Clinical Decision Support Coalition

1227 25th St. NW #700
Washington, DC 20037
http://cdscoalition.org/
202.861.1817

VIA EMAIL

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Bakul Patel
Associate Director for Digital Health
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-5458
Silver Spring, MD 20993

Re: Comments to IMDRF Draft Guidance Document – "Software as a Medical Device (SaMD): Clinical Evaluation"

Dear Mr. Patel:

On December 9, 2016, the Clinical Decision Support Coalition ("CDS Coalition") filed the above-referenced comments in the Food and Drug Administration ("FDA") docket. After you reviewed our comments, you expressed concern that we had misunderstood what the International Medical Device Regulators Forum ("IMDRF") was intending to propose. Accordingly, we set up a conference call later in December where you addressed the coalition members directly to explain the process that IMDRF, together with FDA, was using to obtain comments on this document. In January 2017, you and I then had a call to discuss the specific substance of our comments.

I want to share with you the feedback from the coalition in response to our conversations. The coalition was quite honestly very relieved to hear your explanations with regard to both the process and the substance of the guidance. As you and I discussed, language is a tricky thing. Certain words used by IMDRF had different meanings to the members of the coalition than what IMDRF intended. Further, these issues are extremely complicated, and we at the coalition quite simply did not recognize some of the intended design implications of the IMDRF framework.

Indeed, this is one of the limitations of the notice and comment process. It's all done through writing without oral dialogue. As you have suggested, when dealing with complex and new initiatives such as this, it is very helpful to have a discussion. As such, we would certainly like to have more discussions with you on these issues as they proceed.

As FDA pursues significant regulatory changes in the area of software in the future, we would encourage the agency to weave in opportunities for dialogue early in the process, before publishing written drafts for comment. This is particularly helpful where there is little industry involvement in the organization itself, as with IMDRF. In such cases, for example, FDA could host a workshop open to all

members of the public to engage in dialogue around these new ideas. Indeed, as I understand it, there is an opportunity likely in the future as the IMDRF develops its fifth guidance document in this area. We recognize that such an exercise can be expensive, so an alternative would be to ask an appropriate neutral third party to host an open public event to allow for discussion. There are probably several professional societies such as RAPS, universities and think tanks that would likely be willing to play such a role. In a nutshell, we believe dialogue is a critical precursor to publishing new, important and complex regulatory proposals.

There is tremendous value in global harmonization; it is inherently advantageous for all involved, removing needless inconsistencies that increase the cost of regulatory compliance. As such, we consider the work of IMDRF, and FDA's participation in it, to be exceedingly important. We are very grateful to FDA for its involvement.

We recognize that not only is the topic complex, but the process of developing these proposals is also complex given the number of parties involved and the legal processes at play. Based on your explanation in December, the coalition now understands that FDA's objective in publishing the 2016 Federal Register notice was to encourage comments to the IMDRF docket. We further understand that when IMDRF finishes its work on this clinical evaluation document, the document will not be guidance in the US. Rather, FDA will review and extract only those elements with which it agrees from the final IMDRF document and take the necessary steps to implement such extracted elements. Importantly, then, there will be plenty of opportunity for the US stakeholders to comment on the elements of the IMDRF proposal FDA wishes to incorporate and implement in the US. With that understanding, we are greatly reassured.

As a bottom line, we enthusiastically support FDA's involvement in IMDRF. IMDRF's work is tremendously important both globally and in the US. As we said above, global harmonization is to everyone's benefit. It is apparent from our discussions that FDA has been working hard to both protect patients and reduce unnecessary regulatory burdens on the CDS industry, both domestically and abroad. As a part of global harmonization, it is extremely important that all stakeholders commit to working collaboratively to find the least burdensome and most effective approach that inures to the benefit of the patient who will get better healthcare quicker. We are grateful that FDA sought to encourage the participation of the US stakeholders in the IMDRF policymaking process.

Thank you for all of your hard work in IMDRF. If there's anything we can do to support you in that effort, including participating in any future discussions regarding possible approaches to developing an appropriate risk-based regulatory framework for Software as a Medical Device, we stand ready to help.

Very truly yours,

Bradley Merrill Thompson