AMERICAN ASSOCIATION FOR HOMEOPATHIC PRODUCTS

AAHP

— EST. 1923 —

CHAPTER TWO:

History of AAHP

HISTORY OF AAHP

Introduction

AAHP was founded in 1923 and its early members included Boericke & Tafel, Ehrhart & Karl, Humphrey's Pharmacal, John A. Borneman and Sons, Luyties Pharmacal, and Otis Clapp & Sons.

From the early part of the century until the 1970s, the trajectory of the U.S. homeopathic market was in decline. (Read more in "Homeopathy in the United States and Milestones.") This caused both a decline in homeopathic manufacturers and a shift away from homeopathic products being primary offerings at the remaining manufacturers.

For instance, Standard Homeopathic Company (now Hyland's Consumer Health) focused on Hyland's Pink Aspirin for Children; Borneman and Sons and others were drug wholesalers; and Luyties Pharmacal formed a company called Inland Alkaloids that concentrated on various alkaloids and chemical constituents. The homeopathic industry was shifting from "mom and pop pharmacies" to small manufacturers beginning to operate on larger scales. Due to these divergences, the association functioned more as a friendly social forum for competitors than an association working on behalf of a disparate membership.

The resurgence and consistent growth of the U.S. homeopathic market in the late 1970s through today parallels AAHP's extraordinary growth and its activities, which is the focus of this article.

1970s

Several factors converged in the late 1960s/early 1970s that made the environment ripe for both homeopathy and AAHP to grow in the U.S. At this point in time, 50 years of experience with allopathic "miracle drugs" had been amassed along with increased awareness of these products' side effects. "Health food stores" became common in the United States. A new generation of health care providers sought to learn from the last practicing generation of homeopaths then in their 60s.

Eric Foxman, current and longtime AAHP Secretary, remembers, "I went to my first meeting in 1978 — the year I graduated pharmacy school. The grandfather of Jay Borneman (current and longtime Chair of AAHP's Legal and Regulatory Committee) gave a talk about harvesting plants wherever he could find them. I was in my 20s and this was a group of older guys who knew one another very well; their wives even knew one another well." The small AAHP business meetings would often take place in someone's hotel room — mostly Willard "Bud" Eldredge of Humphrey's Pharmacal. The meeting was followed by an evening dinner for social interaction.

A year later in 1979, the Homeopathic Pharmacopoeia Convention of the United States (HPCUS) was launched at a pivotal meeting of the American Institute of Homeopathy (AIH) in San Francisco. "AAHP leaders Bud Eldredge, Glenn Hill of Luyties Pharmacal, Jack and Jay Borneman of Borneman and Sons, Tariq Kurashi of Standard Homeopathic Company, Bob Pinco, Esq., and Ralph Packman attended along with physicians, including Allen Neiswander, Henry Williams, and Wyrth Post Baker," recalls Jay Borneman. Concurrently, AAHP briefly joined with AIH, the National Center for Homeopathy (NCH), and the American Board of Homeotherapeutics under the umbrella of American Foundation for Homeopathy.

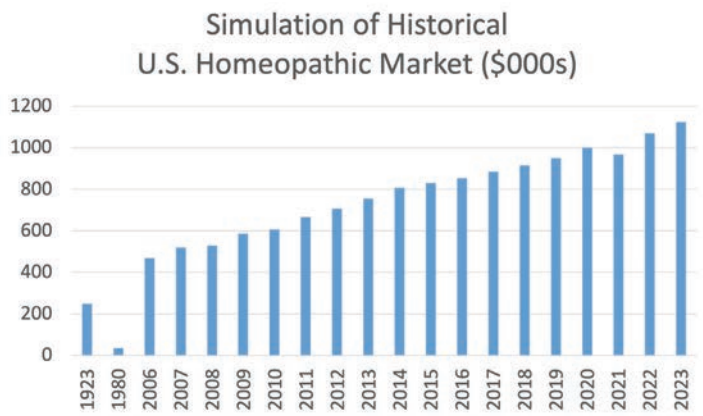
National distribution by homeopathic companies became common; this melted away previous geographic frictions that had existed between manufacturers, and which had limited AAHP activities in its first decades.

As it had been for more than a century, the definition of a homeopathic product continued to be the focus of passionate discussions among manufacturers and the homeopathic community. Traditionalists valued the known while progressives sought to further advance the market. As new members applied for AAHP membership, discussions arose on acceptable methods and dosage forms. Eventually the responsibility to define this class of drug fell to HPCUS. Similar discussions persist today as the industry changes and advances, which illustrates the challenge and success of AAHP in unifying a wide range of manufacturers throughout the years.

The industry truly began to galvanize when faced with common issues, especially negotiating with government agencies and bureaus on matters affecting business in the 1980s such as reimbursement of alcohol drawback tax. AAHP advocated to retain the status that products above 4X were subject to tax reimbursement called "drawback." This status was put at jeopardy following an early 1970s shuffle in government agency duties. AAHP formed a special committee to write and file a petition addressing the points of non-potability and the inconsistencies of the Bureau of Alcohol, Tobacco, and Firearms applying its own standards.

1980s

As consumer demand increased, more manufacturers entered the homeopathic market, including European homeopathic companies. Among the longest lasting is the French homeopathic manufacturer and AAHP member Boiron, which opened its U.S. headquarters in 1983 by purchasing John A. Borneman and Sons outside of Philadelphia.



1923 and 1980 in 2023 dollars; adjusted to current population

More active manufacturers resulted in more association activities that continue to this day. Three educational seminars were organized that decade. In 1981, AAHP proposed to FDA criteria to categorize individual homeopathic products into either prescription drugs or over-the-counter drugs. This occurred against a backdrop of FDA's episodic attention to the 1951 Durham Humphrey Amendment that considered all homeopathic products as prescription only. However, the agency's attention was unevenly applied in relation to imported homeopathic products verses domestically produced homeopathic products. This intermittent attention created problems for FDA, U.S. Customs, and manufacturers — a situation which together cried out for a fair and even-handed resolution.

For five years, AAHP members worked together to address FDA's concerns, which led to an appropriate compliance policy. Al Lorman was brought on as AAHP's Legal Counsel to represent the industry during negotiations with FDA. This resulted in the regulatory framework that governed the marketing of homeopathic products for nearly 30 years: the 1988 Compliance Policy Guide 400.400, Conditions Under Which Homeopathic Drugs May be Marketed.[1] This was a major victory for AAHP and significantly advanced the U.S. homeopathic market.

1990s

The CPG 400.400 brought stability; manufacturers and retailers now felt safe investing in homeopathic products on a wider scale. This resulted in products jumping from health food stores with the then-niche natural shopper to the Food/Drug/Mass retail channel with a wider general audience of shoppers.

With set government rules in place, retail barriers broken down, and demand for products building, the question became, "was the industry equipped to deliver?" AAHP turned its attention to educating manufacturers on quality issues to ensure public safety. At the same time, AAHP wrote and sponsored a Continuing Education Course for pharmacists.

In 1995, AAHP hosted a compliance roundtable for industry with FDA's Edward Miracco, who was assigned by the agency to field questions about CPG 400.400. AAHP's educational programs, now branded as "Compliance Through Education," offered an efficient way for FDA to reach many manufacturers at once.

This industry-wide consensus provided by AAHP is a requirement when dealing with most government entities. Mark Land, current AAHP President and Boiron USA Vice President of Government and Regulatory Affairs, recalls his French-based employer experienced issues importing homeopathic products into the United States. The company filed a petition with the U.S. Customs Service (now the U.S. Customs and Border Protection) in the late 1990s. The petition argued that, although the starting material of a homeopathic product may be too dilute to test at that time, the sugar spheres used as the inactive substrate in homeopathic OTCs were different than sugar used as a sweetener. The Customs Service — much like BATF in the 1980s — asked for industry agreement on the point and AAHP assisted in verifying and speaking on behalf of the industry with an outcome that was favorable to all.

AAHP took full advantage of this decade-long pipeline into FDA created by Miracco, working on the following issues:

- Drug listing complexity/potential solution for homeopathic drug products.
- English names only requirement on homeopathic drug product labels.
- Exemption from the Imprinting of Solid Oral Dosage Form Drug Products for Human Use.
- Exemption from Alcohol Content Limits.
- Solution to BATF drawback issues.

As an approachable liaison to the industry, Miracco formed an invaluable and successful relationship between FDA and the industry through AAHP. Equally significant, AAHP provided FDA with the industry-wide representation it required; the agency did not want to hear viewpoints of single companies. Miracco had a particularly strong relationship with HPCUS President Jack Borneman; they spoke regularly. It is unfortunate that when Miracco retired in 2006, his replacements at the agency were not interested in homeopathic products; this connection between FDA and AAHP was lost to the detriment of both.

2000s

Interest in natural products continued to grow into the new century. Increasing consumer demand enticed "Big Pharma" companies to purchase homeopathic product lines and smaller niche manufacturers. Land notes, "This created new challenges and new opportunities for AAHP." The association entered an era of diversified members: small and large, as well as companies solely dedicated to homeopathy and others with varying product lines.

A new era in adverse event reporting also began in 2006. The reporting requirements applied to homeopathic products as well. From that point on, AAHP emphasized information to its membership on the importance of ensuring public safety through quality controls in production.

Throughout the 2000s the association focused on:

- Presenting 13 educational events for the industry.
- Supporting AIH's rededication of the Samuel Hahnemann Memorial.
- Conducting a market survey on size, sales, and product line distribution.
- Requesting an exemption for a stay of revocation of final product testing.
- Successfully reversing U.S. Customs Service's classification of homeopathic drug products as "foods."
- Contracting a survey of American Association of Poison Control Centers (AAPCC) on the safety of homeopathic drug products.

2010s

AAHP's educational events jumped to the next level; 17 in-person and virtual programs were organized during this decade whereas just one annual seminar was held in the past. During one three-year period, AAHP educated more than 500 people, engaging more and more members of the industry.

AAHP worked with FDA to address challenges with the electronic drug listing that were unique to homeopathic products. For example, multiple attenuations/dosage forms of homeopathic drug products would not require individual submissions and unique identifiers for homeopathic starting materials were created for use by all interested manufacturers.

Behind the scenes, AAHP was also active in maintaining a favorable regulatory environment. It worked with the Consumer Healthcare Products Association, a reciprocal member and ally, to ensure homeopathic prescription drugs were exempt from new requirements on supply chain tracking imposed by the newly passed Drug Quality and Security Act. AAHP also successfully defended the industry against unintended consequences of OTC monograph reform by monitoring and advising lawmakers on provisions of the legislation that would have subjected homeopathic manufacturers to user fees.

Government Relations

The efforts mentioned above were the result of a federal relations program that AAHP launched in 2011. For more than a dozen years, AAHP has worked to educate Congressional members and their staffers on homeopathic drug products and appropriate regulations. AAHP members continue to receive regular and breaking news reports of legislative and regulatory activities that may affect the future of their business.

This program has included:

- A Congressional luncheon briefing at the U.S. Capitol Visitor Center for dozens of Capitol Hill staff.
- Honoring Senator Tom Harkin (D-Iowa) with AAHP's Legislative Excellence Award in appreciation for introducing and supporting legislation that safeguards Americans' right to choose complementary health care.
- Honoring Senator Barbara Ann Mikulski (D-Maryland) with AAHP's Legislative Excellence Award for her support of policies that safeguard homeopathic manufacturers and medicines.
- Organizing an intimate luncheon with Senator Bob Casey (D-Pennsylvania) with prominent members of the homeopathic community in Pennsylvania, including local NCH and AIH representatives and homeopathic manufacturers with employees in the state.

Each year AAHP works to ensure a favorable regulatory climate for homeopathic products while maintaining public safety. Congressional staff are continually educated through meetings. AAHP members also attend fundraisers and local events through organizations such as a Chamber of Commerce to raise awareness of homeopathy directly to Members of Congress.

FDA Hearing and Guidance (2015–2022)

In 2015, FDA held a public hearing on the regulatory framework of homeopathy due to its concerns about unexpected market growth and corresponding safety statistics. Within three weeks, AAHP identified a wide variety of experts, obtained speaker time slots, and hired a firm specializing in FDA communications to review presentations and prepare the speakers. AAHP financially supported these efforts as well as hiring a prominent toxicologist to analyze data maintained by the American Association of Poison Control Centers (AAPCC). Some of the funding for this intensive analysis was contributed by the Consumer Healthcare Products Association, an AAHP member to whom AAHP expresses much gratitude for this support. The analysis revealed the number of exposures to homeopathic medicines in any given year was less than 1 percent of all pharmaceutical reports to AAPCC, which is proportionally below their market share. Furthermore, 99 percent of all exposures were managed outside of a health care facility.

Two years later, FDA published a guidance document[2] on homeopathic product enforcement, which underwent subsequent revisions. (Read more in "Regulatory Framework for Homeopathic Medicines.")

FTC Workshop and Disclaimer (2015–2017)

AAHP rallied again for the Federal Trade Commission (FTC) "Workshop on Homeopathic Medicine & Advertising," also held in 2015. The workshop focused on clinical trials of homeopathic products or a disclaimer statement on labeling and advertising.

The association identified, nominated, and prepped half of the 20 panelists/subject experts in industry growth, scientific support for advertising claims, and legal/regulatory issues, including class action lawsuits. The workshop resulted in FTC publishing an enforcement policy a year later,[3] which included a very negative and lengthy recommended disclaimer. AAHP met with FTC, developed a research protocol leading to the

creation of and consumer-testing of disclaimer language. This was presented to FTC and achieves both of its goals: to inform consumers about the nature of the evidence supporting homeopathic product claims; and to protect the seller from claims of misrepresenting the product. AAHP underwrote the costs of this effort in the amount of $100,000 — a sum that would have been difficult, if not impossible, for most companies on their own. (Read more in "Regulatory Framework for Homeopathic Medicines.")

2020s: Recent Activities

For activities related to the FDA Guidance and the FTC enforcement policy, AAHP members raised around $450,000. "That was heroic by our standards at the time," recalls Land. "It is a strong measurement of how much coalescence could happen within the membership. And it led the entire industry and homeopathic community."

With more members and more budget, the association's focus has shifted to building compliance and a relationship with FDA by working on regulatory and technical ambiguities in cGMP observance. AAHP has hosted a series of industry-wide "summits," the first of which drew more than 100 in-person attendees from the U.S. and five other countries. FDA's Director of Office of Manufacturing Quality served as the keynote speaker; this led to engagement with FDA's Office of Compendial Affairs to identify and solve technical gaps.

The second summit continued to build relations with FDA by together exploring compliance solutions related to the agency's enforcement priorities. This summit included a frank dialogue with the presenter from FDA who also provided breaking insights into FDA's concerns with potential contaminants impacting inactive ingredients commonly used in homeopathic products. These insights helped the industry avoid problems by knowing of their possibilities ahead of time. FDA presentations at AAHP Summits continue an ongoing collaborative educational effort with FDA personnel that began a number of years earlier with their presentations at in-person and virtual seminars.

AAHP responded to FDA's enforcement action against homeopathic injectable products by engaging in meaningful discussions with FDA's Office of Compliance. These meetings revealed the agency's concern about safety. AAHP then filed an amicus curia in support of the safety of homeopathic medicines in general.

On behalf of membership and the industry in general, AAHP filed comments and alerted industry on FDA's draft guidance on annual reporting of quantities of drugs manufactured or compounded. AAHP's comments focused on the large variety of homeopathic drug products and the small quantities produced in comparison with the goals of collecting the information. AAHP requested revision of the guidance to only require submission of relevant and meaningful information.

Last, in recent years, AAHP launched an annual Industry Reception. This forum is designed to connect and support retailers who champion the industry's products with manufacturers' sales executives. At the receptions, the AAHP Integrative Medicine Retailer Award has been presented to Wegmans, Rite Aid, Meijer, H-E-B, and Walgreens. Concurrently, the association launched a successful Annual Executive Briefing for C-level leaders within member companies.

Second Century

As the organization's second century begins, the shifting constellation of members and changing association focus has made the original name misleading to many. As noted above, the "industry" has evolved from individual pharmacies to manufacturing and marketing companies. Thus, beginning in 2024, a new name has been adopted: **American Association for Homeopathic Products.**

AAHP Legacy

The legacy of AAHP is in substantially shepherding the development of the regulatory framework over the last decades. The resulting stable environment attracted investment and business flourished.

The stability in the marketplace increased broader retail access to and visibility of the products. In turn, a broader audience continues to discover and benefit from homeopathic products. Despite a current less-than-friendly regulatory environment, much is built upon AAHP's regulatory expertise and decades of work with FDA and FTC as described throughout this article.

The development of these positive marketing conditions would not have been possible without the support of AAHP member companies, and the collegial relationship fostered through working together.

Many factors have dramatically required AAHP to evolve, yet the core goal remains the same: educating manufacturers to offer high-quality products and communicate clearly with consumers.

References

1. 53 Fed. Reg. 221728 (June 9, 1988).
2. United States Food and Drug Administration, Homeopathic Drug Products Guidance for FDA Staff and Industry. (December 7, 2022).
3. United States Federal Trade Commission, Enforcement Policy Statement on Marketing Claims for OTC Homeopathic Drugs. Federal Register. Vol. 81, No. 239. (December 13, 2016).