the leading concerns to public health in the USA. These diseases include preventable conditions such as: heart disease, diabetes, and obesity (CDC, 2017). Consumers are increasingly turning to 'healthy' food options in an attempt to do their part to fight this increasingly important issue. Food manufacturers have responded by providing ever-greater numbers of foods labelled as 'wholesome' or 'natural'. But are these foods really what they are touted to be? The Food and Drug Administration (FDA) is the US agency tasked with protecting consumers and overseeing food labelling. This paper looks at the monumental task facing this agency and the issues and constraints that hamper their ability to fully fulfil their mandate.

Keywords: Food and Drug Administration; FDA; Federal Trade Commission; FTC; misleading advertising; false advertising; product labelling; food safety; food labelling.

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1 Introduction

As chronic diseases continue to be one of the largest public health concerns in the nation, the demand for healthy food has consequently been increasing at drastic rates. In order to meet this growing demand, food manufacturers have flooded the shelves of supermarkets with ‘natural’ and ‘wholesome’ processed foods. How can obesity numbers be rising along with the demand for healthier food? One possibility is the halo effect – the concept that people overestimate the healthfulness of a food based on claims made on the packaging (Negowetti, 2014; Friedland, 2005). When packages reassure consumers with messages such as ‘all natural’, consumers feel better about purchasing and eating those products, whether or not there is much natural about them (Abrams et al., 2010). How can manufactures be permitted to utilise such claims?

In the USA, the Food and Drug Administration (FDA) is the agency responsible for overseeing food labelling. However, the FDA is strained to effectively carry out its charge (Johnson, 2014). This is due to several factors: lack of clear definitions of labelling terms, an overwhelming amount of products on the market, and a lack of both financial and human resources to complete the job (Johnson, 2014; Olson, 2011). Instead, the task of false/misleading health claims enforcement has essentially been relegated to consumer-generated lawsuits and advocacy groups, investigative reporting, and voluntary compliance.

This paper will provide a historical overview of the FDA’s role in regulating health claims for food, the current state of labelling laws, and a discussion of complaints and cases filed against companies using misleading claims. These cases will be used as a basis to illustrate the impact of potentially misleading labelling on consumer health, and the need for clear rules and regulations when it comes to what is really in the food we consumer. With more substances being added to and used for food than ever before, the need for knowledge and transparency in food products has never been greater. Finally, implications on the hospitality industry will be discussed, including improvements in managerial practices.

2 Some background on US labelling law

2.1 *The Federal Food and Drugs Act of 1906, pre-cursor to the FDA*

2016 marked the 110th anniversary of the Federal Food and Drugs Act of 1906 (‘the act’), the first in a plethora of legislation designed to protect public health. The act was passed in response to the unsanitary conditions in plants and factories, made known to the public in part through the landmark expose *The Jungle*, by Upton Sinclair (Witherspoon, 1998). The act’s purpose was “for preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes” (Druglibrary.org, n.d.).

The act was to be administered by the Bureau of Chemistry, and outlined a seizure of questionable products, a strict fine and and/or one-year’s imprisonment sentence for anyone found in violation. Foods were prohibited from including any ingredients that would substitute for the food, conceal food damage, pose an injury to health, or consist of

a filthy, or decomposed animal or vegetable product. The act further specified the restrictions on misbranding, including products:

“Labelled or branded as to deceive or mislead the purchaser, or purport to be a foreign product when not so ... [and] if the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular.” (Druglibrary.org, n.d.)

Contained within the act, however, were no requirements that companies submit information to FDA before rolling out a marketing campaign, and the burden of proof was on the government to show there was any misrepresentation with the product (Meadows, 2006).

2.2 Food, Drug and Cosmetic Act of 1938

Food, Drug, and Cosmetic Act (FDCA) was signed into law in 1938. The FDCA required legally enforceable food standards set forth by the FDA, including the new ingredients, chemicals, and additives created by advances in food technology. As these new substances hit the marketplace, the FDA pursued numerous cases of food misbranding, most from unsubstantiated nutritional claims, as well as legislation involving pesticide residue, food additives, and colour additives (FDA History, 2009). The FDCA focused more intently on the health of the consumer than did the Food and Drug Act of 1906, as well as included the authority to take action to increase standards when necessary. A recent decision in *Wyeth v. Levine* states that while congress enacted the FDCA “to bolster consumer protection against harmful products”, it did not provide a federal cause of action for consumers injured by those products because it determined that “widely available state rights of action provided appropriate relief for injured consumers” (Endres et al., 2010). It is noted here the beginnings of the FDA’s desire to ‘pass the buck’ for products found to be unsafe. As the FDA is the agency in charge of ensuring safe, unadulterated food and substantiated health claims, why is there no federal action available to those injured by its lack of enforcement? Is it up to the states to provide the relief for a government agency’s oversight?

2.3 Nutritional Labelling and Education Act of 1990 (NLEA)

The next milestone in food regulation appeared in the form of the Nutritional Labelling and Education Act (NLEA), amending the FDCA. This act covers misbranding on food labels, mandates the presence of a nutritional facts panel, and covers approval standards for health and nutritional claims for food products. Under the NLEA, a food is misbranded:

“Unless it bears nutrition information that provides: (1) the serving size or other common household unit of measure customarily used; (2) the number of servings or other units per container; (3) the number of calories per serving and derived from total fat and saturated fat; (4) the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, total protein, and dietary fibre per serving or other unit; and (5) subject to conditions, vitamins, minerals or other nutrients.” (H.R. 3562, 1990)

While the NLEA made meaningful strides in the fight against misleading claims, it is interesting to note that certain products were exempt from the rule if the likelihood existed the public may not see the food containers (such as in restaurants). With more and more consumers seeking healthy menu options, it must first begin with healthy menu ingredients. The fact that restaurants may be unaware of what ingredients comprise the products they use is cause for concern. Why should products sold to consumers in a restaurant be any less regulated than those purchased at a supermarket?

While many manufacturers had little trouble implementing a nutrition facts panel, many others worried about the regulations governing health claims, as they hoped they could utilise specific claims to provide a competitive advantage against other products on the market (Silverglade, 1996). A landmark case in this arena involved beer marketers seeking to put the alcohol content of their beer on the label for consumers to see, and claiming the authorisation process for health claims violates the US Constitution's first amendment, preventing marketers from exercising free speech to promote products through health claims. The government defended the labelling ban by noting that allowing breweries to print the alcohol content on the label, constituting a commercial, would result in 'strength wars'. This case, *Rubin v. Coors Brewing Co.* (1995), reached the Supreme Court, with a verdict stating the labelling ban was indeed a violation of the first amendment, and the government could not forbid brewers from listing alcohol content on their labels.

With support and backlash from both sides, the NLEA not only increased the responsibility of food manufacturers, but also of the public in terms of taking initiative to increase their knowledge on the products they regularly consume (Zarking and Anderson, 1992). Several studies conducted after the passage of the NLEA document an increase in consumer knowledge in regards to diet and health due to the increase in health claims in food labelling and advertising (Silverglade, 1996).

2.4 Dietary Supplement Health and Education Act of 1994

As the years pass, food regulation seems to move farther and farther away from the initial intentions of the Pure Food and Drug Act of 1906 and the FD&C Act of 1938. In 1994, congress passed the Dietary Supplement Health and Education Act (DSHEA), exempting dietary supplements from pre-marketing authorisation by the FDA, and placing the burden of proof on the FDA when determining whether or not dietary supplements are safe. Supplements may carry one of several health claims without approval from the FDA, as long as the manufacturer has substantiation and notifies the FDA within 30 days after the statement is advertised. Finally, the supplement must carry the disclaimer: "this statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease" (DSHEA, 1994).

Not only is the manufacturer solely responsible for ensuring products and ingredients are unadulterated and safe for human consumption, but all compliance is internal and requires no checks or validation before sale. This reliance on internal compliance provides an environment in which it could be relatively easy for a manufacturer to cut corners and send a product to market that should remain in the testing phase. This temptation is heightened by the fact that it is the FDA's responsibility to take any action against the product, after it has already been on the shelves, sold to consumers, and ingested into the body.

Unless the FDA has a watchful eye over every claim on every product on the shelves, it is likely some claims with unsubstantiated evidence will slip through the cracks. This is a concerning thought, as it implies purchasing items could be likened to playing roulette, never knowing when the product you purchase is indeed safe, and when it is not.

3 FDA enforcement of misleading health claims: joint custody with the FTC

While the FDA has authority of regulating the labelling of food and dietary supplements, its authority is severely limited and some is shared with the Federal Trade Commission (FTC) which possesses authority over false, unfair, and deceptive advertising outside of the food packaging. The FDA is unable to issue penalties for materially false or misleading advertisements on packaging. While the FDA cannot prosecute for misleading packaging, it can issue monetary fines for food products found to contain unsafe pesticides, chemical residues, and products in violation of a recall order. However, mis-brandings that result in non-acute health outcomes do not warrant a recall order (Pomeranz, 2013). As such, the FDA is unable to penalise manufacturers for misleading food products on the market, as long as they are not inherently unsafe. The FDA notes that it monitors food product labels to unsure truthfulness, ‘as resources permit’ (Negowetti, 2014).

3.1 Warning letters

Should the FDA discover a violation, it must first issue a warning letter to the violating company, informing them a violation has indeed occurred. This action is the agency’s principal means of achieving voluntary compliance with the act (Pomeranz, 2013). After the warning letter has been issued and the company given time to respond, but only if there is cause to believe the food is dangerous to health or that the labelling is misleading enough to cause injury to the consumer, can the FDA seize the food item. However, this scenario is typically only used with allergen and pesticide matters, not with false nutrient or health claims.

Should the FDA question a labelling claim, the agency bears the burden of conducting the necessary research to prove the claim fraudulent or misleading. The FDA has no authority to require companies to provide documents of substantiation, such as research or scientific data, used as the grounds for the claim. The FTC, however, does have the authority to request such documents. In a situation involving Kellogg’s cereal, some boxes boasted the claim that certain cereals increase children’s immunity. Despite FDA suspicions surrounding the truthfulness of the claim, they were unable to request any documents of proof. Instead the FTC responded to the claim, in the advertising campaign arena, and issued a public reprimand (Pomeranz, 2013).

In 2004, a non-profit consumer advocacy group, Center for Science in the Public Interest (CSPI), established a department dedicated to pursuing legal action over misleading claims not enforceable by the FDA. The group prevailed in several high-profile victories for consumers, including suits against general mills super moist carrot cake mix that contained only carrot-flavoured bits, Sara Lee ‘made with whole grain bread’ with only 30% whole grain used and a nutritional claim of equivalency to

100% whole wheat bread, and suits against Kraft Capri-Sun and Schweppes' 7UP for labelling their drinks as 'all natural' when they contained high fructose corn syrup (Negowetti, 2014). Amid these claims, the US Government Accountability Office (GAO) issued criticism to the FDA for failing to stay on top of the glut of food companies, producers, and their labels. The GAO noted the decrease in inspections and label reviews despite the growing number of food manufacturers, failure to track violations and post them for the public, finally coming to the conclusion that the "FDA has limited assurance that domestic and imported foods comply with food labelling requirements (Negowetti, 2014)..." The CSPI agreed, stating "...the FDA has all but abdicated its responsibility to police inaccurate nutrition statements and misleading health-related claims on food labels" (Negowetti, 2014; Law, 2006).

3.2 Defenses used in misleading product claims

While lawsuits against food companies are not new news, the judicial system experienced an upsurge in the past few years, with more than 150 class action suits filed in the period 2011–2013 (Negowetti, 2014). Lawsuits brought against companies for misleading product claims are filed based on violations of state statutes on false advertising, unfair trade practices, consumer protection, fraud, or breach of warranty (Negowetti, 2014). In cases accusing breach of warranty, there seems to be some disagreement as to whether labelling creates a warranty. Claims that involve warranty by implication (i.e., interpretation of pictures combined with descriptive language, with no specific written statements present) are not considered warranties in court.

There has been a significant increase in labelling lawsuits involving the use of 'all natural', or '100% natural', especially as genetically-modified organisms (GMOs) are currently added to food and yet unregulated. Courts have repeatedly rejected the notion that the FDA has primary jurisdiction over 'all natural' claims. In a decision involving a suit against Hain Celestial seasonings for using the term '100% natural' when their seasonings contain trace amounts of pesticides, the court noted "given the FDA's lack of interest in providing further guidance on the use of the word 'natural' in food labelling, staying or dismissing the case to permit the FDA to do so [decide the propriety of the claim] would likely be futile" (Harrison et al., 2015). Until the FDA becomes involved by clearly defining the terms that manufacturers are putting on their labels, courts will be unable to make truly informed decisions. It is not the job of the courts to determine what is meant by 'natural', or any other such health claims placed on food packaging.

It is clear the 'litigation as regulation' trend is continuing, but how can courts be expected to properly decide these cases when the FDA guidelines are vague and minimal at best, and contain no definitions of hot words such as 'all natural'. No single group exists to enforce labelling claims, and no penalties are levied on companies who practice deceptive labelling. There appears to be a need for an overhaul of FDA regulatory authority in this arena, to strengthen its enforcement power, labelling regulations and standards, and prosecution of violations. It should not be left in the hands of the consumer to pursue legal action against mislabelled, misbranded food.

4 Impact on the hospitality industry

Employees in the hospitality industry are not the only group with stake in the food litigation predicament. Restaurant patrons are becoming increasingly concerned about the foods they are consuming, with regards to country of origin, ingredients, organically or non-organically grown, locally sourced, quality of ingredients, artificial colours and flavours, and the effect of a product on the environment (Roseman et al., 2017; Sulek and Hensley, 2004). With the current labelling regulations by the FDA, it is difficult for hospitality companies to be fully versed about the foods they serve. Food products sold to restaurants are exempt from certain labelling requirements, allowing manufacturers even greater leeway with their labelling (Boger, 1995).

The situation in the USA is greater highlighted by the fact that other countries are taking a harder stand against potentially deceptive labelling and questionable ingredients. The European Union has successfully banned a large number of ingredients and products from use in the food supply that are consumed regularly and in large quantities in the USA. Two compounds used as preservatives, BHA and BHT, are present in many food supply staples such as cereals and meats. These preservatives prevent food from spoiling, but are known carcinogens in rats. BHA is listed in the US Department of Health and Human Services as ‘reasonably anticipated to be a human carcinogen’, as well as a possible cause of hyperactivity. Its partner, BHT, is known to cause organ system toxicity (Lanigan and Yamarik, 2001).

Meat producers, in order to reduce the fat content of its products, have administered the drug ractopamine to conventionally raised cattle, pigs, and turkeys in the USA. Ractopamine is banned for use in animal feed in over 160 countries around the world, due to its harmful effects on the cardiovascular system and behavioural changes. Russia has banned meat imported from the USA until the time when ractopamine is no longer used (Boulanger et al., 2016).

A final example of banned substances outside of the USA comes in the form of ever-popular sports drinks and select sodas (such as Mountain Dew and other citrus-flavoured sodas). The ingredient in question is known as BVO, or brominated vegetable oil, that is exactly what it sounds like – vegetable oil with bromine. BVO was originally used as a flame retardant, before being widely used in the soft drink industry to prevent flavour from separating from the rest of the beverage. Research has found BVO accumulates in breast milk and human tissue, causes reproductive system and central nervous system damage, schizophrenia, skin lesions, and birth defects (Strom, 2012). The FDA removed BVO from the list of substances ‘generally recognised as safe’, instead placing it on the list of interim food additives, used to describe questionable ingredients used in food products (Mercola.com, 2016).

This is but a small sampling of the list of ingredients permitted for consumption in the USA, but banned in many countries across the globe. Besides the toxic nature of these ingredients, and the questions as to why they are still permitted, the FDA is not regulating their usage amounts, nor requiring companies to put warnings on products containing toxic ingredients. The only relief in this arena comes under applicable state laws, most

notably in California, where products can wear the label “this product contains chemicals known to the state of California to cause cancer and birth defects or other reproductive harm”.

5 What is being done in hospitality?

The notion that FDA guidelines regarding misleading claims on packaging are vague and minimal is a disconcerting thought. However, there have been positive strides within the hospitality sector to try and provide consumers with as much health information as possible with regards to the foods they serve. Americans (and millennial in particular) are eating at least five meals a week outside the home (Tulip, 2017); it could be said that purchasing food at restaurants is rivalling purchasing products at a supermarket.

To facilitate and promote healthier choices nutritional information on restaurant menus is becoming more commonplace, and including more detailed information than simply a calorie count. Restaurants are featuring more and more locally grown options that do not require the additives and preservatives necessary for long-haul trips across the country. By choosing to offer locally obtained products restaurants can be confident in providing genuine, honest nutritional information to their guests. Additionally, restaurants are choosing to partner with small family farms and producers across the country to offer more wholesome products.

While in the best interest of the consumer, offering local products or products from small producers can result in a substantial cost increase for the retailer (Hu et al., 2012). However, the burden for this extra cost need not rest on the shoulders of the establishment. Hwang and Lorenzen (2008) concluded that consumers would be willing to pay more (approximately \$2.00 more) for healthier items with nutritional information provided. This shows the value consumers place on healthy choices outside the home, and that they are willing to pay more for this option. Additionally, this practice may serve as a differentiating factor when consumers decide where to dine outside the home. Presenting this nutritional information on menu items has been shown to influence consumer practices more than the information on packaged products at supermarkets (Kozup et al., 2003). There is a fine line, however, as providing too much nutritional information at restaurants may impede enjoyment (Fitzpatrick et al., 1997).

6 Implications and limitations

While this paper cannot provide legal relief in the misleading food labelling arena, it can provide awareness. We live in a time in which topics can go ‘viral’ overnight with the assistance of social media. People can be advocates for change through these different channels and be seen by a global audience. By making the lack of regulation in food labelling a matter of public thought, real change may be forthcoming. It has been shown that providing consumers with nutritional information can have positive financial implications for restaurateurs as well as providing a competitive advantage.

This work provided an overview of the current state of affairs with regards to the FDA and food labels, but did not causally examine the effects of misleading labelling claims on consumer choice. While an introductory review of food labelling in hospitality was provided, future research is needed to further examine the thoughts of consumers

with regards to nutritional labelling in restaurants. Additional topics to cover would be consumer perceptions of restaurant items and how they compare nutritionally with packaged products sold in supermarkets or other retail locations.

7 Concluding remarks

The USA is facing continually rising levels of obesity, and other preventable, costly chronic diseases, encouraged in part by the unhealthy food products found at supermarkets. With the rise in obesity levels has emerged the ‘halo effect’, in which healthiness of a product is overemphasised by the package labelling. Phrases such ‘all natural’, ‘wholesome’, and ‘pure’ are proliferating on food labels, encouraging health-conscious customers to purchase them, despite the fact these products may not be that healthy at all. Meanwhile, the FDA requires only voluntary participation from manufacturers in ensuring their claims are truthful and contain no harmful substances. There are no federal avenues for consumers to seek legal relief; they are forced to use applicable state laws. This has resigned consumer-led litigation as the only avenue by which misleading claims on food packaging can be rectified. Additionally, food sold to restaurants for use is exempt from any FDA involvement whatsoever. This seemingly lax approach to monitoring the food we consume may be held responsible for at least some part of the health crisis facing this country, and resting on the shoulders of the hospitality and foodservice sectors. Without obtaining foods from local or small-business suppliers in which the nutritional information of the products is known, we are unable to properly analyse the food we are serving to guests, who are demanding an increasing number of health-centred options. In order for hospitality organisations to adequately meet these health-centred consumer demands, it is critical for the FDA to take charge of the food arena and provide direction as we move forward in an era of ‘modern food’.

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