Report to Congress

REPORT ON ABUSE-DETERRENT OPIOID FORMULATIONS AND ACCESS BARRIERS UNDER MEDICARE

Submitted Pursuant to Section 6012 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act

U.S. Food and Drug Administration

Executive Summary

On October 24, 2018, the President signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (Pub. L. 115-271). The bipartisan legislation granted federal agencies additional authorities that will meaningfully advance efforts to combat the opioid crisis. Under section 6012, the Secretary of Health and Human Services is required to conduct a study and submit to Congress a report on: 1) the adequacy of access to abuse-deterrent formulations (ADFs) of opioid analgesics for individuals with chronic pain under Medicare Part D, including any potential barriers to access; and, 2) the effectiveness and impact of ADFs more broadly on public health and the opioid epidemic.

Overall, this Report finds that 90% of Medicare beneficiaries enrolled in Medicare Part D (or a Medicare Advantage Plan with Part D coverage) have access to ADF opioid analgesics. However, ADF opioid analgesics have significantly lower utilization in Part D than generic non-ADF opioid analgesics, though a higher rate of utilization than brand non-ADF opioid analgesics. Additionally, the cost to both the Medicare program and to beneficiaries is significantly greater for ADF opioid analgesics than non-ADF opioid analgesics, because ADF opioid analgesics are currently only available as branded drugs, and are therefore significantly more expensive than generic non-ADF opioid analgesics.

As the opioid crisis evolves, federal agencies must reassess their approaches to combatting it. Incentivizing the development of new technologies, including ADFs, has been part of FDA's approach to improving the safety of opioid analgesic products. While currently approved ADFs could reduce manipulation and abuse of these prescription opioid analgesics by non-indicated routes, questions remain about the potential broader public health effects of currently-available ADFs if such products were more widely prescribed.

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I. Introduction

On October 24, 2018, the President signed into law the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act. Under section 6012, the Secretary of Health and Human Services is required to conduct a study and submit to Congress a report, no later than one year after enactment, on:

> (1) the adequacy of access to abuse-deterrent opioid formulations for individuals with chronic pain enrolled in an Medicare Advatange – Prescription Drug (MA – PD) plan under part C of title XVIII of the Social Security Act or a prescription drug plan under part D of such title of such Act, taking into account any barriers preventing such individuals from accessing such formulations under such MA–PD or part D plans, such as cost-sharing tiers, fail-first requirements, the price of such formulations, and prior authorization requirements; and
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> (2) the effectiveness of abuse-deterrent opioid formulations in preventing opioid abuse or misuse; the impact of the use of abuse-deterrent opioid formulations on the use or abuse of other prescription or illicit opioids (including changes in deaths from such opioids); and other public health consequences of the use of abuse-deterrent opioid formulations, such as an increase in rates of human immunodeficiency virus.

In response to this directive, the U.S. Food and Drug Administration (FDA) prepared the following report, summarizing the findings from the Centers for Medicare & Medicaid Services (CMS) on their analysis of access to abuse-deterrent opioid formulations under Medicare Part D and the FDA's findings on the effectiveness and impact of abuse-deterrent opioid formulations.

II. Background

Opioid use disorder and opioid overdose continue to claim a staggering human and economic toll in the United States. From 1999-2017, almost 400,000 people died from an overdose involving any opioid,[1] and the total economic burden of prescription opioid overdose, abuse, and dependence is estimated to be $78.5 billion in 2013.[2] As the opioid crisis and the Nation's responses to it evolve, federal agencies must continually reassess their strategies to ensure that they are doing everything they can to maximize patient and public health benefit and minimize harm.

Section 6012 defines an abuse-deterrent opioid formulation (ADF) as "an opioid that is a prodrug or that has certain abuse-deterrent properties, such as physical or chemical barriers, agonist or antagonist combinations, aversion properties, delivery system mechanisms, or other features designed to prevent abuse of such opioid." FDA has issued official guidance on the topic in the

[1] https://www.cdc.gov/drugoverdose/epidemic/index.html
[2] https://www.ncbi.nlm.nih.gov/pubmed/27623005

document, *Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling*.[3] Only FDA-approved opioids with labeling describing abuse deterrent properties consistent with the Guidance were included in CMS's analysis of ADF opioid analgesics. The commercially available ADF opioid analgesics analyzed were all long-acting brand products, which included OxyContin, Oxycodone ER, Embeda, Hysingla, and Xtampza. Oxycodone ER was treated as a brand ADF opioid analgesic since it is marketed as an authorized generic product under an approved new drug application (NDA). Currently, there are no generic opioids with FDA-approved abuse-deterrent labeling. CMS included only long-acting non-ADF opioid analgesics in the analysis so as to provide a reasonable comparison with the ADF opioid analgesics currently on the market

While recognizing that ADF technology cannot make an opioid analgesic abuse-proof or non-addictive, FDA has supported ADF development as one of many strategies intended to mitigate the harms associated with prescription opioid analgesic abuse while maintaining legitimate access to opioid analgesics for patients who need them.[4] Because of their higher dosage strength and potential for "dose-dumping" (i.e., full release of the drug all at once) if manipulated through crushing or dissolving in solution, extended-release (ER) opioid analgesics have been the primary focus of ADF development. ER opioid analgesics however, represent less than 10% of the outpatient opioid analgesic prescriptions dispensed in the United States annually. As of 2018, ADF opioid analgesic products (both ER and IR) represent only about 2% of the overall opioid analgesic market. Currently available ADF opioid analgesics are designed to deter abuse through unintended routes of administration—primarily snorting and injecting—because of the increased risks associated with abuse through these routes.

Since the approval of the first ADF opioid analgesics, the environment in which prescription opioid analgesics are prescribed, used, and abused has changed considerably. Prescribing of both ER and immediate release (IR) opioid analgesics has declined, while potent, inexpensive heroin and illicitly manufactured fentanyl have become more readily available, greatly contributing to the continuing rise of overdose deaths.[1,2]

III. Evaluating Access to ADF Opioid Analgesics under Medicare Part D

Methodology

The following analyses were limited to Medicare beneficiaries enrolled in either an MA-PD or standalone prescription drug plan (PDP). CMS-approved Part D formulary and plan benefit packages were utilized, as well as prescription drug event (PDE) data from the CMS Integrated

[1] https://www.fda.gov/media/127780/download
[2] https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/abuse-deterrent-opioid-analgesics

Data Repository (IDR).[5] Long-acting oral opioid analgesics were separated into ADF and non-ADF products. Non-ADF opioid analgesics were further separated into brand and generic opioids to allow brand-to-brand and generic-to-brand comparisons.

Several types of analyses were performed. The first analysis evaluated contract year (CY) 2018 formulary design, describing inclusion of formulary ADF and non-ADF opioid analgesics, rates of prior authorization (PA), and rates of step therapy (ST). The second analysis is a summary of overall PDE data from CY2015 to CY2018 describing ADF, non-ADF generic, and non-ADF brand opioid analgesic prescription events and costs. An analysis was performed to quantify the number of beneficiaries that have access to ADF opioid analgesics. Lastly, plan data was linked to formulary data to describe cost sharing, PA, and ST requirements for ADF opioid analgesics compared to generic non-ADF opioid analgesics.

Results

A. Enrollment in Medicare Part D Years 2015 to 2018

Total enrollment in Medicare Part D across all plan types has increased by over a million beneficiaries each year from 2015 to 2018. Enrollment increased from approximately 40 million in 2015 to 45 million in 2018. This includes beneficiaries enrolled in standalone Part D plans (PDPs), Medicare Advantage plans with Part D coverage (MA-PDs), and employer group waiver plans (EGWPs), and beneficiaries both with and without a low-income subsidy.

B. 2018 Formulary Design

CMS reviews and approves all Part D formularies. A single formulary may be used by one or more Part D plans. Table 1 contains the CY 2018 formulary coverage for ADF opioid analgesics. Over 80% of formularies included an ADF opioid analgesic. PA and ST rates for ADF opioid analgesics were 15% and 2% respectively. All formularies included at least one non-ADF long-acting opioid product. The PA and ST rates for non-ADF generics were 16% and 0.2%, respectively. In comparison, the PA and ST rates for brand non-ADF opioids were 34% and 4%. Thus, the majority of ADF opioid analgesics on Part D formularies do not require PA or ST and have similar rates of PA and ST to that of non-ADF generic opioid analgesics.

Prior authorization criteria generally require a prescriber to demonstrate that certain factors are met prior to a plan authorizing coverage of the medication. These requirements are generally not resolvable at the pharmacy counter. Recommendations that are consistent with the CDC Guideline for Prescribing Opioids for Chronic Pain (https://www.cdc.gov/drugoverdose/prescribing/guideline.html) are often incorporated into PA criteria. These criteria can require a prescriber to provide documentation of previous pain management strategies attempted prior to the opioid prescription, as well require activetreatment monitoring for side effects, efficacy, or abuse. “Fail-first” requirements, another term sometimes used to refer to ST, may be included in PA criteria. For example, a

[5] Employer Group Waiver Plans, Program of All_Inclusive Care for the Elderly plans, and Medicare-Medicaid Plans were not included in the cost-sharing or formulary access analyses.

patient may be required to try non-opioid analgesics for treatment prior to the use of opioid analgesics, or use of short-acting opioid analgesics prior to long-acting opioid analgesics. Often, both long-acting ADF and non-ADF opioids share the same PA requirements, since they are high potency opioid analgesics, and may require the patient to try less potent short-acting agents prior to approval.

Unlike PA criteria, drugs that require ST are usually resolved at the point-of-sale based on prior claims for prerequisite drugs, and are typically automated within claims adjudication systems.

C. Abuse Deterrent PDE analysis 2015 to 2018

Table 2 describes the percent of PDEs for ADF brands, non-ADF brands, and non-ADF generics that comprised all long-acting oral opioid analgesics from 2015 to 2018. The total number of long-acting oral opioid analgesic PDEs decreased from approximately 5.6 million to 4.8 million from 2015 to 2018. From 2015 to 2018, generic non-ADF opioid PDEs decreased from 3.6 million to 3.1 million, and ADF opioid analgesic PDEs decreased from approximately 1.9 million to 1.6 million PDEs. Generic non-ADF opioid analgesics were dispensed at approximately twice the rate (65%) as that of ADF opioid analgesics (33%). There was very low utilization of brand non-ADF opioid analgesics at about a 2% PDE rate.

Table 3 provides a more detailed PDE analysis for brand ADF, brand non-ADF, and generic non-ADF long-acting oral opioid products. The average ingredient cost per PDE for generic non-ADF opioid analgesics has decreased from 2015 to 2018, while the cost for ADF opioid analgesics has increased each year. Most recent data indicates that the total cost of ADF opioid analgesics is over 4 times greater than that of generic non-ADF opioid analgesics. In 2018, the average ingredient cost per PDE for beneficiaries receiving generic long-acting non-ADF opioid analgesics was $67.21 compared to $566.29 for beneficiaries receiving ADF opioid analgesics. Non-ADF brand products averaged $723.10 per PDE in 2018.

D. Beneficiary Access to Oral Long-acting Opioids Using Plan Data

Based on the 2018 plan year formulary design characteristics above, 90% of Medicare beneficiaries enrolled in Part D had formulary access to ADF opioid analgesics, while 100% of Medicare beneficiaries enrolled in Part D had access to generic non-ADF opioid analgesics.[6] Embeda and Hysingla ER were the most common ADF opioid analgesics available to beneficiaries at 63% and 57%, respectively, but combined accounted for less than 10% of ADF opioid PDEs. In contrast, Oxycontin was available to about 30% of Medicare beneficiaries but accounted for over 70% of ADF opioid analgesic PDEs. Table 4 demonstrates beneficiary access to oral long-acting opioids. Only 5% of ADF opioid analgesics were on a generic tier, compared to 28% of generic non-ADF opioid analgesics.

[6] Excluding beneficiaries enrolled in Employer Group Waiver Plans, Program of All_Inclusive Care for the Elderly plans, and Medicare-Medicaid Plans

Twenty-seven percent of generic non-ADF opioid analgesics were on a preferred brand tier, while 62% of ADF opioid analgesics were on a preferred brand tier.[7] It should be noted that beneficiaries can request a formulary exception to receive a non-formulary ADF opioid analgesic.

[7] Part D sponsors have the flexibility to place brand drugs on generic tiers, and generic drugs on brand tiers, however, CMS expects Drug Tier Labels to largley be representative of the drugs that make up that tier.

Table 1
CY 2018 Formulary Design and Long-Acting Oral Opioid Analgesics

Number of Formularies	Formularies with ADF (n) (%)	ADF PA Rate (%)	ADF ST Rate (%)	Formularies with Brand Non-ADF (n) (%)	Brand non-ADF PA Rate (%)	Brand non-ADF ST Rate (%)	Formularies with non-ADF Generic (n) (%)	Generic non-ADF PA rate (%)	Generic non-ADF ST Rate (%)
463	378 (81.64%)	15.11%	1.92%	252 (54.43%)	30.98%	4.11%	463 (100%)	15.86%	0.23%

Table 2
CY 2015-2018 PDE by ADF Status

Year	Total Long-Acting Opioid PDE	Number PDE, ADF	% PDE, ADF	Number PDE, Brand Non-ADF	% PDE, Brand Non-ADF	Number PDE, Generic Non-ADF	% PDE, Generic Non-ADF
2015	5,611,858	1,886,439	33.62%	102,215	1.82%	3,623,204	64.56%
2016	5,589,573	1,818,041	32.53%	129,141	2.31%	3,642,391	65.16%
2017	5,231,205	1,680,658	32.13%	130,656	2.50%	3,419,891	65.37%
2018	4,823,478	1,607,716	33.33%	112,354	2.33%	3,103,408	64.34%

Table 3
Results of Brand Long-Acting ADF PDE Analysis

Year	Total PDE	Total beneficiaries	Ingredient cost	Ingredient cost per PDE
2015	1,886,439	274,041	$978,325,344.64	$518.61
2016	1,818,041	258,650	$999,001,081.79	$549.49
2017	1,680,658	238,100	$929,764,773.63	$553.21
2018	1,607,716	217,080	$910,435,325.71	$566.29

Results of Brand Long-acting Non-ADF PDE Analysis

Year	Total PDE	Total beneficiaries	Ingredient cost	Ingredient cost per PDE
2015	102,215	22,698	$56,357,005.87	$551.36
2016	129,141	29,073	$79,368,140.42	$614.59
2017	130,656	28,199	$87,708,986.71	$671.3
2018	112,354	21,700	$81,242,664.33	$723.1

Results of Generic Long-acting Non-ADF PDE Analysis

Year	Total PDE	Total beneficiaries	Ingredient cost	Ingredient cost per PDE
2015	3,623,204	505,849	$385,292,922.25	$106.34
2016	3,642,391	490,779	$322,017,290.96	$88.41
2017	3,419,891	456,479	$268,248,426.07	$78.44
2018	3,103,408	394,924	$208,586,757.54	$67.21

Table 4
2018 Plan-Level Tier and Utilization Management Edit Rates for Part D Beneficiaries

	ADF	Brand Non-ADF	Generic Non-ADF
TIER NAME	**Percent**	**Percent**	**Percent**
Brand	0.29%	0.22%	0.03%
Generic	5.11%	0.35%	27.81%
Non-Preferred Brand	7.06%	18.83%	4.72%
Non-Preferred Drug	14.93%	32.19%	29.93%
Preferred Brand	61.99%	41.65%	27.40%
Preferred Generic	0.10%	0.00%	0.31%
Single Tier	8.87%	5.77%	6.90%
Specialty Tier	1.65%	.99%	2.90%
PA Rate			
Drugs with no PA	85.49%	76.69%	88.48%
Drugs with PA	14.51%	23.32%	11.52%
ST Rate			
Drugs with no ST	98.17%	82.19%	99.74%
Drugs with ST	1.83%	17.81%	0.26%

IV. Evaluating the Effectiveness and Public Health Impact of Abuse-Deterrent Opioid Formulations

Improving the Safety of Opioid Analgesic Products

FDA's work on ADF opioid analgesics applications includes the following components, among other aspects. First, the premarket evaluations of ADF opioid analgesics include assessment of whether the ADF features of a given product can be expected to meaningfully reduce its risk for abuse as well as assessment of the proposed product labeling. FDA's "Guidance for Industry: Abuse-Deterrent Opioids – Evaluation and Labeling"[8] explains the Agency's current thinking about premarket evaluations of ADFs, which should take into consideration the known routes of abuse for the non-abuse-deterrent predecessor or similar products. The premarket evaluation generally also includes review of data from laboratory-based in vitro manipulation and extraction studies, pharmacokinetic studies, and clinical abuse potential studies.

Second, for approved ADF products, FDA requires postmarket studies that are designed to assess whether meaningful reductions in abuse occur once the product is on the market and to collect additional information about adverse outcomes (e.g., overdose) associated with the product. To date, none of the required postmarket studies have been completed, and the 'real-world' impact of ADF opioid analgesics has yet to be fully assessed. This is due, in part, to the significant scientific challenges of conducting these studies. In 2017, FDA held a public meeting to solicit input from leading scientific experts on how to improve the data and methods used to evaluate ADF opioid analgesics in the postmarket setting to meet FDA's high scientific standards.[9] The results of these studies, when available, should provide valuable additional information on the effectiveness of ADF opioid analgesics in reducing abuse and related adverse outcomes associated with these products.

Low market uptake has presented major challenges to studying the effectiveness of ADF opioid analgesics in real-world settings.[10] The exception is ADF OxyContin (ER oxycodone), which replaced original OxyContin in 2010. A large body of published literature on the effect of OxyContin's reformulation as an ADF suggests that the reformulation was associated with a reduction in OxyContin abuse rates, as well as a shift in abuse from non-oral to oral routes.[11] However, these studies have a number of caveats, including lack of published protocols, inherent limitations in the available data, and challenges distinguishing the effects of the ADF from the impact of concurrent interventions and trends,[12] including prescribing guidelines such as the

[8] https://www.fda.gov/media/84819/download

[9] https://www.fda.gov/drugs/news-events-human-drugs/data-and-methods-evaluating-impact-opioid-formulations-properties-designed-deter-abuse-postmarket

[10] ADF opioids currently account for less than 2% of the prescription opioid market.

[11] Dart, R. C., J. L. Iwanicki, N. Dasgupta, T. J. Cicero and S. H. Schnoll (2017). "Do abuse deterrent opioid formulations work?" J Opioid Manag 13(6): 365-378.

[12] By, K., J. K. McAninch, S. L. Keeton, A. Secora, C. J. Kornegay, C. S. Hwang, T. Ly and M. S. Levenson (2018). "Important statistical considerations in the evaluation of post-market studies to assess whether opioids with abuse-deterrent properties result in reduced abuse in the community." Pharmacoepidemiol Drug Saf 27(5): 473-478.

CDC Guideline for Prescribing Opioids for Chronic Pain.[13]

Broader Impacts of ADFs on the Opioid Crisis

In addition to improving the safety of prescription opioids, broader use of ADF products could help mitigate the national public health crisis of opioid use disorders (OUD), opioid overdose, and opioid overdose-related deaths. However, the same challenges identified above will limit our ability to draw firm conclusions about the impact of ADFs on the opioid crisis and in the broader public health setting.

For some individuals who experimentally or casually use drugs, or patients at risk for abusing their prescribed opioid analgesics, ADFs may serve as a deterrent to snorting or injecting, thus reducing the risk of adverse effects associated with these behaviors.[14] ADFs could also help prevent some inadvertent misuse and medication errors involving ER opioid analgesics—for example, a caregiver crushing an ER product to mix in applesauce for an elderly family member, resulting in rapid release of the drug and, potentially, overdose.

Some advocates for ADFs have also posited that by preventing the transition from oral to non-oral abuse in some individuals, ADFs could delay or prevent an escalation of substance use and the development of OUD. This would indeed be a tremendous public health benefit. However, to date, no studies have answered the critical question of whether ADF opioid analgesics reduce the *initiation* of non-oral abuse, or avert, slow or halt the development of OUD. Recognizing that most opioid analgesic abuse occurs through the oral route, FDA encouraged development of ADFs with properties that could meaningfully deter all relevant forms of abuse.

For individuals who develop OUD and begin snorting or injecting opioids, effective ADFs may result in substitution of other opioid drugs, either prescription or illicit. Published studies have suggested that some heroin substitution occurred when ADF OxyContin was marketed in the United States and that this substitution may have contributed to the increase in overdose deaths involving illicit opioids.[15] Although this potential unintended consequence of ADF OxyContin cannot be ignored, it is difficult to draw definitive conclusions about the impact of any single event on the course of this complex and multifaceted epidemic. Another concern that has arisen is the possibility that some ADFs could shift abuse to more dangerous routes and tampering methods. For example, the reformulation of Opana ER (ER oxymorphone) to deter non-oral abuse—although never approved by FDA to be labeled with ADF properties—resulted in a shift in abuse of the drug from snorting to injecting and contributed to an HIV outbreak in rural Indiana..[16,17] However, evidence does not suggest that a similar shift in route of abuse occurred with OxyContin after its reformulation in 2010. In fact, as noted above, some data indicate that

[13] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1
[14] https://www.fda.gov/media/84819/download
[15] Cicero, T. J. and M. S. Ellis (2015). "Abuse-Deterrent Formulations and the Prescription Opioid Abuse Epidemic in the United States: Lessons Learned From OxyContin." JAMA Psychiatry 72(5): 424-430.
[16] https://www.fda.gov/media/104539/download
[17] https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6416a4.htm

after the reformulation, some abuse of OxyContin shifted from non-oral to oral routes. Reformulated Opana ER was removed from the market.

Future Directions

As discussed above, it is important to understand fully the role of ADF opioid analgesics in the larger response to the opioid crisis, beginning with ongoing work to assess the net public health impact of ADFs and other efforts across different populations and over time. This work is challenging, and will require input from many stakeholders including other federal agencies also working on the complicated and evolving landscape of the opioid crisis. It appears there are opportunities for the development of novel technologies that could be brought to bear for new generations of ADF opioid analgesics. We know that low-dose combination products such as Vicodin (hydrocodone-acetaminophen) and Percocet (oxycodone-acetaminophen) are the most frequently prescribed opioid products,[18] and thus, they comprise the majority of the supply of opioid analgesics available for misuse. And, while surveillance data typically do not collect information on specific product and route involved in opioid misuse, swallowing oxycodone combination products was reported substantially more frequently than other oxycodone formulations and routes of abuse, in national data from poison center calls.[19] Because these products do not have the timed-release properties of ER opioid analgesics and because current ADF technologies primarily target non-oral abuse, these technologies have limited capability to reduce abuse and associated harms. Progressive improvements in the technologies used for ADFs could result in products that overcome these challenges and impact the abuse of IR opioid analgesics.

Other strategies, such as innovative packaging and disposal solutions, may also have the potential to improve the safety of opioid products and to help ameliorate the opioid crisis. As an initial focus, FDA is working to identify technologies that may reduce initial exposure to opioid analgesics (including from prescriptions of household members or others), and initiation of opioid misuse, as these factors contributed to the current public health crisis. We also continue to support advances in the critical areas of health care provider education, substance use disorder treatment (e.g., medication assisted treatment for OUD), and harm reduction (e.g., increasing naloxone access in the community). The complexity of this crisis requires a multi-pronged, coordinated approach that can adapt to the evolving nature of the crisis.

[18] Wittayanukorn S, Ibrahim I. Subject: Review of Recent Data on Use, Misuse, and Abuse of Tramadol and Comparator Drugs. FDA Briefing Information for the January 15, 2020 AM Session of the Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. Available online at: https://www.fda.gov/media/134128/download

[19] Daubresse M. Subject: Review of Recent Data on Misuse and Abuse of Oxycodone. FDA Briefing Information for the January 15, 2020 PM Session of the Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee. Available online at: https://www.fda.gov/media/134150/download

Conclusion

While 90% of Medicare beneficiaries enrolled in Medicare Part D have access to ADF opioid analgesics through their PDP or MA-PD plan, ADF opioid analgesics have significantly lower utilization in Part D compared to non-ADF opioid analgesics. Given that ADF opioid analgesics are available on formularies with low rates of PA and ST, the lower utilization is likely related to other factors. As evidenced in Tables 3 and 4, ADF opioid analgesics are brand drugs, and the cost to both the Medicare program and to beneficiaries is significantly greater than generic non-ADF opioid analgesics. The significant cost difference between these products may lead to patient and provider preference in using lower-cost therapies. In addition, while there is no clear evidence, one could speculate that provider preferences for prescribing ADF opioid analgesics may be limited to beneficiaries with a history of altering opioids for unintended routes of administration, or for beneficiaries living in regions where there is evidence or history of community diversion.

ADF opioid analgesics are one tool that has been developed with a goal of reducing opioid misuse. Published data suggest that currently available ADFs may help reduce misuse of these products by unintended routes to some extent, but the results of FDA-required postmarketing studies are still forthcoming. Low market uptake, a complex and changing landscape in terms of the nation's opioid crisis related to the use of prescription and illict opioids, and limitations in the available data have presented challenges to understanding the net public health impact of marketed ADFs. FDA continues to work to obtain the needed data to assess the real world impact of these formulations.