

Journal of Regulatory Science

http://journalofregulatoryscience.org



What is in the Product and How to Measure It?

Susie Y. Dai^{a, b}

Editorial

^a Office of the Texas State Chemist, Texas A&M AgriLife Research, Texas A&M University System, College Station, TX 77841, USA ^b Texas A&M University, Department of Veterinary Pathobiology College Station, TX 77843, USA

Label claim, as its name implies, assures consumers that the claims printed on the label of a regulated product accurately represent the product within. Ruth et al. reports in "Consistency of label claims of internet-purchased hemp oil and cannabis products as determined using IMS and LC-MS: a market survey" of a qualitative and quantitative study of 23 hemp oil products using two advanced instrument methods: an ion mobility mass spectrometry method and a liquid chromatography highresolution mass spectrometry method. Cannabis products have become a hotly debated topic due to recent legislative changes. Although several cannabinoid compounds are designated as Schedule I controlled substances by the U.S. Drug Enforcement Administration (USDEA), many state legislatures have legalized marijuana for medical use, recreational use, or both. Schedule I controlled substances are defined by DEA as "drugs with no currently accepted medical use and a high potential for abuse. Schedule I drugs are the most dangerous drugs of all the drug schedules with potentially severe psychological or physical dependence" (USDEA). Regardless of state-level legislation and on-going debate in state legislature, science-driven research forms the background needed by the general public, public health officials, and policy makers to make informed decisions about cannabis products and marijuana. Particularly important from a public health perspective are methods to assess cannabis product content and safety. Ruth et al. found that some commercial products were not consistent with the label claim, foreshadowing future regulatory challenges of the cannabis industry, such as denoting compounds to be sought in testing, testing methods, and the implementation of quality control and quality assurance.

Not to be confused with hemp, from which recreational marijuana is made, *Apocynum cannabinum*, commonly referred to as dogbane or Indian hemp, is a versatile native North American plant. The bioactive compounds from *Apocynum cannabinum* offer anti-inflammatory and neuroprotective effects and can be used as phytomedicines (botanical remedies) and herbal supplements (Simonyi, Serfozo et al. 2012). In "Identification of unknown compound in *Apocynum cannabinum* by high-resolution mass spectrometry and 600-MHz NMR," Luo et al. successfully extracted, isolated, and identified a compound found to be 4'-hydroxyacetophenone. Also extracted from *Apocynum cannabinum* is apocynin, a well-known natural product with disease-curing properties. The study by Liu et al. proves high-resolution mass

spectrometry to be an effective tool in survey studies for the identification of non-targeted constituents when searching for potential contaminants in a product.

In "Emerging growth of orphan drugs for neurological diseases in Japan: potential benefits for both patients and pharmaceutical companies from a statistical perspective," Shibata et al. analyzed the orphan drug market and its regulation in Japan and suggested that the increase in approval, and thus availability, of orphan drugs occurs at the same time, and is possibly caused by the absence of competition by generic pharmaceuticals. The Japanese orphan drug market is much smaller and less attractive to pharmaceutical companies than that of the US market. The Shibata et al. study shows that the appropriate government regulation and market-economic leverage can arrive at a win-win situation for patients and companies.

The Journal of Regulatory Science (JRS) is devoted to publishing advances in regulatory science, including product testing, monitoring, surveillance method development, quality control, and quality assurance at no cost to the reader and author.