



October 24, 2016

Senator Orrin Hatch
Economic Development Task Force (Task Force)
United States

Mr. José B. Carrión III
President, Financial Oversight and Management Board
Puerto Rico

Dear Senator Hatch & Mr. Carrión III:

On behalf of the Puerto Rico Community Pharmacies Association, *AFCPR* for its Spanish acronym, we hereby express our concern and interest in the approval of local regulation to address the increasing industry of natural/nutritional/dietetic supplements, which has become a potentially harmful one from a health stand point.

On February 9, 2016, the Puerto Rico Health Department approved the Administrative Order Number 346 that, among others, required a registry to those interested in selling and distributing natural products and establishing the need to provide quality certificates and an FDA registry previous to selling such products. Notwithstanding the need to regulate this particular business, the administrative order was vacated, apparently due to Section 409 (g)(3) of PROMESA that imposes upon the Task Force the obligation of providing, not later than December 13, 2016, a report in relation to "... the economic effect of Administrative Order No. 346 of the Department of Health of the Commonwealth of Puerto Rico (relating to natural products, natural supplements, and dietary supplements)...".

Natural products are an international concern. In more cases than not, consumers do not know what they are actually ingesting. "Because of lax policies, supplements that make their way into retail stores ... can pose a number of potential problems. They can be ineffective, contaminated with microbes or heavy metals, dangerously mislabeled, or intentionally spiked with illegal or prescription drugs. They can also cause harmful side effects by themselves and interact with prescription medications in ways that make those drugs less effective".¹ Moreover, approximately 23,000 yearly emergency room visits in the United States can be traced to dietary supplements.²

Current federal law imposes licensing and labeling requirements upon manufacturers. Manufacturers have to report adverse effects and can't claim that their products cure or treat

¹ J. Interlandi, *Supplements: A complete guide to safety*, Consumer Reports, Sept. 2016.

² M. Thielking, *Unregulated supplements send thousands to hospital each year*, Oct. 2015, <https://www.statnews.com/2015/10/14/unregulated-supplements-send-thousands-to-hospital-each-year/>

treat specific diseases. States like Washington abide by the federal legislation.³ States like California have specific regulations, in addition to the federal regulations, such as the one that requires a warning statement on the labels of dietary supplements that contain stimulant laxative ingredients.⁴

The serious health risks imposed by natural products are reason enough to justify all efforts to specifically regulate the natural products industry in Puerto Rico. The interest of avoiding those health risks surpasses any economic effect upon manufacturers and distributors. On the long run, less money will have to be spent in treating the side effects, which can even jeopardize the effectiveness of medical treatment. Thus, the approval of local regulation to address the natural product industry in Puerto Rico should be supported and recommended.

We greatly appreciate the opportunity to present our interest and concern on this matter and kindly request that it be taken into consideration by the Task Force.

Kind regards,



Idalia Bonilla
President



Marylís Gavillán Cruz
Executive Director

³ WSDA, *WSDA Handbook for Small and Direct Marketing Farms*, 2014.

⁴ <https://www.cdph.ca.gov/programs/pages/fdbdietarysupplements.aspx>