Charles N. Kahn III
President and CEO

December 19, 2019

The Honorable Stephen Hahn, M.D.
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff; (Sep. 27, 2019); Docket No. FDA–2017–D–6569

Dear Commissioner Hahn:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching full-service community hospitals in urban and rural parts of America, as well as inpatient rehabilitation, psychiatric, long-term acute care, and cancer hospitals. The FAH appreciates the opportunity to comment to the U.S. Food and Drug Administration (FDA) regarding the *Clinical Decision Support Software* Draft Guidance (CDS Draft Guidance).

On December 8, 2017, FDA first released a draft guidance titled "Clinical and Patient Decision Support Software" as part of its implementation of section 3060(a) of the 21st Century Cures Act (Cures Act).[1] Section 3060(a) amended the Federal Food, Drug, and Cosmetic Act (FDCA) to exclude certain CDS software functions from the statutory definition of a medical device. Congress enacted this provision to prevent the over-regulation of certain rapidly-evolving technologies with the potential to transform the way we use information to facilitate and improve patient care, provided those technologies satisfy four (4) criteria enumerated in the statute. On September 27, 2019, FDA issued a revised Draft Guidance (the CDS Draft Guidance) describing its proposed interpretation of those criteria.[2]

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1 FDA, Clinical and Patient Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff; Availability, 82 Fed. Reg. 57987 (Dec. 8, 2017).

2 FDA, Clinical Decision Support Software; Draft Guidance for Industry and Food and Drug Administration Staff; Availability, 84 Fed. Reg. 51167 (Sep. 27, 2019).

We have multiple concerns with the revised CDS Draft Guidance. As an initial matter, the Draft Guidance purports to substantively interpret and expand upon the statutory criteria set forth in the Cures Act by Congress. In a recent Executive Order, however, the President directed that agencies should *not* conduct this substantive interpretative activity through guidance, but should instead engage in notice-and-comment rulemaking as contemplated by the Administrative Procedure Act.[3] Indeed, the Department of Justice has explicitly instructed its civil litigators to ignore guidance documents of the sort proposed here in civil enforcement actions.[4]

The problems with the CDS Draft Guidance, however, run far deeper than procedural impropriety. While certain aspects of the revised CDS Draft Guidance reflect a reasonable and appropriate interpretation of the statutory criteria, other aspects are highly problematic. It is axiomatic that "an administrative agency's power to promulgate [rules] is limited to the authority delegated by Congress" via statute,[5] and "agency interpretations must fall to the extent they conflict with statutory language."[6] Yet, as discussed in detail below, the CDS Draft Guidance repeatedly conflicts with the statute. To name just one of many examples, the Cures Act provides that certain "software function[s]" categorically cannot be regulated as "devices,"[7] including those that (among other things) "support[] or provid[e] ***recommendations*** to a health care professional about prevention, diagnosis, or treatment of a disease or condition."[8] Despite that clear statutory command, the CDS Draft Guidance provides that software that "drives" or "guides" clinical decisions *is* subject to regulation as a device. But, provided that a human (and not the software) makes the *actual* decision, then by any reasonable definition of the term the software is only providing a "recommendation," whether a strong one that "drives" or a weaker one that merely "informs." FDA cannot create "artificial distinctions" to avoid clear statutory language.[9] For this and additional reasons discussed below, FDA's interpretation of section 3060(a) of the Cures Act, as proposed in the CDS Draft Guidance, would be contrary to law.

We also have significant concerns regarding numerous vague definitions and significantly over-broad interpretations advanced in the CDS Draft Guidance. If implemented in its current form, the CDS Draft Guidance will likely stifle critical innovation, and ultimately cause patient harm, by impeding the development of CDS algorithms. We therefore submit these comments to alert FDA to the confusing and potentially harmful implications of the policy

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3 Executive Order 13891—Promoting the Rule of Law Through Improved Agency Guidance Documents (Oct. 9, 2019), https://www.govinfo.gov/content/pkg/DCPD-201900706/pdf/DCPD-201900706.pdf.

4 Memorandum from the Associate Attorney general to the Heads of Civil Litigating Components of United States Attorneys re: Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases (Jan. 25, 2018), https://www.justice.gov/opa/press-release/file/1028756/download ("[T]he Department may not use its enforcement authority to effectively convert agency guidance documents into binding rules.").

5 *See Bowen v. Georgetown University Hosp.*, 488 U.S. 204, 208 (1988).

6 *See Public Employees Retirement System of Ohio v. Betts*, 492 U.S. 158, 171 (1989).

7 21 U.S.C. § 360j(o)(1).

8 *Id.* § 360j(o)(1)(E)(ii) (emphasis added).

9 *See PUD No. 1 of Jefferson County v. Washington Dep't of Ecology*, 511 U.S. 700, 719 (1994) (rejecting as "artificial distinction" the argument that the Clean Water Act is "concerned with water 'quality'" and not water "quantity" as inconsistent with statutory text).

proposed in the CDS Draft Guidance; the extent to which this policy strays from the language of the governing statute; and the revisions to this policy needed to ensure that the benefits of CDS software are not lost to the burdens of over-regulation, consistent with the letter and spirit of the Cures Act.

I. BACKGROUND AND OVERVIEW

Pursuant to section 201(h) of the FDCA, FDA has regulatory authority over software that meets the statutory definition of a medical device—namely, any software that is "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." However, section 3060(a) of the Cures Act added section 520(o)(1)(E) to the FDCA, which supplemented this definition by excluding certain CDS software functions from regulation under FDA's medical device purview. Under the statutory scheme, a software function is <u>not</u> considered to be a device if it meets all of the following criteria:

1. The software function is not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic ("IVD") device or a pattern or signal from a signal acquisition system.

2. The software function is 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. The software function is intended for the purpose of supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition.

4. The software function is 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 rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient.

In recent years, health care providers across the country have begun to implement a variety of CDS algorithms that utilize available clinical data to generate patient-specific recommendations, thereby facilitating the efforts of health care providers to analyze increasingly large quantities of information in support of patient care. Where CDS software is intended to provide but one of several pieces of information that a provider may choose to use in making diagnostic and treatment decisions, subject to the provider's own clinical judgment and expertise, the software appropriately falls within the Cures Act exemption. In contrast, in cases where an algorithm *supplants* rather than supplements the decision-making authority of a health care provider, we fully support the regulation of the algorithm as a medical device, due to the risk of patient harm that may result when an algorithm is directly responsible for dictating treatment or diagnosis. However, FDA's CDS Draft Guidance is not tailored to address this risk. Rather, it proposes to implement the Cures Act in a manner that would regulate a far larger universe of algorithms associated with far less risk, stretching beyond the scope of the Cures Act to create substantial regulatory burdens and uncertainty as well as potential impediments to patient care.

Indeed, if the CDS Draft Guidance becomes final in its current form—particularly with inclusion of the ambiguous International Medical Device Regulators Forum ("IMDRF") classification system—many existing non-device CDS algorithms currently being used to help clinicians and patients could require deactivation while their sponsors seek regulatory approval and work to comply with ongoing post-market requirements. This increased regulatory burden would slow, and may even prevent, the development and use of low-risk algorithms that could otherwise make substantial contributions to patient care. FDA's proposed implementation of section 520(o)(1)(E) of the FDCA may thus impede the highly iterative, rapid-cycle nature of CDS algorithm innovation that the Cures Act intended to protect.

We therefore urge FDA to more closely align its interpretation of the four (4) criteria established under section 520(o)(1)(E) with the language and purpose of the statute, as described in more detail below.

II. STATUTORY CRITERION 1: NOT INTENDED TO ACQUIRE, PROCESS, OR ANALYZE A MEDICAL IMAGE OR A SIGNAL FROM AN IVD DEVICE OR A PATTERN OR SIGNAL FROM A SIGNAL ACQUISITION SYSTEM

Under the first criterion of the CDS software exemption, the software function must not be "intended to acquire, process, or analyze a medical image or a signal from an [IVD] device or a pattern or signal from a signal acquisition system."[10] The CDS Draft Guidance does not define the term "signal," other than to state that FDA considers the term "physiological signal" to include signals that require the use of either an IVD device—defined in the CDS Draft Guidance as "typically includ[ing] an electrochemical or photometric response generated by an assay and instrument that may be further processed by software to generate a clinical test result"—or a signal acquisition system—defined in the CDS Draft Guidance as something that "measures a parameter from within, attached to, or external to the body for a medical purpose."[11]

We are concerned about the lack of clarity in this discussion regarding what constitutes a "signal from an [IVD] device" or a "pattern or signal from a signal acquisition system." The term "physiological signal" does not appear in section 520(o)(1)(E) of the FDCA, and it is unclear if and why FDA interprets the term "physiological signal" to be synonymous with the term "signal" as used in the statute.[12] Moreover, FDA's proposed definition of the term "physiological signal" is overbroad, and it creates significant uncertainty regarding what may constitute the acquisition, processing, or analysis of a signal from an IVD device or a pattern or signal from a signal acquisition system. FDA's definition should be limited to software that directly obtains or transduces electrochemical, photometric, or other physiologic inputs from an IVD device or other instrument to generate a specific, pre-defined output. It should *not* include software that is used downstream to combine, aggregate, or compare those outputs as data points

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10 21 U.S.C. § 360j(o)(1)(E).

11 CDS Draft Guidance, *supra* note 1, at 10.

12 We note that the word "signal" has different meanings in other contexts—in fact, all other occurrences of the word "signal" in the FDCA are in reference to a *safety* signal (*see* 21 U.S.C. §§ 355(k), 355(o) and 355-1(b)), while various sections of FDA's regulations use the word signal to mean an *electrical* signal (*see, e.g.*, 21 C.F.R. § 870.2050 ("A biopotential amplifier and signal conditioner is a device used to amplify or condition an electrical signal of biologic origin")).

in a larger algorithmic analysis to generate recommendations for health care providers. Otherwise, the breadth of FDA's definitions of the terms "physiological signal" and "signal acquisition system" make it difficult to imagine what would *not* qualify as analysis of a signal from an IVD device or signal acquisition system under FDA's interpretation—a result that would write section 3060(a) of the Cures Act right out of existence.

FDA's proposed interpretation advanced in the CDS Draft Guidance could impede the development of CDS software and subject such software to regulation as medical devices even where only basic patient data sourced from medical records or real-time data collection sources are included as inputs and all other statutory criteria are satisfied. FDA's position that such inputs constitute "signals" from an IVD device or signal acquisition system is inconsistent with Congress's intent to exclude low-risk, downstream CDS software from FDA regulation. Accordingly, we urge FDA to revise its interpretation of the first criterion of the CDS software exemption to clarify that the analysis of clinical data obtained from a patient's health record or a dynamic patient data collection source does not constitute the analysis of a signal from an IVD device or a pattern or signal from a signal acquisition system, and thus does not render an algorithm ineligible for the exemption under section 520(o)(1)(E).

To resolve the potential confusion created by FDA's interpretation, it should make clear that only software functions that process or analyze physiological inputs that have not already been transduced into data should be excluded from the CDS software exemption outlined in the Cures Act. We fully recognize the need for regulatory oversight to ensure that data points obtained from IVD devices or signal acquisition systems are created correctly, and software functions that process or analyze physiological inputs without relying on an FDA-regulated device to convert those physiological inputs into data are appropriately regulated by the agency. However, once the data are created by an FDA-regulated device, any software that further collects, collates, and analyzes the data downstream to provide insights and recommendations to health care providers is properly eligible for the exemption. Moreover, an algorithm that utilizes patient data for CDS functions performs the same task regardless of whether the data is static (e.g., sourced from patient health records) or dynamic (e.g., collected in real time for downstream algorithmic processing)—it is the original data transduction itself that must be correct in either case for the utility of the CDS function to be assured, which is where medical device regulation is needed and intended by the Cures Act. This interpretation also remains consistent with the statutory text, which states that a software function will not be carved out from the definition of a medical device if it analyzes "a signal ***from an [IVD] device*** or a pattern or signal ***from a signal acquisition system***."[13] An algorithm that instead utilizes data from a health record or from other real-time sources that do not generate the original data does not engage in such analysis.

[13] 21 U.S.C. § 360j(o)(1)(E), emphasis added.

III. STATUTORY CRITERION 2: DISPLAYING, ANALYZING, OR PRINTING MEDICAL INFORMATION ABOUT A PATIENT OR OTHER MEDICAL INFORMATION (SUCH AS PEER-REVIEWED CLINICAL STUDIES AND CLINICAL PRACTICE GUIDELINES)

Under the second criterion of the CDS software exemption, the software function must be 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)."[14] In the CDS Draft Guidance, FDA states that it interprets this criterion to include software functions that display, analyze, or print patient-specific information, such as demographic information, symptoms, test results, medical device outputs (e.g., heart rate, blood pressure), patient discharge summaries, and/or medical information (e.g., clinical practice guidelines, approved drug labeling), all of which is the type of information generally used to make decisions about prevention, diagnosis, or treatment of a disease or condition for an individual patient.

We support FDA's interpretation of this criterion. In particular, we believe that FDA's recognition of the broad types of patient-specific information that may be utilized in CDS software subject to the Cures Act exemption reflects a reasonable policy position and is consistent with the objectives of the statute.

IV. STATUTORY CRITERION 3: SUPPORTING OR PROVIDING RECOMMENDATIONS TO A HEALTH CARE PROFESSIONAL ABOUT PREVENTION, DIAGNOSIS, OR TREATMENT OF A DISEASE OR CONDITION

Under the third criterion of the CDS software exemption, the software function must be intended for the purpose of "supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition."[15] As explained in the CDS Draft Guidance:

> Such functions are intended to assist HCPs in making patient-specific care decisions. These functions are evidence-based tools that support HCP decision-making when considering treatment options or diagnostic tests for a patient. They do not treat a patient, determine a patient's treatment, or provide a definitive diagnosis of a patient's disease or condition. Instead, these functions collate or develop recommendations based on an analysis of patient-specific information to an HCP, who may then use this information to make a decision about the care of the patient (e.g.,

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[14] *Id.* § 360j(o)(1)(E)(i).

[15] *Id.* § 360j(o)(1)(E)(ii).

> treatment), along with other information and factors of which the HCP is aware.[16]

We agree with this description. As noted above, algorithms that take the agency and ultimate decision-making authority away from the health care provider should be regulated as medical devices. In contrast, lower risk algorithms that merely "assist HCPs in making patient-specific care decisions" and "support HCP decision-making" are appropriately subject to the exemption from medical device regulation that Congress enacted.

However, the CDS Draft Guidance deviates from the express language of the statute and introduces unnecessary uncertainty with its proposed use of the IMDRF framework to implement this criterion. Specifically, the CDS Draft Guidance attempts to draw a distinction between CDS software that, in IMDRF terminology, *informs* clinical management, versus CDS software that *drives* clinical management. In particular, according to the CDS Draft Guidance:

- Software that *informs* clinical management provides information that "will not trigger an immediate or near-term action" and "is not necessary to decision-making for a patient's care."[17]

- Software that *drives* clinical management provides information that "will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition" and that "will be used to guide next diagnostics or next treatment interventions."[18] This includes software intended to "aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis."[19] According to FDA, such software functions are always considered to be medical devices because they fail to satisfy the third criterion of the Cures Act statutory exemption—they "provide enhanced support beyond simply supporting or providing a recommendation about prevention, diagnosis, or treatment" to a health care provider.[20]

This classification is vague, arbitrary, impossible to implement on a fair and consistent basis, has no clear distinction in clinical practice, and is unsupported by the text of the statute. Almost all algorithmic CDS output is intended to "trigger immediate or near-term action." Even where providers rely on their professional judgement and utilize information in addition to the algorithm to decide whether to take action, FDA's interpretation would appear to consider the algorithm to be a medical device solely by reason of the temporal relationship to the provider's follow-up activity.

In addition, there is no clear distinction in clinical practice between software that is "simply supporting or providing a recommendation" versus software that is "used to guide next diagnostics or next treatment interventions." All CDS algorithmic outputs may be used as one of

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16 CDS Draft Guidance, *supra* note 1, at 11.

17 *Id*. at 13-14.

18 *Id*. at 14.

19 *Id*.

20 *Id*.

several sources of information that a clinician may consider to guide next steps in the course of patient care. Moreover, CDS software is often used to "identify early signs of a disease or condition" in complex situations, or where a provider has competing demands that prevent continuous focus on a particular patient. These are precisely the types of scenarios in which CDS software holds the most promise to improve patient care, without imposing a corresponding increase in *risk*. Nevertheless, FDA's proposed interpretation would render such software ineligible for the CDS software exemption, and subject it to regulation as a medical device, based on the ambiguous determination that such software provides "enhanced" support to the health care provider. The implementation of section 520(o)(1)(E) in this manner would contravene the fundamental objective of the statute, which Congress enacted in order to protect certain CDS software, designed to transform the way we utilize medical information, from being burdened with unnecessary regulation.

FDA's proposed distinction between software that "informs" clinical management and software that "drives" clinical management has no foundation within the text of section 520(o)(1)(E). The statute states that to be eligible for the CDS software exemption, the software must be intended for "supporting or providing recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition." [21] The statute includes no further caveat or condition. The output of algorithms intended to help "identify early signs of a disease or condition," to "analyze relevant information to help predict risk of a disease or condition," or to otherwise "drive" clinical management as described in the CDS Draft Guidance squarely fit within the plain meaning of the word "recommendation."[22] Moreover, even if FDA was correct in its interpretation that "drive" functions provide "enhanced support" to health care providers, "enhanced support" is still "support." The statute draws no distinction based on the *extent* of support provided. As a result, FDA's interpretation of the third criterion of the CDS software exemption is inconsistent with the plain language of the statute.

We therefore request that FDA eliminate the ambiguous distinction between *informing* and *driving* clinical management in favor of a much clearer line—if an algorithm takes the agency and decision-making authority away from the clinician and dictates the next course of diagnostic testing or treatment without any reasonable opportunity for intervening clinical judgment, then such software functions should be regulated as devices. All other CDS software functions should be considered to support or provide recommendations to a health care professional about prevention, diagnosis, or treatment of a disease or condition, as set forth in the statutory language. This line between device and non-device is more harmonious with the statutory text than FDA's arbitrary distinction between informing and driving. The statute requires that non-devices be intended for supporting or providing recommendations to health care professionals, which acknowledges that the information gleaned from an algorithm may in fact inform a clinician's judgment.

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[21] 21 U.S.C. § 360j(o)(1)(E)(ii).

[22] *See* Oxford Dictionary of English (3d ed. 2010) (defining "recommendation" to mean "a suggestion or proposal as to the best course of action, especially one put forward by an authoritative body"); Shorter Oxford English Dictionary on Historical Principles (5th ed. 2002) (defining "recommendation" to mean "a recommended course of action").

V. STATUTORY CRITERION 4: ENABLING A HEALTH CARE PROFESSIONAL TO INDEPENDENTLY REVIEW THE BASIS FOR THE RECOMMENDATIONS THAT THE SOFTWARE PRESENTS, SO THAT IT IS NOT THE INTENT THAT SUCH HEALTH CARE PROFESSIONAL RELY PRIMARILY ON ANY OF SUCH RECOMMENDATIONS TO MAKE A CLINICAL DIAGNOSIS OR TREATMENT DECISION REGARDING AN INDIVIDUAL PATIENT

Under the fourth criterion of the CDS software exemption, the software function must be 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 rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient."[23] FDA interprets this provision in the CDS Draft Guidance to require that software functions subject to the Cures Act exemption be described in plain language to providers, including:

1) The purpose or intended use of the software function;
2) The intended user (e.g., ultrasound technicians, vascular surgeons);
3) The inputs used to generate the recommendation (e.g., patient age and sex); and
4) The basis for rendering a recommendation.[24]

FDA further states that "regardless of the complexity of the software and whether or not it is proprietary, the software developer should describe the underlying data used to develop the algorithm and should include plain language descriptions of the logic or rationale used by an algorithm to render a recommendation."[25]

We support FDA's interpretation of this criterion, but request further specificity on the format in which such information may be provided, consistent with the intent of the Cures Act. For instance, clinicians frequently rely on complex calculations obtained from CDS algorithms, and while clinicians could do these calculations themselves, they typically do not and often rely significantly on the algorithmic results, thereby reducing the time and potential for error that manually undertaking such complex calculations may entail (for example, software functions that use nomograms to predict the probability of disease, or determine drug dosing based on numerous variables). Furthermore, many algorithms that clinicians currently use rely on complicated mathematical calculations of correlations and probabilities. It is not necessary for a CDS algorithm to be easily replicated by the clinician, so long as clinicians understand the inputs and general function used to make a recommendation. As an example, providers may leverage tools that analyze electronic medical record data to flag patients who may be at risk of an event, or have indicators that suggest the need for further follow-up. In order for a provider to "independently review the basis for such recommendations," as the statute requires, the provider

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[23] 21 U.S.C. § 360j(o)(1)(E)(iii).

[24] CDS Draft Guidance, *supra* note 1, at 12.

[25] *Id*.

need not be able to recreate the modeling that is behind the algorithm. Instead, a general description of the inputs and the fact that the algorithm is the result of studies of how these inputs interact should be sufficient to allow the provider to review the basis for the recommendation.

While we agree that the information described by FDA in the CDS Draft Guidance should be made available to health care providers, we do not believe it necessary to embed all of this information within the algorithmic output, nor we do we believe it necessary to affirmatively require or confirm that providers review this information each time the algorithm is used. In addition, in certain mobile interfaces, there is limited space to provide a full explanation of all the items noted above. We therefore request that FDA make clear that, as long as the information is accessible to the clinician as part of the software function—such as by links to separate webpage locations, if not immediately next to or within the algorithmic output, and regardless of whether it is actually accessed—then such information has been adequately provided in satisfaction of the fourth criterion of the CDS software exemption.

VI. CONCLUSION

While certain aspects of the CDS Draft Guidance reflect a reasonable interpretation of section 520(o)(1)(E) of the FDCA, consistent with both the letter and the spirit of the statute, other aspects of the CDS Draft Guidance—particularly FDA's interpretations of the first and third statutory criteria—are overly-broad, ill-defined and unsupported by the statutory text. These interpretations threaten to undermine the fundamental purpose of the CDS software exemption by subjecting low-risk technologies that promise to improve patient care to unnecessary and burdensome FDA regulation, notwithstanding Congress's determination that such regulation should not apply.

Moreover, pursuant to Executive Order 13891, issued by President Trump on October 9, 2019, agencies in the executive branch (such as FDA) have been directed not to use non-binding guidance documents to inappropriately regulate the public without following the rulemaking procedures of the Administrative Procedure Act (APA).[26] We submit that in its current form, the CDS Draft Guidance provides more than a clarification of existing regulatory authority, and instead oversteps the statutory language that it purports to explain. Accordingly, to the extent FDA seeks to finalize the CDS Draft Guidance in its current form, it should be subject to APA rulemaking procedures.

In addition, as FDA is aware, the APA prohibits agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.[27] We encourage FDA to reexamine its approach in the CDS Draft Guidance, particularly in connection with its use of the IMDRF framework, and to avoid future APA challenges to any regulatory action taken on this extra-statutory basis.

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[26] Executive Order, *supra* note 4.

[27] 5 U.S.C. § 706.

We appreciate the opportunity to provide comments on the CDS Draft Guidance, and look forward to working with FDA as its proposed method of implementing section 520(o)(1)(E) of the FDCA continues to evolve. We are happy to discuss the issues raised in these comments at FDA's request. Please do not hesitate to contact me or a member of my staff at 202-624-1500.

Sincerely,