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

Re: Docket No. FDA-2018-N-3519: Collaborative Communities Toolkit

Dear Sir or Madame:

The Advanced Medical Technology Association (“AdvaMed”) appreciates the opportunity to provide comments on the Food and Drug Administration (“FDA” or “Agency”) publication, Collaborative Communities Toolkit (“CC Toolkit”). Like many stakeholders, we are focused on understanding how and in what circumstances collaborative communities will operate, so we welcome publication of the CC Toolkit and FDA’s stakeholder engagement while the collaborative community initiative evolves.

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed’s member companies range from the largest to the smallest medical product innovators and manufacturers, with nearly 70 percent of our members generating less than $100 million in annual sales. AdvaMed’s member companies produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments.

The CC Toolkit is an important mechanism to empower diverse stakeholders to identify and solve problems to assure device quality, safety, and effectiveness and to enhance patient outcomes. We recognize the benefits of the toolkit’s development and use – and development and use of collaborative communities more broadly – subject to applicable legal and regulatory requirements. To that end, we offer recommendations to promote appropriate use of the toolkit and to clarify FDA’s role in relation to collaborative communities.

FDA should clarify the distinction between “establishing,” “convening,” and “leading,” collaborative communities.

The CC Toolkit states that collaborative communities “are not convened by FDA . . . .” and “are not led by the FDA . . . .” CC Toolkit, p. 3. But at the same time, CDRH’s 2018-2020 Strategic Priorities document states that, “By December 31, 2020, [FDA will] establish at least 10 new Collaborative Communities.” CDRH 2018-2020 Strategic Priorities, p. 19. (emphasis added). FDA should help stakeholders and collaborative community participants understand the difference between “establishing,” “convening,” and “leading” collaborative communities. For example, how is convening a collaborative community different than establishing a community? Does “establishing” a collaborative community mean that FDA creates it? Does it mean that FDA promotes and supports the
collaborative community, e.g., through funding and staff time? And once FDA establishes a collaborative community, what is its role? Is there any leadership role for the Agency or will it step back and either participate in or exit the community? Answers to these questions will help stakeholders and community participants understand the role that FDA plays in establishing and sustaining collaborative communities.

**FDA should clarify the circumstances in which it will establish or join collaborative communities.**

There may be circumstances in which FDA need not establish or join collaborative communities, relying instead on existing organizations to provide information and input. Professional medical associations, for example, possess deep understanding of disease states and stand ready to educate FDA about device use for disease detection, treatment, and prevention. In such cases, FDA might proceed most efficiently by leveraging existing organizations.

But at other times, collaborative communities will form on their own or at FDA’s suggestion. Some of these communities will operate without FDA’s involvement, while the Agency will join others. For this latter group, FDA should clarify the criteria that it will apply in deciding whether to join a collaborative community. These criteria should reflect basic principles of fairness and inclusiveness. Thus, for FDA to join a collaborative community, it should:

- be subject to a publicly-available charter;
- be open to all interested stakeholders;
- seek input on and publicize agendas before meetings;
- provide advance notice to members of meeting dates, times, and locations, and support remote participation;
- use clearly-defined leadership and decision-making structures; and
- maintain publicly-available meeting records that include participants, topics, and decisions.

In addition, FDA should maintain a publicly-accessible list of the collaborative communities in which it participates. We also recommend that FDA maintain an open docket to permit stakeholders to comment on the collaborative communities in which the Agency participates. By following these steps, FDA will signal that collaborative communities should be open to all interested participants and that they should operate with transparency, predictability, and accountability.
FDA should clarify that it will follow Good Guidance Practice for recommendations adopted from collaborative communities.

FDA acknowledges that it “may support, leverage, and/or adopt solutions that emerge from the collaborative communities, consistent with the statute, regulations, and agency priorities . . .” CC Toolkit, p. 3. FDA should add to this caveat the Good Guidance Practices that may apply to collaborative community output. For example, were FDA to develop guidance based on collaborative community output, or adopt guidance developed by a collaborative community, then the Agency should publish that guidance in draft with an opportunity for public comment. See, 21 CFR 10.115.

FDA should alert collaborative communities to possible legal prohibitions.

FDA acknowledges that “[c]ollaborative communities are working environments where sensitive information may be discussed.” CC Toolkit, p. 7. Some discussions of “sensitive information,” however, may be inappropriate. For example, discussions among collaborative community members about product pricing, supply, or distribution might violate antitrust provisions. Or, committee service or output to FDA characterized as “advice” might implicate the Federal Advisory Committee Act. This is especially so where FDA has “established” the collaborative community, which then advises FDA. To avoid such risks, FDA should identify possible legal constraints on collaborative community work. Further, FDA should advise community members that, in cases where their work might trigger these constraints, they should seek legal counsel.

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AdvaMed thanks FDA for its consideration of these comments. Please do not hesitate to contact me at 202-434-7243 or ssilverman@advamed.org if you have any questions.

Respectfully Submitted,

Steve Silverman
Vice President
Technology & Regulatory Affairs
AdvaMed

1 Notably, the assurances of transparency and other protections provided by law and regulations for advisory committees apply whether such groups are established by FDA or simply utilized by it, whenever the Agency intends to obtain advice or recommendations. See, 21 CFR 10.3 and 21 CFR Part 14.