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HOMEOPATHIC PRODUCT REGULATION: EVALUATING THE FOOD AND DRUG ADMINISTRATION'S REGULATORY FRAMEWORK AFTER A QUARTER-CENTURY

OUTLINE OF PROPOSED PRESENTATION

ALVIN J. LORMAN

1. Introduction

   Experience in representing homeopathic industry
   Interaction with FDA in connection with present CPG

2. Origins of the current CPG

   FDA perception of growth of market
   Disparate treatment of domestic and foreign manufacturers

3. Growth of the industry and FDA's role in that growth

   Indications v. standard homeopathic indications

4. Relationship between industry and FDA

5. Legal status of homeopathic drugs

   1962 Drug Amendments
   NAS-NRC Review
   Origins of OTC Review
   Exclusion of homeopathic drugs from OTC Review
   Legal alternatives to the current CPG approach

6. FDA enforcement activities

7. Rx-OTC dichotomy and homeopathic claims

8. Conclusions and recommendations