

Linda M. Dempsey

Vice President

International Economic Affairs

February 26, 2015

Ms. Leslie Kux
Associate Commissioner for Policy
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Ref: Docket No.: FDA-2015-N-0045

Dear Ms. Kux:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide these written comments concerning recommendations by the World Health Organization (WHO) to impose global manufacturing and distribution restrictions under international treaties on certain substances.

The NAM is the largest manufacturing association in the United States, representing more than 14,000 businesses of all sizes in every industrial sector and in all 50 states. Manufacturing employs more than 12 million women and men across the country, accounting for two-thirds of private sector research and development and contributing over \$2.08 trillion to the U.S. economy annually.

To promote growth, serve the general public and protect individuals and the environment, the NAM supports regulatory policies designed to favor markets and adhere to sound principles of science, risk assessment and cost-benefit analysis. While some objectives of government can be achieved only through regulation, we believe regulatory systems can protect public health, worker safety and the environment while minimizing unnecessary burdens on regulated entities. Added costs imposed by unnecessary regulation can hinder economic growth without a commensurate benefit. Critical inputs, including reliable scientific and technical data, should help regulators design frameworks that meet objectives while minimizing costs.

In this spirit, the NAM appreciates this opportunity to comment on the WHO's December 2014 recommendation to place gamma-butyrolactone (GBL) and 1,4-butanediol (BDO) on Schedule I of the 1971 Convention on Psychotropic Substances (1971 Convention). GBL and BDO are high-volume industrial chemicals with multiple uses that touch nearly every part of the manufacturing economy. According to Environmental Protection Agency data, over 249 million pounds of GBL and over 583 million pounds of BDO were either manufactured in or imported into the United States in 2012.¹

GBL and BDO are essential substances used in a wide variety of industrial applications, including cleaning circuit boards in electronics industries, manufacturing high performance, energy efficient plastics for automotive, electronics, construction and consumer applications,

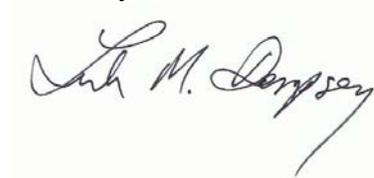
¹ Latest information available from the United States Environmental Protection Agency, [Chemical Data Access Tool \(CDAT\)](#).

producing spandex fibers for textiles and as intermediaries in the production of pharmaceuticals and crop protection products.

As the Food and Drug Administration and other federal agencies prepare for next month's 58th WHO session in Vienna, Austria, the NAM urges you to take fully into account the widespread and legitimate industrial uses of GBL and BDO and the significant damage further restrictions on their use would have on the U.S. manufacturing economy and jobs.

The NAM appreciates this opportunity to comment and looks forward to working with you to prevent imposition of burdensome and disruptive new global rules that are unlikely to deliver benefits sufficient to justify their cost.

Sincerely,

A handwritten signature in black ink on a light yellow background. The signature is written in a cursive style and reads "Linda M. Dempsey".

Linda Dempsey