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AHIMA Response to FDA Information Request

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- MD NY Medical College, 1971; Family Practice, 1971-1974; Fellow, American Academy of Family Practice, 1975 to present (40 Years)
- Diplomate, British Institute of Homeopathy, 1990; Fellow, BIH, 1993
- Arizona Homeopathic Board appointments: 1996, 1999, 2002, 2013; Board President, 1998-2003 and 2014-2015
- President, Arizona Homeopathic and Integrative Medical Association (AHIMA), 2005-2013
- AMA Distinguished CME Award 1978, 1981, 1984, 1987, 1990, 1993, 1996, 1999, 2002, 2005, 2008, 2011, 2014

What are consumer and health care provider attitudes towards human drug and biological products labeled as homeopathic?

QUESTION

Provider Attitudes Toward Homeopathics

- **Personally have overseen 20,000 patient visits in practice over 25 years**, many of whom benefit from homeopathy
- **Homeopathy is critical to my success in helping patients**, particularly those who haven't been helped elsewhere
- **Truly complementary practice**: Times when traditional medicine is essential; times when homeopathics are more appropriate

Provider Attitudes Toward Homeopathics

- **Have never experienced safety or quality issues**
 - In my 25 years of practice using homeopathic therapy with over 20,000 patient visits , I have had very few if any material adverse events reported by my patients and have helped many recover from symptoms that did not respond to other types of medical care.
 - There are almost a hundred AHIMA practitioners who we estimate to have seen 1,500-2,000 patient visits each year over the course of the last 15 years, leading to a conservative estimate of about **2 million patient visits** seen over this time period.
 - During that time period, there have been only 3-6 complaints per year to the Homeopathic Medical Board, which oversees these practitioners and for which I was President, each year, **usually over non-homeopathic issues.**

Provider Attitudes Toward Homeopathics

- The federal regulations are clear: **Homeopathy should be available for use and regulated under the HPUS guidelines**
 - Important for practitioners to be able to **choose the appropriate medical path** for patients, especially in non-life-threatening situations and in areas where other medical options have failed for patients

Is there information regarding the regulation of homeopathic products in other countries that could inform FDA's thinking in this area?

QUESTION

Homeopathy in Other Countries

- **No major organization, country, or government in the world has determined that homeopathy is not safe.**
 - **All major countries allow homeopathics** to be used as one of many available medical therapies
 - According to a WHO report entitled *Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review*, only Honduras does not allow the practice of homeopathy (along with other types of alternative medicine)

Homeopathy in Other Countries

- **Homeopathy is recognized and utilized as a system of medicine by most major countries**
 - WHO published the top 20 ranked healthcare systems by country in 2000 (latest report). Of the top 20 countries worldwide (with population of greater than 5 million):
 - All 12 of the top 20 countries with populations greater than 5 million allow homeopathy to be utilized
 - 9 of the 12 have officially recognized homeopathy as a medical therapy

Homeopathy in Other Countries

- Homeopathy is a material portion of the medical systems in many countries throughout the world, including those in countries with **first-rate medical systems** such as France, Germany, and Great Britain.
- Many doctors in these countries use homeopathic therapies along with non-homeopathic drugs to great effect.
- France was rated the #1 medical system by WHO
 - In 1997, it recognized homeopathy as a “medical therapeutic method.” 39% of French physicians have prescribed homeopathics.
 - Multiple French medical schools offer a degree in homeopathy, and all pharmacy schools in France teach homeopathy courses.

Homeopathy in Other Countries

- According to the *BMJ*, in the Netherlands, 40% of general practitioners use homeopathy
- A five-year comprehensive review completed by the Swiss government examined efficacy, real-world effectiveness, appropriateness, safety, and economy of medical therapies. This review found that *the individual CAM interventions, especially homeopathy, were effective, under Swiss conditions safe and, as far as could be judged from the trial situation, also cost efficient.*

Homeopathy in Other Countries

- Homeopathy is a major source of healthcare in India:
 - Recent *Lancet* paper says that over 100 million Indians use it as their sole source of healthcare
 - According to *MedIndia*, there are 185 homeopathic colleges and 11,000 homeopathic hospital beds in India

Are the current enforcement policies under the CPG appropriate to protect and promote public health in light of the tremendous growth in the homeopathic drug market? Are there alternatives to the current enforcement policies of the CPG that would inform FDA's regulatory oversight of drugs labeled as homeopathic? If so, please explain.

QUESTION

Current Enforcement Policies are Appropriate

- **No need to change guidelines; the public is currently adequately protected by FDA regulatory authority, 400.400 CPG, GMP practices, the FTC, and the legal system**
- **FDA has substantial regulatory authority to ensure public safety**
 - Homeopathics are manufactured under strict GMP guidelines with the homeopathic process defined in the HPUS
 - Current 400.400 CPG **provides substantial guidance** for the marketing of homeopathic products.
 - Effectively regulates all users to ensure safety, product quality, labeling guidelines and OTC indications for the majority of the homeopathic products
 - Ensures that homeopathics are not used for non-OTC indications

Current Enforcement Policies are Appropriate

- **The FTC monitors the healthcare industry, including homeopathics**, focusing on issues such as false advertising and unreasonable claims.
- The FDA and FTC are also able to work jointly when needed and have the regulatory power to educate consumers, and ensure proper messaging and marketing to provide public safety and awareness

A large majority of human drug products labeled as homeopathic are marketed as OTC drugs. These products are available for a wide variety of indications, and many of these indications have never been considered for OTC use under a formal regulatory process. What would be an appropriate regulatory process for evaluating such indications for OTC use?

QUESTION

Current Regulatory Process for Indications is Appropriate

- Homeopathic indications have **always been regulated** through the HPUS and other accepted monographs/scientific data
 - Any other regulation of indications would mean that these substances would no longer fall under the definition of a homeopathic
 - Homeopathic principles, as directed by the HPUS, dictate a specific method of determining correct indications
 - The current system of determining the appropriate indications is a fundamental and core premise of homeopathy and has been safely and effectively used since inception

Current Regulatory Process for Indications is Appropriate

- The FDA has provided clear guidance that an OTC indication can only apply for conditions that a consumer can:
 - Self-diagnose
 - Self-treat and
 - Self-manage
- **Homeopathics are safe and appropriately regulated for OTC conditions**

Current Regulatory Process for Indications is Appropriate

- **FDA currently has ample regulatory power** to ensure that indications are appropriate for OTC use
 - There is a clear standard for the FDA to regulate current indications that fall outside these guidelines for non-prescription homeopathic products
 - The FDA already provides appropriate guidance and enforcement
 - The FDA issues warning letters to manufacturers or sellers of homeopathics that have promulgated indications that are outside the realm of an OTC indication

Do consumers and health care providers have adequate information to make informed decisions about drug products labeled as homeopathic? If not, what information, including, for example, information in labeling, would allow consumers and health care providers to be better informed about products labeled as homeopathic?

QUESTION

Consumers and Providers Can Make Informed Decisions Now

- Current labeling and available resources provide substantial information to support use of homeopathic products with consumers and inform them about use of these products
 - Detailed labeling guidelines are robust and adequate
 - Indications provided are simple and straightforward
 - Individual ingredient information is readily available to the public through multiple sources

Consumers and Providers Can Make Informed Decisions Now

- Healthcare providers have even greater access to help them make informed patient decisions
 - Textbooks, educational courses, software programs, and internet compendiums are available to provide further understanding of how homeopathics might best be used with an individual patient

Conclusion

- **Homeopathics are safe, effective, and crucial** to our ability to treat patients
- The current regulatory structure meets the needs of consumers and healthcare providers and ensures standards of quality by homeopathic drug manufacturers
- **No changes to the current regulations are necessary**