Codex, Medical Malpractice, FDA Commissioner, and Healthcare Choice Developments

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Trade Promotion And Codex Update

On August 6th, President Bush signed into law the trade promotion legislation (HR 3009) after a House/Senate Conference committee approved compromise legislation in late July resolving the differences in House and Senate versions passed earlier this year. The reconciled legislation includes provisions to help American workers displaced by international trade to pay for health insurance while being unemployed and being retrained for a different job.

Dietary supplement manufacturers 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), agreed upon CODEX “guidelines” in the form of a separate treaty, or as a part of larger multinational treaties. And, concerned that with the enactment of the reauthorized trade promotion law (TPA) and “fast track” Presidential treaty approval the Congress would not be involved and not be able to prevent the adoption of a treaty or trade agreement that would adversely impact dietary supplement manufacturing standards and the US supplement market.

Much of the press and media attention has focused on issue of allowing the President to submit treaties for Congressional approval on a straight up-or-down vote without amendments legislative process. What have not been covered in much of the reporting are the specific requirements relating to the involvement of the Congress in drafting and reviewing regular and fast track trade agreements and treaties.

While the final trade legislation contains provisions that allow a President to submit treaties for Congressional approval on a straight up-or-down vote basis, the enacted law spells out the specifics for the level of Congressional involvement and a process that must be followed to fit the fast-track approval standard. The Congressional involvement in the initial drafting and approval process for a regular or a fast-track international treaty or trade agreement allows affected industries to present their concerns and have them addressed before Congressional approval is granted for final trade or treaty ratification.

The TPA law contains a provision that requires a President to notify Congress of his intent to enter into an agreement at least 90 days before signing a treaty or trade agreement. A new requirement mandates that a 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 or treaty

agreement. Most importantly, fast track promotion authority would not apply if the House and Senate separately agree to a disapproval resolution within the 60-day waiting period.

The TPA law requires that after entering into a treaty or trade agreement, the President submit formally the draft agreement, implementing legislation, and a statement of administrative action. Congressional committees of jurisdiction can 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 to the President and the members of his cabinet involved in treaty negotiations before the treaty approval legislation is formally introduced and before the Congressional straight up or down with no amendment process takes place.

Congressional Action On Medical Malpractice Reform Done For This Year

The Senate on July 30 voted 57-42 to reject an amendment to a generic drug bill that would have capped damage awards in medical malpractice lawsuits against doctors and insurers. The House of Representatives approved similar malpractice reform legislation earlier this year. President Bush has called on Congress to pass legislation that would cap malpractice awards. The amendment, sponsored by Sen. Mitch McConnell (R-KY) would have limited punitive damages in malpractice suits to twice the amount of compensatory damages, require that 50% of punitive damage awards go to state activities, and restrict trial attorneys' fees. Under the bill, non-economic damages would have been capped at $250,000. The amendment was favored by Republicans, who maintain that many doctors have left certain states, retired early or dropped certain high-risk specialties because of high malpractice insurance premiums. Senate Democrats, however, said that the bill "favored the insurance industry at the expense of victims" of malpractice. Further action is not expected during the remainder of this Congressional session given the shorter election year schedule.

White House Health Policy Adviser McClellan Front-Runner for FDA Commissioner

Dr. Mark McClellan, a member of President Bush's Council of Economic Advisers, has emerged as the leading candidate to take over as commissioner of the Food and Drug Administration (FDA). The position has been vacant since Bush took office. McClellan, a physician and economist, has been a "loyal champion" of the White House's health care proposals, including its versions of a Medicare prescription drug benefit and discount drug card program. In addition, he does not appear to have any links to the pharmaceutical industry, an issue that Democrats on the Senate Health, Education, Labor and Pensions Committee (HELP) have said would be a concern. This committee has jurisdiction over the confirmation of the FDA Commissioner.
Most recently, McClellan was a professor of economics and medicine at Stanford University. Lester Crawford, director of food and nutrition research at Virginia Polytechnic Institute, has filled the FDA position, which requires Senate confirmation, on a temporary “Acting Commissioner” basis. White House officials said that the timing of an announcement about a possible McClellan nomination is uncertain.

Recommendations To Expand Healthcare Treatment Choices

The Integrated Healthcare Policy Consortium (IHPC) has issued its final report of recommendations to be made to the Congress and federal agencies in regards to changes in federal health care policy to advance the availability of integrated complementary and alternative medical care. Key report recommendations are to establish a federal office to foster the creation of an integrated healthcare (IHC) system focused on health promotion and disease prevention; significantly increase federal research allocations for health promotion and disease prevention, and examine the role of CAM and integrated approaches in health promotion and disease prevention; to establish a national consortium of conventional and CAM educators and medical practitioners; to assure widespread access to CAM/IHC in rural areas and under served communities; to achieve regulatory recognition for each alternative medical care profession seeking it in every state and within federal health programs; to develop a national agency that acts as a clearinghouse for defining the qualifications and scope of medical practice for healthcare providers in each discipline, system or modality; and, to ensure that complementary and alternative medicine (CAM) is effectively integrated into the federal government's Healthy People 2020 program. The complete final report, "National Policy Dialogue Final Report", can be viewed on the American Association for Health Freedom (AAHF) website at:

Guidelines for Complementary and Alternative Medical Practice

The Federation of State Medical Boards (FSMB) recently released a policy/position paper entitled "Model Guidelines for the Use of Complementary and Alternative Therapies in Medical Practice", and is asking all state medical boards to adopt the guidelines. The guidelines allow a wide degree of latitude in physicians' exercise of their professional judgment and do not preclude the use of any methods that are reasonably likely to benefit patients without undue risk. They recognize that there are varying degrees of potential patient harm that can result from either conventional medical practices or complementary and alternative medical therapy (CAM) practices. The guidelines recommend that State Medical Boards recognize that the standards used in evaluating health care practices should be consistent, whether such practices are regarded as conventional or CAM and that licensed physicians not be found guilty of unprofessional conduct solely on the basis of utilizing CAM treatment modalities.

The guidelines can be viewed on FSMB website at:
http://www.fsmb.org/siteassets/advocacy/policies/model-guidelines-for-the-use-of-complementary-and-alternative-therapies-in-medical-practice.pdf