Publish and Perish: A Disturbing Trend in the European Union's Regulation of Nutrition Health Claims Made on Foods

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Recent developments in the European Union's regulation on health claims used in food labeling could have the effect of suppressing publication of scientific research on the health benefits of food substances. Given that scientific research and collaboration is an international phenomenon, the negative effect of the European Commission's (the Commission) current direction might well be felt in the United States.

The seeds of this controversy were sown in December 2006, when the European Parliament issued Regulation (EC) No 1924/2006, which stipulates the circumstances under which health claims may be made for foods marketed in the European Union.[2] At the outset, it's important to note that the definition of "health claim" as that term is used in EU regulations is considerably broader than the definition of "health claim" in the Federal Food, Drug, and Cosmetic Act and its implementing regulations. The EU health claims regulation defines "health claim" as "any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health."

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This EU definition of "health claim" (hereinafter "EU health claim") is sufficiently broad as to encompass several different types of claims that can be made for foods marketed in the United States, including: (1) "health claims," defined as claims that expressly or impliedly characterize the relationship of a nutrient required to be included in nutrition labeling to a disease or a health-related condition; and (2) "structure/function claims," defined as claims that describe "the role of a nutrient or dietary ingredient intended to affect normal structure or function in humans," or that characterize "the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function."[3] Thus, developments in the regulation of EU health claims have the potential to alter the landscape in the United States for both health claims and structure/function claims.

The EU health claims regulation requires that new health claims (i.e., those not already on a list of approved claims) be the subject of a premarket approval application that includes relevant scientific studies and other information,

"including, where available, peer-reviewed studies." However, an applicant has the option of designating data and other information in the application as "proprietary," so long as the designation is accompanied by "verifiable justification." If the applicant has "exclusive right of reference" to the information designated as proprietary, and if the proprietary information is deemed essential to the authorization of the health claim, then that information cannot be relied upon by subsequent applicants for a period of five years. In other words, the EU health claims regulation grants five-year exclusivity with respect to use of the information designated as proprietary if the applicant meets the conditions described above.

Late last year, the Commission issued the first authorization of a health claim that granted protection of proprietary information pursuant to the EU health claims regulation.[4] The applicant designated nine studies in the application as proprietary. The European Food Safety Authority (EFSA) agreed with the applicant that the claim could not have been granted without relying on the studies designated as proprietary.[5] However, the Commission concluded that only information in those studies which were unpublished was entitled to protection. With respect to studies that had been published, the Commission concluded that protection of those studies was "not justified" in light of the regulation's objectives, among which is "to protect the investment made by innovators in gathering the information and data supporting an application." In summary, the Commission concluded that if a study is published, then nobody (including those who funded and conducted the study) can assert that the study represents an "investment" that is cognizable under the EU health claims regulation.

As written, the decision provides little insight into the Commission's rationale. According to the decision, the Commission sought clarification from the applicant with regard to whether the criterion of "exclusive right of reference" was satisfied, but the commission made no explicit finding on this point. Rather, the basis for the decision was cast in terms of the perceived need to protect investment made by innovators. Although this is a worthy objective, it is not clear why the Commission concluded that this objective is incompatible with scientific publication. One can readily envision arrangements through which an innovator that sponsors or conducts a study could document its investment and assert exclusive right of reference to data yielded by that study for purposes of an EU health claim application – even if the results of the study are published prior to submission of the application. Furthermore, if the main objective of the regulation is to foster innovation, then the Commission's approach could be counterproductive in the long run. By creating a disincentive to publication, the Commission's approach slows the flow of scientific information to the scientific community, where that information can be most thoroughly vetted and used to spur additional innovation.

Also problematic is the fact that the objective of fostering innovation is not the regulation's sole objective. The regulation has other important objectives, namely to "ensure a high level of protection for consumers," and to "give the consumer the necessary information to make choices in full knowledge of the facts." These objectives would seem to be ill-served by an approach that discourages peer review and lacks transparency. As noted previously, the regulation specifically calls for EU health claim applicants to submit peer-reviewed studies where available – a tacit acknowledgment that peer-review generally provides assurances of superior quality and integrity. The value of peer review is recognized by the EFSA, which states in a guidance document that "[d]ata provided to substantiate a health claim should be of the quality expected from a peer-reviewed journal."[6] Further, as noted in the EU health claims regulation, "[h]ealth claims should only be authorized for use in the Community after a scientific assessment of the highest possible standard." Although the regulation assigns the task of performing that assessment to EFSA, that body's assessment is not a substitute for peer review. The value of transparency is also recognized by the EFSA, which states in a guidance document that "EFSA applies a high level of transparency when processing information unless a clear regulatory requirement exists for a defined level of confidentiality. Transparency is the rule and confidentiality the exception."[7]

Although the Commission's decision is becoming the subject of heated debate in the EU, scant attention has been paid in the U.S. And yet, the Commission's decision ought to be of more than academic interest to a U.S. audience. In the U.S., health claims must be based on publicly available evidence, much of which is generated abroad. Thus, any incentive in an influential jurisdiction that discourages the publication of scientific information that could be used in support of a health claim petition could have significant adverse effects.

With respect to structure/function claims, there is no requirement in the United States that information used to substantiate a structure/function claim be publicly available, nor is there a requirement that companies seek approval of a structure/function claim prior to using it in the marketplace. As a result, many companies compile their

substantiation information in a confidential file that is held in reserve in case of a challenge by a regulator. In case of such a challenge, a company will make its substantiation information available for the regulator's review. However, the information is regarded as confidential commercial information that is not subject to public disclosure under the Freedom of Information Act.

Many companies in the United States choose to keep their substantiation information confidential precisely so that they can achieve or maintain a competitive advantage by making structure/function claims that their competitors cannot make without developing their own substantiation. The importance of the potential competitive advantage gained through this strategy should not be minimized. However, the EU health claims regulation (as interpreted by the Commission) goes beyond recognizing the potential value of this strategy to encouraging its pursuit by all parties with an interest in making an EU health claim. In doing so, the Commission fails to recognize that maintaining the confidentiality of scientific information that substantiates a claim potentially imposes costs on both individual companies and the broader society. The potential cost to a company is that an increasingly skeptical public, weary of being bombarded with claims that range from the plausible to the incredible, could shy away from products that make claims based on information that has never seen the light of day. The cost to society is that important scientific information is unavailable to the public longer than it otherwise would be.

There is no ready solution to this dilemma in the United States, where the current regulatory scheme does not provide for the premarket approval of structure/function claims or the accompanying recognition of any type of exclusivity. Further, any proposal for premarket approval would be met with strong resistance grounded in the right to free speech provided by the First Amendment to the U.S. Constitution. For the European Union, where a premarket approval scheme is already in place, the solution to the dilemma appears obvious: provide an incentive for the development of scientific data and other information to substantiate a claim, and structure that incentive so that it is not contingent on the maintenance of confidentiality. The EU health claims regulation (if properly interpreted) could offer precisely that solution. One can only hope that the Commission will not squander the opportunity by adhering to an unnecessarily cramped interpretation of the regulation. If the Commission reverses course, the result could be an enviable balancing of private and public interest that could serve as a model for other jurisdictions with similar regulatory schemes – and could lift the cloud that now hangs over those contemplating publication of any scientific research that might be used in support of an EU health claim.

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2 Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods, Official Journal of the European Union L 12/3, January 2007.

3 Claims That Can Be Made for Conventional Foods and Dietary Supplements, September 2003, available at http://www.fda.gov/Food/LabelingNutrition/LabelClaims/ucm111447.htm.

4 Commission Decision of 17 December 2009 authorising a health claim on the effect of water-soluble tomato concentrate on platelet aggregation and granting the protection of proprietary data under Regulation (EC) No 1924/2006 of the European Parliament and of the Council, Official Journal of the European Union L 336/55, December 2009.

5 EFSA provides scientific advice and opinions but is not part of the Commission, which is responsible for initiating legislation and implementing policies. See Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, Official Journal of the European Communities L 31/1, January 2002.

6 Scientific and Technical Guidance for the Preparation and Presentation of the Application for Authorisation of a Health Claim, The EFSA Journal (2007) 530, 1-44.

7 Transparency in Risk Assessment Carried Out by EFSA: Guidance Document on Procedural Aspects, The EFSA Journal (2006) 353, 1-16.