ACADEMY of GENERAL DENTISTRY
560 W. Lake St.
Sixth Floor
Chicago, IL USA
60661-6600
312.440.4300
Fax: 312.440.0559
Toll-free: 888.243.3368
agd.org

February 7, 2022

Janet Woodcock, MD
Acting FDA Commissioner
Food and Drug Administration (FDA)
10903 New Hampshire Ave.
Silver Spring, MD 20993

Docket Number: FDA-2021-N-1272

Dear Dr. Woodcock:

On behalf of its 40,000 members, the Academy of General Dentistry (AGD) appreciates the opportunity to provide comments on the *Discussion Paper: 3D Printing Medical Devices at the Point-of-Care.*[1] AGD members use 3D printing at point-of-care to varying degrees. Some general dentists use 3D printing for select applications, while others do not use the technology at all. The AGD appreciates the opportunity to provide input to the FDA on burgeoning issues relating to 3D printing at the point-of-care.

The AGD understands that the FDA may seek to draft guidance on this topic and/or may elect to draft proposed regulations in the future. Our overarching comment to this possibility is to advise that the regulatory burden should rest with the manufacturers of 3D printing devices including their software. Manufacturers adhere to consensus standards developed through organizations such as the American National Standards Institute (ANSI), ASTM International (ASTM) and the International Organization for Standardization (ISO).

According to the FDA guidance document on the *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,* "the use of consensus standards can increase predictability, streamline premarket review, provide clearer regulatory expectations, and facilitate market entry for safe and effective medical products. Consensus standards provide a consensus approach to certain aspects of the evaluation of device safety and effectiveness, such as testing methods, acceptance criteria, and processes to address areas such as risk management and usability."[2]

The AGD maintains that it is inappropriate to extend any federal regulatory measures to the users of 3D printing devices. The practice of dentistry and medicine is regulated at the state level with licenses being granted and overseen by state dental and medical boards as safeguards for the public. Furthermore, the FDA has long established the Medical and User Facility Device Experience (MAUDE) database to capture adverse event reporting from medical device failures or malfunctions. General dentists report that dental applications for 3D printing, such as creating a model or a bite splint,

[1] U.S. Food and Drug Administration. Discussion Paper: 3D Printing Medical Devices at the Point of Care. December 10, 2021. https://www.fda.gov/medical-devices/3d-printing-medical-devices/3d-printing-medical-devices-point-care-discussion-paper
[2] Appropriate Use of Voluntary Consensus Standards (fda.gov)

present very low risk to the patient. Detailed below are the AGD's responses to some of the enumerated questions posed in the FDA discussion paper.

AGD Answers to FDA Questions

9. How should each of the following be weighed or considered to assess whether the device being 3D printed is very low risk? Are there other considerations that should also be included?

a. Intended use, such as for personal assistive, quality of life devices, or life supporting/sustaining, whether the product would be adjunct to standard clinical methods or procedures, or redundancies will be available (such as an ergonomic scalpel handle when other handles are available);

Answer: AGD agrees that intended use is an appropriate benchmark for assessing that a device is very low risk.

b. Device class;

Answer: AGD assumes that the device class would primarily be Class II allowing for 510k submissions of the 3D printing systems and resins. As noted previously, adherence to consensus standards allows for greater uniformity and easier assurances of safety and effectiveness profiles.

c. Nature and duration of body contact (e.g., intact skin for < 24 hours, mucosal membrane, permanent implant);

Answer: General dentists purchase a variety of resins depending on the dental application to be printed (examples: clear orthodontic aligners, dentures, etc.). The resins are usually Class II devices and list the instructions for use.

d. Available information about safe use, including history of material used and other available information;

Answer: Resins bought from dental supply manufacturers list safety information and instructions for use. General dentists buy resins cleared for a specific use**.** Curing is sometimes accomplished post processing.

e. Whether the device is intended to be sterilized;

Answer: Resins for dental applications state if they are to be sterilized and if they are appropriate for surgical procedures in their instructions for use.

f. Whether the product is patient-matched or a discrete stock size (e.g., 14 French- surgical drain);

Answer: Dental applications could be either patient-matched, a discrete stock size, or a combination of both.

and

g. Nature of reasonably foreseeable adverse events.

Answer: Manufacturers include information in their instructions for use on particular resins. As always, if adverse events occur, users and patients are encouraged to report an event to MedWatch.[3]

10. Understanding that different HCFs may have different 3D printing capabilities and expertise, how do a facility's capabilities and expertise factor into its ability to print a "very low risk device"?

Answer: As these applications are software dependent, manufacturers are regulated on all parts of the device processes. Most dental applications produce a very low risk device (example: bite splint) when adhering to a manufacturer's instructions for use.

[3] MedWatch: The FDA Safety Information and Adverse Event Reporting Program | FDA

11. What best practices or oversight programs (e.g., accreditation, certifications, clinical guidelines) or internal PoC procedures that exist currently (or may in the future) could positively contribute to device safety, effectiveness, and quality when 3D printing "very low risk" devices at the PoC?
Answer: The AGD believes that the onus for oversight should rest with the manufacturer of the 3D printing devices.

12. If FDA determines it is appropriate to provide a degree of regulatory flexibility regarding certain requirements for devices determined to be very low risk, should this approach apply to very low risk devices 3D printed at the PoC by a co-located Traditional Manufacturer, or only to those devices printed by the HCF?
Answer: The AGD believes that only traditional manufacturers should be subject to regulatory oversight; users at health care facilities are printing 3D devices within the specifications of the manufacturer and therefore should be exempt (or excluded from) any regulatory requirement.

13. How can the terminology and the parties involved in 3D printing at the PoC be improved or clarified?
Answer: Manufacturers should ensure that the appropriate resins are designed for distinct applications such as intraoral use for dental applications.

14. FDA believes we should have visibility to the entities involved in 3D printing at the PoC. Do you have recommendations for how the Agency can achieve this in a least burdensome way, for example, through existing mechanisms, such as registration and listing? Are these recommendations different if it is a Traditional Manufacturer that is printing at the PoC, or if it is an HCF using an MDPS, or an HCF assuming the responsibilities of a Traditional Manufacturer?
Answer: Registration and listing is a requirement that manufacturers must adhere to and pay an annual fee according to the user fee laws passed by Congress every five years. FY 2022 fees for small businesses are $5672.[4] The AGD is unsure if the FDA is suggesting that dental offices should be required to register and list their devices if using 3D at the point-of-care or if the FDA is suggesting that manufacturers list their customers of 3D printing devices on the manufacturers annual registration and listing forms.

The AGD does not believe that the relationship of manufacturers and users of 3D printed devices is any different than that of manufacturers of orthopaedic devices and orthopaedic surgeons. Slight modifications may be made to accommodate patient anatomy. The practice of dentistry is regulated at the state level with licenses being granted and overseen by state dental boards as safeguards for the public.

15. FDA is open to suggestions for other approaches/models for PoC manufacturing of medical devices that would facilitate future innovation while still providing reasonable assurance of device safety and effectiveness. Please provide other options you believe FDA should consider.
Answer: The AGD believes that the onus for oversight should rest with the manufacturer of the 3D printing devices. Resins should be used for their intended use; protocols are followed for post printing including washing and curing.

[4] U.S. FDA CDHR Registration and Listing FY2022: Device Registration and Listing | FDA

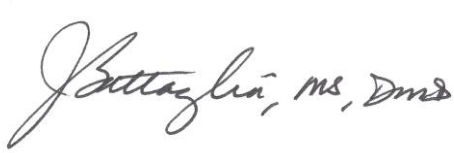
16. COVID-19 PHE-specific questions
a. During the response to the COVID-19 pandemic, what information did you need to 3D print a product that you had not printed before?
Answer: During the COVID-19 pandemic, dental users only needed the electronic file that a software designer developed to print.
b. Are there situations where 3D printing was used during the COVID-19 pandemic that are not discussed here? If so, what are those situations, and how did you address them?
Answer: During the COVID-19 pandemic, some dentists printed face masks when the U.S. was experiencing a national shortage.
c. Do you have suggestions for FDA based on what you learned from your experience during the COVID-19 pandemic?
Answer: During the COVID-19 pandemic, the private sector was innovative in bringing needed products to market such as face shields, hand sanitizer, and surgical masks. Users of 3D printing devices state that the software design is perhaps the most important component of the device.

Conclusion

The AGD thanks the FDA for soliciting input into 3D printing at the point-of-care. We stand ready to partner with you on this issue and invite you to contact Daniel J. Buksa, JD, Associate Executive Director, Public Affairs, by phone at (312) 440-4328 or via email at daniel.buksa@agd.org if you have questions or would like to discuss our comments in greater detail.

Sincerely,

Gerald J. Botko, MS, DMD
MAGD AGD President



Joseph Battaglia, MS, DMD
AGD Chair, Dental Practice Council

Myron (Mike) Bromberg, DDS
AGD Chair, Legislative & Governmental Affairs Council
AGD Congressional Liaison