701 Pennsylvania Avenue, Ste. 800
Washington, DC 20004–2654
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

AdvaMed
Advanced Medical Technology Association

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

RE: Notice on Parallel Review of Medical Products (Docket No. FDA-2010-N-0308)

Dear Sir or Madam:

We are writing on behalf of the Advanced Medical Technology Association (AdvaMed) in response to the CMS and FDA's *Federal Register* notice and request for comments on parallel review of medical products (75 Fed. Reg. 57045, Sept. 17, 2010). AdvaMed appreciates that CMS and FDA have provided the public this opportunity to offer input and feedback in response to CMS and FDA's plans in this area.

AdvaMed 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. AdvaMed members range from the largest to the smallest medical technology innovators and companies.

Below we provide the following: (1) general comments on "parallel review" and (2) answers to each of the seventeen questions posed in the *Federal Register* notice and request for information.

I. General Comments

AdvaMed agrees with and supports the stated objective articulated in the *Federal Register* notice on parallel review: Timely access to innovative medical technologies is critical for patients and the quality of the overall health care system.[1]
As strongly articulated in the notice, FDA and CMS operate under separate and distinct statutory standards with completely different regulatory mandates and processes.[2] FDA is a regulator with appropriate emphasis on public health by ensuring the safety and effectiveness

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1 FDA and CMS envision creating a "parallel review" process "to accelerate consumer access to new, particularly innovative, safe and effective medical products" and to "create incentives for venture capitalists and companies to increase their investment in innovative medical products." 75 Fed. Reg. at 57046-47.

2 *See id.* at 57045-46.

of a new medical technology, whereas CMS is a third party payer of health care services for Medicare beneficiaries. FDA makes decisions about medical technologies that directly affect *all* patients in the United States. By contrast, CMS decisions directly affect only Medicare and Medicaid patients. CMS reviews items and services in the following circumstances: if Medicare coverage determinations need to be made, if new or revised procedure codes need to be assigned under certain payment systems, and if payment rates need to be set or adjusted. AdvaMed has been a longstanding supporter of the separate and distinct missions of FDA and CMS, and has consistently supported improvements to processes at each agency.

To the extent that a FDA-CMS "parallel review" process is considered, the critical questions are: what is parallel review, how would it work, and under what constraints must it operate? There are two key principles that AdvaMed espouses as these critical questions are addressed: (1) parallel review should only be triggered at the request and consent of the submitting manufacturer; and (2) parallel review should allow manufacturers to request, and CMS to consider, Medicare program changes relating to national or local coverage, coding, and payment.

First, AdvaMed supports the concept articulated in the *Federal Register* notice that FDA-CMS "parallel review" would only be triggered "*at the request of the manufacturer* and with the agreement of both agencies, thus making the process *voluntary for all parties involved.*"[3] If FDA and CMS create a parallel review process, it must be purely voluntary in nature and only at the initiation of the submitting manufacturer. Particularly when inter-agency collaboration involves the transfer of confidential and proprietary company information and data between FDA and CMS, that collaboration should occur only at the request and permission of the submitting manufacturer. AdvaMed would not support a parallel review scheme that could be initiated by any party other than the submitting manufacturer.

The manner in which FDA and CMS handle confidential company information and data is specifically prescribed by law and regulation. Both FDA and CMS must strictly preserve the confidentiality of all company trade secrets and other proprietary information and data that are provided by submitting manufacturers, as well as the existence of the premarket application.[4]

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3 *Id.* at 57047 (emphasis added).

4 *See* Federal Food, Drug & Cosmetic Act (FDCA) § 301j (21 U.S.C. § 331j) stating: "[t]he use by any person . . . or revealing, other than to the Secretary or officers or employees of the Department . . .any information acquired . . . concerning any method or process which as a trade secret is entitled to protection . . . is prohibited;" Freedom of Information Act (5 U.S.C. § 552b) stating that the public disclosure of information does not apply to "trade secrets and commercial or financial information obtained from a person [that is] privileged and confidential;" 18 U.S.C. § 1905 regarding the penalties for public disclosure of confidential information generally; 21 C.F.R. § 20.61, which defines trade secrets and privileged and confidential commercial or financial information, and states "data and information submitted or divulged to the Food and Drug Administration which fall within the definitions of a trade secret or confidential commercial or financial information are not available for public disclosure;" 21 C.F.R. § 20.85 regarding disclosure to other Federal government departments and agencies, stating that "trade secrets and confidential commercial or financial information prohibited from disclosure by . . . may be released only as provided by those sections. Any disclosure under this section shall be pursuant to a written agreement that the record shall not be further disclosed by the other department or

Additionally, Congress has reemphasized the importance of confidentiality in all premarket states of medical device development. In the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Congress provided an exception for public disclosure of clinical trial information on "Clinicaltrials.gov" until after, and if, the device or diagnostic is cleared or approved for marketing.[5]

AdvaMed cannot emphasize too strongly the importance of protecting trade secret, confidential commercial information (and other proprietary information). Release of such information before a product is on the market could undermine intellectual property rights, creating competitive harm and disadvantaging originator companies – especially small companies – relative to their competitors. Release of this information also could benefit foreign competitors, providing them with heretofore unavailable intellectual property and commercially sensitive information. Most importantly, disclosure would reduce the attractiveness of financially risky investments in novel, breakthrough products; ultimately harming the public health by limiting the development of new treatments and diagnostics. Thus, both as a matter of law and policy, it is critical to maintain the confidentiality of proprietary information to protect and preserve intellectual property rights and to promote innovation.

A manufacturer may currently choose to request that FDA and CMS communicate early in the process (e.g., to discuss clinical trial design) and during pre-market review. This type of collaboration at the request of the manufacturer should continue to be available and be publicized more widely. In fact, early FDA-CMS collaboration at the request and consent of the submitting manufacturer may be all that is necessary to constitute "parallel review." Notwithstanding, creation of any parallel review process should not end the submitting manufacturer's ability to request and facilitate early collaboration between FDA and CMS.

Second, if a parallel review process is created, manufacturers should be allowed to request specific Medicare program change relating to local or national coverage, coding and payment, and not be limited to the National Coverage Determination (NCD) process or any NCD-related review. Moreover, the NCD process or NCD-related review should not take place unless it has been specifically requested by the manufacturer. The *Federal Register* notice exclusively emphasizes CMS coverage determination reviews with a strong focus on *national* coverage,[6] but it is important to note that, in general, Medicare's local coverage process is the most appropriate avenue to determine coverage for advances in medical technology. The local coverage process is prompt and allows for appropriate considerations

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agency except with the written permission of the Food and Drug Administration;" and 21 C.F.R. §§ 812.38(a), 812.38(b)(3), and 814.9(c), which state that the existence of an IDE or PMA, or data contained in the PMA, which have not been publicly disclosed, cannot be disclosed by FDA.

5 *See* FDAAA Section 801(j)(2)(D)(ii)I) (42 U.S.C. §282) stating: "[t]he Director of NIH shall ensure that clinical trial information for an applicable device clinical trial submitted in accordance with this paragraph is posted publicly in the registry data bank—''(I) not earlier than the date of clearance under section 510(k) of the Federal Food, Drug, and Cosmetic Act, or approval under section 515 or 520(m) of such Act, as applicable, for a device that was not previously cleared or approved, and not later than 30 days after such date."

6 *See* 75 Fed. Reg. at 57047.

related to patient access and quality of care. AdvaMed is concerned that subjecting new medical technology to the national coverage process (either during pre-market review or immediately following clearance or approval) could delay patient access to important advances and have an overall negative impact on innovation. Automatic linkage to a national coverage determination, before or after FDA clearance or approval, is likely to deter the vast majority of manufacturers from seeking parallel review altogether.

Instead, any parallel review process should allow manufacturers to obtain coverage through Medicare's local coverage process. The Medicare local coverage process works well and is geared to meet the goals articulated in the *Federal Register* notice, specifically to ensure timely patient access to innovative medical technologies and to protect and enhance the quality of the overall health care system. At the request and consent of the manufacturer, parallel review could be used as a tool to better inform Medicare contractors and CMS alike about the evidence supporting a given product as it comes to market.

In addition, consistent with the notice's objective to accelerate access to innovative medical products, we urge CMS to also consider (in addition to coverage decisions) the time lag after FDA clearance or approval that is required to obtain new procedure codes and appropriate payment rates for new therapies and diagnostic tests. For example, we urge CMS to update the coding systems under its control (e.g., HCPCS and ICD-9-CM) more often than annually. Also, we encourage greater flexibility within the payment systems to ensure sufficient payments for those innovations that are more costly than predecessor technologies. We would be happy to work with CMS on specific options in this regard.

AdvaMed appreciates this opportunity for public comment. AdvaMed has consistently supported timeliness at both FDA and CMS, and support for patient-centered policies and processes that take into consideration the unique needs of individual patients to ensure access to tailored, appropriate care. AdvaMed looks forward to continuing to work with FDA and CMS to support timely patient access to safe and effective medical technologies.

II. Specific Responses to Questions Posed

In addition to the general comments provided above, AdvaMed provides the following specific responses to the seventeen questions posed in the *Federal register* notice.

1. Should anyone other than the product sponsor be able to initiate a request for parallel review (for example, the FDA, CMS, an interested third party)?

AdvaMed believes that any FDA-CMS parallel review process should be strictly voluntary (i.e., at the request and consent of the submitting manufacturer), and that any inter-agency collaboration involving the transfer of confidential company information and data between FDA and CMS should occur only at the request and permission of the submitting manufacturer. As stated above, AdvaMed would not support such a process other than at the initiation of the submitting manufacturer. Someone other than the product sponsor cannot have access to that product sponsor's confidential proprietary information and therefore cannot compel the sharing of that information.[7] Furthermore, a third party's request for

[7] *See* FDCA § 301j.

parallel review would not be consistent with the Memorandum of Understanding (MOU) between FDA and CMS and existing legal requirements protecting proprietary information.[8]

AdvaMed is concerned that allowing a party other than the submitting manufacturer to initiate a parallel review could contribute to delays in FDA's review of a manufacturer's premarket application. Third parties may request parallel review in an effort to limit access to, or coverage of, the technology, or simply to complicate and slow down the regulatory process. Such third parties may also be interested in obtaining confidential, proprietary company data or information and should be prohibited from doing so pursuant to existing law and regulation.

Submitting manufacturers currently have the ability to voluntarily initiate collaboration between FDA and CMS. At the request and consent of the submitting manufacturer, FDA and CMS currently can communicate with submitting manufacturers early in the process (e.g., to discuss clinical trial design) and during premarket review. This type of collaboration should continue to be available at the request and consent of the submitting manufacturer and should be publicized more widely.

2. ***For which classes of products would consumers, payers, or sponsors benefit most from parallel review? Why?***

AdvaMed has no specific recommendations regarding product *classes* that might benefit most from a parallel review process, but believes that, in general, patients would benefit most from processes that would speed access to critical, often life-saving medical technologies. Should a manufacturer choose to initiate a parallel review process, it should be flexible enough to encompass facilitating local or national coverage, and result in more timely coding and payment determinations by CMS. A voluntary FDA-CMS parallel review program that enables expedited consideration of coverage for products that currently have national non-coverage or very limited national coverage determinations also would benefit affected patients if CMS expanded coverage, enabling patient access to beneficial uses of new technology.

3. ***FDA and CMS may propose to limit the number of products concurrently under parallel review. How should limits be placed on the number and/or type of products concurrently under parallel review?***

Recommendations on priorities and limits concerning the number of products undergoing parallel review cannot be advanced before understanding how a proposed parallel review process would work and what the demand might be among medical technology developers for requesting a parallel review. If national coverage is the focus of parallel review, one potential approach would be for FDA and CMS to prioritize those products or related services about which CMS has national non-coverage decisions. After these, products can be

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[8] Memorandum of Understanding between the U.S. Food and Drug Administration and the Centers for Medicare and Medicaid Services. MOU 225-10-0010. June 2010. Available at: http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm217585.htm.

prioritized based on their severity of disease state and the potential benefit to the unique needs of the Medicare population.

- ***Should CMS be permitted to review indications for which the sponsor is not seeking FDA clearance or approval under parallel review?***

To ensure that Medicare beneficiaries have access to appropriate treatments for their unique individual needs, and to protect the physician-patient relationship and independent medical decision-making, AdvaMed recommends that CMS remain silent or neutral in relation to physician-directed uses to allow local contractor flexibility. The local coverage process is well equipped to make case-by-case decisions about such uses.

4. ***Are there disadvantages to parallel review?***

The relative advantages and disadvantages of parallel review would depend on what constitutes parallel review, how it would work, and under what constraints it would operate. Without further detail, it is difficult to speculate as to specific disadvantages.

Notwithstanding, AdvaMed is concerned that creating a parallel review process may result in CMS influencing or providing input into FDA's review of products, determinations of safety and efficacy, or orders. Pursuant to section 903(d)(2) of the Food Drug and Cosmetic Act (FDCA), the United States Secretary of Health and Human Services is responsible – *through the Commissioner of FDA* – to execute the FDCA. Execution of the FDCA includes the review of and decisions regarding products regulated by FDA. Specific actions under the FDCA – such as determinations of substantial equivalence – may not be delegated. *See, e.g.*, FDCA § 513(i)(E)(iii) (stating that the responsibilities of the director of the Center for Devices and Radiological Health cannot be delegated). The functions of FDA review and decision-making rest with the FDA alone. Moreover, FDA, not CMS, has the expertise necessary to execute the FDCA. If CMS influences or provides input into FDA's pre-market review, this would be a violation of law.

In addition, as stated above, AdvaMed is concerned that if parallel review is tied to national coverage determinations, it may lead to denial of patient access to beneficial, often life-saving, medical interventions. This would be contrary to the stated objective articulated in the *Federal Register* notice[9] of timely access to innovative medical technologies, which is critical for Medicare patients and the quality of the overall health care system. As we state above, if implemented, a parallel review process should allow manufacturers to obtain coverage through Medicare's local coverage process. The Medicare local coverage process works well for patients and is geared to meet the goals articulated in the *Federal Register* notice, specifically to ensure timely patient access to innovative medical technologies and to protect and enhance the quality of the overall health care system.

5. ***Are there any barriers (for example, regulatory, legal, scientific) to parallel review and if so, how might they be overcome?***

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9 75 *Fed. Reg.* 57045, September 17, 2010.

If a manufacturer requests and consents to parallel review involving an NCD, one issue is that the NCD process is required by statute to be a public process, whereas the FDA premarket review process protects knowledge of the existence of the application, as well as trade secrets and other proprietary information contained in the premarket application. The protection of trade secrets, confidential commercial information, and proprietary information is mandated by statute and regulation,[10] and would likely be difficult to overcome without statutory change or sacrificing essential protections that facilitate the iterative development of critical, often life-saving medical technology.

In addition, as mentioned above in response to question number 4, CMS cannot influence or provide input into FDA's pre-market review without violating the Food, Drug and Cosmetic Act. If FDA and CMS pursue creation of a parallel review process or other FDA-CMS collaboration initiative, the agencies must address this issue with great care so as not to have either agency influence the clear statutory mandates of the other. Addressing these legal requirements would be critical to ensuring the viability of any inter-agency collaboration.

6. ***Should a voluntary process be put in place to encourage the conduct of clinical trials that are appropriately designed to support both FDA approval/clearance and CMS national coverage decisions? If so, what process should be established?***

As previously mentioned, CMS and FDA can communicate now at the request and consent of the submitting manufacturer to discuss mutually supportive clinical trial designs. AdvaMed reiterates that this early collaboration opportunity should be more widely publicized. Early collaboration at the request of the submitting manufacturer should continue to be available regardless of any decision by FDA and CMS to create a parallel review process. The opportunity for formal collaboration should be allowed pursuant to the request and consent of the submitting manufacturer.

7. ***What criteria should the FDA and CMS use to decide whether to grant a request for parallel review?***

Please see AdvaMed's response to question 3.

8. ***At what point during FDA premarket review for prescription drugs, biologics, and medical devices, should parallel review begin in order to reduce the time between FDA marketing approval or clearance decisions and CMS national coverage decisions while avoiding the risk that CMS would initiate an NCD for a product whose premarket application the FDA subsequently does not approve or clear?***

As stated in the response to question 5, CMS's NCD process is required by statute to be a public process (with specific requirements for notice and open public comment), whereas the FDA premarket review process protects knowledge of the existence of the application, as

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[10] *See*, FDCA *supra* Note 4.

well as trade secrets and other proprietary information contained in the premarket application. The protection of trade secrets, confidential commercial information, and proprietary information is mandated by statute and regulation,[11] and would likely be difficult to overcome without statutory change or sacrificing essential protections that facilitate the iterative development of critical, often life-saving medical technology.

As we state above, early communication between FDA and CMS at the request and consent of the submitting manufacturer may be valuable to all parties. If a parallel review process is created, it should be an initiative that is broader in scope than the national coverage process, allowing manufacturers to request specific Medicare program change relating to local or national coverage, coding, and payment. If the agencies move forward with a parallel review process, it should not be specifically limited to the NCD process or any NCD-related review, and the NCD process or NCD-related review should not take place unless it has been specifically requested by the manufacturer.

9. ***How should parallel review be implemented? Should the agencies use means in addition to a guidance document, such as designating agency liaisons, to educate sponsors about parallel review?***

AdvaMed supports the designation of agency liaisons as informational resources for manufacturers interested in initiating early collaboration between FDA and CMS.

10. ***When, if at all, should the agencies offer joint meetings to interested sponsors during parallel review? Before parallel review begins? Before a premarket application is submitted to the FDA?***

AdvaMed supports the concept of early consultation with FDA and CMS at the request of the submitting manufacturer. A joint meeting could occur as early as during the "pre-IDE" meeting phase, but the actual timing and frequency of any joint meetings or consultation should be left to the discretion of the submitting manufacturer.

11. ***Should FDA and CMS have access to the same data and information about the product during parallel review? (Note: Both agencies will protect the confidentiality of proprietary information used in the parallel review process, as they currently do under their respective approval/clearance and coverage processes.)***

AdvaMed supports the sharing of data and information between the two agencies only *at the request of the submitting manufacturer and in compliance with all relevant statutes and regulations pertaining to protection of trade secret, confidential commercial information and proprietary information* (see supra note 1). Additionally, Congress reemphasized the importance of confidentiality in all premarket states of device development. In the Food and Drug Administration Amendments Act of 2007 ("FDAAA"), Congress provided an

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[11] *See* FDCA *supra* Note 4.

exception for public disclosure of clinical trial information on "ClinicalTrials.gov" until after, and if, the device or diagnostic is cleared or approved for marketing.[12]

AdvaMed cannot emphasize too strongly the importance of protecting trade secret, confidential commercial information, and other proprietary information. Release of such information before a product is on the market could undermine intellectual property rights, creating competitive harm and disadvantaging originator companies – especially small companies – relative to their competitors. Release of this information also could benefit foreign competitors, providing them with heretofore unavailable intellectual property and commercially sensitive information. Most importantly, disclosure would reduce the attractiveness of financially risky investments in novel, breakthrough products; ultimately harming the public health by limiting the development of new treatments and diagnostics.

While the FDA has regulations and procedures in place related to limitations on release of confidential commercial information, less is known regarding CMS's procedures in this regard. Particularly as it relates to information that FDA has shared with CMS, it would be helpful to better understand the procedures CMS will use to protect from disclosure confidential commercial information, and whether there may be a time limit that may apply to this protection. AdvaMed recommends that CMS provide more details about its procedures for protecting confidential commercial information.

Provided that there is a request from the submitting manufacturer to have confidential and proprietary information and data shared between FDA and CMS, the extent of the specific information and data shared should be prescribed by the submitting manufacturer. Thus, CMS should not have access to the same data the FDA possesses unless the submitting manufacturer specifically consents to sharing of these data.

As stated above, CMS cannot influence or provide input into FDA's pre-market review without violating the FDCA. If the agencies move forward with a parallel review process or initiate FDA-CMS collaboration activity, they must handle this issue with great care so as not to have either agency influence the clear statutory mandates of the other. Addressing these legal requirements would be critical to ensuring the viability of any inter-agency collaboration.

12. ***It is CMS' policy to inform the public when it begins an NCD process for a particular product. However, under applicable statutes and FDA's regulations, the existence of a premarket application is considered confidential commercial information prior to approval or clearance unless the sponsor has publicly acknowledged the application. With the consent of the sponsor, should CMS make public that it has begun the NCD process, as part of parallel review, for a product still undergoing FDA premarket review? As a condition of the agencies' agreement to initiate parallel review, should a sponsor have to inform the public, or consent to the agencies informing the public, that the product will be evaluated under parallel review? If the sponsor declines to consent to disclosure, should it be permitted to request parallel review anyway, which***

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12 *See supra* Note 5.

would prevent CMS from disclosing the NCD process until after the product is approved by the FDA? How can the transparency of CMS' NCD process be reconciled with the need to retain confidentiality of certain commercial information?

Pursuant to both law and regulation, confidentiality concerning the existence of premarket applications at FDA, as well as the protected data and information contained in such applications, must be strictly maintained unless the sponsor chooses to make the information public.[13] As noted above, publicly exposing the existence of premarket applications can present a competitive disadvantage to the manufacturer if others are aware of the existence of their marketing application and details concerning the product under review.

AdvaMed supports the option of early consultation with the two agencies and the sharing of information between the agencies at the submitting manufacturer's request. As noted above, AdvaMed strongly recommends that FDA and CMS clarify and publicize the currently available early consultation process, which is not a decisional process, and is separate from the parallel review process contemplated in the September *Federal Register* notice.

13. ***At present, sponsors whose medical products will undergo both FDA premarket review and CMS national coverage review submit separate application packages to FDA and CMS that, in part, contain the same data, and, in part, contain different data. Keeping in mind the limited resources available to the agencies, what steps can the agencies take to minimize duplication of data submissions? Would the use of electronic submissions reduce submission burdens and facilitate data transfers? Are there other steps the agencies can take to streamline a parallel review process without modifying the regulatory standards and evidentiary requirements of both agencies? Would the transparency of CMS' NCD process subject the FDA to additional public pressure regarding marketing authorization?***

AdvaMed believes that the information and data to be provided to each agency must be determined at the submitting manufacturer's request, consent, and discretion on a case-by-case basis.

Electronic submissions for the applications to each agency may be considered, but this should not be a consideration for parallel review. Generally speaking, however, the device description, performance data, and labeling from the FDA application may be made available with the submitting manufacturer's consent and appropriate protection of confidential information.

14. ***Should the agencies convene a joint advisory committee to consider common issues needing public discussion and advice during the parallel review process?***

AdvaMed is concerned that convening joint advisory committee meetings would lead to blurring of the purpose of such meetings, and may lead to intermingling of the statutory

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13 *See supra* Note 4.

mandates of each agency. FDA and CMS have separate and distinct statutorily delegated duties that cannot be either blurred between the two, or shared. As stated in the response to question 4 above, FDA and CMS must proceed cautiously to preserve these separate duties and mandates and to ensure that each agency does not influence or provide input into the functions and decisions of the other.

As stated above, submitting manufacturers currently have the ability to voluntarily initiate collaboration between FDA and CMS. At the request and consent of the submitting manufacturer, FDA and CMS currently can communicate with submitting manufacturers early in the process (e.g., to discuss clinical trial design) and during premarket review. This type of collaboration should continue to be available at the request and consent of the submitting manufacturer and should be publicized more widely.

15. ***What other concerns or considerations should the agencies take into account when developing a process for parallel review?***

Please see AdvaMed's general comments above.

16. ***Once FDA and CMS have opened a parallel review should a sponsor be able to terminate or withdraw the request for parallel review? If this happens, should that information be made public?***

AdvaMed believes that a manufacturer should be able to terminate or withdraw its request for parallel review at any time. This information should not be made public.

17. ***Sponsors who submit a PMA or 510(k) to the FDA generally must pay a user fee. One key advantage of parallel review is to streamline the current process by allowing engagement by a sponsor with both FDA and CMS concurrently. Earlier engagement could shorten the time between FDA approval or clearance of the PMA or 510(k) and a coverage decision from CMS. Parallel review could, however, entail additional costs for the agencies (for example, if the product ultimately does not receive FDA approval or clearance). Changes to a user fee would also require legislative changes. Given these factors, should the current Medical Device User Fee be restructured to support the FDA and CMS costs of this parallel review and if so, how?***

AdvaMed does not believe that additional user fees should be created or restructured to support parallel review. If the agencies move forward to create a parallel review process, it should be supported through the regular appropriations provided by Congress to CMS and FDA. FDA already receives Medical Device User fees to supplement congressional appropriations, and the user fees need not be restructured to accommodate a parallel review process.

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AdvaMed appreciates this opportunity to offer input and feedback in response to CMS and FDA's plans relating to parallel review. If FDA and CMS decide to move forward to create a parallel review process, AdvaMed recommends strongly that there be a public comment period of at least sixty days on the details of such a process. AdvaMed has consistently supported timeliness at both FDA and CMS, and support for patient-centered policies and processes that take into consideration the unique needs of individual patients to ensure access to tailored, appropriate care. AdvaMed looks forward to continuing to work with FDA and CMS to support timely patient access to safe and effective medical technologies.

If you have any questions, please contact Sharon Segal (ssegal@advamed.org or 202/434-7243) or Teresa Lee (tlee@advamed.org or 202/434-7219).

Sincerely,

Janet Trunzo
Executive Vice President
Technology and Regulatory Affairs

Ann-Marie Lynch
Executive Vice President
Payment and Healthcare Delivery Policy