

## The Orphan Drug Act of 1983: A case study of issue framing and the failure to effect policy change from 1990--1994

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**Publication info:** The University of North Carolina at Chapel Hill, ProQuest, UMI Dissertations Publishing, 2009. 3352655.

[ProQuest document link](#)

**Abstract:** Both low- and high-commercial-potential (LCP and HCP) orphan drugs are eligible for benefits provided by the Orphan Drug Act of 1983 (ODA). During 1990-1994, legislators attempted to amend the law to better target benefits to LCP drugs and "restore the spirit of the law" to promote the development of LCP drugs for rare diseases that might otherwise be abandoned, or "orphaned." These amendment attempts were not successful.

This dissertation research examines: (1) how ODA stakeholders attempted to shape the debate about HCP orphan drugs in the 1990s, and, (2) potential factors that may have impeded or promoted ODA reform in the 1990s.

ODA reforms were debated in four Congressional hearings from 1990-1994. Hearing transcripts were obtained and thirty-eight statements were coded. The qualitative research method of memoing was used to construct four frames from the Congressional text: (1) ODA Reform as Economics and Access, (2) ODA Reform as Patient Relief, (3) ODA Reform as Rules of Participation, and (4) ODA Reform as Congressional Action.

Potential reform factors were proposed *a priori* and subsequently evaluated based on a review of over 100 documents and ten informant interviews.

The research offers a microcosmic window into how policy stakeholders define problems, propose solutions, and advance their interests in debates over social conditions and public policies. In the 1990s, legislators asked: does market exclusivity for HCP orphan drugs provide an unnecessary monopoly that leads to excessively high orphan drug prices, windfall profits, and other problems? The research illustrates how disputants chose to define, or avoid defining, terms such as "unnecessary monopolies," "excessively high drug prices," "windfall profits," and "problems" that result from these conditions.

The research demonstrates how policy development and framing theory can structure inquiry into attempted policy reform, aid in developing *a priori* hypotheses, and, shape analyses and recommendations. The dissertation includes a guide for analyzing policy development and a guide for constructing and deconstructing issue frames. These are applied to the historical case of attempted ODA reforms, but may be useful for other cases.

**Links:** [Linking Service](#)

**Subject:** Pharmacy sciences; Public health; Health care management;

**Classification:** 0572: Pharmacy sciences; 0573: Public health; 0769: Health care management

**Identifier / keyword:** Health and environmental sciences, Health policy, Issue framing, Orphan drugs

**Number of pages:** 191

**Publication year:** 2009

**Degree date:** 2009

**School code:** 0153

**Source:** DAI-B 70/04, Oct 2009

**Place of publication:** Ann Arbor

**Country of publication:** United States

**ISBN:** 9781109106244

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**Committee member:** Dardess, Margaret B., Murphy, Michael D., Paul, John E., Silberman, Pam C.

**University/institution:** The University of North Carolina at Chapel Hill

**Department:** Health Policy & Administration: Doctoral (residential)

**University location:** United States -- North Carolina

**Degree:** Dr.P.H.

**Source type:** Dissertations & Theses

**Language:** English

**Document type:** Dissertation/Thesis

**Dissertation/thesis number:** 3352655

**ProQuest document ID:** 304959421

**Document URL:**

<http://libproxy.lib.unc.edu/login?url=http://search.proquest.com/docview/304959421?accountid=14244>

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**Database:** ProQuest Dissertations & Theses Full Text

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