

# Congressional Outlook On Codex, Medical Privacy, And Stem Cells

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## Codex and Trade Promotion Legislation

For years, people who use dietary supplements have been concerned about the actions of the CODEX and the United States having to adopt, as a member of the World Trade Organization (WTO), international vitamin-and-mineral regulations that would determine what vitamins and minerals could be sold in the United States (see February/March NHF). Some individuals have expressed concerns that if the current Trade Promotion Act (TPA) legislation, HR 3005, is enacted future Presidents could use the law to unilaterally adopt international treaties, specifically the Codex and/or agreements involving the FDA role in implementation of dietary supplement international trade or manufacturing standards. This would occur as a result of the WTO adopting agreed upon CODEX "guidelines" in the form of a separate treaty, or as a part of larger multinational treaties. There is another concern of CODEX opponents. This concern is that the Congress has and would not protect dietary supplement maker's interests and would not be involved in the treaty/trade agreement ratification process if CODEX is presented for US approval in the future.

The pending versions of the House and Senate TPA bills contain provisions that make it harder for the current or future Presidents to unilaterally approve trade agreements approved or not by the WTO. Specifically, the President would be required, at least 90 days before entering into an agreement, to notify Congress of his intent to enter into an agreement. A new requirement would establish that the President, within 60 days of signing an agreement, submit to Congress a preliminary list of existing laws that he considers would be required to bring the United States into compliance with a trade treaty/agreement. And, the bills propose that trade promotion authority would not apply if both Houses separately agree to a procedural disapproval resolution within any 60-day period.

Further, the pending versions of the TPA legislation would establish that after entering into a trade treaty/agreement the President would be required to submit formally the draft agreement, implementing legislation, and a statement of administrative action. Once the treaty/trade agreement legislation was formally introduced, the Congressional committees of jurisdiction would hold hearings, "unofficial" or "informal" mark-up sessions and a "mock conference" with the Senate committees of jurisdiction in order to develop a draft implementing bill and to make their concerns known before the legislation is formally introduced.

HR 3005, the Bipartisan Trade Promotion Authority Act, otherwise know as "Fast Track Trade Promotion" passed the US House of Representatives in December of 2001.

A substantially amended version was voted out of the US Senate Finance Committee at the beginning of March 2002. The Senate version of HR 3005 has since been pending on the Senate Calendar (General Calendar No. 319). Many objections and potential Senate amendments to the committee bill have surfaced. Several Congressional staffers involved with the legislation believe that the bill may eventually pass the Senate. However, the House/Senate Conference Committee to work out differences between the two bills will not be able to reach consensus. The prospects for final passage in this session of Congress are, according to a staff person, "a real long shot".

## **Developments With Medical Privacy**

Following the release of the Bush administration's revised regulation on Medical Records Privacy (MRP) (as reported in the April/May HFNews), the US Senate Health, Education, Labor and Pensions (HELP) Committee, chaired by Senator Edward Kennedy (D-Mass.) held a hearing. Senate Democrats criticized the Bush administration's proposal to roll back certain medical privacy provisions put in place by the Clinton administration. The Administration would drop a requirement that doctors, hospitals and other health care providers obtain written consent from patients before using their personal health information for treatment, reimbursement, or other health care operations or administrative activities.

Under the proposed regulation, doctors, hospitals and other health care providers would still have to inform patients of their privacy rights. People receiving medical care would acknowledge receipt of such notices during office or hospital visits, as opposed to having to sign off on the release of information before receiving medical care. The Bush administration's proposal would also redefine the previous regulatory ban on using patient information for the purpose of marketing by exempting materials that recommend alternative medical treatments, therapies, drugs, or alternative medical providers for an individual patient. In short, exempting from prohibited actions the ability of physicians to communicate freely with patients about alternative forms of individual treatment options and other health-related information.

During the hearing, Senator Kennedy called the proposed changes, which would take effect in April 2003, a "serious step backwards" and said he would introduce legislation to reinstate mandatory consent by patients before being able to receive medical care, except in emergency cases. Congress is unlikely to pass legislation this year to overturn the Bush administration's new medical privacy guidelines because the issue is extremely complicated and there just isn't enough time, or interest, to do much legislatively with it.

## **Access to Medical Treatment Legislation**

The Access To Medical Treatment legislation (HR 1964 and S 1378) would allow a person to receive, and a licensed practitioner to provide or administer any unapproved drug or medical device while requiring that persons be informed about potential medical side effects. The Act would allow physicians to proscribe investigational or alternative medical care treatments without fear of FDA retribution. The bills were introduced earlier

this year. The legislation has been stalled in the US Senate and the House of Representatives. The Energy and Commerce Committee in the House of Representatives has held no hearings.

In the Senate, Senator Charles Grassley (R-IA) tentatively agreed to join as an important cosponsor of the legislation. His fellow state Senator, Senator Tom Harkin (D-IA) is a sponsor and fellow Republican Orrin Hatch (R-UT) is a cosponsor. Senate Majority Leader, Tom Daschle (D-SD) and five other Senators have signed on. Senator Grassley's staff had concerns with the proposed reporting requirements that were clarified and resolved after several months of negotiations with representatives of the American Association for Health Freedom (AAHF). The Congressional legislative agenda is so backup with budget and federal appropriations legislation, and with Medicare reform and other issues, the prospects for serious consideration this year are very slim

### **Update on Stem Cells**

In early May, the US Senate voted to confirmed Dr. Elias Zerhouni as Director of the National Institutes of Health (NIH). The position had remained vacant for more than two years. During his confirmation hearing, Zerhouni, who had currently served as the Executive Vice Dean of the Johns Hopkins University School of Medicine, reaffirmed his "strong support" for federal funding of embryonic stem cell research. But he also told Senators that he would "abide" by President Bush's restrictions on federal funding for the research. Bush's guidelines call for dollars to be allocated only to research conducted on stem cell lines isolated on or before the policy announcement date of Aug. 9, 2001. Zerhouni added that he felt the existing stem cell lines approved for use in federally funded research would be sufficient, but he did not say definitively whether he would urge Bush to reconsider his policy if the existing lines proved inadequate. Zerhouni said he intends to focus on boosting recruitment, improving morale and determining the best ways to spend the NIH budget, which is expected to reach more than \$27 billion in 2003. The NIH funds more than 2,000 biomedical projects in the United States and employs more than 10,000 people.

President Bush and US Senator Bill Frist (R-Tenn.) have endorsed a measure that is currently pending in the Senate that would ban cloning of stem cells for reproductive and research purposes. Senator Frist is the Senate's only physician, and many members of both parties look to him for advice on health and science matters. Senate Majority Leader Tom Daschle (D-S.D.) had promised a vote on the bill before Memorial Day. The Senate vote did not occur because neither supporters nor opponents could line up the 60 votes needed to end a potential filibuster. The bill is currently pending on the Senate calendar and could be brought up for a vote before the end of the session.

### **Dietary Supplement Tax Fairness Act**

Senators Tom Harkin (D-IA) and Orrin Hatch (R-UT) have introduced legislation (S.1330) to make the cost of dietary supplements medical use foods, when offered as a

health insurance plan, tax deductible for employers and excluded from taxable income for employees. The legislation is pending before the Senate Finance Committee but no hearings have been scheduled.

The proposed legislation requires that dietary supplement products meet FDA Good Manufacturing Practice (GMP) standards in order to receive the improved tax treatment. On introduction, the Senators noted that many Americans are using these healthcare products to improve their health and to stay healthy and would like to be able to have access to these products in the form of an insurance benefit. Insurance companies and employers responding to this consumer demand have been frustrated by not being able to offer a benefit. The proposed legislation would offer a strong incentive to maintain and improve the quality of dietary supplement products and give tax code treatment that is consistent with pharmaceutical drug products.

## **2002 State Legislation**

The following summarizes some of the bills under consideration that may have an impact on state public health policy and laws that relate to the use of dietary supplements and a person's medical information privacy. The legislative status summary presented here may have changed since this article was written.

In New York, SB 5563 has been introduced by State Senator Rath and a similar Assembly Bill, AB 7838, has been introduced to direct the State Department of Health to conduct a review of current risks associated with the unregulated sale and use of herbal remedies and dietary supplements. The bills also require the department to work with the State legislative health committees in Senate and Assembly and report findings. The Senate bill is currently pending before the Senate Committee on Health.

Several states have responded to the proposed changes in the federal medical records privacy regulation. In California, State Representative Migden has introduced AB 2191. The bill would prohibit pharmaceutical companies or their agents or representatives from disclosing patient medical information without authorization. The bill is currently pending before the Committee on Appropriations. In Georgia, SB 210 was pending before the Conference Committee. The bill relates to release of patient records and requires the development of patient privacy regulations. In Illinois, HB 5775 amends the existing state medical patient rights law. The proposed change would grant the right of each patient, in non-emergency care situations, to be informed of their privacy rights.

## **Federal Agency Developments**

In early May, dietary supplement maker Biogenics, Inc. signed a consent decree with the Food and Drug Administration (FDA) prohibiting the company from making or distributing unapproved new drugs, including products containing ephedrine hydrochloride or any synthetic ephedrine alkaloid. The company's AMP II Pro Drops, which were marketed and sold as a dietary supplement for treating obesity, are to be destroyed.

The marketers of a do-it-yourself anthrax test kit and a dietary supplement touted as curing hundreds of diseases have settled federal charges of deceptive advertising. The cases are the latest in a series of actions by the Federal Trade Commission (FTC) to combat deceptive promotion of products related to last year's anthrax attacks.

By settling, neither Vital Living Products Inc., which marketed anthrax test kits, nor Kris Pletschke, the operator of the Raw Health Web site, who sold a colloidal silver supplement product claiming it would treat or cure 650 different diseases, including anthrax, Ebola and flesh-eating bacteria, admit to breaking the law.

Under the settlement, Pletschke, based in Beaverton, OR, must offer refunds to consumers who bought the colloidal silver supplement. The FTC has worked with the Food and Drug Administration (FDA) and law enforcement officials in 30 states to search the Internet for misleading bioterrorism claims. Since November of 2001, the FTC has sent warnings to the operators of more than 120 Web sites that promoted questionable products for treating and protecting against anthrax, smallpox and other potential biological weapons. The ineffective remedies have included dietary supplements such as oregano oil and zinc mineral water.

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