

**DELTA CARE RX  
COMMENT LETTER  
TO THE FDA**

Regarding Fixed-Quantity  
Unit-of-Use Blister Packaging for  
Certain Immediate-Release Opioid  
Analgesics for Treatment of  
Acute Pain

July 30, 2019

Norman E. Sharpless, MD  
Commissioner  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, Maryland 20993

**Subject: Re Fixed-Quantity Unit-of-Use Blister Packaging for Certain  
Immediate-Release Opioid Analgesics for Treatment of Acute Pain**  
(Docket No. FDA-2019-N-1845)

Dear Dr. Sharpless:

Delta Care Rx appreciates the opportunity to share our perspective on the issue of Fixed-Quantity Unit-of-Use Blister Packaging for Certain Immediate-Release Opioid Analgesics for Treatment of Acute Pain.

Delta Care Rx is a pharmacist-founded, pharmacist-owned and pharmacist-operated pharmacy benefit management company that works exclusively with and for hospice and palliative care providers, primarily community-based, not-for-profit hospice and palliative care organizations. We provide our pharmaceutical care through our own mail order pharmacy and a nationwide network of highly regarded local retail pharmacies. With a mission to transform and improve the hospice pharmacy industry through business transparency, innovation, unyielding customer service and community pharmacy relationships, Delta Care Rx has been privileged since our founding in 2008 to work with some of the nation's most highly regarded community-based hospice providers. At Delta Care Rx, we pride ourselves on being an industry disruptor, having created a revolutionary transparent pass-through pricing model and having introduced a number of innovative technologies designed to support clinicians at the bedside in delivering quality, compassionate, cost-effective pharmaceutical care for patients with a life-limiting diagnosis.

With roots in western Pennsylvania and eastern Ohio, as pharmacists and as citizens of the communities in which we live and work, we know all too well the dangers and impact of widespread opioid addiction. Delta Care Rx applauds the Food and Drug Administration's commitment to developing innovative and far-reaching policies to end the scourge of opioid addiction.

As a relatively young company, this is the first time we have chosen to speak out individually on an issue before federal regulators rather than deferring solely to our respected industry and trade representatives. We do so out of a profound concern for the impact (intended or unintended) of any regulation that could affect the most vulnerable among us—the 1.5-plus million Americans who will benefit from hospice care this year.

Whatever the final outcome, we urge the FDA to consider specifically the impact of such regulation on the provision of essential pain medications to hospice and palliative care patients and, where appropriate, make specific exceptions in such regulations specifically for hospice and palliative care patients.

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**Impact on Hospice Pharmacy Practice**

As the impact of the opioid addiction crisis grows, we have seen ever-increasing regulatory and compliance burdens placed on dispensing pharmacies that fill a significant portion of the pain medications prescribed for hospice and palliative care patients. Delta Care Rx recognizes the important role of local pharmacies in ensuring quality patient care, responsive service, ethical practices and access to essential medications particularly for geriatric populations. We are further concerned about the increased burden on the pharmacy community nationwide—including our own hospice mail order pharmacy service—as it would endeavor to comply with this additional regulatory requirement.

While it's not much of a problem in populous, prosperous suburbs, the ready availability of Schedule II narcotics in exurban and rural areas as well as low-income/inner-city neighborhoods is certainly a genuine problem. And it's getting more dire—so-called "opioid deserts" are, in fact, real. Blister packaging will increase labor costs for retail pharmacies dispensing immediate-release opioid analgesics. Many of these retail pharmacies operate on very slim margins and at some point the conflict between managing a sustainable business and meeting a community's need for access to the broadest possible range of prescription medications forces retail pharmacies to opt to make the difficult decisions to stop carrying certain classes of prescription medications simply to keep their doors open.

**Impact on Hospice Providers**

Blister packaging also will result in increased costs for the hospice providers responsible for providing all medications necessary and appropriate for the care of each patient. Blister packaging likely will increase the cost of immediate-release opioid analgesics by as much as 20–25 percent. Hospice providers will have no choice but to absorb those increased costs. And for community-based, not-for-profit hospices already existing on thin margins, the impact of such a cost increase could severely affect the long-term sustainability and mission-fulfillment work of these hospices.

**Impact on Hospice Patients and Their Caregivers**

We are also concerned about the effect blister packaging will have on hospice patients themselves and/or the loved ones caring for them. Blister packages understandably are difficult to open. For anyone. They're challenging for a young person with no tactile limitations. They're infuriatingly difficult—if not impossible—for a geriatric population with sometimes significant tactile limitations. We can't imagine there are many hospice patients who could open a blister package on their own. We're concerned for the hospice patient without a full-time caregiver in the home to open blister packages. We're concerned for the hospice patient whose full-time caregiver in the home is a spouse, sibling or other loved one with tactile limitations who could be equally challenged in opening a blister package. We're used to hearing the stories of Medicaid, Medicare and commercial insurance patients forgoing essential prescription medications due to cost. We don't want to start hearing stories of hospice patients forgoing essential prescription medications because they can't get the pills out of the blister packaging. Patients can't adhere to a physician's prescribed regimen if they can't get the blister package open.

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**A Proposed Solution**

We do recognize the obvious advantages for the population at large in utilizing blister packaging for immediate-release opioid analgesics.

As pharmacists who work exclusively with hospice providers and patients, we support a greater decision-making role for pharmacists—at the bedside, in the weekly hospice interdisciplinary team meetings, at the administrative level. In this case, we would like to see primary pharmacists given leeway within this proposed regulation to utilize alternate packaging modalities. Such a solution could range from traditional age-friendly pill bottles to individual pill pack envelopes to bingo dispensers or bingo cards—based in large part on patient need and the patient's/caregiver's ability to manage medications.

The hospice movement was founded in the United States 40+ years ago on the steadfast commitment that patients should be supported as they die at home, in familiar surroundings, in the presence of their loved ones, with end-of-life symptoms managed effectively and their pain under control. Combating the opioid epidemic does demand a universal call to arms. We just don't want to see the goal of managing the pain of hospice patients become an unintended casualty in the battle against opioid addiction.

We trust you will keep the needs and limitations of hospice patients in mind as you formulate this modification to the Opioid Analgesic Risk Evaluation and Mitigation Strategy.

Respectfully submitted,

Mary Mihalyo, B.S., PharmD, BCPS, CDE  
Chief Executive Officer  
Delta Care Rx