Clinical Decision Support Coalition

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VIA EMAIL AND DOCKET SUBMISSION

September 29, 2017

Bakul Patel
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 66, Rm. 5458
Silver Spring, MD 20993

Re: Digital Health Innovation Action Plan Docket No. FDA-2017-N-4301

Dear Mr. Patel,

The Clinical Decision Support Coalition ("CDS Coalition" or the "Coalition") was delighted when the Center for Devices and Radiological Health ("CDRH") released its Digital Health Innovation Action Plan ("Action Plan") this past summer. The Coalition applauds CDRH's efforts to improve the regulatory environment for digital health products and believes that the Action Plan is a tremendous step forward toward that goal.

We are excited about many of the elements of the Action Plan, including the Agency's intention to issue draft guidance clarifying the regulation of clinical decision support ("CDS") software during the first quarter of 2018, and the opportunity for digital health developers to work collaboratively with FDA through the Software Precertification Pilot Program. The Coalition also commends FDA's intention to issue draft guidance interpreting the medical software provisions included in the 21st Century Cures Act and finalize guidance related to 510(k) requirements for software changes to an existing medical device. While these planned activities are incredibly encouraging, one area within the digital health space that we believe deserves greater FDA attention and focus is machine learning.

By way of background, the CDS Coalition is a diverse group of stakeholders consisting of software providers, IT infrastructure manufacturers, healthcare providers, medical device and pharmaceutical manufacturers, trade groups and members of the clinical community. Focused on CDS software, the Coalition's goal is to ensure a risk-based and clearly defined regulatory system for such software that appropriately balances the need for regulatory oversight with the need for innovation and access to new technology.

The Coalition expects that going forward, machine learning, in all of its various iterations, will be one of the most important technologies in the CDS software arena. Dozens of companies are already exploring the use of machine learning as the backbone of future CDS software across a variety of domains, including cardiology and oncology. However, there is significant regulatory uncertainty in this area, particularly with respect to how FDA will review new CDS software that employs machine learning.

We know that FDA has fairly substantial experience with machine learning in the context of computer-assisted detection devices ("CAD"). Further, we are aware of a handful of FDA 510(k) clearances in recent years involving software that employs machine learning in domains beyond CAD. While it is likely

too early for FDA to try to write a guidance document on the use of machine learning in the context of CDS software, we think the time is ripe to begin a dialogue on this topic to allow for mutual learning. We would not expect such dialogue to lead to concrete premarket review guidelines, but rather deepen the understanding of the review issues from the perspectives of the Agency and industry.

Although the Coalition believes that this dialogue on machine learning and CDS software should be ongoing, making use of the various trade association and professional society venues available for such discussion, we also have a specific idea that we think would provide for a very effective exchange between FDA and industry. We propose that at one of these professional society meetings, FDA participates in a mock presubmission meeting.

As far as logistics, the CDS Coalition would prepare a presubmission request for a fictitious product that involves machine learning for CDS software, following the Agency's guidance on "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" (February 18, 2014). For the mock presubmission meeting, we would have on stage all of the people who would normally be present at a presubmission meeting (perhaps a half-dozen of the relevant FDA staff and a like number for the CDS Coalition). The dialogue would proceed like an actual presubmission meeting, only it would be on stage for the audience to observe.

This exercise would allow the audience to get a very concrete understanding of the issues that FDA considers when reviewing a submission that includes machine learning intended for CDS software. It would also be a very useful way for FDA to learn about ideas that industry has for utilizing machine learning in CDS software, and some possible intended uses. Further, from an FDA standpoint, FDA would simply be answering questions for a very concrete proposal just like it does in every single presubmission meeting.

This approach is not unprecedented. For example, the Prototype Regulatory Submission Working Group (with approximately 20 participants from industry, clinicians, standards development organizations, and the FDA) developed a detailed risk model for a conceptual integrated medical device system.[1] Here the task is much less ambitious, and would simply focus on getting FDA reactions to a specific case study. Likewise, it is common for FDA speakers to be asked concrete, technology specific questions in open public forums. The approach outlined above would simply give FDA advanced warning to think about the questions.

Would you please let us know whether FDA would be willing to participate in such a mock presubmission meeting? We think it would be a terrific way to advance both the Agency's and industry's understanding of the issues associated with machine learning in CDS software.

Very truly yours,

Bradley Merrill Thompson
General Counsel, CDS Coalition

[1] http://www.mdpnp.org/MD_PnP_Program___MDISWG.html