AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

February 13, 2019

Steven Pearson, MD
Institute for Clinical and Economic Review
2 Liberty Square, Ninth Floor
Boston, MA 02109

Dear Dr. Pearson:

Aimed Alliance is a 501(c)(3) non-profit organization that seeks to protect and enhance the rights of health care consumers and providers in the U.S. On behalf of Aimed Alliance, I respectfully submit the following comment in response to the "Unsupported Price Increase Assessment" Draft Protocol ("Protocol") published by the Institute for Clinical and Economic Review ("ICER") on January 17, 2019.

We acknowledge that the cost of health care in the United States has become unjustifiably high and that certain brand and generic manufacturers have contributed to this problem with continued, unjustified price increases on their medications. We are pleased to see that the United States Federal Government has begun to take steps to address this issue and to craft policies that protect consumers, such as the recent proposal from the Department of Health and Human Services ("HHS") to end the practice of pharmaceutical rebates in the supply chain.[1] Additionally, a handful of states have enacted laws to combat pharmaceutical price gouging, and many more are currently considering similar legislation.

In the Draft Protocol document, ICER proposes to generate a report of the 13 medications that have experienced substantial price increases over the past two years. While the objective of this effort is commendable, we believe that the federal and state governments are the appropriate entities to determine whether price increases are justified – not ICER. Therefore, we urge you to abandon this project. If you insist on moving forward with the Unsupported Price Increase Assessment, we hope that you will address some of the critiques of the Protocol we set forth below.

An imperfect process could produce results that have a negative downstream effect on patient access. For instance, if ICER erroneously identifies medications for which price increases are not justified, insurers and pharmacy benefit managers ("PBMs") can rely on this faulty information when imposing stricter utilization management restrictions on those medications. Additionally, if ICER's report extracts price concessions from manufacturers, there is no guarantee that any savings would be passed along to patients and ICER lacks the authority to require savings to be passed on by actors in the pharmaceutical supply chain.

I. Study Design May Not Identify Most Egregious Price Increases

The Protocol proposes to assemble a list of the top 100 medications, determined by sales revenue in the United States. ICER will then identify the medications that have experienced a list price increase "over

[1] https://www.federalregister.gov/documents/2019/02/06/2019-01026/fraud-and-abuse-removal-of-safe-harbor-protection-for-rebates-involving-prescription-pharmaceuticals

two times the medical Consumer Price Index over a two-year period."[2] ICER will then analyze the net price increase that these medications experienced and select the top 10 medications whose price increases would generate the "largest increase in budget impact at the national level."[3] We believe that this approach is flawed because it will not necessarily identify the medications that experienced the most unreasonable price increases. For example, several generic manufacturers have increased the prices of their products significantly, including products that have been in the market for many years.[4] This protocol would exclude these price increases from the scope of ICER's review. We find this troubling because generic medications should offer the most promise for increased competition and lower prices for patients. When generics fail to provide this benefit, the manufacturers are likely exploiting market forces to achieve unjustified profits. We recommend that ICER adjust its Protocol in order to identify the top bad actors in the industry, regardless of sales revenue.

II. Study Design Should Include Critical Actors in the Supply Chain

The Draft Protocol, by design, only analyzes data from manufacturers and excludes information from other actors in the supply chain who have a significant influence on the prices that consumers pay for their medications at the pharmacy counter. Without considering the behavior and trade practices of these entities, ICER's review will be incomplete. We recommend that ICER solicit data from insurers, PBMs, distributors, hospitals, and pharmacies, which could provide additional context for the prices that consumers pay for medications, inefficiencies or waste in the supply chain, whether drug prices are reasonable, and which entities are most responsible for high prices.

III. Wholesale Acquisition Costs Are Likely to Lead to Inaccurate Assessments

ICER's Protocol proposes to compare the wholesale acquisition cost ("WAC") and Consumer Price Index ("CPI") to determine the theoretical budget impact that a reference medication has on the national level. We recommend against using WAC as a variable in this calculation because other factors, such as rebates, discounts to PBMs, best price mandates, discounts to hospitals and health systems, wholesaler fees, copay assistance programs, and administrative fees to group purchasing organizations ("GPOs") and PBMs account for a significant portion of a medication's price. These factors are included in a medication's net price, but not the WAC. Determining whether a price increase is reasonable based on the WAC ignores the true cost of medications and may produce misleading results. For these reasons, we recommend that ICER only use net price as a reference and exclude WAC from these calculations.

IV. Length of Time on the Market Can Impact Drug Pricing

The Protocol does not account for fluctuations in price that are typically associated with the length of time that a product has been available on the market. When medications are introduced in the market, prices are often high, but they usually come down as patent and exclusivity protections expire.[5] Therefore, depending on the situation, a price increase after the drug has been on the market for several years may be less justified than a price increase for a medication that is new to the market.

Drug prices may also increase right before patent and exclusivity periods are scheduled to run out. We do not support tactics to keep drug prices artificially high and prevent generic drug entry into the

[2] https://icer-review.org/material/unsupported-price-increase-assessment-draft-protocol/
[3] https://icer-review.org/material/unsupported-price-increase-assessment-draft-protocol/
[4] https://arstechnica.com/tech-policy/2018/05/drug-made-famous-by-shkrelis-5000-price-hike-is-still-750-a-pill/
[5] https://www.commonwealthfund.org/publications/journal-article/2017/sep/determinants-market-exclusivity-prescription-drugs-united

marketplace, such as patent evergreening and other strategies that extend the life of patents without providing new clinical benefits to patients. These tactics are bad for patients and the health system overall. Therefore, investigating the length of time the drug is on the market, especially in relation to its patents and exclusivities could be helpful in assessing whether a pricing increase is justified or not. We recommend that ICER incorporate this data into its review to account for secondary factors that could influence pricing decisions.

V. Manufacturers May Not Be able to Share Requested Information

ICER proposes to solicit information from manufacturers about their medications and competitor medications that could justify a substantial price increase. Notably, ICER proposes to publish this information publicly in the final report. We caution that some of the data that ICER seeks from manufacturers may be prohibited. For example, the Food Drug and Cosmetics Act prohibits manufacturers from sharing certain data with the public if such data is not listed on the product's FDA-approved labeling because the information could be considered false and misleading.[6,7] As such, manufactures may be prohibited from sharing information on potential new clinical indications or uses with ICER. However, such information may be critical in assessing a pricing increase.

The FDA recently released guidance titled "Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities – Questions and Answers" ("Guidance").[8] The Guidance notes that manufacturers may share health care economic information, including information on different dosing or use regimens, different endpoints, more-limited or targeted patient populations, with payers, formulary committees, and "other similar entities with knowledge and expertise in the area of health care economic analysis."[9] Therefore, we recommend that ICER request an advisory letter from the FDA that would confirm that ICER is a "similar entity with knowledge and expertise in the area of health care economic analysis" in accordance with the Guidance. ICER should delay its implementation of this Protocol until it receives this confirmation from the FDA.

VI. Non-Clinical Factors Do Not Receive Proper Consideration

In the Protocol, ICER indicates that it will request "other potential justifications for a price increase, including . . . a large increase in costs of production . . . large price savings attributable to the drug in other parts of the health system . . . [and] all other reasons deemed relevant by the manufacturers."[10] Yet, the Protocol also states that "non-clinical rationales will not be evaluated by ICER as a determinant in whether the drug is categorized as having its price increase unsupported by clinical evidence."[11] It is unclear why ICER is requesting other potential justifications for a price increase when such information will not be incorporated into the final assessment of drug price increases. Considerations should be given to valid business practices that could contribute to increased drug prices, such as drug shortages due to shortages of raw materials or unanticipated demand, and manufacturing issues. This information should be given weight because unexpected increases in production costs are a legitimate reason to increase the price of a medication.

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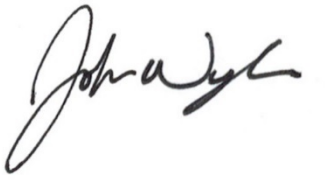
[6] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=312.7
[7] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=201.100
[8] https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf
[9] https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm537347.pdf
[10] https://icer-review.org/material/unsupported-price-increase-assessment-draft-protocol/
[11] https://icer-review.org/material/unsupported-price-increase-assessment-draft-protocol/

VII. Orphan Drugs

As ICER acknowledged in its Orphan Drug Assessment published in November 2017, orphan drugs should be treated differently. For individuals with rare diseases, it is typical for very few medication options to be available. Pharmaceutical manufacturers do not prioritize developing these types of medications because generally there is little-to-no return on investment. Without being able to charge prices for these medications that could potentially generate at least some level of return on investment, there would be no incentive to bring these medications to the market. Due to these factors, we recommend that ICER exclude these types of medications from its assessment.

Thank you for the opportunity to comment on the Draft Protocol.

Respectfully submitted,



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