An Overview of the Regulation of Homeopathic Drug Products in the United States and the Role of the Homoeopathic Pharmacopoeia Convention of the United States

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Objectives

• Discuss the regulatory status of homeopathic drug products in the United States
• Contrast with Dietary Supplements and Allopathic Drug Products
• Present a brief history of the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS)
• Review the current Procedures and Practices of the HPCUS
Homeopathy- Definitions

- Homeopathy
  - Natural Medicines, classified as drugs under FDCA since 1938
  - Long History of safety
    - Observed to work according to ‘Principle of Similars; Like ‘cures’ like
    - Uses small doses of drugs
    - Controversial: paradoxical drug effects- smaller doses seem to produce larger clinical effects
CHAPTER II—DEFINITIONS

SEC. 201. [21 U.S.C. 321] Definitions; generally

For the purposes of this Act—

(a)(1) The term "State", except as used in the last sentence of section 702(a), means any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico.

(2) The term "Territory" means any Territory or possession of the United States, including the District of Columbia, and excluding the Commonwealth of Puerto Rico and the Canal Zone.

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term "Department" means the Department of Health and Human Services.

(d) The term "Secretary" means the Secretary of Health and Human Services.

(e) The term "person" includes individual, partnership, corporation, and association.

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

http://www.fda.gov/opacom/laws/fdcact/fdca1.htm
(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) or sections 403(r)(1)(B) and 403(r)(5)(D), is made in accordance with the requirements of section 403(r) is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading statement is made in accordance with section 403(r)(6) is not a drug under clause (C) solely because the label or the labeling contains such a statement. (emphasis added)
Compliance Policy Guide 7132.15 - the critical link

- Announced June 9, 1988, effective in 2000
- CPG 7132.15 “Conditions Under Which Homeopathic Medicines May Be Marketed”
- Provides guidelines for OTC and prescription homeopathic drugs
- Provides guidelines for labeling, indications for use and homeopathic names
## Allopathic Drugs, Homeopathic Drugs and Dietary Supplements are Regulated Differently

<table>
<thead>
<tr>
<th>Type of entity</th>
<th>Applicable Legislation</th>
<th>Is there premarket approval</th>
<th>Are there labeling guidelines?</th>
<th>Are there good manufacturing practices?</th>
<th>Who enforces labeling guidelines?</th>
<th>Are claims on the label?</th>
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<tbody>
<tr>
<td><strong>Dietary Supplements</strong></td>
<td>1994 amendment to FDCA, the Dietary Supplement Health and Education Act (DSHEA)</td>
<td>No</td>
<td>Yes: DSHEA</td>
<td>Yes, lower level than for drug products</td>
<td>FTC</td>
<td>&quot;structure-function&quot; claims only</td>
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Regulation 1906, 1938, 1962

- 1906, Pure Food and Drug Act.


- 1962, Kefauver amendments to FDCA respond to thalidomide scandal. Standard is now **safe and effective**
  - Makes all homeopathic drugs prescription. Un-enforced.
An HPUS timeline: Phase One 1841-1897

The Homoeopathic Pharmacopoeia of the United States has been in continuous publication since 1897

Roots:

1841- Jahr's Pharmacopoeia and Posology, which appeared in Germany, and was translated into English by Kitchen and published in Philadelphia in 1842

First Independent US Publication:

1868- American Institute of Homeopathy Committee to produce a Dispensatory chaired by Carroll Dunham

1882- Boericke and Tafel Homoeopathic Pharmacopoeia of the United States
An HPUS timeline: Phase Two 1897-1980

Publication by the American Institute of Homeopathy

1897- Committee on Pharmacy of the American Institute of Homeopathy. Homoeopathic Pharmacopoeia of the United States (Otis Clapp, Boston), First Edition

1901- Second edition (Mohr/Clapp)

1914- Third edition (TH Carmichael/Clapp)

1936- Fourth edition (TH Carmichael)

{1938- Passage of Food, Drug and Cosmetic Act (Copeland)}

1938- Fifth edition (TH Carmichael)

1941- Sixth edition (TH Carmichael)

1964- Seventh edition (Roger Schmidt)

1974- Compendium of Homeotherapeutics (Baker)

1978- Seventh edition, Volume 1 (Rogers/Baker)
An HPUS timeline:
Phase Three, 1980-Present

Publication by the independent Homoeopathic Pharmacopoeia Convention of the United States

1980- HPCUS is incorporated as an independent body. (Baker, Eldredge, Borneman III, Coulter, Neiswander)
1982- Eighth edition, Supplement A (Baker)
{1983-1988- Development of Compliance Policy Guide 7132.15 (Borneman)}

1988- HPUS Revision Service (HPRS)
{1990- Compliance Policy Guide 7132.15 becomes effective}

1992- HPRS is complete, semi-annual updates: Supersedes Compendium and Supplement A as the official compendium.
1992-2004- Monographs, General Pharmacy, Standards and Controls updated semi-annually
2004- HPUS online begins, immediate/real-time updates
Article Three
The purpose or purposes for which the corporation is organized is []:

to accumulate pertinent information, and to publish and sell the Homœopathic Pharmacopoeia of the United States and any additions or supplements thereto;
to promote the art of healing according to the natural laws of cure from a strictly homœopathic standpoint;
to diffuse knowledge among the laity and professionals in the health care field concerning homœopathic principals through means, of publications;
to research and obtain a thorough knowledge of the pathogenicity of each drug offered for inclusion in the Homoeopathic Pharmacopoeia of the United States as a homœopathic drug; to develop criteria for eligibility of drugs for inclusion in the Homœopathic Pharmacopoeia of the United States;
to serve as a repository for homœopathic literature and drugs;
and generally to do, perform, undertake, direct, encourage and investigate all aspects and functions of any nature directed to the furtherance of homœopathic healing.
HPCUS has Four Important Functions

*focus on Safety.*

- Monograph Approval
- Pharmacy Practices and Procedures
- Technical data production for drug standards and controls
- Establishment of safe minimum potencies appropriate to Rx, OTC and external use.
# HPCUS Operating Structure

## HPCUS Operating Committees 2009

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<tr>
<th>Monograph Approval</th>
<th>Pharmaceutical Procedure and Practice</th>
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<td>Monograph Review Committee</td>
<td>Council on Pharmacy</td>
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<tr>
<td>Mark Land, Chair</td>
<td>Eric Foxman, R.Ph, Chair</td>
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<tr>
<td>Pharmacopoeia Revision Committee</td>
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<tr>
<td>Joyce Frye, DO, MBA, MSCE, Chair</td>
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<tr>
<td><strong>Technical Standards</strong></td>
<td><strong>Safety</strong></td>
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<td>Standards and Controls Committee</td>
<td>Toxicology and Safety Committee</td>
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<tr>
<td>Mark S. Phillips, PharmD, Chair</td>
<td>Khalil Taoubi, Ph.D, Chair</td>
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### Administrative

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<th>Publications Committee</th>
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<td>Clark Baker, MS, Chair</td>
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<th>Finance Committee</th>
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<td>Thierry Montfort, Chair</td>
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<th>Membership Committee</th>
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<td>William Shevin, MD, DHt, Chair</td>
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Monograph Approval
Criteria for Eligibility

*Two Important Aspects:*

Safe/Effective (1,2,3) AND Homeopathic (Principle of Similars 4,5,6 or 7)

To be eligible for inclusion in the Homœopathic Pharmacopœia of the United States, the drug must meet criteria 1, 2, 3, and at least one of 4, 5, 6, or 7 as set forth below:

1) The HPCUS has determined that the drug is safe and effective.

2) The drug must be prepared according to the specifications of the General Pharmacy and relevant sections of the Homœopathic Pharmacopœia of the United States.

3) The submitted documentation must be in an approved format as set forth in the relevant sections of the Homœopathic Pharmacopœia of the United States.
4) The therapeutic use of a new and non-official homeopathic drug is established by a *homeopathic drug proving and clinical verification* acceptable to the HPCUS. During the period of clinical verification the drug will be accepted for provisional review and should be available on a monitored basis. Refer to the guideline for Homeopathic Drug Provings and the guideline for Clinical Verification for further information.

5) The therapeutic use of the drug is established through published documentation that the substance was *in use prior to 1962*. This documentation must include the symptom picture, including subjective and any available objective symptoms. Such use and documentation may include but are not limited to the medical literature of the following homeopathic authors: S. Hahnemann, C. Hering, T.F. Allen, H.C. Allen, J.H. Clarke, and J.T. Kent.
Monograph Approval
Criteria for Eligibility

6) The therapeutic use of the drug is established by at least two adequately controlled double blind clinical studies using the drug as the single intervention; the study is to be accompanied by adequate statistical analysis and adequate description of the symptom picture acceptable to the HPCUS which includes the subjective symptoms and, where appropriate, the objective symptomatology.

7) The therapeutic use of the drug is established by a) data gathered from clinical experience encompassing the symptom picture, pre- and post-treatment, including subjective and any available objective symptoms or b) data documented in the medical literature (all sources of medical literature may be considered on a case by case basis) subjected to further verification (statistical and/or other forms of verification).
HPCUS Monograph Evaluation Process

Monograph Sponsor → Editor → Monograph Review Committee → Public Comment

More data via editor

Pharmacopoeia Revision Committee

Recommendation via editor

Board of Directors

Clinical Verification

Accept/reject

Notify Sponsor via Editor

Publication in HPCUS

Pharmacopoeia Revision Committee

Recommendation

Board of Directors

Accept/reject
Pharmacy Practices and Procedures

- **General Pharmacy Committee**
  - Pharmacy Practices and Procedures
  - Manufacturing Techniques
  - Good Manufacturing Practices (GMP) specific to homeopathic pharmacy
  - Labeling Guidelines
Technical data production for drug standards and controls

- Standards and Controls Committee
  - Technical data production for drug standards and controls
  - QC Standards for raw materials and finished product (when appropriate)
Establishment of safe minimum potencies appropriate to Rx, OTC and External Use.

- **Toxicology and Safety Committee**
  - Establishes homeopathic potency minimums for:
    - OTC (Non-Prescription, unrestricted sale)
    - Rx (Sale limited to or on the prescription from a licensed provider)
    - HPN, Homeopathic Pharmaceutical Necessity (Sale restricted to licensed manufacturers)
    - External use, use of the homeopathic drug for External Use Only.
  - Standards based on single exposure and chronic exposure
  - OTC potency typically 2 order of magnitude from NOEL (if known)
Why is HPUS Necessary for Users?

- The legal basis for homeopathic drugs in the U.S.
- Official Drug Monographs
- Standards and assay procedures
- Tables with potency recommendations
- Complete guidelines for:
  - Manufacturing
  - Dosage Forms
  - Good Manufacturing Practices
  - Labeling
  - Guidelines for safe OTC and Rx potencies
For more information…

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About the speaker:

John P. (Jay) Borneman, PhD

Dr. Borneman earned a Bachelors degree in Chemistry from St. Joseph's University (Philadelphia) in 1980, a Masters in Chemistry from SJU in 1983 and an MBA with a concentration in Finance from SJU in 1986. An alumnus of the Harvard Business School, Borneman subsequently earned his PhD from the Department of Health Policy and Public Health at the University of the Sciences in Philadelphia. His research interests are in the health policy considerations of healthcare access and Complementary and Alternative Medicine (CAM).

He is the fourth generation of his family in the business of homeopathic pharmacy and has been associated with homeopathic firms throughout his life; serving as Vice President of John A. Borneman and Sons, later Boiron-Borneman, from 1980 through 1987; and joining Standard Homeopathic Company and Hyland's, Inc. at that time. He is a principal owner of the company and also serves as CEO of Hyland's, Inc., the company's wholly owned distribution subsidiary. In addition to serving on Standard's Board, Dr. Borneman serves on the Boards of the Homoeopathic Pharmacopoeia of the United States as its President, Consumer Healthcare Products Association as Chairman of the CHPA Political Action Committee, Southwest College of Naturopathic Medicine and as an emeritus director of The National Center for Homeopathy. He serves on various advisory boards including the College of Arts and Sciences at St. Joseph’s University and the National Association of Chain Drug Stores. He has chaired the Legal and Regulatory Affairs Committee of the American Association Of Homeopathic Pharmacists since 2001. He currently has a faculty appointment as Adjunct Associate Professor of Health Policy and Public Health at the University of the Sciences in Philadelphia.