



June 2, 2017

Submitted electronically to: publiccomments@icer-review.org

Steven D. Pearson, MD, President
Institute for Clinical and Economic Review
Two Liberty Square, Ninth Floor
Boston, MA 02109

Re: Feedback on ICER's Abuse Deterrent Formulations of Opioids: Effectiveness and Value report

Dear Dr. Pearson:

On behalf of the Institute for Patient Access, I thank you for the opportunity to provide feedback on the Institute for Clinical and Economic Review's draft report evaluating the effectiveness and value of abuse deterrent formulations (ADF) of opioids.

About the Institute for Patient Access

The Institute for Patient Access (IfPA) is a physician-led policy research organization dedicated to maintaining the primacy of the physician-patient relationship in the provision of quality healthcare. To further that mission, IfPA produces educational materials and programming designed to promote informed discussion about patient access to approved therapies and appropriate clinical care. IfPA was established in 2012 by the leadership of the Alliance for Patient Access, a national network of more than 800 physician advocates committed to patient access. IfPA is a 501(c)(3) public charity non-profit organization.

Feedback on Draft Report

ICER's report on opioid ADFs lays out several important facts. First, pain is a significant medical problem with potentially devastating costs for patients, particularly for chronic pain patients. Second, opioids can be a valuable medicine for pain patients, but they also present certain risks. And third, ADF opioids are an emerging technology that can help protect pain patients' access to necessary medications while helping to reduce costs associated with the current opioid addiction crisis.

Due to several decisions made by the authors, however, the ICER report significantly understates ADFs' value by underestimating or overlooking certain key benefits.

1. The ICER model makes imprecise calculations about ADFs’ value and impact on the opioid abuse epidemic.

Cost and Value

Currently, effectiveness data for ADFs is available only for OxyContin. Instead of using an OxyContin model, however, the ICER report uses a “market basket” ADF model to estimate costs and benefits. It is unclear whether assumptions based on OxyContin studies apply to a market basket of ADFs.

Similarly, it is unclear how the results from a model based on a market basket ADF can be applied to any specific ADF drug. For example, the ICER model estimates the cost of opioid drugs using the weighted average cost of the drug in each category (ADF versus non-ADF drugs). The estimate for an ADF opioid is \$11.60 for 90 mg per day. The report then concludes that the weighted average cost needs to decline by 39 percent, to \$7.04 for 90 mg per day, to achieve cost neutrality.

Claiming that the weighted average cost of an ADF opioid should be 39 percent lower is not the same as saying that the cost of any specific ADF opioid should be 39 percent lower. Yet this detail could be overlooked, leading health plans to misapply the recommended price reduction in determining their ADF opioids coverage policies.

Impact on Opioid Abuse

There are also specific questions regarding how the ICER report applies empirical results to the cost benefit model. The ICER report uses the results from one oxycodone study (Rossiter et al., 2014), but ignores the results from 14 U.S.-based studies (16 overall) that was also reviewed in the report. These other studies, summarized in Table 11 of the ICER report, found, on average, that abuse deterrent OxyContin reduced the incidence of abuse in the U.S. by approximately 41 percent. This abuse reduction impact is significantly larger than the abuse reduction assumptions used in the ICER model (approximately 30 percent).

To the extent that health plans use ICER data to shape and justify their coverage policies, these figures could have the effect of reducing patients’ access to ADF opioids. In light of these concerns, ICER should reconsider the cost-benefit model and assumptions used in the report.

2. ICER’s baseline analysis ignores ADFs’ ability to curb opioid diversion.

The ICER report focuses on the abuse and misuse of opioids by patients who are prescribed the medication; however, a large part of the opioid crisis is caused by diversion. The CDC has estimated that “between 25% and 74% of overdose decedents” did not have “a prescription for at least one of the drugs that contributed to their death.”¹ The ICER report itself has noted that “about 50% of people who misused prescription opioids got them from a friend or relative for free”.²

¹ https://www.cdc.gov/drugoverdose/pdf/hhs_prescription_drug_abuse_report_09.2013.pdf.

² “Deterrent Formulations of Opioids: Effectiveness and Value: Draft Evidence Report” May 5, 2017, Page 12.

Studies cited in the ICER report itself found that ADFs can significantly reduce diversion. Severtson et al. (2013) found that OxyContin diversion fell 53 percent in the period immediately following the introduction of the ADF version. By five years after the introduction Severtson et al. (2016) found that diversion fell by 89 percent. In the other diversion study reviewed by ICER, Coplan et al. (2016), diversion rates declined by 66 percent.

By reducing diversion, ADFs could also reduce the costs that diversion generates. To ignore these savings, therefore is to ignore one of ADFs' foremost potential benefits – significantly understating abuse-deterrent opioids' overall value.

While the model limitations section explains that ADFs impact on diversion is not considered, the exclusion bears pointing out again. Ignoring a crucial potential benefit of ADFs can only result in an assessment that underestimates the therapies' value to patients, their families and communities, and public health.

3. ICER's cost model omits expected savings that ADFs generate with respect to the social costs of the opioid addiction crisis.

As exemplified by the analytic framework described in Figure 1, and in the model limitations sections, ICER recognizes that the opioid crisis imposes costs on society beyond the health care costs associated with patient abuse and misuse. These additional problems include increased criminal activity, increased criminal justice costs, reduced workplace productivity, and adverse impacts on education outcomes.

These costs are substantial.

The oft-cited study by Birnbaum (2011) estimated the total costs of opioid abuse were \$55.7 billion in 2008, which comprised criminal justice costs (\$5.1 billion), workplace costs (\$25.6 billion), and health care costs (\$25.0 billion).³ An updated study in 2016 by the National Center for Injury Prevention and Control estimated that these costs have grown to \$78.5 billion, with only one-third associated with increased health care expenses.⁴

The size of these non-health care related costs indicates that the ICER report is ignoring a large potential benefit of ADFs.

4. The ICER report overlooks ADFs' ability to reduce the conflict between ensuring pain patients' access to necessary medicine and addressing the problem of opioid abuse.

Opioid medications are highly valued by pain patients, particularly chronic pain patients. Due to the opioid addiction crisis, however, legitimate access to these medicines is becoming jeopardized.

For example, the Centers for Disease Control (CDC) has issued new, more stringent prescription guidelines. While not mandatory, the guidelines discourage clinicians from prescribing opioids

³ <http://www.asam.org/docs/advocacy/societal-costs-of-prescription-opioid-abuse-dependence-and-misuse-in-the-united-states.pdf>.

⁴ <https://www.sciencedaily.com/releases/2016/09/160914105756.htm>.

to patients other than pain associated with “active cancer, palliative, and end-of-life care” and then suggest that “the lowest possible effective dosage should be prescribed”.⁵

A 2017 survey by the *Pain News Network* and the *International Pain Foundation* found that “over 70 percent of pain patients say they are no longer prescribed opioid medication or are getting a lower dose. While reducing opioid prescriptions may have been the ultimate goal of the guidelines, it came with a heavy price: **Eight out of ten patients say their pain and quality of life are worse.** Many are having suicidal thoughts, and some are hoarding opioids or turning to illegal drugs for pain relief.”⁶

These survey results illustrate that pain patients put a high value on having effective pain management drugs available to them. Not having these drugs available can have a significant, negative impact on their quality of life.

ADFs challenge the notion that treating pain and curbing addiction must be an either-or proposition. Specifically, they limit situations in which pain patients who live with a person at high risk for diversion might opt to sacrifice needed pain treatment in order to safeguard a family member who is at high risk of abuse.

However, once again, ICER’s cost-benefit model does not consider these benefits.

Conclusions

For the above reasons, we have reservations regarding how the ICER report may impact patient access to opioids with abuse deterrent formulations. We encourage ICER to reconsider its model assumptions; incorporate into its analysis the estimated impact from ADF opioids on reducing the broader social costs associated with the opioid crisis; and, incorporate into the analysis the impact from ADF opioids on reducing the large problem of opioid diversion and theft. Without these factors taken into account, any value assessment of ADF opioids remains incomplete.

If IfPA can provide further detail or aid the Institute for Clinical and Economic Review in incorporating any of the above recommendations into its final draft, please contact us at 202-499-4114.

Sincerely,



Brian Kennedy
Executive Director

⁵ https://www.cdc.gov/drugoverdose/pdf/guidelines_at-a-glance-a.pdf.

⁶ Emphasis added, <https://www.painnewsnetwork.org/stories/2017/3/13/survey-finds-cdc-opioid-guidelines-harming-patients>.