February 5, 2018

By Electronic Delivery

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 17 Fishers Lane, Rm. 1061
Rockville, MD 20852.

RE: **Docket No.: FDA-2017-D-6569**
       Draft Guidance, *Clinical and Patient Decision Support Software*
       Comments of the Consumer Technology Association

To Whom It May Concern:

The Consumer Technology Association ("CTA") respectfully submits these comments regarding the Food and Drug Administration's ("FDA" or "the Agency") December 8, 2017, draft guidance document, *Clinical and Patient Decision Support Software.*

CTA is the principle trade organization for the consumer technology industry, comprised of more than 2,000 member companies covering a broad range of technology segments. CTA also owns and produces CES® –the world's gathering place for all who thrive on the business of consumer technologies. Profits from CES are reinvested into CTA's industry services. In particular, of relevance to these comments, CTA represents many companies operating in the digital health and medical technology space in the United States. CTA's Health and Fitness Technology Division strives to grow the health, fitness and wellness technology category. We do this in part by working to ensure that health and fitness technology devices, services, and apps operate in a clearly defined regulatory environment that balances innovation with safety and privacy.

CTA thanks FDA for issuing this long-awaited guidance providing further clarity regarding how the Agency intends to regulate software that supports clinical decision-making. As FDA is aware, this is a growing and evolving area of medical technology, with increasing demand for

tools that reliably aid health care practitioners in making diagnoses and treatment recommendations. The draft guidance is a helpful step toward clarification of what has been a challenging issue for industry for many years. In addition, CTA applauds FDA for including clarification on a newly defined category of patient decision support tools. CTA appreciates the Agency's willingness to take a least burdensome approach to regulation and focusing regulatory oversight only on products most warranting FDA's attention.

In keeping with CTA's appreciation for the Agency's efforts, we would like to bring to FDA's attention several questions and issues that our members believe may warrant further consideration in order to make the final guidance optimally useful.

I.   Clarification of the Analysis of Medical Data Criterion Would Be Helpful

The guidance defines "CDS" solely in the context of Section 3060(a) of the 21st Century Cures Act ("Cures Act"), which amended Section 520 of the Federal Food, Drug and Cosmetic Act ("FDC Act") to exclude certain software functions from the statutory definition of a device. That section described unregulated clinical decision support tools as being those that are:

> (1) not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
>
> (2) intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information (such as peer-reviewed clinical studies and clinical practice guidelines);
>
> (3) intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition; and
>
> (4) intended for the purpose of enabling such health care professional to independently review the basis for such recommendations that such software presents so that it is not the intent that such health care professional to rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

With respect to the first criterion above, the draft guidance explains that software which is intended to acquire, process or analyze one of the types of noted data remain devices and, therefore, continue to be subject to FDA oversight. As an example of this type of functionality that remains regulated, FDA notes algorithms that process physiologic data to generate new data points, such as ST-segment measurements from ECG signals. The guidance goes on,

however, to provide as an example of an unregulated product "software that provides health care professionals with a report based on arterial blood gas results that includes a calculated anion gap and recommends whether the patient has high anion gap metabolic acidosis and possible next steps, based on practice guidelines."

The inclusion of the two examples referenced above raises potential confusion because in both cases the software is providing recommendations based on physiological signal data. Based on comments from the Agency made during public webinars regarding the guidance, we understand that FDA views as a critical differentiator whether the CDS uses existing clinical metrics or physiological data to produce recommendations that are based on published information (not a device), or whether it analyzes existing patient data to produce new, stand-alone clinical metrics (regulated device). However, this distinction could be further clarified in the guidance, including how this distinction will be drawn in practice

II. FDA Should Further Clarify the Meaning of "Independent Reviewability"

FDA explains in the draft guidance that software meeting the first three criteria outlined in the section above will be considered clinical decision support tools. FDA continues, "Only when a CDS function also meets the fourth criterion of section 520(o)(1)(E), which relates to enabling independent review of the basis for recommendations, is the CDS function excluded from the definition of a device."

CTA appreciates the importance of the fourth criterion in evaluating the impact of particular clinical decision support tools. Clearly, use of an automated program to facilitate straightforward clinical tasks (*e.g.,* advising a dosage schedule that is consistent with FDA-approved labeling) differs from reliance on an automated program to produce a novel treatment recommendation that the clinician would be unable to fully review before applying it in clinical practice. However, to be most useful to industry, further granularity regarding this final criterion would be helpful.

First, FDA's draft guidance currently explains that "In order for the software function to be excluded from the definition of device, the intended user should be able to reach the same recommendation on his or her own without relying primarily on the software function. The sources supporting the recommendation or underlying the rationale for the recommendation should be identified and easily accessible to the intended user, understandable by the intended user (e.g., data points whose meaning is well understood by the intended user), and publicly available (e.g., clinical practice guidelines, published literature)." CTA agrees with the importance of the first few suggestions in this statement, namely that the sources supporting

the rationale should be identified and understandable to the intended use. However, it is possible that requiring the sources to be publicly available may be overly restrictive.

Certain recommendations may extrapolate from public information to generate a clinical recommendation. There are instances in which an informed clinician's independent evaluation of the underlying public information would likely result in the same extrapolation as the software's. Such software functions would appear to satisfy the standard set forth in the draft guidance for exclusion from the definition of a device, namely that the intended user is able to reach the same recommendation on his or her own. However, it is unclear whether FDA would consider these to satisfy the Cures Act requirement of independent reviewability, given that the public information would not then explicitly dictate the recommendation. In addition, it may be possible for the recommendations to be based on well-accepted medical practices rather than specific published guidelines or literature. Additional insight on what types of analysis or processing by software is permissible for a tool that aims to remain unregulated – or whether FDA might accept varying degrees of transparency in this context – would be extremely useful.

In addition, there are numerous types of "publicly available" information that reflect varying degrees of complexity and accessibility. For instance, established clinical practice guidelines are perhaps the clearest and most easily understandable basis for CDS recommendations; FDA also recognizes published literature as appropriate. However, there are additional information reservoirs that would appear to meet the requirement of being accessible to the public, such as white papers distributed by accredited medical organizations and analyses from academic institutions. Yet it is unclear whether these resources, or even all publicly available published literature, would be considered sufficiently public such that a software program relying on them to support clinicians would still be excluded from the device definition. If all public information is viewed equally by the Agency and the determination as to whether the information is sufficient to warrant use is left to the user, it would be helpful to clarify this in the final guidance. On the other hand, if FDA intends to use specific factors in assessing the underlying information for a CDS tool (*e.g.,* reliability, scope of applicability, etc.), it would be helpful to publicly disclose those factors so that industry can take this into account when designing decision support software.

III. FDA Should Recognize Nuance in Assessing CDS that Still Meets the Device Definition

FDA indicates that the purpose of the draft guidance is to identify three types of decision support software functionalities:

1. Those that do not meet the amended definition of device;

2. Those that may meet the definition of a device but for which FDA does not intend to enforce compliance with applicable requirements of the FDC Act, including but not limited to premarket clearance and approval; and
3. Those on which FDA intends to focus its regulatory oversight.

As noted above, several examples of the first and third categories are provided. With respect to the second, FDA recognizes a new category, "patient decision support" (PDS), which encompasses software functions that resemble CDS but, because they are intended for use by patients or their caregivers rather than by health care professionals, cannot meet the third Cures Act criterion for exclusion from the device definition. The draft guidance indicates FDA's intent to adopt an enforcement discretion policy for these products that parallels the CDS excluded from the device definition. Thus, PDS tools that meet the first two Cures Act criteria, support or provide clinical recommendations to patients or non-health-care professional caregivers, and enable those persons to independently review the basis for the recommendation are still medical devices but will not be subject to active regulation by the Agency at this time. CTA appreciates this effort by FDA to focus regulation on higher-risk products. However, to avoid the uncertainty about regulatory status that can create a disincentive for innovation, it would be helpful for the final guidance to provide more granularity regarding how to assess whether a PDS application would be actively regulated, particularly in terms of the "independent reviewability" criterion discussed above for CDS tools. This goal would also be furthered by providing additional examples of PDS applications that are and are not actively regulated.

In addition, the draft guidance provides very little information regarding CDS tools that may still meet the definition of a medical device, but are not subject to active FDA oversight. Its only elaboration on this point appears to be the following statement:

> "There are many types of software intended to support health care professionals that are not affected by section 520(o)(1)(E) of the FD&C Act or this guidance. Some of these, such as software that performs calculations routinely used in clinical practice, are devices for which FDA maintains its existing policy of not intending to enforce compliance with applicable regulatory requirements. FDA also provides additional examples of such software in the Mobile Medical Applications (MMA) guidance."

This language appears to suggest that certain software that is not excluded from the amended device definition and is intended to support clinicians may not be held to all of the applicable regulatory requirements. However, it is not clear whether this regulatory status is relevant only for specific examples already outlined in the MMA guidance or whether there are other types of CDS tools that would also be subject to enforcement discretion.

Software that simply applies existing clinical guidelines to patient data without autonomous analysis has long been essentially unregulated in practice by FDA. The new guidance provides formal recognition from the Agency that as long as these guidelines are available for the clinician's review, such software is not subject to regulation as a medical device. While memorializing this approach in writing provides an additional level of certainty around these tools, FDA should also consider providing additional clarity regarding CDS tools for which the regulatory outlook was more ambiguous prior to the Cures Act. It would be very helpful to industry to know if FDA will consider other factors in determining whether and to what extent to regulate CDS, besides the single factor focused on in the draft guidance, *i.e.,* whether the software allows independent review of the basis for its recommendations. Would CDS that is not entirely transparent automatically be regulated, regardless of risk to the patient?

CTA endorses FDA's intent to tailor the regulation of PDS tools based on the risk they present, and strongly recommends that the same approach be taken in determining how to regulate CDS tools that are not categorically excluded from regulation. Until the 21st Century Cures Act was enacted, it is CTA's impression that FDA applied such a risk-based framework in deciding on which CDS tools to focus its regulatory efforts. At that time, all such tools met the statutory definition of a device, but FDA determined – and CTA wholeheartedly agrees – that not all of them merit the same level of oversight. The final guidance should build on this approach, defining a continuum or spectrum for industry to rely on in determining the level of regulation likely to apply to CDS functions that remain medical devices under current law.

CTA acknowledges that FDA maintains the authority to actively regulate all such software in the interest of public health and safety. Nevertheless, consistent with its policy in other areas associated with digital health – *e.g.,* general wellness products, mobile apps, and as proposed in this draft guidance, patient decision support software – FDA should tailor the projected level of regulation to the intended use of, and risks presented by, the software. For instance, the medical ramifications of the software should be taken into consideration in determining the appropriate level of regulation; greater openness to predictive analytics is warranted when the CDS-generated recommendations are in the context of a low-risk disease/condition for which errors would lead, at most, to only minor injury or delay in treatment. A risk-based framework would not only be a more logical scheme that all members of industry could understand, but would also support the continued development of machine learning and complex algorithms that have so much potential for furthering modern medicine. It would be counterproductive to FDA's stated aim to support innovation in the name of technological advancement and medical breakthroughs to subject all machine learning and artificial intelligence (AI) to the same high regulatory standards.

Simultaneously, CTA understands that FDA has been working on a new draft guidance to clarify the Agency's assessment of machine learning and AI technologies. We would welcome the opportunity to comment on that guidance as well and believe that it would be quite valuable to the digital health and technology industry as a whole. FDA's list of "priority" guidance documents for 2018 did not include this topic, but we hope that efforts are still underway to issue it soon.

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CTA appreciates this opportunity to comment on FDA's *Clinical and Patient Decision Support Software* draft guidance. CTA supports FDA's efforts to clarify how devices in these categories will be regulated moving forward, and hopes that these comments are helpful in explaining some of the industry's concerns and recommendations as the Agency prepares the final version of the guidance.

We would be pleased to answer any questions you might have about these comments. Please contact me at 703-907-7544 if CTA can be of any assistance.

Sincerely,

Michael Petricone

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