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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2016-D-1307; Revised Draft Guidance for Industry on Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities: Questions and Answers

Dear Sir or Madam:

The Advanced Medical Technology Association (or "AdvaMed") provides these comments in response to the Food and Drug Administration ("FDA" or "Agency") revised "Draft Guidance for Industry—Drug and Device Manufacturer Communications with Payors, Formulary Committees, and Similar Entities: Questions and Answers (or "the Guidance").

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and other medical technology. AdvaMed's member companies produce the innovations that are transforming healthcare through earlier disease detection, less invasive procedures and more effective treatments. AdvaMed has more than 650 member companies, ranging from the largest to the smallest medical technology innovators and manufacturers.

We appreciate FDA's efforts to revise the guidance to help incorporate statutory changes adopted in Section 3630 of the Consolidated Appropriations Act. Such provisions expressly recognize the public health benefits of truthful and nonmisleading communications regarding healthcare economic information (HCEI) about products or uses that are not yet approved or cleared, including the important role such information plays in supporting coverage and reimbursement planning before a product reaches the market.

While many aspects of the draft guidance remain unchanged, our comments are intended to help ensure that the final guidance is practical and appropriately tailored for the medical device sector. Specifically, we encourage FDA to provide greater clarity regarding the guidance's scope and to accurately reflect device-specific data generation and relevant terminology.

Our general comments are provided below. They are followed by additional specific comments and proposed revisions in the table of remaining technical comments.

GENERAL COMMENTS

Clarification of Scope to Specific Audience

AdvaMed appreciates FDA's efforts to provide clarity on communications with payors and similar entities. We concur with FDA on the value of payors, technology assessment committees, and similar entities receiving truthful and nonmisleading information, including about products or uses that are not yet approved or cleared. At the same time, we believe it is important that the guidance clearly delineates that other audiences are not covered in this guidance so as not to sweep too broadly. We believe that is the intent as FDA notes that "[f]irms' communications to other audiences about unapproved medical products or unapproved uses of approved/cleared medical products are beyond the scope of the guidance." FDA also cites a number of other guidances of import that could apply to firms' communication to other audiences, including, for example, the draft guidance on "Responding to Unsolicited Requests for Off-Label Information about Prescription Drugs and Medical Devices" and guidance on "Communications from Firms to Health Care Providers Regarding Scientific Information on Unapproved Uses of Approved/Cleared Medical Products: Questions and Answers." Such scientific exchange and related communications with other audiences are recognized and appropriate and all efforts should be made so as not to infer this guidance is applicable, particularly in light of the broad definition of HCEI. While we believe that it is FDA's intent, we want to reinforce the importance of distinguishing from other audiences for purposes of this policy—all for whom scientific discourse is not only important, but in the best interests of patient care and the overall public health.

Clarification of Communication Frameworks

Similar to our previous comments on audience and types of communications, we would also suggest improved differentiation with the distinct statutory framework of section 502(a) under the Federal Food, Drug, and Cosmetic Act. Clarification is needed that, although HCEI is considered "promotional labeling", section 502(a) establishes a distinct statutory framework for payor-directed economic communications.

We would suggest adding the following language under Q9 after the first sentence to help stakeholders better distinguish HCEI from other FDA communication pathways, including scientific information on unapproved uses (SIUU) communications, unsolicited request responses, general promotional communications, and communications under section 502(gg):

"FDA recognizes, however, that firms may communicate information to payors under multiple regulatory and policy frameworks. HCEI communications under section 502(a) are distinct from general promotional communications because they consist of health care economic information

directed to payors and, when they satisfy the statutory requirements of section 502(a), are not considered false or misleading. HCEI communications may also be distinct from communications regarding scientific information on unapproved uses of approved/cleared medical products, responses to unsolicited requests for information, and communications regarding investigational products or investigational uses under section 502(gg) of the FD&C Act. FDA recognizes that a single interaction with a payor may include information that falls within more than one communication framework. Firms should clearly identify the purpose and context of the information being communicated and maintain appropriate documentation regarding the applicable communication framework."

Such clarification is particularly important because payor engagements frequently involve multiple types of information within a single interaction, making it difficult in practice to determine where one communication framework ends and another begins. Clarifying these distinctions would improve regulatory certainty while preserving the intended operation of the section 502(a) safe harbor for qualifying HCEI communications.

We appreciate FDA's work to develop the revised draft guidance and stand ready to assist. If we can answer questions or be of further assistance to the Agency, please do not hesitate to contact me.

Best Regards,

Khatereh Calleja

Khatereh Calleja
Senior Vice President
Technology & Regulatory Affairs

Edit Number *– Comment number* ***Change*** *– Proposed change to the guidance*

Line No. *– Section of the guidance* ***Comment/Rationale*** *– Reason for proposed change*

Edit No.	Line No.	Change	Comment/Rationale
1.	248-252	Revise as follows (add text in underline): "For example, when evaluating HCEI based on indirect treatment comparisons in the absence of data from head-to-head controlled clinical trials, FDA may refer to guidelines issued by external expert bodies regarding current rigorous methodologies and best practices for such comparisons (e.g., network meta-analyses). <u>For medical devices, FDA may also consider, for example, generally accepted scientific standards applicable to device-generated real-world evidence, device and procedure registries, analytical performance and accuracy studies, evidence derived from predecessor technologies, patient-reported outcomes, adherence and persistence analyses, workflow and healthcare resource utilization assessments, and other scientifically valid methodologies commonly used to evaluate device performance and value.</u>" <u>The acceptability of such evidence should be based on methodological rigor, fitness for purpose, transparency of assumptions, and relevance to the decision-making context rather than on the type of evidence source alone.</u>	The proposed language would help ensure the guidance reflects the range of evidence commonly used to evaluate medical devices. While competent and reliable scientific evidence (CARSE) is intended to be method-agnostic, the current examples are largely pharmaceutical-focused and do not adequately address evidence sources routinely used in device assessment. Medical device evaluations frequently rely on real-world data, registries, analytical performance studies, patient-reported outcomes, and evidence from predecessor technologies among others. These evidence types are recognized within FDA's medical device evidentiary framework and are commonly used to support regulatory and payer decision-making. Explicit recognition of these methodologies would reduce uncertainty regarding their eligibility under CARSE and reinforce that evidence should be evaluated based on methodological rigor, fitness for purpose, transparency, and relevance to the decision-making context—not the evidence source alone. This clarification would promote consistent application of CARSE across product categories while aligning the guidance with FDA's established approach to medical device evidence.
2.	253-255	Revise as follows (add text in underline): "HCEI should clearly and prominently present the applicable information discussed in Q7 and Q8 of this guidance, including study design and methodology, generalizability, limitations, sensitivity	The reference to a "balanced and complete presentation" is vague and may suggest the need for extensive supporting materials beyond what payors need for evaluation. This is especially true for medical devices, where evidence often includes real-world data, registries, device performance studies, post-market evidence, and

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		analyses, and information relevant to providing a balanced and complete presentation. For medical devices, such information may include material assumptions, data source characteristics, device-specific limitations, uncertainty analyses, and factors affecting the applicability of results across patient populations, sites of care, or clinical practice settings. A balanced and complete presentation does not require inclusion of all underlying analyses or supporting evidence, or reproduction of a full evidentiary dossier. Rather, it should provide sufficient context for the intended audience to understand the strengths, limitations, and relevance of the information presented and to evaluate its appropriateness for population-level healthcare decision-making.”	healthcare utilization analyses, rather than a single clinical program. Clarifying that balance is achieved through transparent disclosure of assumptions, limitations, and uncertainties—not by full evidentiary dossiers—would better meet the needs of sophisticated payor audiences. This maintains FDA's goal of truthful, non-misleading communication while keeping HCEI practical, decision-relevant, and aligned with the evidence for medical devices. An additional suggestion might be to delete the reference to “complete” to avoid confusion while allowing for more understandable language.
3.	320-321	Revise as follows (add text in underline): “Comparator: The choice of comparator (e.g., other medical products, other medical care, no treatment) should be explained (Gold et al. 1996; Husereau et al. 2013). For medical devices, relevant comparators can include, for example, predecessor devices, alternative technologies, diagnostic strategies, digital health platforms, procedures, sites of care, clinical pathways, or standard management, rather than specific products. This can be especially important for technologies such as continuous glucose monitoring (CGM) systems, where economic value may be compared to self-monitoring, intermittently scanned CGM, management platforms, insulin delivery, or other strategies. Since medical devices often innovate iteratively, economic analyses may compare earlier or similar versions when direct evidence is not available.”	Unlike pharmaceuticals, medical devices are updated through iterative innovation. For example, a CGM platform may undergo multiple software updates, algorithm improvements, changes in features, sensor generation advances, and expanded indication reviews within a coverage contract period. Payors routinely require advance information about planned product enhancements, new indications under development, interoperability capabilities, software upgrades, and expanded patient populations to make multi-year coverage decisions.

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4.	376-382	Revise as follows (add text in underline): "Conspicuous and Prominent Statement Describing Material Differences: If HCEI includes material differences from the FDA-approved labeling (e.g., new or increased risks, different dosing/use regimens, different endpoints, more limited/targeted patient populations), including assumptions that vary in certain respects from the information presented in the FDA-approved labeling, "a conspicuous and prominent statement describing any material differences between the health care economic information and the labeling approved for the drug or device" must be presented. <u>Disclosures should be reasonably designed to inform payors of information material to the interpretation of the analysis. Such disclosures may be concise and may refer to other portions of the communication where more detailed information is provided. Firms are not expected to separately disclose differences that are immaterial to the economic conclusions or that are otherwise adequately described elsewhere in the HCEI presentation</u>."	The draft guidance recognizes that disclosures may be concise when material information is provided. Because payors are sophisticated audiences that routinely evaluate economic analyses, requiring extensive disclosures for every difference between HCEI and FDA-approved labeling may be unnecessarily burdensome and could distract from information most relevant to coverage and reimbursement decisions. This is particularly relevant for medical device HCEI, which often relies on real-world evidence, registries, and economic models that may differ from FDA-required labeling but remain scientifically valid and informative. We recommend that the FDA clarify that disclosures should focus on material differences that could reasonably affect the interpretation of the HCEI and may be provided through concise statements and cross-references to detailed methodology, assumptions, or limitations presented elsewhere in the communication.
5.	427-439	Revise as follows (add text in underline): "When HCEI includes COAs (e.g., patient-reported outcomes, including work productivity, basic activities of daily living) or other measures of health outcomes (e.g., quality-adjusted life years) information regarding the validity and reliability of the measures used in assessments of the COA (as determined by experts familiar with evaluating the merits of a particular COA) or the health outcome measure should be included. <u>For example, measures that have been described, evaluated, or validated in peer-reviewed scientific literature may provide relevant support regarding the validity, reliability, and appropriateness of the</u>	As FDA recognizes, healthcare economic information may be communicated to payors through a variety of formats, including peer-reviewed journals. Further, peer-reviewed clinical outcome assessments (COAs), including PROs and work productivity measures, are frequently used in HCEI to assess outcomes that are meaningful to patients, employers, payors, and healthcare systems. This addition is intended as a helpful example that such evidence may support the validity and reliability of such measures.

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		COA for the population and outcomes being assessed. Such measures may include, but are not limited to, patient-reported outcomes (PROs), work productivity measures, functional status assessments, and other clinical outcome assessments used to evaluate health outcomes relevant to HCEI."	