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AdvaMed
Advanced Medical Technology Association

June 27, 2011

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket Number: FDA-2011-N-0259 – Periodic Review of Existing Regulations; Retrospective Review Under Executive Order 13563

Dear Sir/Madam:

On behalf of AdvaMed, the Advanced Medical Technology Association, we are pleased to submit these comments in response to the Food and Drug Administration's (FDA) review of regulations to assess whether they can be made more effective and less burdensome in achieving regulatory objectives.

AdvaMed is the largest medical technology association in the world. Our member companies produce the medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. We applaud the spirit behind the President's Executive Order and, in particular, its emphasis on the need for the regulatory system to promote economic growth, innovation, competitiveness, and job creation while protecting public health, welfare, safety, and the environment.

Our industry has historically been an engine of job creation and economic growth. The jobs our companies create are good ones, with wages well above average both for the economy as a whole and even substantially above the average for other manufacturing sectors. We are one of the few manufacturing sectors with a consistently favorable balance of trade. America's medical technology industry is the acknowledged world leader.

While our industry has had a strong record of success, we are increasingly challenged in our efforts to maintain our leadership relative to other countries and to continue to provide economic growth in America. Our industry is more dependent than most on a favorable

government regulatory climate because we are so heavily intertwined with federal policy in so many ways. Particularly important for us are the policies of FDA. Every product we manufacture is regulated by FDA and most require pre-clearance or approval before they can be marketed.

As you develop your response to the President's Executive Order, we thought it would be helpful to identify for your consideration FDA rules affecting our industry that might be made less burdensome or altered in other ways to achieve the President's goals consistent with the agency's underlying responsibility. While the Executive Order only refers specifically to regulations, we have identified subregulatory rules since the impact of these rules on industry can be as important as rules established by formal rulemaking. In addition, we have included rules and policies that are currently under consideration or development as well as those already on the books.

FDA Identification of Areas for Less Burdensome Approach

Before we identify FDA rules which we believe might be made less burdensome, we would like to support and commend FDA for its identification of several medical device regulatory items in the Department of Health and Human Services' May 18, 2011 *Preliminary Plan for Retrospective Review of Existing Rules.* FDA identified three areas:

- Revise the Adverse Events reporting system to convert to a paperless, electronic reporting system. We agree this will help FDA more quickly review these reports and identify emerging public health issues.
- Continue its ongoing review of medical device classifications based on risks to determine whether particular devices can be reclassified to a lower level. FDA indicated that this would reduce burdens for industry while maintaining the safety and efficacy of the products.
- Allow validated symbols in certain device labeling without the need for accompanying English text. We agree with FDA that this change will reduce the burden of having unique labeling requirements for the U.S. market and achieve consistency with labeling requirements for international markets.

Identification of FDA Rules and Policies for a Less Burdensome Approach

Posting Device Labeling in an Online Repository

FDA is considering requiring posting all current device labeling in an on-line resource. Such a general requirement would be highly burdensome, potentially counterproductive for patients, and not improve patient safety. Devices are shipped with the most up-to-date information (labeling) needed by the healthcare providers and patients to safely and effectively operate the device. For some devices, safe operation of the device and its accessories requires training; labeling alone is not sufficient and reliance on a printed label alone could create hazards. Labeling relating to operation or programming of a device can be quite voluminous, intended for providers, and not only unhelpful but potentially misleading to patients. Finally, selecting the correct labeling from an online repository could be quite difficult given the number of similar devices and the rapid upgrading of devices. Incorrectly identifying the labeling associated with a device could create hazards for patients. Reliable

transmission of labeling information to an online repository would also likely require the use of an HL7 Structured Product Label (SPL) messaging standard. The SPL process is formulaic and very cumbersome, particularly as device labeling is very different and not nearly as standardized as drug labeling. AdvaMed does see benefit to patient users and family caregivers in a more uniform, recognizable access point on manufacturers' website for device labeling. To that end AdvaMed recommends the development and use of a branded "banner button" on manufacturers' website home pages to guide patient users and family caregivers to needed device labeling. Labeling information available through this link would be limited to safety-related elements, e.g. alarms and error messages, warnings, precautions, and contraindications; and patient user or family caregiver operating and maintenance instructions. The manufacturer labeling information webpage should also contain a toll-fee customer service telephone number and email address.

Eliminate Class I Reserved List

As a result of the Food and Drug Administration Modernization Act of 1997 (FDAMA), all Class I devices are exempt from the requirement of premarket notification, unless the device is intended for a use that is of substantial importance in preventing impairment to human health or presents a potential unreasonable risk of illness or injury ("reserved" criteria). Therefore, only those Class I devices that meet the reserved criteria remain subject to premarket notification requirement. (See 63 FR 5387, February 2, 1998, for a listing of Class I "reserved" devices.) Many of these reserved devices do not present hazards that require premarket notification and, thus, their retention on the list creates an unnecessary burden for manufacturers and for FDA. FDA should determine that all devices remaining on the reserved list are exempt or FDA should reclassify them. This is consistent with FDA's plan to review medical device classifications based on risk.

Exemption of In Vitro Diagnostic Devices

As part of the qualitative goal commitments of the Medical Device User Fee and Modernization Act of 2007 (MDUFMA), FDA agreed to facilitate the development of *in vitro* diagnostic (IVD) devices and improve the premarket regulatory process for IVD medical devices through consideration of low-risk Class I and Class II IVD devices for exemption from pre-market notification. Similarly, AdvaMed agreed to identify suitable exemption candidates from among test systems that still require 510(k) clearance. As part of that effort, AdvaMed developed a systematic, risk-based process and provided those criteria and candidate IVDs to FDA. FDA has acknowledged that ever-increasing numbers of premarket notifications for IVDs, which require formal review under section 510(k) of the Food, Drug and Cosmetic Act (FD&C Act), are stretching their resources and leading to longer review times, thereby delaying the availability of important diagnostic tools. Preparation of 510(k) submissions for well-established, low-risk IVD test systems divert critical resources that could otherwise be dedicated to bringing new, advanced diagnostic markers and analytical technologies to the public. To ensure effective use of resources, FDA should now review the list of low-risk IVDs provided by AdvaMed and exempt suitable IVD devices from pre-market notification. Furthermore, FDA should consider similar exemptions for other devices being reviewed by the CDRH that are suitable for exemption in order to support the overall review process and promote less burdensome regulation that supports the

public health and innovation. Again, this is consistent with FDA's plan to review medical device classifications based on risk.

ClinicalTrials.gov Proposed Rule

FDA and the National Library of Medicine (NLM) are developing a proposed rule to implement portions of Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). The statute directs FDA and NLM to determine whether to require disclosure of the full clinical trial protocol, whether to require disclosure of trials associated with unapproved/uncleared products, and whether to retroactively require trials conducted prior to the effective date of FDAAA to be entered in the databank. AdvaMed believes that current detailed disclosure requirements provide the needed information for clinicians and patients and that a requirement to disclose the full trial protocol would divulge confidential commercial information and would harm competitiveness without commensurate public health benefits. Similarly, disclosure of trial information associated with unapproved/uncleared products would divulge confidential commercial information and harm competitiveness with little public health benefit, since these products cannot be marketed. Existing regulations already require disclosure of trial results to patients that participated in the trial. AdvaMed supports (as indicated in our previous comments to the docket) disclosure of trial results for unapproved/uncleared products for the small subset of products whose trials were stopped for safety reasons. With respect to retroactive application of Title VIII requirements, it would be tremendously burdensome to require manufacturers to enter registry and results data for trials conducted prior to the effective data of FDAAA due to the time and resources required to compile the clinical trial information and revise it to fit the format required for the ClinicalTrials.gov database, with no apparent public health benefit.

Assurance Cases

In draft guidance issued in April 2010 titled *"Total Product Life Cycle: Infusion Pump – Premarket Notification [510(k)] Submissions,"* FDA is requiring all 510(k)s for infusion pumps to include assurance case reports for review. Such reports have never been used in the medical device industry. They also duplicate and require conversion of existing risk management information – required as part of the Quality System Regulation (QSR) (21 C.F.R. § 820) and pursuant to *ISO 14971 Medical devices – Application of risk management to medical devices* – into the assurance case format. Compliance with the QSR of medical devices cleared through the 510(k) pathway is typically determined through FDA's inspection process, not the FDA review process. In addition to unnecessarily requiring the conversion of existing information to the assurance case format, assurance cases can be challenging and burdensome to develop, to maintain and to reuse, and FDA has provided no guidance on acceptable assurance case approaches. Since the assurance case requirement was instituted over a year ago, only one infusion pump 510(k) has been cleared which signals the inherent challenges and difficulties associated with assurance case reports for medical devices. FDA is taking other steps to assure the safety and effectiveness of infusion pumps including an enhanced focus on pre-inspections and standards development involving key stakeholders and the additional assurance case requirement is unnecessarily burdensome.

Clinical Evaluations

FDA is requiring clinical evaluations for all new or significantly modified infusion pumps as a condition of clearance. Since legally-marketed infusion pumps are currently available, it may be very difficult to recruit patients for clinical evaluations of new ones. Moreover, clinical evaluations are not the best method for evaluating the safety problems with infusion pumps that FDA has identified. Such evaluations would create substantial, unnecessary burdens for manufacturers compared to alternative approaches. AdvaMed has recommended an alternative method to test infusion pumps that has been described as "real-use environment evaluations." Real-use environment evaluation protocols *would not* require pumps to be connected to a patient but *would* require clinicians to perform scripted tasks on the test device. Clinicians would be exposed to lighting and noise challenges, would be required to respond to audible alarms and would have scheduled and unscheduled interactions with the pump to test the user-device interface as the clinician programs complex drug regimens in the pump's intended environment (e.g., hospital). We believe this approach would meet FDA safety objectives in a less burdensome and more practical manner while facilitating expeditious patient access to safer infusion pumps.

Device Listing and UDI May Be Redundant

21 CFR § 807.25 delineates the "Information required or requested for establishment registration and device listing." Many of the data elements required by the Registration and Listing Rule (§ 807.25) are expected to be required by the Unique Device Identifier Rule, due to be published by June 30, 2011. Reporting the same information into two separate databases would be overly burdensome and unnecessary and FDA should assure that duplicative information is not required.

Malfunction Adverse Event Summary Reporting for Low-Risk Devices

Section 227 of FDAAA 2007 directed FDA to establish criteria for quarterly summary reporting of malfunction adverse event reports for Class I and Class II devices that are not permanently implantable, life-supporting, or life-sustaining. Nearly four years later FDA has yet to develop the criteria. In a March 8, 2011 Federal Register Notice on this topic, FDA advised manufacturers to continue to submit individual reports for these devices, and indicated it would, in the future, develop criteria for quarterly reporting through rulemaking. Such a process unnecessarily delays the implementation of this provision. The requirement to continue individual reporting of device malfunctions where Congress has already determined quarterly summary reporting is appropriate is unnecessary and burdensome. FDA should take immediate action to implement quarterly summary reporting for device malfunctions.

Medical Device Innovation Initiative

In February, 2011, the Center for Devices and Radiological Health released the *CDRH Innovation Initiative*.[1] We support FDA focus on fostering innovation to enhance patient

[1] These comments are intended to summarize AdvaMed's views on whether certain regulations or future regulations can be made more effective or less burdensome. It should be noted AdvaMed submitted comprehensive comments on the CDRH Innovation Initiative to Docket No. FDA-2011-N-0063.

care, and improve U.S. competitiveness but we believe several elements of the Innovation Initiative are off-track. AdvaMed has a number of recommendations to revise the elements of the proposal to make them more effective. Rather than investing limited FDA resources in developing a totally new and resource-intensive pathway for just one or two devices per year, CDRH should focus on incorporating elements of the Innovation Initiative into the existing expedited review process so that the expedited review process works as intended by Congress. For example, more devices could benefit if FDA implemented interactive review with an experienced review team, utilized external experts and utilized the resources and expertise of the Center Science Council (CSC) to make the expedited pathway work. In addition, the proposed eligibility criteria for the Innovation Pathway and for expedited review are nearly identical and as the Innovation Initiative report noted, only 23 applications have been accepted for expedited review in the 5-year period 2005 to 2010. AdvaMed recommends that the existing expedited review criteria be preserved.

AdvaMed also recommends against using limited CDRH resources to certify sites for device design/redesign and development. These sites would replicate what device manufacturers already do and the concept raises troubling conflict of interest questions. These sites would, in effect, compete with manufacturers to develop medical devices while having the full imprimatur of U.S. government support and approval. Finally, AdvaMed also questions whether it is the best use of CDRH's time and resources to develop a publicly-available core curricula – particularly given the large number of guidance documents that the Agency is committed to issuing this year and the ongoing need to update device-specific guidance. CDRH could instead restore the previous format and content of Device Advice which effectively operated as a core curricula. Unfortunately it is more difficult to find substantive and helpful content in the redesign of Device Advice on FDA's website.

510(k) Report Recommendations Referred to Institute of Medicine

When FDA issued its 510(k) and Science Report Recommendations it announced that several proposals would be referred to the Institute of Medicine for consideration. We understand FDA will seek additional public comment on any IoM proposals before deciding whether to implement any particular IoM proposal. Although it is not clear IoM will endorse any of the proposals, in the spirit of open communication, we offer the following comments on certain of the proposals referred to the IoM.[2]

Consolidation of the Terms "Indication for Use" and "Intended Use"

Consolidation of "intended use" and "indications for use" into a single term will result in many more NSE determinations and thus substantially increase the number of PMA applications. PMA applications require substantial company investment and resources and user fees associated with PMA applications are significantly higher. It is not clear there is

[2] These comments are intended to summarize AdvaMed's views on whether certain regulations or future regulations can be made more effective or less burdensome. It should be noted AdvaMed submitted comprehensive comments on FDA's 510(k) and Science Report Recommendations to Docket No. FDA-2010-N-0348.

any substantive public health benefit to consolidating the two terms but there is clear value in preserving the terms as separate concepts. "Intended use" broadly describes the use of a generic type of device (i.e., what the device does) while "indications for use" more specifically describes the device's clinical uses and patient population(s). Examples of intended use and indications for use include:

- The *intended use* of an electrosurgical cutting and coagulation device is to remove tissue and control bleeding by use of high-frequency electrical current (21 C.F.R. § 878.4400). Electrosurgical cutting and coagulation devices, however, may be specifically designed to accommodate different anatomies. They may have *indications for use* in thoracic, gynecologic, ENT, or other procedures, as illustrated by the 31 product classification codes for electrosurgical instruments.
- The *intended use* of an infusion pump is to deliver fluid to a patient in a controlled manner (21 C.F.R. § 880.5725). External infusion pumps may have any of the following *indications for use*:
    - general administration of drug solutions vs. blood vs. insulin.
    - intravenous, epidural, subcutaneous, subarachnoid, etc.
    - patient-controlled analgesia
    - hospital versus home use
- The *intended use* of a gas analyzer is to provide a means of monitoring gas concentration and to alert clinical personnel when limits fall outside of a pre-specified range (there are over 15 classification regulations for gas analyzers). The indications for use of a gas analyzer could be for an anesthetic agent, or oxygen, carbon dioxide, or nitrous oxide.

Combining the two terms may constrain the meaning of intended use, remove the flexibility that is currently afforded to the Agency in determining what new uses should be regulated within the confines of Section 510(k), and unnecessarily narrow the meaning of substantial equivalence. Indeed, combining the terms eliminates the distinction between "general" and "specific" uses that FDA has relied upon in determining whether the addition of a specific indication for use may trigger the need for additional data, including clinical data, and may necessitate the need for a PMA. FDA has recognized that the addition of a specific indication may or may not alter a device's intended use, depending on a multitude of factors. Furthermore, removing the "Indications for Use" terminology will result in confusion among patients and health care professionals who rely on the indications for use appearing in product labeling consistent with other FDA-regulated products. Consolidating the two terms could also delay patient access to new devices because of a potential increase in NSE determinations. We do not believe consolidation of the terms "intended use" and indications for use" is an effective use of FDA resources.

Expansion of Statutory Authority to Consider Off-Label Use When Determining Intended Use

FDA has indicated it should seek explicit statutory authority to allow FDA to consider possible off-label use when determining intended use. This would give FDA authority to require a company to develop and submit additional data for the potential "off-label" use in order to obtain FDA clearance or approval. This could be quite burdensome for companies

who would be required to develop data for an off-label use they never intended. Such a requirement could represent an undue hardship to a smaller company that does not have the economic means to pursue a use it did not intend. It may also result in the company's decision not to pursue commercial development of a new and potentially useful device or diagnostic, further stifling innovation. The existing statute provides a remedy for any FDA off-label concerns. CDRH has authority to require statements in the labeling including limitations within the intended use statement if there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device, and if such use could cause harm. This Congressionally-mandated path provides a more flexible path for CDRH to follow while protecting public health, and is less onerous for both the Agency and industry. Likewise, in the postmarket period, the Agency has the ability to deal with manufacturers that engage in off-label promotional activities. Specifically, 21 C.F.R. § 801.4 provides the Agency with considerable discretion in identifying off-label uses and company activities geared toward off-label promotion. When these situations arise, FDA can take many actions to stop off-label promotion and to encourage compliance with applicable requirements.

Requirement to Keep One Unit of a Device Available

FDA has proposed requiring each submitter to keep one unit of a device available for CDRH to access upon request. AdvaMed believes this is a burdensome proposal and it presents numerous practical challenges. Keeping a device available indefinitely so it can be examined when it is cited as a predicate is impractical for industry and would provide limited benefit. Providing the space necessary to ensure secure storage with appropriate environmental conditions would present a financial and logistical burden on industry, especially on small companies with limited facilities, with no commensurate benefit to public health. Indefinite retention of devices, especially IVD products, with limited shelf-lives would not provide an accurate representation of the device after the use-before date has passed. In some cases, minor changes are made to devices during their marketed life. Retaining a sample of each version of the device would add to the storage burden. AdvaMed recommends a much more limited approach that would enable CDRH to request (but not require) a submitter to provide a unit of the device only when seeing the actual device is necessary for determining substantial equivalence with the understanding that the device is used for education of the reviewer, is not appropriate for testing, and that the request does not delay the review of the submission.

Proposal to Issue Guidance to Create a Class IIb

CDRH proposed to develop guidance defining a subset of class II devices, called "class IIb" devices, for which clinical information, manufacturing information, or, potentially, additional evaluation in the postmarket setting, would typically be necessary to support a substantial equivalence determination. AdvaMed believes that the scope of the products proposed by FDA for Class IIb is too broad and that the proposed requirements, when considered in their totality, are overly and unduly burdensome for Class II devices. AdvaMed recommended instead providing enhanced transparency and predictability for a very small, focused subset of Class II devices for which CDRH would provide advanced notice that additional information beyond that normally provided in a 510(k) may be expected to support a

substantial equivalence determination. The AdvaMed proposal provided suggestions for a number of additional submission requirements that could be required for a device in the subset but it **did not** recommend that all devices in the subset be required to comply with all enhanced requirements. Nor did it suggest that all devices for which CDRH currently requires clinical information automatically become members of the subset. In contrast to the FDA proposal, the AdvaMed proposal would not create a new classification scheme for medical devices in the United States but rather the development of risk-based guidance establishing standards and clear direction for certain device types within the current Class II program. Because these appropriately identified devices will require additional resources by both industry and FDA, it is important that they are limited to a small number of higher risk devices where public safety will benefit from the extra expenditure of resources, otherwise the extra requirements will not be practically implementable and will detract from the focus on the truly higher risk devices. We believe the AdvaMed proposal represents a less burdensome approach.

Seek Authority to Require Postmarket Surveillance Studies as a Condition of Clearance
FDA proposed obtaining broader authority to require condition-of-clearance studies. AdvaMed believes such authority is unnecessary and duplicative of existing authority in Section 522 and that it could lead to a proliferation of burdensome postmarket studies that fail to enhance public health. FDA may already request postmarket studies through Section 522 postmarket surveillance orders.

Implementation of Multiple Regulations/Policies/Guidances Simultaneously
In general, FDA should evaluate the impact of developing and implementing multiple changes to existing programs at the same time. AdvaMed is concerned FDA does not have the resources to effectively implement all of the program changes it has recently proposed such as the 510(k) and Science Implementation Plan initiatives, the Innovation Initiative, and purported upcoming changes to the PMA program. The disruption caused by "changing the rules" across so many programs can be burdensome and lead to inefficiencies and errors by both agency staff and industry. It will also further slow an already unacceptably slow review process due to the diversion of resources. FDA should create and implement change in a structured manner that does not place additional burden on the existing work flow. New and modified requirements always result in a period of adjustment and implementation of several changes at the same time can simply multiply the inherent problems.

Color Additives Used in Medical Devices
The FD&C Act states that devices containing a color additive are considered unsafe, and thereby adulterated, unless a regulation is in effect listing the color additive for such use. The FD&C Act limits applicability of these provisions to color additives that directly contact the body for a significant period of time. At the present time, "significant period of time" is not defined by FDA regulation. Current CDRH policy does not consider the period of time a color additive is in contact with the body and therefore typically requires maximum test data for the use of color additive for all uses (e.g., both contact that is measured in minutes and long-term contact through an implanted device), which often consists of thousands of pages of data. Color additive petitions are filed with CDRH and processed by CFSAN. Current

FDA processes and requirements fail to clearly delineate color additive roles and responsibilities assigned to CDRH and/or CFSAN. As a result, color additive petitions languish for years. Section 706 of the Act and 21 CFR Parts 73 and 74 should be reviewed and revised to ensure the less burdensome approach to evaluating the safety of color additives used in medical devices.

Posting of Untitled Letters on FDA Website

FDA announced on May 26, 2011 that it will expand disclosure of Untitled Letters on its website by the end of 2011. AdvaMed commented previously and continues to believe that posting of this information is not an effective use of FDA resources and has little public health value. FDA issues Untitled Letters when it is unclear that a practice is violative or that it presents a public health threat. They may be issued for minor violations or where the line between what is acceptable and what is violative is unclear. Disclosing Untitled Letters effectively elevates them to the status of Warning Letters and impugns a company's products or practices where no clear violation or public health issue exists.

Searchable Inspections Database

FDA announced on May 26, 2011 that it will include a searchable inspections database that includes the names and addresses of inspected facilities, inspection dates, final inspectional classification and a summary of common inspectional observations of objectionable conditions or practices found during inspections. AdvaMed commented on this initiative previously and continues to believe it is not an effective use of FDA resources and that it will have adverse consequences on companies with little public health value. We believe foreign regulators will misunderstand the inspectional classification and will inappropriately exclude products from their market or will take inappropriate punitive action against companies and that it will be inappropriately used for litigation purposes. We also believe the lay public may misinterpret the significance of Voluntary Action Indicated (VAI) inspectional findings. AdvaMed recommends that the searchable inspectional database be limited to Warning Letter recipients only (i.e., Official Action Indicated [OAI] inspectional classifications). Such letters are already available on FDA's website. Warning Letters identify a clear regulatory threshold. This threshold does not exist for VAI or No Action Indicated (NAI) inspection classifications. Where inspections result in no objectionable conditions or the objectionable conditions do not meet the threshold of regulatory significance there is little public value in disclosing the information. Finally ensuring accurate and up-to-date maintenance of yet another website will consume FDA resources without adding commensurate public health benefits.

CMS Collaboration with the FDA

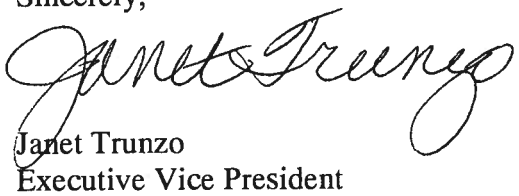
The scope and timing of collaboration between CMS and the FDA has been an ongoing area of concern for AdvaMed. The two agencies are currently considering guidance on "parallel review" of device marketing applications. AdvaMed believes very strongly that any parallel review envisioned by FDA and CMS should be triggered only at the request of the individual submitting manufacturer. Further, both agencies have separate and distinct missions. To this end, strong safeguards must be included to ensure that CMS only makes coverage determinations pursuant to its statutory mission of determining what is "reasonable and

necessary" for Medicare beneficiaries and not attempt to replicate FDA's role of determining what is "safe and effective." Conversely, safeguards should be implemented to ensure that FDA continues to determine what is safe and effective and not require that products provide outcomes evidence designed to support Medicare coverage decisions in order to receive marketing clearance or approval. One potential outcome of the proposed parallel review program is that companies would be required to conduct clinical trials that will support both FDA and CMS determinations. Designing and conducting medical device clinical trials that can support both FDA's (safety and effectiveness) and CMS' requirements (reasonable and necessary) is extremely difficult, if not impossible, and therefore, overly burdensome and should only be done at the request of the individual manufacturer.

Conclusion

Thank you for considering these comments. We hope they are helpful as you respond to the President's Executive Order and seek to achieve our mutual goal of effective and less burdensome regulatory policies that promote economic growth, innovation, competitiveness, and job creation while protecting and promoting the public health.

Sincerely,



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