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## INTRODUCTION

# Governing lipitor and lipstick: Capacity, sequencing, and power in international pharmaceutical and cosmetics regulation

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## ABSTRACT

Over the last three decades, the pharmaceutical and cosmetics industries have become increasingly global. To ensure product safety and consumer protection, regulators in leading markets have applied domestic rules extraterritorially and have joined forces to harmonize rules through transgovernmental cooperation. Yet whereas the United States has long been the dominant player in international market regulation of pharmaceuticals, the European Union has decisively shaped global rules for cosmetics. What explains differences in agenda setting power across the two closely-related industries? We compare and contrast the expectations of a realist account focused on market size and a liberal functionalist argument centered on the role of market friction with a historical institutionalist explanation stressing the relative sequential development over time of domestic regulatory capacity in leading markets. The empirical evidence shows that domestic regulatory institutions systematically shape international market regulation. Historical institutionalism

provides an important complement to existing transgovernmental research, offering clear expectations for the origins of and terms of influence within such cooperation. More generally, it opens up a rich toolbox for the analysis of industry-level global market governance, which affects the daily lives of many millions of consumers.

Q KEYWORDS: Sequencing transgovernmental politics regulatory capacity historical institutionalism pharmaceuticals cosmetics

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## Notes

1 Many issues shape international markets for pharmaceuticals and cosmetics. This paper focuses on the fundamental decision of whether to allow a product to enter the consumer market and the safety standards that producers must follow during production.

2 This argument draws on historical institutional work such as [Zysman \(1994\)](#) and [Thelen \(2004\)](#).

3 Jurisdictions can consciously build-up regulatory capacity, as happened during the period of telecommunications liberalization, but such build-up does not happen

overnight. See (Vogel, 1996; Gilardi, 2002).

4 The paper focuses on structural power embodied in regulatory capacity and not the underlying preferences of the lead regulators. For an examination of preferences see (Singer, 2007).

5 A growing rationalist literature on the design of international institutions considers these questions. See (Koremenos, Lipson and Snidal, 2001).

6 This transposes sequencing arguments developed in the comparative setting to international issues. See (Posner, this issue; Newman 2008b; Pierson, 2004).

7 IMS Health, 2004. IMS World Review. Norwalk, CT.

8 The World Health Situation. Geneva: World Health Organization. Chapter 3.

9 See [www.ich.org](http://www.ich.org).

10 See “EMA inspections growing, get tougher than FDA audits, Wyeth exec says,” Warning Letter Bulletin, 12 July 2004.

11 See (Henney, 2001).

12 International Accord on Drug Testing Standards Will Delete LD50 Animal Testing Requirements, F-D-C REP. (“The Blue Sheet”), Nov. 20, 1991, at 9.

13 Data are taken from presentations made in April 2004 and April 2007 by Euromonitor.

14 Data are taken from presentations made in April 2004 and April 2007 by Euromonitor.

15 Author interview with an industry spokesperson. Brussels, 2007.

16 See Shefali Srinivas, “Tougher Regulations for Cosmetics Next Year.” Straits Times, November 22, 2007.

17 See the ASEAN Cosmetics Association at <http://www.aseancosmetics.org/default>.

18 See Laurel Naversen Geraghty, “Should You Worry About the Chemicals in Your Makeup?” The New York Time, July 7, 2005.

19 On the issue of preference formation, see (Fioretos, this issue).



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