SPECIAL ORDERS

The SPEAKER pro tempore. Under the Speaker's announced policy of January 7, 2003, and under a previous order of the House, the following Members will be recognized for 5 minutes each.

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Kansas (Mr. MORAN) is recognized for 5 minutes.

(Mr. MORAN of Kansas addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

PUBLICATION OF THE GMPs

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from New Jersey (Mr. PALLONE) is recognized for 5 minutes.

Mr. PALLONE. Mr. Speaker, I rise on the House floor this evening to express my appreciation for the publication of the proposed rule for dietary supplement current good manufacturing practices, or GMPs. After many years of delay and inquiry, I am pleased that the Food and Drug Administration finally put forth this proposed rule earlier this year as required by the Dietary Supplement Health and Education Act, also know as DSHEA. This is truly a step forward in health care and will help to ensure that the public has access to high-quality, safe dietary supplements.

Overall, Mr. Speaker, I have found that the FDA's proposed rule works in favor of both consumers and the industry. The public should expect nothing less than safe and effective supplements, and it is encouraging to witness the government and industry joining together to provide consumers great confidence that supplements are free from contamination, accurately labeled and effective in improving personal health.

The GMPs also provide guidelines that assist the dietary supplement industry in manufacturing safe, effective, unadulterated products. The industry fully appreciates the economic consequences of these proposed regulations and is prepared to invest in the future of the natural products that they sell.

However, there are some concerns that will be expressed by both the public and the industry during the comment period, and I am hopeful that the FDA will be responsive, given the FDA's shared commitment to deliver products with only optimum health benefits. For example, Mr. Speaker, although the GMPs steer dietary supplement manufacturers down the right path, there are several outstanding issues that must be raised.

Mr. Speaker, I am concerned about finished product testing and the scientifically validated measures to be used. It is crucial that the FDA and the dietary supplement industry agree on the methods and scientific criteria required of product testing in order for consumers to compare products based upon the same standards.

I recognize that the best standards are those developed from scientific and clinical research, and I have always supported efforts to promote research and development of dietary supplement products. It is imperative that the GMPs include incentives for stimulating clinical and scientific research. This research is important for establishing scientifically validated methods for dietary supplement testing and for providing uniform standards that can be accessed and utilized by consumers when comparing the health benefits of supplements.

In addition, Mr. Speaker, the economic pressure that the GMPs will place on small companies, manufacturers and raw material suppliers with less than 500 employees, troubles me. Analysis shows that the cost of compliance for small companies is estimated at $100,000 the year of implementation and $61,000 the following years. The intent of this financial burden is to rid the market of unscrupulous players. However, small companies and mom-and-pop shops comprise approximately 90 percent of the dietary supplement industry, and I fear that many operations will be forced to go out of business due to the high cost of compliance.

As currently proposed, it is estimated that up to 50 percent of the very small companies could go out of business and that product prices could increase by 35 percent. Retailers, small business manufacturers and consumers will ultimately have to absorb these costs, which will most likely result in fewer consumers being able to purchase dietary supplements.

Mr. Speaker, I would also like to note that GMPs also place a fair amount of pressure, economic or otherwise, on the FDA once they are finalized. Enforcement of the rules will be costly. One way for the U.S. Government to minimize these costs will be to allow independent, third-party organizations to conduct inspections and certify establishments as if they were government inspectors.

This is not a unique concept. For instance, the Joint Commission on Accreditation of Health Care Organizations accredits nearly all the hospitals in the United States.

Another good example of industry and government cooperation is the memorandum of understanding that was established between the American Council for Food Safety and Quality, formerly the Dried Food Association of California, and the FDA. The MOU allows the association to inspect member facilities as if they were government inspectors. The program has paid benefits for all involved. The agency would realize reduced administrative cost burdens as inspection costs could be borne by the manufacturer, while also providing expertise and guidance, thereby allowing manufacturers to come into compliance with the new GMP regulations.

Again, Mr. Speaker, I am pleased with the FDA for finally coming forth with this proposed rule, and I remain hopeful that the benefits will include improved health as a result of better access to quality dietary supplements. It is imperative that the FDA use the instructive recommendations it receives during the comment period and that the public and the industry play a significant role in ensuring improved access to safe and effective dietary supplement products.

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The SPEAKER pro tempore (Mr. CARTER). Under a previous order of the House, the gentleman from Indiana (Mr. BURTON) is recognized for 5 minutes.

(Mr. BURTON of Indiana addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Ohio (Mr. RYAN) is recognized for 5 minutes.

(Mr. RYAN of Ohio addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Michigan (Mr. MCCOTTER) is recognized for 5 minutes.

(Mr. MCCOTTER addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Illinois (Mr. EMANUEL) is recognized for 5 minutes.

(Mr. EMANUEL addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Pennsylvania (Mr. SHUSTER) is recognized for 5 minutes.

(Mr. SHUSTER addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Ohio (Mr. BROWN) is recognized for 5 minutes.

(Mr. BROWN of Ohio addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)

The SPEAKER pro tempore. Under a previous order of the House, the gentleman from Oregon (Mr. DEFAZIO) is recognized for 5 minutes.

(Mr. DEFAZIO addressed the House. His remarks will appear hereafter in the Extensions of Remarks.)