The Role of the Homoeopathic Pharmacopoeia Convention of the United States in the Regulation of Homeopathic Drug Products

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Homoeopathic Pharmacopoeia Convention of the United States

HPUS
HOMOEOPATHIC PHARMACOPOEIA *of the United States*

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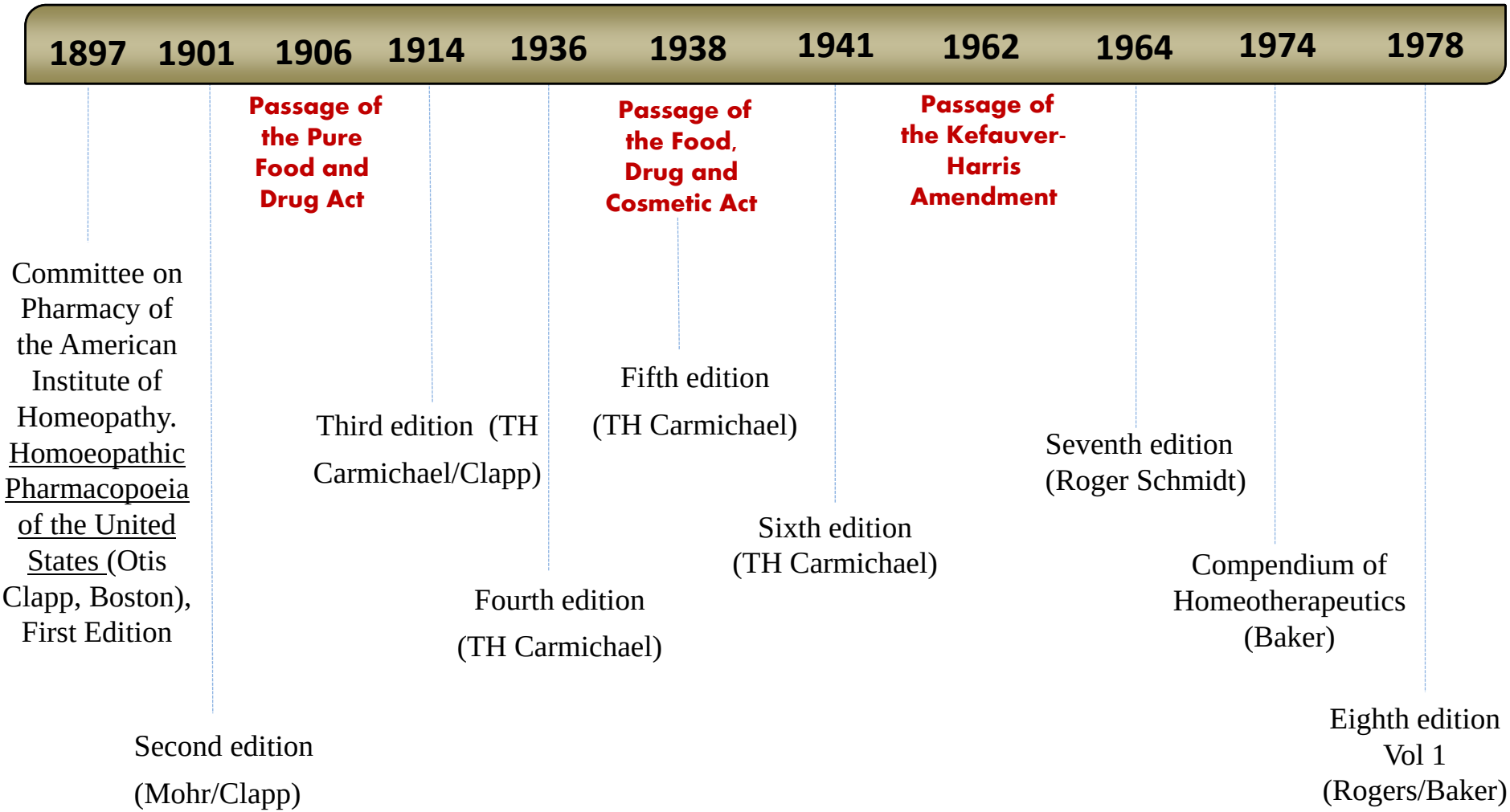

Publication by the independent Homoeopathic Pharmacopoeia Convention of the United States

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HPCUS is incorporated as an independent body.

Eighth edition, Supplement A (Baker)

Development of Compliance Policy Guide 7132.15

HPUS Revision Service (HPRS)

Compliance Policy Guide 7132.15 becomes effective

HPRS is complete, semi-annual updates: Supersedes Compendium and Supplement A as the official compendium.

Monographs, General Pharmacy, Standards and Controls updated semi-annually

HPUS online begins, immediate/real-time updates

Publication by the independent Homoeopathic Pharmacopoeia Convention of the United States

HPCUS Mission

1. **"To accumulate pertinent information and publish and to sell the *Homoeopathic Pharmacopoeia of the United States* and any additions or supplements thereto,**
2. **to promote the art of healing according to the natural laws of cure from a strictly homoeopathic standpoint;**
3. **to diffuse knowledge among the laity and professionals in the health care field concerning homoeopathic principles through means of publications;**
4. **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 homoeopathic drug;**
5. **to develop criteria for eligibility of drugs for inclusion in the *Homoeopathic Pharmacopoeia of the United States* to serve as a repository for homoeopathic literature and drugs;**
6. **and generally to do, perform, undertake, direct, encourage and investigate all aspects and functions of any nature directed to the furtherance of homoeopathic healing."**

HPCUS Activities

- Drug Monograph Evaluation
- Pharmaceutics and Pharmaceutical Methods including GMPs
- Generation and evaluation of Standards and Controls parameters
- Continual Safety and Toxicology evaluation
- Continuous improvement to methods of data

1906

Food and Drugs Act, Pub. L. No. 59-384, only listed the United States Pharmacopoeia ("USP") and the National Formulary.

1912

Senator Jacob Gallinger (R-NH), a homeopathic physician, sponsored a bill that would have added the Homeopathic Pharmacopoeia of the United States (HPUS) to the 1906 Act.

1934

Senator Royal Copeland (D-NY), also a homeopathic physician, became the sponsor of legislation for a New Food and Drug Act that included reference to HPUS.

Senator Copeland sought a bill that would recognize the diversity of medical practice in order to gain support for the legislation.

1938

The Federal Food, Drug and Cosmetic Act finally passed and it included reference to the HPUS.

Definition

Drug – 21 U.S.C. §321(g)(1)

The term “drug” means (A) articles recognized in the official USP, official HPUS or National Formulary, or any supplement.

In 1972, in a meeting concerning the OTC Review between a homeopathic representative and FDA, the agency decided to postpone the review of homeopathic drugs until after the OTC Review.

(37 Fed. Reg. 9464, Comment 25 (May 11, 1972))

1988

FDA issued Compliance Policy Guide (CPG) Section 400.400 Conditions Under Which Homeopathic Drugs May be Marketed.

1995

The CPG was revised.

Over the 77 years since the 1938 Federal Food, Drugs, and Cosmetic Act was passed, FDA has taken action against adulterated and misbranded drugs whether non-homeopathic or homeopathic.

Monographs by the Numbers

699 Monographed substances in HPUS Eighth edition

\+ **428** Substances in Compendium of Therapeutics

\+ **167** Substances in long term use (prior to 1972)

\+ **9** Recently completed monographs (2007 -2015)

\- **8** Substances found in the literature or submitted that were duplicates under other names

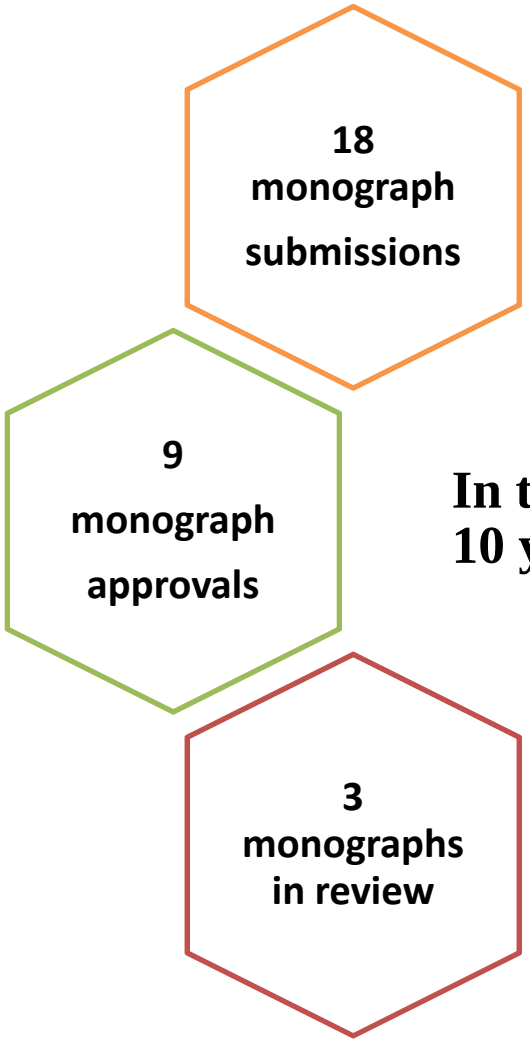
1295 present monographs

HPUS Guidance

- Guidelines for homeopathic manufacturing
  - GMPs
- Official Short Names
- Official Synonyms
- Labeling Guidelines
- Minimum Safe Potency Guidelines

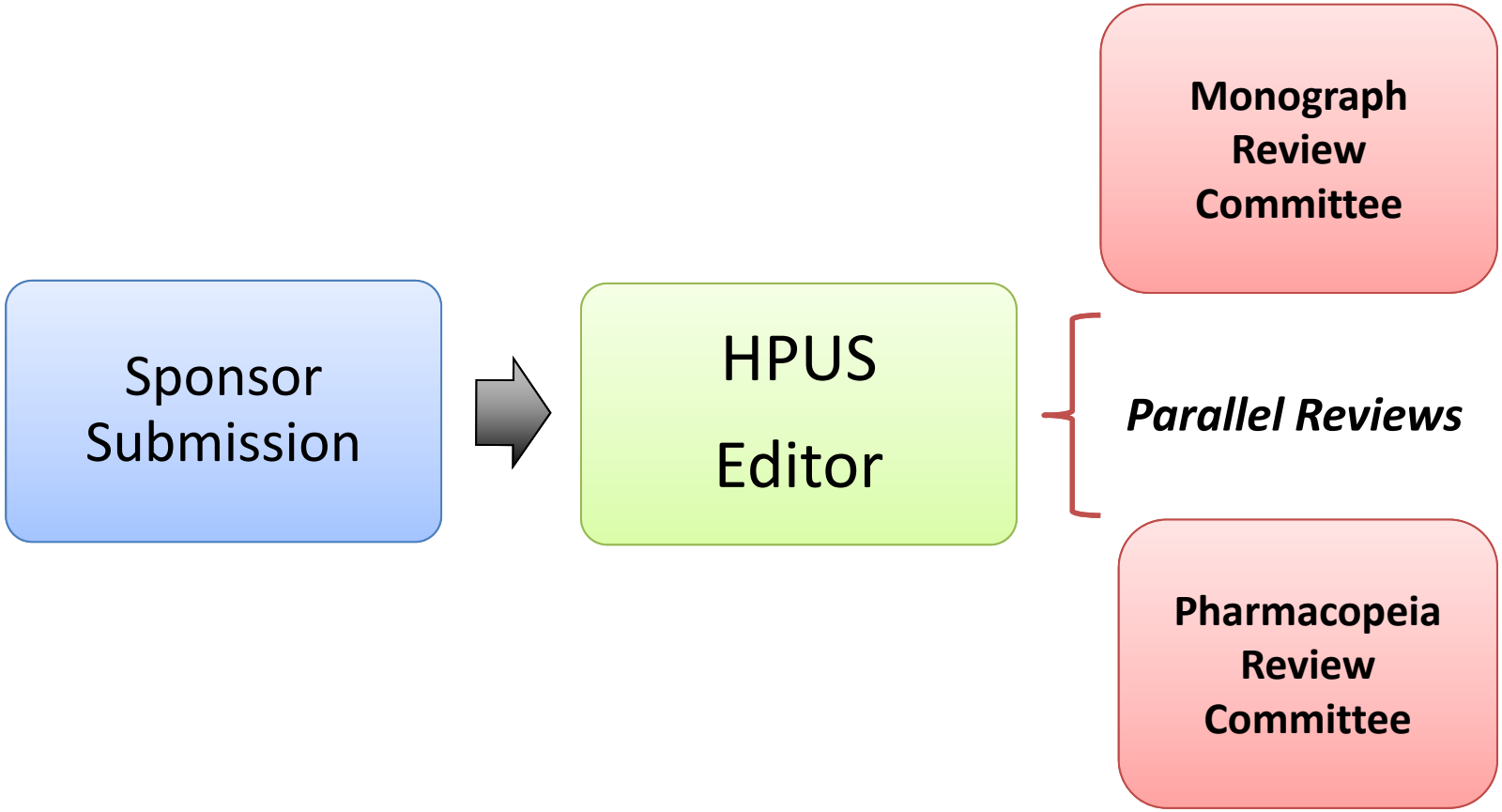
  (Drug Tables)

Monograph Review History



In the past 10 years

Monograph Process Overview



Monograph Review Committee

Experts in homeopathic pharmacy, toxicology, and analytic methodology

Primary evaluation tasks:

- GMP
- Safety

Monograph Review Committee

1. Substance Identification
2. Quality standards
3. Manufacturing process
4. Analytic procedures
5. Storage and stability data
6. Toxicology
7. First safe OTC and Rx attenuations

Pharmacopeia Review Committee

Expert panel of physicians, methodologists, and epidemiologists with experience using and researching homeopathic medicines

Primary evaluation tasks:

- Safety
- Potential usefulness

Pharmacopeia Review Committee

1. Investigator qualifications
2. Historical information
3. Study design and methodology
4. Data collection and recordkeeping
5. Safety assurance
6. Ethical and legal compliance
7. Analysis of study results

Monograph Process Overview