FDA SERVICING VERSUS REMANUFACTURING WORKSHOP REPORT

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This report was primarily drafted by Samantha Jacque and Binseng Wang but includes input from FDA Task Force members, as well as ACCE members who attended the Workshop in person.

The FDA hosted a 2-day public workshop (Dec 10 and 11) as a follow up to the May 2018 report entitled "FDA Report on Quality, Safety and Effectiveness on Servicing of Medical Devices." The Workshop was opened by Dr. William H. Maisel, Director of the Office of Device Evaluation and acting-Director of the Office of Compliance, CDRH-FDA. He stated that the goal of this Workshop was to gather feedback and comments concerning the distinction between servicing and remanufacturing using the White Paper issued previously, thus allowing FDA to draft a new Guidance Document.

In addition to some members of the FDA Task Force (David Francoeur, Barbara Maguire, and Binseng Wang (ACCE representative for Day 1)), several other ACCE members were present: Samantha Jacques (Board member and ACCE representative for Day 2), Matt Dummert - Froedtert Health, Scot Mackeil – Mass Gen Hospital, and Courtney Nanney – Catholic Health Initiative, as well as Suly Chi – ACCE Secretariat.

The first day was divided into four parts. The first one was used by FDA officials to provide background, goals, objectives, and methodologies for the Workshop. The second part was a breakout session focused on clarifying the distinction between servicing and remanufacturing, aimed at pressure test the methodology proposed in the White Paper. The third part was another breakout session, this time focused on access to appropriate servicing information, labeling and other considerations. The fourth and last part was a panel discussion on the Guiding Principles proposed in the White Paper.

For Day 1, FDA intentionally distributed the stakeholders according to their affiliation category (OEM, ISO, healthcare organization, trade association, etc.), so each table had multiple stakeholder categories. This allowed ACCE members to be widely scattered in the room and interact with other stakeholders.

During the pressure testing of the FDA proposed methodology using the examples provided in the White Paper, it became apparent that while theoretically useful, the guiding principles, flowchart and software "complementary approach" are very challenging and time consuming to apply. Furthermore, the information provided in the examples are often incomplete and proper distinction between servicing and remanufacturing would depend on several additional assumptions. While most participants seemed to be genuinely interested and cooperative, a few OEMs were clearly less than enthusiastic.

During the public comment period after the pressure test, Binseng Wang—representing ACCE—offered ACCE's recommendation for additional examples of software-related activities that should be explicitly allowed for servicers, as listed below:

- Accessing (using the "software keys") diagnostic and repair information that manufacturers currently provide to its own and distributors' service staff;
- Collecting data generated by the device operating and self-diagnostic software for analyses that can potentially improve its safety and maintenance ("on-condition" or predictive maintenance);
- Running network-based diagnostic and cybersecurity scanning software;
- Performing back-up of data and software to organization's storage systems.

The second breakout session on access to appropriate servicing information, labeling and other considerations was sometimes somewhat contentious. While servicers, including ACCE members, emphasized the need for service manuals and software keys, some manufacturers claimed they cannot share service information and grant access to diagnostic software due to their need to protect trade secrets and intellectual property.

The last part of Day 1 was dedicated to the Guiding Principles proposed in the White Paper. Nine panelists were invited by FDA, representing OEMs, servicers, and trade associations. ACCE was represented by Binseng Wang, who expressed concern about the excessive burden placed on the front-line service staff—regardless of the category of employer (OEM, healthcare organization or third party)—if they are required to apply the Guiding Principles, flowchart and, if needed, software "complementary approach" after each and every service activity. He also reminded that risk assessment—even when properly conducted with real data—does not guarantee perfect outcomes, as proven by the huge number of infusion pump recalls in the last decade. Other topics discussed during the panel included documentation, cybersecurity, training, service information feedback to OEM, and AI and big data analyses.

The second day started with opening remarks of Dr. Jeffrey Shuren, Director of CDRH/FDA. While most of his remarks were friendly and even jovial, he said that FDA hopes the collaborative communities will yield results acceptable to FDA, otherwise FDA will have no option but to impose requirements.

Next, a diverse panel of representatives from OEM, ISOs, trade and professional organizations were asked to report on past collaboration activities, recommend topics of shared interest that are most likely to yield cooperation, and seek volunteers for hosting and coordinating future events with timeframes for deliverables. FDA also made it clear that it will not serve as the convener and reserves the right to adopt and implement only the recommendations of collaborative communities that it deems acceptable.

All panelists, including ACCE's representative, indicated willingness to participate in the collaborative communities but some—notably OEMs and their trade associations—again cited trade secrets and intellectual property concerns. The topics that gather most support among the panelists were: (1) training, (2) quality management systems, (3) information/evidence generation and sharing, and (4) cybersecurity. AAMI offered to host the next meeting in first quarter of 2019. MITA objected to AAMI becoming the convener, so FDA recommended creation of a multi-stakeholder steering committee instead. This committee would then define and create sub-committees (or task forces) to address the priority topics identified. FDA also asked for and received numerous suggestions on entities that should be on the steering committee and collaborative communities.

In summary, this Workshop was useful for the stakeholders to understand FDA's current thinking and gain insight into the likely content of the Guidance Document to be issued next year. Hopefully, FDA gathered enough feedback to simplify the criteria for distinguishing servicing from remanufacturing, as well as encouraging more sharing of information ("labeling") by OEMs.

The FDA Task Force and other ACCE members present at the Workshop would like to recommend the following follow-up actions to the Board:

(1) Send FDA an official correspondence reiterating ACCE's willingness to participate in collaborative communities and, in particular, serve on the steering committee;
(2) Submit written comments to the Servicing versus Remanufacturing docket by the end of January.
(3) Share this report and the written comments with all ACCE members by posting them on ACCE's website.