

Can INTERNATIONAL POLITICS control your health?

by Jonathan W. Emord

Codex Standards, the EU Directive and the Future of Health Freedom

In a world that respects individual liberty, ingestible substances that cause no harm at recommended dose levels and information concerning their potential health benefits are freely available. Sadly, that is not the world in which we live. We live in a world in which regulators, at the behest of powerful special interests, determine what may be sold and what may be said about products in the food and dietary supplement markets. They do so based more on politics than on science.

Law is Necessarily a Coercive Force

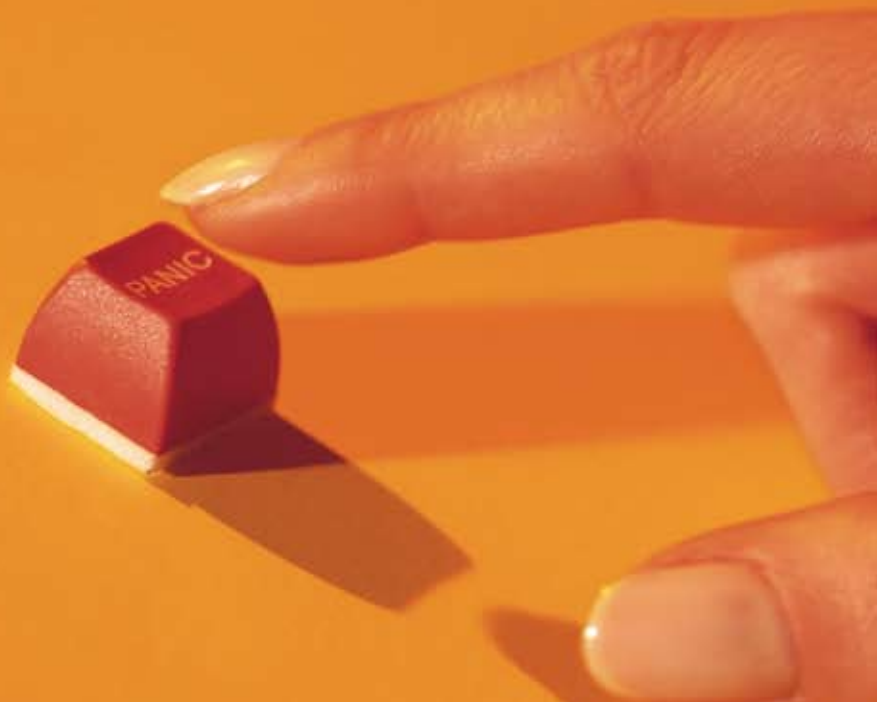
When law governs food science, standards are necessary to define points at which rights of access to substances and information will be denied. The Codex Alimentarius (Latin for food code) is a commission of the United Nations' World Health, and Food and Agriculture Organizations. The Codex commission was created to establish food standards for all member nations. In July of 2005 the food standards adopted included the Guidelines for Vitamin and Mineral Food Supplements. Codex proposes the standards for each member state to adopt through that state's domestic laws. Member states that do not intend to implement the standards are obliged to state their reasons for not doing so to the Codex Alimentarius Commission. The adoption of domestic laws that are

more stringent than recommended by Codex, however, need not be explained. As a practical matter, when standards are established by a majority of the 170 U.N. member nations that participate in Codex deliberations, the failure to adopt them makes the state in question suspect. There is, to be sure, coercive pressure that comes with an international body's adoption of a global standard.

The Drug Industry's Influence

For each nation member, legal, economic, political, and cultural interests within the nation influence how that nation's representatives view particular standards for the regulation

of foods and food supplements. For the developed world, the greatest economic interest affecting the positions of member nations is the drug industry. The multinational corporations that dominate the drug industry are state-sponsored monopolies in the United States and throughout the developed world. They are the wealthiest institutions on earth. Most developed countries principal health regulatory agencies are captives of the pharmaceutical industry, and that industry heavily influences not only how drugs are regulated but also how non-drug substances that pose a potential competitive threat to approved drugs are regulated.



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The Right to Make Treatment Claims Belongs to the Drug Industry Alone

State drug approval processes, often the product of drug industry lobbying and consent, depend on prior restraints that preclude foods and dietary ingredients from being represented to the public as having therapeutic effects (even if they do have such effects). That prohibition on foods and dietary ingredients comes in the form of commercial speech bans that prevent the promotion of such products with such claims, even if the claims are true. So, for example, in virtually no nation in the industrialized world (not even in the United States) can a bottle of prune juice be sold with the label claim "helps treat chronic constipation." Although there is scarcely a person in the industrialized world who would question that proposition, the drug industry holds a state enforced monopoly over the right to make all treatment claims. The law in every nation prohibits therapeutic claims on foods and dietary ingredients, regardless of their validity. If a bottle of prune juice was to display that claim, the bottle could be banned from the market. The executives, who own and run the company responsible for so labeling, could be prosecuted civilly and criminally, and the distributors of the product could be enjoined from distributing it.

Strict Limits on Dose Levels

Some Codex member nations favor strict limits on dose levels of nutrients, on the availability of nutrients, and on the claims that can be made for those nutrients. They want the Codex Guidelines for Vitamin and Mineral Food Supplements to include those strict limits. Germany is perhaps the most obvious leader of this movement

against freedom of choice. In 1996, for example, Germany advocated that no herb, vitamin or mineral be sold for preventive or therapeutic reasons and that dietary supplements be reclassified as drugs. Others favor less drastic but still disabling restrictions, such as the imposition of laws that require all vitamins and minerals to be evaluated by member states to determine whether dose levels above recommended daily intake levels (i.e., levels below which nutrient deficiency diseases commonly occur) are virtually free of risk and, if not, to restrict their availability. The text of the present Codex standard recommends labeling and packaging requirements, recommends that member states establish maximum and minimum dose levels for supplements and calls for safety and efficacy determinations to be made about supplements, thus inviting each state to commit to a comprehensive review of all vitamins and minerals sold in their countries but not specifying outcomes of that review. The UN has described the Guidelines as measures "to stop consumers overdosing on vitamin and mineral food supplements."

Bias Against Dietary Supplements

Stated in the very first paragraph in the preamble to the document: "Most people who have access to a balanced diet can usually obtain all the nutrients they require from their normal diet" and "people should therefore be encouraged to select a balanced diet from food before considering any vitamin and mineral supplement." The notion that above recommended daily intake levels of certain nutrients (e.g., vitamin C, folic acid, vitamin D) when ingested daily are beneficial to health is a proposition that, while scientifically valid, is not

stated in the Codex Guidelines. That is because the Guidelines, in the end, are products of politics more than science. When science favors a politically preferred end, it is advanced; when it disfavors a politically preferred end, it is distinguished, rejected or passed by without comment. The Codex Guidelines recommend vitamins and minerals only when “intake from the diet is insufficient” (i.e., when a person is at risk of contracting a deficiency disease like scurvy or berry-berry), while most leading authorities in nutrition science world round advocate daily ingestion of higher than RDI levels of antioxidant vitamins, among certain other substances like minerals, amino acids, lactobacillus and botanicals shown to have a beneficial impact on health and disease risk reduction or disease mitigation.

Guidelines are Influenced by Politics More than Science

The Codex Guidelines are specific in their demand that states must review all vitamins and minerals to determine which ones and which dose levels should be excluded from the market, but are vague in their absence of a listing of such vitamins and minerals or such dose levels. In short, they cajole members to adopt proscriptive regulations but do not define the nature of those regulations except by categorical references. No precise limits are articulated; instead, member nations are directed to set limits predicated on “scientific risk assessment based on generally accepted scientific data” and on “the daily intake of vitamins and minerals from other dietary sources.” The Guidelines “should not lead to setting of maximum levels that are solely based on recommended nutrient intakes.”

Consumer Freedom of Choice is Threatened


Having veered from a core purpose of eliminating known contaminants and into regulating substances that have a long history of safe use, the Codex Guidelines invariably call for action that threatens consumer freedom of choice. Increasingly the Codex Alimentarius encourages the creation of standards governing the availability and use of substances that are, with very rare exceptions, safe at dose levels recommended to the public. It encourages the adoption of prior restraints that can limit consumer choice by removing doses that while safe may have therapeutic effects that compete with those of government approved and protected drugs (e.g., glucosamine and chondroitin sulfate repairing joint damage due to osteoarthritis that is otherwise treated solely by ingestion of government approved, but harmful non-steroidal anti-inflammatory drugs).

Vitamins and Minerals are Safer to Ingest Than Some Foods and Drugs

From a utilitarian perspective, there is no need for an international body to possess coercive recommendatory power over individual nations on the subject of how best to protect their citizens' health and safety from substances that have not been proven unhealthy or unsafe. Because vitamins and minerals are the safest ingestible substances in the world, we know our liberty is violated when government presumes to tell us which of those safe substances we may consume, how much of them we may eat, and what health information about them we may receive. There is no international health crisis associated with vitamins and minerals anywhere in the world (i.e., there is no place on earth where people are suffering serious injuries

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A man in a dark suit and tie is looking down at a document he is holding. The image is overlaid with a semi-transparent orange filter. The background is a solid orange color at the top of the page.

Under that principle, a substance is presumed unsafe at every dose level unless it can be proven safe at every dose level (a scientific impossibility because everything, even water, is unsafe at some dose level).

from ingesting vitamins and minerals). Year after year statistics of injury from ingestible substances reveal dietary supplements to be the safest, safer than foods in common form and far safer than government approved drugs. In short, there is no sound reason to second-guess consumer choice on ingestion of vitamins and minerals.

The European Union Directive is a Slippery Slope

If we needed any proof of the imprudence of having the Codex Alimentarius Commission we need look no farther than the European Union. While it is true that Codex standards are "voluntary" in the sense that member states are free to reject them; it is also true that rejecting a standard accepted by the rest of the world comes at a huge cost economically and politically and that regardless of how any one country reacts to the standards, the international Codex Alimentarius forum itself has served to unite many intent on regulating out of the market many demonstrably safe vitamins and minerals. Indeed, the Codex Alimentarius Commission has helped unite health regulators in Europe in a common cause to remove from the European marketplace many substances that had been consumed beneficially by Europeans for decades.

The European Union Commission Directive 2006/37/EC bans from sale in every country in Europe all products containing vitamins, minerals, herbs and botanicals not listed in Annex II to the directive. The ban reaches hundreds of dietary supplement formulations marketed without serious, adverse effects prior to its adoption. The law in Europe is perverse. Under the directive, every dietary supplement is banned except that which is expressly

allowed. Harm is presumed unless safety is proven to a near conclusive degree and to the satisfaction of European Union officials. A concept known as the precautionary principle is employed with a heavy dose of politics to determine who may enter the European dietary supplement market. Under that principle, a substance is presumed unsafe at every dose level unless it can be proven safe at every dose level (a scientific impossibility because everything, even water, is unsafe at some dose level). Consequently, political decision making is rendered paramount (the European Food Safety Authority can preclude any substance from being allowed on the market under this slippery slope safety regime; thus, all who wish to escape a strict application of the rule and thereby sell dietary supplements in Europe must satisfy whatever demands EFSA and the EU wish to impose upon them). European regulators are intoxicated (to use an upper dose level term) with the notion of the precautionary principle as a political means to limit the number of players in the dietary supplement field and force those admitted to do the bidding of the powers that govern the EU.

How the Codex Guidelines and EU Directive Will Affect the US

Many question whether Codex Guidelines and the EU Directive will affect access to dietary supplements and health information about them in the United States. Many ingredients used in dietary supplements sold in the United States come to us from Europe. Likewise, many domestically produced dietary supplements are sold in Europe. The United States and Europe are inextricably intertwined in most aspects of business and finance. It is

unlawful under domestic American law to export for sale to Europe a dietary supplement that is unlawful there. The impact of moves to restrict dietary supplements in Europe is thus global and, in some instances, devastating to companies in the United States and in other non-European countries.

The Dietary Supplement Industry's Loss is the Pharmaceutical Industry's Gain

Moreover, the EU Directive became law in Europe without so much as a peep of opposition from the United States. That mum response is intentional and meaningful. The Bush Administration's failure to fight against the adoption of EU restrictions on the availability of dietary supplements was a conscious choice. Without question, the Bush Administration knew that failure to fight against the restrictions would harm domestic supplement companies and would reduce the size and economic power of the entire dietary supplement industry, and they chose to permit that harm to occur. As is often the case, harm to one industry benefits another. In this case, harm to the dietary supplement industry benefits the pharmaceutical industry in many ways.

The US is Becoming Less Free

Moreover, the precautionary principle, used by the European Food Safety Authority, is already being applied in the United States regulatory community. Leading members of Congress who favor replicating in the United States the restrictions adopted in Europe, such as Congressmen John Dingell and Henry Waxman, have allies now in place in the Obama Administration's Department of Health and Human Services, Food and Drug Administration, Environmental

Protection Agency, and Federal Trade Commission. We are becoming more and more like Europe. We are becoming less free.

We Have to Fight a Global War to Protect National Rights

In summary, to protect access to dietary supplements and health information concerning them inside the United States, we have to fight a global war against restrictions on dietary supplements and health information related to them. We cannot concede Europe but must help roll back regulatory strictures there. We cannot sit idly by while Canada now endeavors to adopt new restrictions of its own that will reduce the availability of dietary supplements and health information concerning them. We also must be heard to oppose and condemn any efforts to establish international standards to govern vitamins and minerals through the Codex Alimentarius Commission, regardless of how innocuous they may seem at first blush.

Remember that a command to governments world round to review the safety and efficacy of vitamins and minerals and determine what levels should be prohibited for sale is an invitation to restrict freedom of access to the safest dietary ingredients on earth. For the sake of liberty, it should be a cardinal principle that governments may only act to restrict freedom of choice when a substance is proven harmful. When you cannot enjoy the basic freedom of selecting what foods you eat and what nutrients you ingest, you have precious little freedom left. As with all freedoms, legal limits should be placed upon them only when they are employed to cause harm to others. **HK**

***Jonathan W. Emord** is a constitutional and administrative lawyer in Washington, D.C. He has defeated the FDA in federal court a remarkable six times. Congressman Ron Paul calls Jonathan a "hero of the health freedom revolution." He is the author of three critically acclaimed books, "Freedom, Technology, and the First Amendment" (1991); "The Ultimate Price" (2008); and "The Rise of Tyranny" (2009). His books are available for purchase through Amazon.com. He is the host of Health Law and Politics on the Talk Star Radio Network. He is the 2008 recipient of the Cancer Control Society's Humanitarian of the Year award.*

