Inexpensive Gadgets: Solving the Drug-Device Cost Conundrum

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In my 2022 article "Costly Gadgets: Barriers to Market Entry and Price Competition for Generic Drug-Device Combinations in the United States," I highlight challenges for competition and pricing associated with generic competition for drugs and biologics that have proprietary delivery devices. Often, patents covering the delivery device (described in Costly Gadgets as "tertiary patents") expire well after primary patents covering the active drug or biologic component(s). Recently, FTC Commissioner Lina Khan announced that she would be targeting "junk listings" of patents that, when listed in the FDA's Orange Book, delay cheaper alternatives from entering the market.

Yet even when all drug and device patents expire, the introduction of complex generics and biosimilars is often complicated by stringent requirements for device similarity between the brand and the competitor. Costly Gadgets highlighted that for the Advair Diskus, Mylan's Wixela Inhub received two Complete Response Letters from the FDA before its ANDA approval over 2 years after all patents on the Advair Diskus had expired. Other products, which did not attempt to mimic the Diskus design, reached the market sooner but struggled to gain market share. With several blockbuster drugs and biologics containing drug delivery devices, like respiratory inhalers or pens for products like insulin, Humira, or GLP-1 agonist weight loss drugs, tertiary patents threaten to significantly delay market competition absent intervention.

This article advocates for the development of uniform standard medical devices for which similar products can be used interchangeably after the primary patent(s) expire. For respiratory inhalers, this could take the form of a uniform respiratory inhaler and cap, for which generic cartridges containing albuterol (or other respiratory medicines) can be easily inserted and used by patients. By shifting from a standard of substantial medical device similarity and toward a uniform standard medical device, generic products can flood the market soon after primary patent expiration and drive prices lower, much as they do in the small-molecule generic sector. The article will assess the theoretical risks associated with standardization (e.g., decreased incentives to innovate or improve drug delivery devices) against the benefits (e.g., lower costs, more rapid uptake of generics/biosimilars, and ease of patient training) and conclude that, for some drug-device products, uniform standard medical devices can substantially improve patient access and improve health outcomes.

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