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MEMORANDUM

TO: Leslie Kux, Assistant Commissioner for Policy, Food and Drug Administration

FROM: The Medical Information Working Group

RE: Use of Health Care Economic Information Under Section 114 of the Food and Drug Administration Modernization Act

DATE: October 31, 2014

We write on behalf of the Medical Information Working Group[1] (MIWG) to provide input on the draft guidance document on Section 114 of the Food and Drug Modernization Act of 1997 (FDAMA) that your June 6 citizen petition response indicates Food and Drug Administration (FDA) officials are developing for publication by year's end.[2] The members of the MIWG are committed to the dissemination of high-quality evidence that satisfies the needs of formulary committees or other similar entities. Below, we offer our interpretation of key statutory terms and propose specific language for the agency to consider incorporating into the forthcoming guidance document.

INTERPRETATION OF KEY FDAMA 114 TERMS

With the passage of FDAMA 114 in 1997, Congress made clear that drug manufacturers are permitted to share health care economic information (HCEI) with formulary committees or other similar entities when the HCEI is "directly related to an approved indication" and is based on "competent and reliable scientific evidence" (CARSE). However, key statutory terms remain undefined, and the term "health care economic information" is inadequately defined. The lack of clarity around these terms has been a significant barrier to companies that seek to communicate HCEI under Section 114. To facilitate the effective dissemination of HCEI, we offer below our interpretation of key statutory terms, which we urge FDA to adopt as it develops draft guidance in this area.[3]

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[1] Members of the MIWG are: Allergan, Inc.; Amgen Inc.; Bayer Healthcare Pharmaceuticals Inc.; Boehringer Ingelheim Pharmaceuticals, Inc.; Eli Lilly and Company; Genentech, Inc.; GlaxoSmithKline LLC; Johnson & Johnson; Novartis Pharmaceuticals Corporation; Novo Nordisk, Inc.; Pfizer, Inc.; and Sanofi US.

[2] See Letter from Leslie Kux, Assistant Commissioner for Policy, to Alan R. Bennett, Joan McPhee, Paul Kalb, & Coleen Klasmeier, Docket Nos. FDA-2011-P-0512 and FDA-2013-P-1079, 9 (June 6, 2014).

[3] This paper focuses on dissemination of HCEI under FDAMA 114. We do not here address FDA's regulation of payer-directed communications more broadly, except to state that the agency may have jurisdiction over such communications only insofar as they constitute advertising, labeling, or evidence of intended use, as those terms are properly construed in accordance with the Food, Drug, and Cosmetic Act (FDCA) and constitutional protections.

I. HCEI

The definition of HCEI in FDAMA 114 is a broad one that includes "any" analysis related to the economic consequences of a drug. Accordingly, information gleaned through a broad range of methods and techniques may properly be disseminated to formulary committees or other similar entities pursuant to FDAMA 114 so long as other elements of the statutory provision are satisfied. The statute's reference to HCEI as the comprehensive "analysis" of economic consequences, moreover, (as opposed to, for example, economic data or outcomes) indicates that *all* components of the analysis—such as the data, inputs, assumptions, methods, results, and other components comprising the analysis—are covered by the statutory provision and thus subject to the CARSE standard.

We believe that FDA should affirm in the FDAMA 114 guidance that:

- "Health care economic information" (HCEI) is "any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention."[4]

- HCEI encompasses all components of the analysis, including data, inputs, assumptions, methods, and results. *See* H.R. Rep. No. 105-310, at 65 (1997) ("Data about health outcomes associated with the use of a drug, other treatments, or no treatment are . . . incorporated into the economic analysis," as are the "costs of health outcomes" and "all assumptions.").

- HCEI can involve a number of techniques, including but not limited to economic modeling, cost minimization, cost effectiveness, comparative effectiveness, cost utility, cost benefit, cost of illness, cost consequences, and any other economic analytic technique that may shed light on resource allocation.

- The clinical data incorporated in an HCEI analysis can be generated using evidence from different sources or using different types of methodologies, whether prospective or retrospective, including but not limited to randomized controlled trials, pragmatic clinical studies, meta-analyses, observational studies, modeling techniques, case studies, patient-reported outcomes, epidemiologic studies, prescription claims database analyses, and outcomes research.

II. "Directly Related to an Approved Indication"

FDAMA 114 provides that HCEI "shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence." The statute does not elaborate upon what it means for HCEI to "directly relate" to an approved indication, and FDA has not issued official guidance interpreting the statutory provision. Because, as noted above, HCEI is an "analysis" of

[4] This language comes directly from the statutory provision at 21 U.S.C. § 352(a).

economic consequences, including the costs of "represented health outcomes," HCEI by definition must do more than simply reiterate the clinical benefits of a drug as set forth in approved labeling. Indeed, if FDAMA 114 were intended to enable manufacturers solely to provide economic analyses of the labeled clinical benefits of drugs, then the provision would not have been necessary. FDA has never required "substantial evidence" to support an economic analysis, as such evidence is only necessary to substantiate *clinical* claims. To avoid rendering FDAMA 114 a nullity, therefore, the provision must be interpreted to apply to a category of speech that had not been clearly permitted prior to enactment in 1997.

The meaning of "directly relates" is clear from the references to closely related statutory provisions—Sections 502(a) ("this paragraph") and 505(a) of the FDCA and Section 351(a) of the Public Health Service Act (PHSA). Before FDAMA 114 was enacted, a manufacturer wishing to provide HCEI would have confronted regulatory obstacles: FDA might well have objected to the communication on the ground that (1) the information was "false or misleading" under Section 502(a); (2) the information caused the drug to be an unapproved "new drug" in violation of Section 505(a) of the FDCA or Section 351(a) of the PHSA; or (3) the information misbranded the drug under Section 502(f)(1) (requiring "adequate directions for use"). FDAMA 114 altered that landscape by clarifying that FDA could not proceed against a manufacturer on either of the first two grounds, provided the manufacturer disseminated HCEI as described in FDAMA 114. The phrase "directly relates" therefore signifies that Congress intended for HCEI to include communication relating to the labeled indication, and even to uses of the drug for that labeled indication that vary to some degree from the approved labeling or are not included in such labeling, provided only that the communication does not claim that the drug has been approved for, or is safe and effective for, an entirely "new use" of the drug as defined in 21 C.F.R. § 201.128. The House Report accompanying FDAMA 114 supports this interpretation. It specifies that "economic claims based on preventing disease progression would ordinarily not be considered to be directly related to an approved indication for the treatment of symptoms of a disease, for a drug for which the use in prevention of disease progression has not been approved."[5] To illustrate this point, the House Report provides two examples:[6]

1) Economic claims based in part on an assumption of prevention of deformity for rheumatoid arthritis drugs, which are approved for the treatment of symptoms and not for the prevention of deformity;

2) Economic claims based on prolonging patient survival for agents approved for the symptomatic treatment of heart failure, but not approved for prolonging survival in heart failure patients.

As the statutory references to "analysis" of "outcomes" indicates, HCEI that includes a clinical component is properly considered HCEI governed by FDAMA 114, rather than a clinical claim subject to the substantial evidence standard. In the past, an FDA official has advanced a contrary interpretation. Dr. Robert Temple, Deputy Center Director for Clinical Science, FDA Center for Drug Evaluation and Research (CDER), stated in 2011 that any clinical assumptions

[5] *Id*.
[6] *Id*.

that underlie HCEI must be supported by substantial evidence.[7] Manufacturers, in other words, may not make economic comparisons with other drugs unless head-to-head studies demonstrate that the products have comparable clinical efficacy; similarly, manufacturers may not describe the economic consequences that follow from a labeled indication unless the primary outcomes have been established by substantial evidence, as opposed to CARSE. This interpretation is at odds with Congress's intent to provide a more flexible standard for the communication of HCEI, as Congress clearly envisioned FDAMA 114 to encompass more than simple "costing studies," or economic calculations applied to clinical endpoints that had been demonstrated by substantial evidence.[8] Moreover, such an approach would undermine the statutory provision and would deprive formulary committees or other similar entities of the information needed to evaluate the economic consequences of products as used in clinical practice.[9]

Accordingly, we suggest that FDA state in the FDAMA 114 guidance that:

- HCEI "directly relates" to an approved indication when it is based on clinical or economic data cited in FDA-approved product labeling. HCEI also "directly relates" to an approved indication when it is based on economic or health outcomes not cited in product labeling if such outcomes are shown by competent and reliable scientific evidence to flow from the use of a drug in its approved indication. Examples of HCEI directly related to an approved indication would include but are not limited to the following:

    - HCEI obtained through actual use (e.g., not controlled for factors such as diet, exercise, concurrent medication use, etc.; not limited by inclusion criteria of registration studies)

    - HCEI based on a longer duration of use (e.g., for drugs indicated to treat chronic conditions)

    - HCEI based on commonly prescribed dosage levels and dosing regimens, including levels and regimens that differ from product labeling (e.g., as gleaned from prescription claims databases)

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[7] *See Communication of CER Findings, Asymmetry in the Ability to Communicate CER Findings: Ethics and Issues for Informed Decision Making* (Feb. 9, 2012) *available at* http://www.npcnow.org/system/files/conferences/download/rtemple_asym12.pdf.

[8] In drafting the provision, the Senate acknowledged the importance of HCEI and concluded that "[u]ndue restrictions on the ability of companies to make competent and reliable claims on the basis of cost, effectiveness, or safety of approved uses of products interfere with the public health by encouraging the sale and use of needlessly expensive products." S. Rep. No. 105-43 (1997), 1997 WL 394244 at *42-43.

[9] Drawing economic comparisons among treatment options on the basis of adequate and well-controlled studies is particularly impracticable, because adequate and well-controlled head-to-head trials are exceedingly expensive to conduct, require a complex design, and can take years to generate meaningful results. Meta-analyses, observational studies, and certain other types of research, however, frequently *do* compare the economic consequences associated with various products that are used to treat a certain disease or condition; such studies and analyses also more accurately reflect actual use, and in turn, provide "real world" results that are useful to the stakeholders involved in health care decision-making. *See, e.g., AMCP Format for Formulary Submissions* Version 3.1 (Dec. 2012), at 9; *see also* Louis P. Garrison Jr. et al., *A Flexible Approach to Evidentiary Standards For Comparative Effectiveness Research*, 29 Health Affairs 1812, 1815-16 (2010).

- HCEI specific to patient subgroups (e.g., demographic groups, with co-morbidities)

- HCEI related to health outcomes (e.g., quality of life impacts of a drug for osteoarthritis)

III. Permitted Audience

FDAMA 114 explicitly permits manufacturers to provide HCEI to a "formulary committee or other similar entity in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations."[10] The legislative history clarifies that Congress intended the permitted audience to include individuals or entities "that are charged with making medical product selection decisions for managed care or similar organizations,"[11] but does not elaborate further on which individuals may receive information pursuant to the statute, or what it means for those individuals to be carrying out a duty to select drugs. Instead, Congress focused on the importance of providing health care decision-makers with enhanced access to economic information and reasoned that "such entities are constituted to consider this type of information through a deliberative process and are expected to have the appropriate range of expertise to interpret HCEI presented to them to inform their decision-making process, and to distinguish facts from assumptions. This limitation is important because it will ensure that the information is presented only to parties who have established procedures and skills to interpret the methods and limitations of economic studies."[12]

In today's environment, where value-oriented considerations are increasingly influencing health care delivery, the decision-making that Congress contemplated when enacting FDAMA 114 occurs not just among payers, but also at hospitals and clinics where HCPs, administrators, and other professionals are responsible for recommending drug acquisition, selection, and treatment guidelines. Just as managed care formulary committee members may consider evidence related to a range of therapeutic options and assign preferred or restricted status to a particular drug or drugs, professionals in a care-based setting may develop standard order sets, clinical care pathways, or similar management plans that delineate key steps—such as ordering diagnostic tests or prescribing particular drugs—in the treatment of patients with certain diseases or conditions. The appropriate audience for receipt of information pursuant to FDAMA 114 includes, consistent with Congress's intent, individuals or entities with the capacity to make decisions related to health care resource or utilization management for a defined population of patients, as well as individuals or entities that advise such decision-makers. The fact that the individuals and entities engaged in such decision-making are increasingly resource-constrained, and by their very nature inclined to skepticism regarding a therapy's value, bolsters the rationale for broadly permitting dissemination of HCEI; these stakeholders, moreover, are increasingly required to assess treatment value, and ensuring that they have the proper tools to do so not only benefits their decision-making process, but is consistent with public health and policy goals of enhancing value-based care.

[10] 21 U.S.C. § 352(a).
[11] H.R. Rep. No. 105-310 (1997), at 66.
[12] 143 Cong. Rec. H8455-01, *H8482 (Oct. 7, 1997).

Although the law does not elaborate upon what it means to be in the course of carrying out a responsibility to select drugs, that term warrants a broad interpretation considering the sophistication with which such individuals and entities review and analyze economic analyses and the evolving way in which information is shared. So long as the HCEI is provided to inform drug-selection decisions with respect to a population of patients, as opposed to a prescribing decision made by a single physician with respect to a single patient, its dissemination is appropriate under the statute.

Precisely *how* the material may be provided is similarly deserving of a broad interpretation. It would be appropriate, for example, for manufacturers to present HCEI at managed care and other payer conferences, which the professionals who comprise such committees attend to learn about and share best practices for designing coverage programs that deliver high quality, cost-effective care. Similarly, it would be appropriate for a manufacturer to post HCEI on a closed-access electronic platform for formulary committees or other similar entities to download or view, or to submit HCEI for publication in the trade press or journals that focus on HCEI and other issues related to health care cost, quality, or outcomes. These practices would encourage the flow of information to health care decision-makers while retaining the necessary safeguards to ensure that the information shared is not deceptive or otherwise misleading.

Accordingly, we believe that FDA should make clear in the FDAMA 114 guidance that:

- A "formulary committee or other similar entity" encompasses any individual, group of individuals, or entity responsible for contributing toward, advising, or facilitating organizational decisions directed at selecting the drugs that may be used within a certain patient population, improving population health, lowering health care costs, or improving patient experience through the availability or management of pharmaceutical treatments or programs (i.e., "population-based" decision-makers). Such individuals or entities include, but are not limited to, pharmacy and therapeutics committees; new product committees; therapeutic assessment committees; drug utilization management or review committees; integrated delivery networks; drug information centers; medical advisory boards; technology assessment panels; plan medical or pharmacy directors; compendium publishers; pharmacy benefit managers; group purchasing organizations; health care plan executives; employers; third-party payers; developers of clinical practice guidelines, clinical pathways, or clinical decision support systems; developers of preferred drug lists, formularies, and standard order sets; developers of provider incentives; health economists or pharmacoeconomic experts; consultants retained to conduct outcomes or economic analyses; comparative effectiveness experts; and other multidisciplinary committees within health care organizations at the regional and federal level that review scientific, technology, and health assessments.
- HCEI is provided "in the course of the committee or the entity carrying out its responsibilities for the selection of drugs" when it is provided to inform drug-selection decisions with respect to a population of patients, as opposed to prescribing decisions made by a single physician with respect to a single patient in a one-on-one setting (e.g., a typical office visit). A physician who makes individual prescribing decisions and also

serves on a formulary committee or similar entity may receive HCEI "in the course the committee or the entity carrying out its responsibilities for the selection of drugs." Formulary committees, and those individuals serving on, consulting with, or otherwise aiding such committees, may have access to and take into account HCEI when choosing which drugs will be used for a population of patients. HCEI can inform formulary committees and committee members about the health economics impact of selecting a particular drug for a population of patients.

- "Managed care or other similar organizations" include, but are not limited to: health maintenance organizations; independent practice associations; preferred provider organizations; exclusive provider organizations; designated provider organizations; accountable care organizations; point of service plans; pharmacy benefit management firms; hospitals, clinics, and other integrated health care delivery systems; integrated delivery networks; medical service organizations; employers; patient-centered medical homes; medical group practices; professional medical societies; quality measure development and endorsement organizations; health care consulting organizations; and other entities at the regional or national level that make coverage or payment decisions regarding the drugs provided to patients, have some level of financial responsibility for patient care, or are responsible for selecting drugs offered to patients.

IV. CARSE

To fall within the scope of FDAMA 114, HCEI must be "based on competent and reliable scientific evidence."[13] The level of substantiation required by this standard has never been elucidated by FDA in the context of FDAMA 114, but the legislative history clearly indicates that Congress adopted it to facilitate the effective communication of HCEI to formulary committees or other similar entities.[14] Requiring HCEI to meet a higher standard, Congress reasoned, could negatively impact the public health and contribute to increased health care costs.[15]

The CARSE standard in FDAMA 114 was modeled off the Federal Trade Commission (FTC) standard for the support of promotional claims. Unlike the rigidity of FDA's substantial evidence standard, the FTC requires that where a claim expressly or impliedly refers to the amount of support for the claim (e.g., "tests prove" and "studies show"), the claim be backed by at least the advertised level of substantiation." Where a claim makes no reference to the level of substantiation supporting the claim, however, "the Commission assumes that the audience expects a "reasonable basis" for claims." The FTC's determination of what constitutes a "reasonable basis" is variable and depends on a number of factors, most notably "the amount of substantiation experts in the field believe is reasonable." Specifically, the FTC takes into account the "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner

[13] 21 U.S.C. § 352(a).
[14] S. Rep. No. 105-43 (1997), 1997 WL 394244 at *42-43 ("The committee believes that the FDA should allow companies to share health economic information about approved "on label" uses for products under the same standard applied to over-the-counter drugs and other products. The agency currently requires these claims–which differ from efficacy claims–to be subjected to two clinical trials. The agency on several occasions conceded that this standard is inappropriate for such claims and agreed that it should be modified to a more appropriate standard.").
[15] *See id.*

by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results."[16] Regarding HCEI in particular, the FTC has cautioned that "[t]he substantiation rules governing such claims should be sufficient to prevent deceptive or unsubstantiated claims, but not too rigid or too costly to undermine firms' incentives to develop and provide a wide range of truthful, non-misleading economic information."[17]

Consistent with Congress's intent in enacting FDAMA 114, the rigor of the CARSE standard should be largely dictated by the audience that will receive the information. Rather than adopting inflexible criteria that all studies and analyses must satisfy regardless of the circumstances, or stating at the outset that certain types of studies and analyses can never be considered "competent and reliable," FDA should instead (1) presume that recipients of HCEI pursuant to FDAMA 114 will possess the requisite knowledge and experience to understand and interpret HCEI in all its forms; and (2) take note of the prevailing and dynamic principles, standards, and guidelines that health care decision-makers, researchers, academics, government agencies, and other stakeholders have established relating to the development, reporting, and evaluation of HCEI. These authorities on HCEI[18] have described best practices relating to a variety of study types, data sets, and models, and the guidance that they have provided emphasizes that the research is not a "one-size-fits-all" proposition, but rather should be fit for its intended purpose. Accordingly, it is not appropriate to define the criteria that particular studies, analyses, or materials disseminated pursuant to FDAMA 114 must satisfy.

FDA should state in the FDAMA 114 guidance that:

- "Competent and reliable scientific evidence" (CARSE) includes "tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results." *FTC v. Iovate Health Sciences USA, Inc*., No. 10-cv-587, at 8 (W.D.N.Y. 2010). When claims describe a particular level of substantiation (e.g., "tests prove" or "studies show"), CARSE consists of "at least the advertised level of substantiation." 49 Fed. Reg. 30999, 31000 (Aug. 2, 1984). "Absent an express or implied reference to a certain level of support," CARSE consists of sufficient evidence to form a "reasonable basis" for claims. *Id*.
- The requirement under § 352(a) that HCEI be "based on competent and reliable

[16] *See, e.g., FTC v. Iovate Health Sciences USA*, no. 10-cv-587, at 8 (W.D.N.Y. 2010).
[17] Comments of the Staffs of the Bureaus of Economics and Consumer Protection of the Federal Trade Commission, In the Matter of Pharmaceutical Marketing and Information Exchange in Managed Care Environments; Public Hearings, Dkt. No. 95N-0228 (Jan. 16, 1996).
[18] *See, e.g.*, Hay et al., *Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: Issues and Recommendations: The ISPOR Drug Cost Task Force Report*—Part I, 13 Value in Health 3 (2010); Mycka et al., *Good Research Practices for Measuring Drug Costs in Cost Effectiveness Analyses: An Industry Perspective*, 13 Value in Health 25 (2010); Garrison et al., *Using Real-World Data for Coverage and Payment Decisions: The ISPOR Real-World Data Task Force Report*, 10 Value in Health 326 (2007); Dryer et al., *GRACE Principles: Recognizing High-Quality Observational Studies of Comparative Effectiveness*,16 Am. J. Managed Care 467 (2010); Siegel et al., *Guidelines for Pharmacoeconomic Studies: Recommendations from the Panel on Cost Effectiveness in Health and Medicine*, 11 Pharmacoeconomics 159 (1997); Russell et al., *Consensus Statement: The Role of Cost-effectiveness Analysis in Health and Medicine*, 276 JAMA 1172 (1996); Siegel et al., *Consensus Statement: Recommendations for Reporting Cost-effectiveness Analyses*, 276 JAMA 1339 (1996).

scientific evidence" applies to all components of the HCEI analysis, including health outcome data, comparative clinical information, and any other inputs or assumptions used in the analysis. Components of the HCEI analysis, including those involving clinical information, are not required to meet the substantial evidence standard applicable to stand-alone clinical claims. To the extent that HCEI implies claims, including any implied claims of clinical superiority, such claims must be supported by CARSE, not substantial evidence, to meet § 352(a)'s substantiation requirements.

- Due to the inherent flexibility in the CARSE standard, it is not appropriate to identify specific criteria that all HCEI disseminated under FDAMA 114 must satisfy. Features that may be commonly associated with, but not required of, HCEI based on CARSE include the following:
  - An identification of the research question;
  - A description of the design underlying the analysis (e.g., the source of data, method or techniques used, assumptions, and inputs);
  - A description of any limitations of the analysis;
  - An explanation of the rationale for any conclusions reached, including generalizability of results to other settings and patient groups;
  - An identification of the costs and consequences for each alternative included in the analysis, including the perspective(s) considered, measurements of costs and outcomes in physical units, and sources used to value costs and clinical outcomes;
  - An explanation of whether discounting was used for costs and clinical outcomes and the discount rate used; and
  - An explanation of whether results represent marginal or incremental costs and outcomes.

In addition to the above features related to the quality of the HCEI, we propose that the manufacturer describe any differences between the labeled indication and any HCEI component, and explain whether the manufacturer or anyone acting on its behalf contributed to the development or funding of the analysis. Such an approach would facilitate access to information and is in alignment with the First Amendment.[19]

CONCLUSION

At a time in which federal health care policy is encouraging payers and providers to focus limited health care resources on providing quality, cost-effective care, FDA should adopt clear

[19] *See, e.g., 44 Liquormart, Inc. v. Rhode Island*, 517 U.S. 484, 496-97 (1996). Where less restrictive methods exist to render such lawful speech truthful and non-misleading, such as disclosure regimes, the First Amendment favors these methods over outright bans on speech. *Zauderer v. Office of Disciplinary Counsel of the Sup. Ct. of Ohio*, 471 U.S. 626, 651 n. 14 (1985) ("[A]ll our discussions of restraints on commercial speech have recommended disclosure requirements as one of the acceptable less restrictive alternatives to actual suppression of speech."); *United States v. Caronia*, 703 F.3d 149, 168 (2d Cir. 2012) (suggesting, as an alternative to a ban on promotion of new uses, development of "warning or disclaimer systems"). Additionally, the October 1997 House Report states that "[t]he provision presumes that the current standard practice of including full disclosure of all assumptions and health outcomes used in the economic analysis will continue." H.R. Rep. No. 105-310 (1997), at 65-66.

policies that enable manufacturers to share HCEI about their products with those responsible for contributing toward, advising, or facilitating health-care decisions for a patient population. Vagueness surrounding permissible manufacturer speech has significant consequences to manufacturers, the government, physicians, and patients. It also has significant consequences to the decision-makers both public and private that rely upon manufacturers to provide information necessary to predict the specific benefits and costs that their products will have for a covered population. Absent clarity regarding communications with formulary committees and other similar entities, many manufacturers will err on the side of caution and withhold communications. Ultimately, the under-communication of economically and clinically relevant information is detrimental to the public health. To ensure that formulary committees and other similar entities have access to and manufacturers are able to provide this information, we respectfully request that FDA consider the proposed language and rationale provided in this submission as it develops draft guidance on FDAMA 114.