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Public Health Product Hops

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Public Health Product Hops

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Public Health Product Hops

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Saint Louis U. Legal Studies Research Paper No. 2023-03

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Abstract

Pharmaceutical product hops are anticompetitive maneuvers that often represent a last-ditch effort by brand manufacturers to preserve market share in the face of generic competition. An integral part of product life cycle management strategies, product hops may offer marginal benefits to patients but can substantially increase costs to payers and patients alike. Yet industry advocates maintain that this is essential follow-on research and development, resulting in the development of novel products that would otherwise never reach the market.

Is there a middle ground between these two diametrically opposed views? Might certain product hops be considered beneficial, perhaps if they furthered important public health interests? Sometimes product hops arise due to safety concerns raised by FDA or pressure from other public health agencies. For instance, a push from Congress and the EPA to remove chlorofluorocarbons from all consumer and industrial products resulted in a switch from chlorofluorocarbon to hydrofluoroalkane propellants in respiratory inhalers. In another instance, concerns about the opioid crisis fueled the development of abuse-deterrent formulations of opioids as part of a public health response to the crisis. Despite the public health motivations driving each scenario, I find that some public benefit may have been achieved, but at substantial expense to both payers and patients.

I explore the potential benefits of a “public health product hop” in more detail using the recent push to approve over-the-counter versions of intranasal naloxone as a case study. I develop a framework for rewarding product hops that provide a meaningful and quantifiable public health benefit. In these instances, I argue for time-limited patent incentives that more equitably reward manufacturers for advancing important public health-goals while ending regulatory incentives for purely profit-driven product hops.

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This paper is dedicated to the memory of Dmitry Karshtedt, JD, PhD, Professor of Law at George Washington University School of Law in Washington, DC. Dmitry's research overlapped with mine, including some of the ideas in this paper and a coauthored project on product hopping. Perhaps due to his training in chemistry and his 13 patents, Dmitry fundamentally disagreed with the premise that product hops are inherently bad. Perhaps some of his patented compounds were secondary patents that form the basis of many product hops. His article, "The More Things Change: Improvement Patents, Drug Modifications, and the FDA," published in the *Iowa Law Review* in 2019, details his conflicting opinions on the issue. In this article, the first draft of which was completed a week before his death in October 2022, I identified case studies to test a theory Dmitry inspired: that perhaps certain types of what I term "public health product hops" could be justifiable and perhaps even rewarded or incentivized. Rest well, Dmitry.