

July 17, 2018

Bakul Patel
Associate Director for Digital Health
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
WO66-5458
Silver Spring, MD 20993

Re: **Developing a Software Precertification Program – A Working Model v 0.2 June 2018,
Docket Number FDA-2017-N-4301-0073**

Dear Mr. Patel:

In response to FDA's request for public input on version 0.2 of the Software Precertification Program (hereinafter the "precertification program" or "precert program") working model, the Clinical Decision Support Coalition ("CDS Coalition" or the "Coalition")¹ would first like to compliment FDA on both its vision for a better, more effective regulatory approach for software as a medical device ("SaMD"), as well as the Agency's approach of periodically putting drafts of the working model out for public comment. Seeking public comment along the way as FDA develops its working model is a much more efficient and effective way of engaging the public than waiting until the very end, when frankly, making changes would be much more difficult. We greatly appreciate your public outreach and consideration of our feedback.

Further, and as stated in our prior comments, the Coalition believes this is an incredibly important initiative that the Agency is undertaking. Software is different from hardware, and the best approach to regulating software is likely to be quite different than the best approach to regulating hardware. As the Agency correctly points out, there are ways to regulate software that are simultaneously more effective – utilizing the unique characteristics of software to, for example, continuously collect real-world evidence – while at the same time expediting the process for introducing new software and keeping it up-to-date. We commend FDA for pursuing this vision.

¹ 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 clinical decision support 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.

At this juncture, we would like to offer comments on five different topics:

1. How does the precertification program address low risk and ultra-low risk products?
2. The need to include software used with drugs.
3. Missing programmatic elements.
4. What is FDA's claimed legal authority for conducting the pilot program in 2019 and for implementing the program thereafter?
5. The staffing challenges of regulating corporate entities and their cultures, as compared to evaluating the safety and effectiveness of a device.

We will explore each topic in turn.

1. How does the precertification program address low risk and ultra-low risk products?

Before diving into this topic, we would like to define low risk and ultra-low risk SaMD. As we use those terms, low risk refers to class I medical devices that are subject to the general controls such as part 820 quality systems, adverse event reporting, facility registration and product listing, but are not subject to premarket review. Ultra-low risk products refer to class I medical devices that are so low risk that they should be exempt from part 820 quality systems, adverse event reporting, facility registration and product listing, in addition to premarket review.

The reason we said "should be" – instead of just saying those that actually are exempt – is that we believe there are a lot of ultra-low risk devices out there that should be exempted under law, but FDA has not exempted them. Instead, for many of these devices, FDA has put them in the Agency's category of enforcement discretion. Enforcement discretion has some of the same practical effects as exempting the devices, but without following the legal process for creating the exemption. So we are adopting simply the terminology of ultra-low risk devices, and hopefully you will appreciate that we are referring to products that should be legally exempt, but that may only be presently treated by FDA as under enforcement discretion.

Now that the precertification program is beginning to take more substantive shape, it seems obvious that the program will entail a greater regulatory burden on low risk and ultra-low risk devices than the current framework. To be sure, FDA has not said whether the new framework will replace such regulatory requirements as:

1. registration and listing;
2. adverse event reporting; and
3. part 820 quality management system requirements.

FDA has indicated that the precert program would replace the existing premarket review process, whether 510(k) or otherwise. We are guessing that FDA plans to take the position that the precert program exists alongside part 820. Indeed, FDA may take the position that precert participants need to satisfy the part 820 requirements in addition to the extra requirements imposed in the excellence appraisal. But all of that is guesswork – FDA has not clearly explained its view.

But what the Agency plans to do about registration and listing as well as adverse event reporting requirements is not at all clear. It seems likely that FDA might exempt a company in the precert program from adverse event reporting by virtue of participating in the collection of real-world evidence. But we anticipate that the registration and listing requirements will continue unaffected.

When we think about a developer of low risk, and ultra-low risk SaMD, and the potential attractiveness of the precert program, the following seems to be the potential cost/benefit analysis of participation.

Cost and Benefits of the Precertification Program From the Perspective of a Low Risk and Ultra-low Risk SaMD Developer

Cost of Participation	Benefit of Participation
Preparing for and applying for excellence appraisal.	Avoid MDR obligations?
Agreeing to collect real-world evidence.	N/A
Agreeing to a broader scope of inspection that parallels the topics covered in the excellence appraisal.	N/A
Agreeing to be subjected to broader FDA powers to direct the company to conduct postmarket remediation and/or recalls.	N/A

Frankly, regardless of whether the precert program comes with an exemption from the MDR obligations, the cost of participation for a low risk or ultra-low risk SaMD developer would far exceed the benefits. In fact, just the cost of preparing for and applying for an excellence appraisal – considering the potential 12 excellence principles – is likely to be burdensome enough so as to outweigh the need to occasionally file an MDR for a low risk or ultra-low risk device. Most class I device companies face very few MDRs. The costs of participating in the precert program only become potentially worthwhile for class II companies that are faced with premarket review.

For those products that are ultra-low risk, the calculus is even more tilted toward staying out of the precert program. For those companies, the precert program offers nothing, so the burdens of the program entirely outweigh the benefits. For ultra-low risk SaMD, the only real consequence of being regulated is that developers need to avoid producing and selling adulterated or misbranded devices.

So the question is, why would class I products – whether low risk or ultra-low risk – be included in the scope of the precert program? FDA may respond to this question with, “Why not?” FDA may say that the program is voluntary anyway, so why not open it up to class I SaMD developers?

The harm comes when FDA rhetorically uses the precert program as a reason to treat ultra-low risk SaMD as low risk SaMD. Dr. Jeff Shuren, the Director at CDRH, in a meeting with the Coalition, told us that the existence of the precert program means that FDA will exempt from regulation fewer SaMD products in the future. In other words, FDA will treat all ultra-low risk products as low risk products. More specifically, in the context of a discussion of ultra-low risk clinical decision support software, while the Agency has been saying now for several years – and all through the FDASIA health information technology (“HIT”) process – that FDA would exempt from regulation ultra-low risk CDS, the Agency has

now done an about-face and has suggested that it will not exempt ultra-low risk CDS because of the precert program.

We are trying to understand that thought process when the precert program is entirely unattractive to developers of low risk CDS and entirely inappropriate for ultra-low risk CDS. What difference does it make to have the precert program if it's actually a higher level of regulation than class I (ultra-low risk and low risk) CDS software developers are currently experiencing? The existence of this program – even voluntary – would seem to have no impact on those developers. It makes no sense for those developers to pursue this program.

We would like to request that FDA clarify its plans for the precert program as it relates to ultra-low risk and low risk SaMD. Does FDA plan to impose the precert program on ultra-low risk and low risk SaMD? If the plan is not to impose it in a mandatory way, but make it an option for voluntary use, could the FDA explain how that voluntary option is relevant to the Agency's scope of regulating ultra-low risk software as a medical device in light of the fact that the precert program represents a higher level of regulation than the current system for class I software – both ultra-low risk and low risk?

2. The need to include software used with drugs.

We have on several prior occasions urged FDA to consider software used with pharmaceutical products in its policy development. On August 16, 2016, the CDS Coalition filed a Citizens Petition (Docket ID: FDA-2016-P-2497) articulating why software used with pharmaceutical products holds such great promise for advancing public health. In that petition, we urged FDA to develop a guidance document to answer some very fundamental questions regarding the scope of FDA regulation of such software. The Agency has never responded to that petition. On June 21, 2018, we filed comments on the importance of such software in response to the Agency's general solicitation of information on the risks and benefits of software exempted under the 21st Century Cures Act. See *Docket No. FDA-2018-N-1910: Development of 21st Century Cures Act Section 3060 Required Report: Request for Input*.

We also are aware that on September 25, 2017, the Combination Products Coalition sent a letter to the directors of CDRH, CDER and CBER asking them to develop a coordinated policy on software used with pharmaceutical products. That coalition, which includes the vast majority of the largest pharmaceutical companies in the world, observed:

Unfortunately, in the experience of our members, the lack of consensus among the three centers on issues regarding software extends well beyond just the scope of regulated CDS to other technologies and other regulatory issues. That lack of clear consensus positions by FDA is producing a substantial drag on innovation in digital health pharmaceutical products in the US and causing pharmaceutical companies to focus initial launch and application of their most innovative and promising digital technologies in non-US markets.

Both the CPC and CDS Coalition are concerned that the software review practices across CDRH and CDER are at risk of further divergence.

Unfortunately the Agency has done little, publicly, to clarify and harmonize its regulatory approach to software used with pharmaceutical products. Yet the category is simply way too important to ignore. In

those two other comments, we outlined just how important this category of software is to the public health. We won't repeat all of that here, but rather incorporate it by reference.

Such software is in some ways fundamentally different from ordinary SaMD. In particular, it raises complex regulatory issues that cut across the drug and medical device categories, and therefore implicate all three human therapeutic centers at FDA.

These issues, given their complexity and importance, need to be considered from the very beginning as FDA develops the precert program. For example, as FDA develops its excellence appraisal, there are likely differences between the typical developer of software for use with pharmaceuticals and other software developers. Indeed, many pharmaceutical companies are developing software for use with their drug products, and the structure of pharmaceutical company operations is notably different than other software developers. In addition, the kinds of issues that may arise during the collection of real-world evidence are likely to be different. Further, the review pathway determination is likely to be different because of the separate risks that must be considered in connection with pharmaceutical products.

If FDA ignores all of these differences as it develops the program, it is likely to miss substantial opportunities to improve the public health by extending the program to pharmaceutical-related software products. And that opportunity will not easily be accomplished later, after the precert program has taken final form.

Our understanding is that CDRH is shying away from working on SaMD used in tandem with pharmaceuticals, because to do so necessarily would require CDRH to work with CDER and CBER in the design of the program. While we understand that adding cooks to the kitchen adds complexity and potentially creates delay, this is far too important of a topic to omit for the sake of expediency. We would implore the three centers to work together on this topic for the sake of the patient.

The decision of CDRH not to collaborate with CDER and CBER on this important new regulatory framework creates the risk that the regulatory treatment of software used with pharmaceuticals will diverge even more greatly among the centers. CDER and CBER likely will not have complete confidence in the precertification program, and how it can be used for software meant to complement pharmaceutical products. That most assuredly will create future regulatory problems, and frustrate innovation in the space.

3. Missing programmatic elements.

There are numerous programmatic elements that are equally important to the details that are included in the present working draft, but not addressed. They include the following:

- a. What current regulatory controls does the precert program replace?

As we recited above, we are pretty confident that FDA's intent is to replace the 510(k) process. But is that the only regulatory control that the precert program will replace? We suspect that the precert program will not replace part 820, but rather constitute a framework through which compliance with part 820 will be assessed. Are we correct in that? Does the collection of real-world evidence under the precert program mean that companies that participate will be exempt from the MDR regulation? We assume that precert program participants will still need to comply with the registration and listing

requirements, but obviously, we would like to know if we are wrong. On the whole, for companies to evaluate the purpose of the program and decide what its elements should be, there should be at least some discussion now about what regulatory controls this program will replace.

b. Mandatory versus voluntary.

We have heard FDA repeatedly characterize this program as voluntary. The word “voluntary” is always a bit ambiguous when the topic is a compliance measure designed by a regulatory agency with law enforcement powers. We assume that what FDA really means is that companies will have a choice: regulatory program A versus regulatory program B. And in this case, we assume that, as just outlined above, the precert program will be an alternative to compliance with at least certain existing regulatory requirements, such as the 510(k) process. That’s not really the definition of voluntary. That’s the definition of an alternative.

While there might be an opportunity to make an election between which regulatory program a particular company wants to participate in, once they make the election to participate in the precert program, we assume the company’s compliance with that program will no longer be in any sense voluntary. If a company elects to participate in the precert program, we guess they will be then legally obliged to follow all of the elements of that program. If we are right about that, it will certainly no longer be voluntary in any sense.

We request that, in the next draft, FDA start to explain the degree to which the program will become binding for those who elect to participate. Will they have to enter into an agreement such that – if they fail to comply with the elements of the precert program - they could suffer all of the usual potential consequences of a violation of the Federal Food, Drug and Cosmetic Act (“FDCA” or the “Act”), including fines, injunctions and even criminal sanctions?

And just to be clear, FDA should discuss the fact that really what the Agency is talking about is having two alternative pathways to market for SaMD. Thus, in a sense, both become voluntary in that they are alternatives to each other. But it is in no sense voluntary that the company has to comply with one or the other. Compliance with one of them is necessary to avoid violating the underlying statute. Properly understood, they are just two different alternatives for compliance with the mandatory requirements of the statute. They are really in no sense voluntary.

In the same vein, FDA needs to tackle the question of how one both enters the program and chooses to leave it. There may be plenty of organizations that start down the precertification road, but decide that the traditional approach is better for them. There needs to be a way to switch back easily. It also has to be clear that companies can selectively include some products within the precert program, and not others, even though the other products might qualify as software as a medical device. And there may be companies that start off with the traditional regulatory approach, and want to switch midstream into the precert program. All of this needs to be considered and addressed.

c. How will FDA carry out its law enforcement obligations for companies that are participating in the precert program?

As you well know, FDA is not a nonprofit standards organization or an accreditation body. It is a law enforcement agency of the federal government. It has the power to investigate criminal wrongdoing, and, together with US attorneys, pursue civil enforcement actions against medical device

manufacturers, including developers of SaMD. It has the power to determine which products may lawfully be marketed, and it has the power to demand, in certain cases, the removal of products from the market.

So this precert program will operate in that context. It will be a program of a law enforcement agency. As a consequence, FDA will need to import all of its law enforcement authority into the precert program context. Exactly how will FDA do that?

The following are some specific areas where questions arise:

- Under section 704 of the FDCA, FDA has the legal authority to conduct mandatory inspections of facilities to assess compliance with the statute. The authority given to FDA is directly related to that purpose, so the scope of the inspection authority is only as large as is necessary to determine compliance with the adulteration and misbranding provisions of the Act. That means, for example, examining manufacturing processes for regulated articles, and examining records required to be kept under the quality system. It also means examining records required for compliance with the adverse event reporting obligations. However, it does not mean that FDA can meander throughout other parts of the company and look at records such as financial data, pricing data, personnel data, research data or sales data (other than shipment data regarding sales).
 - As of right now, the various requirements of the precert program are not authorized by statute. We will discuss below the fact that we believe such statutory authority is necessary for FDA to implement this program. But in the meantime, what is FDA's thinking about how the precert program affects the Agency's authorized scope of facility inspections? There are several elements such as the excellence appraisal and the collection of real-world evidence that – because they are not authorized by statute – get into company operations that are not presently within the permitted scope for an FDA inspection. Is FDA asserting the legal right to inspect beyond the statutorily required operations of the company? Or is FDA suggesting that it will have a program – the precert program – where it will not be able through inspection to verify compliance?
- If a company is not complying with the collection of real-world evidence requirements under the program, does FDA envision being able to get an injunction to require compliance with that requirement? If not, what is the remedy for the failure to comply with the real-world evidence requirements?
- Does FDA believe that it will have the power to pursue the seizure action against software if, for example, a company doesn't comply with an FDA directive to change labeling in response to a concern FDA has based on the collected real-world evidence?
- If a company intentionally does not follow the precert program, does the Agency believe that it will be able to pursue criminal or civil penalties?
- Does the Agency believe that it will be able to pursue an administrative or criminal search warrant based on concerns that the company is not complying with the precert program, even though there is no evidence the company is failing to comply more generally with the FDCA?

At a little bit higher level, the question is: how does FDA plan to fulfill its enforcement function with regard to noncompliance with the precert program?

d. How does FDA define its authority for participants in this program with regard to FDA's ability to order postmarket corrective actions?

In the working model, FDA says that it will use real-world performance analytics ("RWPA") for the following purposes, among others:

1. Monitoring safety, effectiveness, and performance of marketed SaMD products.
2. Supporting modifications of clinical and performance claims for safety and effectiveness.

In those sections, however, FDA does not discuss *who* will use the data – FDA or the company – and what the process will be for any decision-making.

Currently, FDA has specified authorities for requiring postmarket remediation of medical devices. For example, under section 518 of the Act, FDA has authority to demand that the manufacturer repair, replace or refund the purchase price for a device. Under section 516, FDA has the ability to ban devices altogether. The recall provisions of the FDA regulations are largely voluntary, but FDA can request that a company recall a product. In some cases, FDA argues that it can revoke an approval or clearance of a medical device.

Will the FDA follow that existing law, or will FDA take the position that by "voluntarily" entering the program, the company agrees to do whatever FDA tells it to do postmarket? What will protect the rights of companies against what a company might view as overly demanding postmarket directives from the Agency? What due process protections will be put in place to ensure that a company gets to express its point of view prior to any decision? Will FDA be able to unilaterally declare that a company has not complied with the precert requirements, and if the Agency does that, what will be the legal consequence? Will FDA take the position that the products need to be immediately removed from the marketplace?

Obviously, with the real-world evidence, the company can decide that it wants to do something with it, and FDA can suggest that something be done. The question is, what will happen if the Agency and the company do not agree?

We request that FDA move to address these important topics in the next working draft.

4. What is FDA's claimed legal authority for conducting the pilot program in 2019 and for implementing the program thereafter?

On page 3 of the working model, at the bottom of the page, FDA has substantially changed its tune regarding legal authority. In the last model, FDA simply punted the legal issues, saying that it wanted to focus on identifying the best program and worry later about what sort of legal authorization will be necessary. FDA takes a very different stance in this new draft. The FDA is now asserting that it ought to be able to do a pilot test "within FDA's current authorities in 2019."

a. 510(k) requirements.

Section 510(k) of the FDCA (21 U.S.C. § 360) provides:

- (k) Report preceding introduction of devices into interstate commerce

Each person who is required to register under this section and who proposes to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary or person who is accredited under section 360m(a) of this title (in such form and manner as the Secretary shall by regulation prescribe)-

(1) the class in which the device is classified under section 360c of this title or if such person determines that the device is not classified under such section, a statement of that determination and the basis for such person's determination that the device is or is not so classified, and

(2) action taken by such person to comply with requirements under section 360d or 360e of this title which are applicable to the device.

A notification submitted under this subsection that contains clinical trial data for an applicable device clinical trial (as defined in section 282(j)(1) of title 42) shall be accompanied by the certification required under section 282(j)(5)(B) of such title. Such certification shall not be considered an element of such notification.

That's it. That's the sum total of the section. And FDA, as a dutifully bound federal agency, cannot add to that section or subtract from that section. It is not lawful to require more of a notice, and it is not lawful to require less of a notice, without following the legal process for an exemption.

Years ago, FDA interpreted that statutory provision through several regulations all found in subpart E of part 807, including:

Subpart E-Premarket Notification Procedures

§ 807.81 - When a premarket notification submission is required.

§ 807.85 - Exemption from premarket notification.

§ 807.87 - Information required in a premarket notification submission.

§ 807.90 - Format of a premarket notification submission.

§ 807.92 - Content and format of a 510(k) summary.

§ 807.93 - Content and format of a 510(k) statement.

§ 807.94 - Format of a class III certification.

§ 807.95 - Confidentiality of information.

§ 807.97 - Misbranding by reference to premarket notification.

§ 807.100 - FDA action on a premarket notification.

Each of those regulations is fairly detailed. We will not provide a detailed discussion of each of those, but would like to call out two in particular.

Section 807.87 provides very specifically the content that is required to be in a premarket notification. In addition to requiring that the submitter provide the appropriate classification, the regulation requires, among other things, that the submitter provide: “(f) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.”

Section 807.85 provides very specifically when a device is exempt from premarket notification. It says that the manufacturer of a custom device – and the regulation defines custom device – need not submit a premarket notification and provides a couple other exemptions.

Again, as with the statute, nothing more may be added, and nothing may be subtracted, from these regulations. They are what they are. They require what they require, and nothing else.

As an overarching comment, it should also be clear that these requirements are not voluntary if a company wishes to place a device in commercial distribution. There are plenty of FDA warning letters accusing companies of failure to comply with the premarket notification requirements, and threatening legal action. They are the law of the land to be obeyed.

b. How does the precert program comply with the section 510(k) of the FDCA and FDA regulations?

Conceptually, it would seem FDA has two options:

1. Claim the precert program is a new form of 510(k) and compliant with the statute and the implementing regulations; or
2. Claim that FDA has the authority to make the 510(k) process optional in a way not specified by the exemptions in the regulations.

Neither of those claims have legal merit.

The precert program in no way meets the statute or regulations for the 510(k) process in any of its specifics. In section 6 of the working model, FDA makes no reference to including the information that is the core of the 510(k) review – identification of an FDA classification and the provision of evidence necessary to demonstrate substantial equivalence to devices in that classification. That is the essence of the 510(k) review process, and it is entirely omitted from the working model. Equally revealing, the precert process – taken as a whole – focuses on evidence that has nothing to do with substantial equivalence to a predicate device. The process – as a whole – focuses on such things as an excellent appraisal of the organization, which doesn’t have anything to do with the product, and therefore can’t be relevant to a determination of substantial equivalence.

Similarly, the precert process makes no attempt to fit within any of the exemption categories from the 510(k) requirement. The program is certainly not focused on custom devices or any other category that is excluded from the requirement of a premarket notification. Further, without a rulemaking, FDA has made no effort to amend its classification regulations to make SaMD exempt from the premarket

notification requirement. There is simply no legal authority anywhere in the existing statute or regulations to remove software as a medical device from the standard 510(k) process.

- c. There are other statutes and regulations that specify how products are supposed to reach the market, and FDA seems to be ignoring all of them.
 - i. *The classification regulations are the law of the land and define how particular classes of devices are to be treated under the FDA regulations.*

Instead of following the laws set by Congress and the Agency's own regulations, FDA is guided by the IMDRF model that provides for risk stratification. However sensible that risk stratification might be (and we generally like it), it is not the law in the United States. In the United States, the Medical Device Amendments of 1976 are crafted around a classification system that puts each medical device in a classification that determines the corresponding regulatory requirements for that product. And, the process of putting medical devices into a new classification is governed by significant procedural laws found in the statute for adopting new classifications. FDA is not complying with any of that.

- ii. *The exact approach for requiring postmarket data is specified by the statute that addresses postmarket surveillance.*

In the Safe Medical Devices Act of 1990, Congress added section 522 to the Act, requiring all manufacturers of certain types of devices to conduct postmarket surveillance studies. In this section of the Act, Congress specified the types of devices for which this obligation applied, and a process by which these determinations are to be made. It is obvious to anyone who reads them that FDA's new concept of requiring the collection of real-world evidence is not in any way consistent with the postmarket surveillance requirements set forth by Congress.

- d. Judicial review.

As you well know, all agency authority to regulate must derive from a duly enacted statute, unless the agency is relying on what it believes to be an "inherent power" of the executive branch. Inherent powers track constitutional authority, and so come into play in such matters as the national defense. We assume that FDA is not asserting that its authority for the precert program derives from an inherent power of the President.

So if the basis for the precert program is the existing FDCA, it would be up to the courts to decide whether the program is a legitimate exercise of that statutory authority. Here's how a court would approach that issue:

- i. *If the precert program is promulgated in the form of a new regulation, the court would review it under the section 706(2)(C) of the Administrative Procedures Act ("APA"), which prohibits regulations "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right."*

Of course, the most widely referenced judicial interpretation of the APA is Chevron USA Inc. v. National Resources Defense Council, 467 U.S. 837 (1984). That case articulates a two-part test as follows:

- (1) Has Congress “directly” spoken to the “precise” question at issue? “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress;” and
- (2) If Congress has not done so, the statute is “silent or ambiguous with respect to the specific issue,” then the question for the court is whether “the agency’s answer is based on a permissible construction of the statute.”

We need not spend too much time on this question, because it seems pretty clear that a precert program regulation would fail under the first prong of that test. Congress has spoken very specifically about the requirement of the 510(k) notification, the classification scheme for medical devices, the MDR requirements and frankly comprehensively about how medical devices are to be regulated. And the precert program, by design, rejects all of that statutory construct. In fact, FDA itself says that it started with a blank sheet of paper and with indifference to the current statutory framework, and sought to design the optimal regulatory approach. It’s hard to imagine a clearer case of a regulatory program that contradicts the specific intent of Congress with regard to how medical devices are to be regulated.

Again, we as said above, that does not make the program bad. We like the program. It just means the existing statute can’t serve as authority for the program.

- ii. If FDA chooses not to adopt the precert program through rule-making, that decision will certainly not save the program.*

Properly understood, the precert program is a modification of the existing regulations governing the 510(k) process, the classification process, the MDR process and so forth. As explained more fully above, while the Agency wants to call it voluntary, more properly, it is simply an alternative to the existing approach specified by regulation. If it were truly voluntary, for example, it would be something that companies would do in addition to complying with everything else that exists now. It would not replace any other legal requirements. Properly viewed, the program is a modification or amendment to the existing FDA medical device regulations. It adds an alternative to what is presently specifically required in the regulations.

Amending FDA’s existing regulations without following a notice and comment process is hardly something that courts would greet warmly. The notice and comment process is specified in the APA – section 553 – as the binding procedural law of the land for developing a substantive rule, or amending an existing substantive rule. It serves a very important purpose of giving the public the legal opportunity to insert content into the administrative record that could later be used by a court in reviewing the Agency’s decisions.

Again, we support and frankly applaud the decision by FDA to maintain an open public docket and to periodically review comments from the public. We think that will improve the process enormously. But the very casual process of soliciting public comment through an open docket does not replace the procedural elements of notice and comment rulemaking. To comply with the APA, once the program is fully designed, FDA would have to state it in regulatory terms and publish it for comment through a notice in the Federal Register. FDA would also have to comply with the other statutes that impose procedural requirements on the promulgation of a new rule. For example, there would be real value in subjecting the program to appropriate economic impact analysis (comparing the costs, benefits and

cost-effectiveness of the program against the most promising alternative actions) to ensure that the program would, in fact, save more resources than it would require.

Ignoring those procedural statutory requirements is not going to save the precert program.

iii. The precert program is not going to be saved by a claim of enforcement discretion.

We have in the past tried to explain to FDA why enforcement discretion is not a good option for policymaking, at least not long term. The policy creates confusion, and in some cases, can violate section 553 of the APA because it is being used in lieu of notice and comment rulemaking to remove a substantive requirement FDA no longer wants to enforce.

But frankly we don't need to concern ourselves with those issues here, because in this instance there isn't even any enforcement discretion that could help accomplish the adoption of the precert program. Enforcement discretion has been used by FDA as a basis for choosing not to enforce some regulation or statute on the books. It would be a whole new level of illegality for FDA to say that enforcement discretion can also be used to affirmatively adopt new regulatory requirements. Enforcement discretion, even at its most aggressive use, is only the ability of an agency to avoid enforcing a requirement. Enforcement discretion has never been used to substitute new requirements for old requirements.

We've given this topic relatively light treatment here because the precert program is only in its infancy with respect to its design. But even at this early stage, it seems patently obvious that where FDA seems to be going will require new statutory authority.

e. The big picture – why is this a problem?

There may be some who think we are just being kill-joys in raising these issues. Some might say that the precert program is wonderful, so why talk about all this legal stuff?

We support FDA's efforts to think outside the box and develop an entirely new approach to regulating SaMD. We have consistently expressed that point of view, and this comment is no different. FDA has said throughout the past year that they don't want to think about the existing law, and they don't want to have blinders on, but rather they want to identify best practices for regulating software. We think that's fantastic. We support that effort wholeheartedly.

Where we may depart from the Agency – and we don't know the Agency's position other than the Agency's assertion that it can pursue a pilot program in 2019 without any legal authority – is that we think at the end of this process, FDA needs to go to Congress to get authorizing statutory authority, and then implement the program through authorizing regulations.

We think FDA has done a terrific job of putting intermediate drafts out in order to get comment. We deeply appreciate that process, and indeed it encourages us to think that the resulting work product will be that much better, and more acceptable to most of the parties. But there are two reasons why we think obtaining the required legal authority is important.

First, we think FDA needs to respect the rule of law. We have had numerous discussions with FDA regarding its use of enforcement discretion, and how that disrespects the rule of law. The statutes and regulations don't exist so that FDA can simply pick and choose which ones they want to follow at any given moment. They are the elements of a social contract written by the stakeholders and need to be

respected. FDA is not supposed to either add or subtract from the laws without following due process, either going to Congress if it's the statute or following rulemaking if it's a regulation.

Second, there is a practical reason that obtaining the required legal authority is important. Like a contract, statutes and regulations exist for when things go sideways. When everyone's getting along, they seem unnecessary. But they are quite necessary when citizens and their government see things differently, and that situation is actually fairly common. For example,

- There will be disputes, and probably lots of them.
- There will be times when FDA thinks a product should be withdrawn from the market, and the company thinks that the real-world data they are collecting is misleading and that there is a larger context of information that leads to a different conclusion.
- There will be other times when FDA thinks that a company does not possess a culture of excellence, when the company vehemently disagrees.
- There will be times when a company clearly thinks the data should lead to a positive marketing decision, and FDA has lots of additional questions that the company thinks are unreasonable.
- And there will be times when a company cuts corners, and the FDA has to take them to task.

In all of those cases, it is absolutely essential to have clear legal authority spelled out. This is both with regard to substantive requirements, as well as procedural protections to ensure that companies get treated fairly.

Congress didn't take the time to specify the classification process, the 510(k) notification process, the process for requiring postmarket surveillance, and the Agency's enforcement powers only to have FDA chuck the entire thing and replace it with an entirely new and different system at the will of the Agency. Congress has to be involved. And the rights of the parties have to be codified.

5. The staffing challenges of regulating corporate entities and their cultures, as compared to evaluating the safety and effectiveness of a device.

On page 14 of the new working model, FDA starts to describe the appraisal process. FDA has some interesting ideas here. But something that FDA doesn't address is the fundamental shift in the Agency's mission and activities necessary to implement the appraisal of the precert status.

The skill sets involved in this appraisal are as different as going to business school versus going to engineering school. Appraising an organization is fundamentally different than appraising technology. FDA has been hiring people for decades to appraise technologies. Where is the Agency going to get the people with the expertise necessary to appraise organizations? If this program is popular, there will be a very large bolus of appraisals that need to be done, and so far, there's been absolutely no discussion about how to do this.

Unfortunately, there is a view held by some who are smart that being smart means they can do anything intellectual. But that's just not true. Scientists often make poor business leaders, and business leaders often make poor scientists. People, however smart, are not fungible. This is true not only in the sense that people have certain innate abilities that make them strong at one task and not another, but it's also true that we all spend a lifetime acquiring experiences that make us strong at some things and not others. So the tasks that need to be done are not simply going to be well performed by folks who are scientifically smart, but have little business experience.

Presumably, one way FDA could administer this program is by engaging third parties to help, but again, that requires legal authority. This aspect of the existing working model is very thin, and we would like to see it addressed more substantially in the next draft.

Conclusion

FDA is using the existence of the precert program as a reason for, in the future, regulating a broader profile of SaMD from a risk standpoint. First, that is not logical because low risk devices, and certainly ultra-low risk devices, merit a lower level of regulation than precert, so why would the existence of precert lead FDA to want to regulate more low risk devices? But also, that means the program isn't a harmless voluntary program. It becomes coercive, using it as a basis for expanding the scope of FDA's active regulation, arguing that the scope of regulation should be expanded because there's a more suitable program for low risk and ultra-low risk SaMD. That statement simply isn't true.

We like the precert program. We think it's extraordinarily innovative. In fact we'd like to see it expanded to consider software used with pharmaceutical products. While there are some elements that need to be fleshed out in the next draft, we also think the Agency is making terrific progress in a very short period of time.

As much as we like the program, we think it's unavoidable that it will require new legal authority. It's so innovative it simply doesn't fit the existing legal framework. That's not a criticism, in fact that's a compliment. But it's also a fact, and something that will soon need to be dealt with.

Thank you again for the opportunity to offer comments. We really appreciate the public solicitation of input.

Very truly yours,

A handwritten signature in black ink, appearing to read "Bradley Merrill Thompson". The signature is fluid and cursive, with the first name being the most prominent.

Bradley Merrill Thompson
General Counsel, CDS Coalition