Parallel Review From Two Perspectives

The Advantages of Parallel Review:“We Have Nothing to Fear but Fear Itself”

Parallel Review: Not for Everyone, Useful for Some, and Additional Considerations for Improvement
The Advantages of Parallel Review: “We Have Nothing to Fear but Fear Itself”

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Parallel review of medical products—a joint U.S. Food and Drug Administration (FDA) and Centers for Medicare & Medicaid Services (CMS) initiative. Is this a step forward for new technologies, or is it simply another tedious pathway through the complex process of obtaining FDA approval and then passing the obstacles of Medicare payment and coverage policy? It certainly is not a novel concept; for years, the United States has been criticized for lagging behind the United Kingdom in getting drugs and devices out on the market\(^1\)—a trend that may be attributable to the fact that the United Kingdom currently allows for a type of parallel review. While the Committee on Safety of Medicines (CSM) evaluates whether or not a treatment should be granted a license based on its safety and effectiveness, manufacturers who opt for “fast track” review can have the National Institute for Health and Clinical Excellence (NICE) evaluate data on the treatment from the cost effectiveness standpoint at the same time. This allows NICE to release coverage guidance soon after CSM issues a license.\(^2\)

Following the joint agency announcement in September 2010,\(^3\) there has been a great deal of speculation as to how FDA-CMS parallel review might take place; as of this


moment, no company has stepped forward and volunteered. In fact, there seems to be
a general consensus that dealing with the agencies simultaneously is fraught with the
possibilities of prolonged approvals and slow, limited National Coverage Decisions
(NCDs). The as yet unanswered question is “how can a product sponsor use parallel
review to its advantage?” In an examination of how a parallel review will likely be
treated, this article will consider how the interaction of the agencies might be structured
to prevent delays and achieve market entrance with an assured Medicare coverage
policy.

**Background**

The developer of a new medical product—whether it is a drug, biologic, medical device,
or diagnostic—is likely required to deal with two different federal agencies and usually in
a serial manner. First, to gain access to the marketplace, a company must submit its
application for safety and effectiveness to FDA. After FDA approval or clearance is
obtained, the company must then ensure appropriate coverage, coding, and payment.
In some cases, if the product or service does not meet Medicare’s statutory benefit
categories, or there is question as to the product’s medical necessity, access could be
slowed or limited to non-Medicare insurers.

Under current practice, CMS does not routinely undertake an NCD unless it accepts a
formal internal, local Medicare contractor, or other stakeholder request for review.
However, in most cases, coverage is determined at the local level without significant
policy intervention. In certain limited cases, where the statutory benefit category is
unclear, such a parallel review may be beneficial to improve the timeline to patient
access. In a recent example, for a product with questionable Medicare coverage upon
launch, it took over a year post-FDA approval before Medicare clarified coverage
through an NCD. Commercial payers often delay coverage decisions pending a
Medicare decision in these circumstances. Such a parallel review could have expedited
the coverage, coding, and ultimately payment timelines. The agencies envision parallel
review as a collaborative effort in which CMS will begin its NCD-related review process
to determine whether the product is reasonable and necessary for the Medicare population while FDA is completing its premarket review. FDA and CMS solicited public comment on this review process.\(^4\)

A memorandum of understanding (MOU) was formed and published between the two agencies, signed and effective June 25, 2010—for five years.\(^5\) The purpose of the MOU, according to the agencies, is “to promote collaboration and enhance knowledge and efficiency by providing for the sharing of information and expertise between the Federal partners” (i.e., data sharing).\(^6\) On October 6, 2011, the agencies announced a two-year pilot demonstration project inviting medical device companies to voluntarily submit applications for parallel review. Two to five submissions will be accepted per year. FDA and CMS hope to use lessons learned from the pilot project to refine the process and eventually expand parallel review to drugs and biologics.\(^7\)

\(^4\) Id.


\(^6\) Id.

CMS- FDA Joint Agency Announcement

FDA and CMS share a common interest in improving the health of patients through the availability of safe, effective, and affordable medicines and medical products and fostering product innovations.

The mission of the FDA is to protect and promote the public health. It accomplishes this task, in part, by the following:

- Assuring the safety, efficacy, and quality of human drugs, biological products, and medical devices;
- Fostering innovations to make medical products safer and more effective; and
- Helping healthcare providers and the public get the accurate, science-based information they need to use medical products to improve public health.\(^8\)

The mission of CMS is to ensure effective, up-to-date Medicare coverage and to promote the continual improvement of the quality care for its beneficiaries. CMS accomplishes this mission by continuing to transform and modernize America's healthcare system, in part, by the following:

- Fostering accurate and predictable payments;
- Ensuring high-value healthcare; and
- Promoting understanding of CMS programs among beneficiaries, the healthcare community, and the public.\(^9\)

Advantages of Parallel Review

The often expressed fear is that parallel review will change the way FDA conducts reviews, resulting in comparative effectiveness trials. There may be some justification to this fear, as the Center for Devices and Radiologic Health has begun to lean in this direction on its own initiative. However, what seems more likely is that there will be some interchange between FDA and CMS about the protocol under review. CMS expresses the need for health outcomes, while the FDA generally prefers quantifiable data, which are often surrogate endpoints that may predict health outcomes. Protocols

\(^8\) 75 Fed. Reg. at 57045.
\(^9\) Id.
might develop that will have elements of both. While this might make the trial design appear somewhat more complex, the benefits appear worthwhile in certain cases.

**Trial Design and Funding**

Rather than guess about what kind of data CMS will require, the sponsor of the trial will have the assurance that CMS will not object to the nature of the trial. Not only will there be a level of comfort about the trial design, but a CMS staff person will be in a position to support the trial design.

Additionally, CMS usually takes the position that trials, which are not published and peer-reviewed, are not generally acceptable. Since the trial and data will be analyzed and reviewed by the FDA and CMS in concert, the need to fund additional studies and wait until they are accepted, reviewed, and published will be eliminated.

**Clarifying Agency Interaction**

FDA’s approval process is well defined as an interaction between manufacturer and agency. In contrast, when dealing with CMS, it is never quite clear how the parties relate to each other, particularly as it is generally not the manufacturer who submits claims to the Medicare program. This is partly due to the multifaceted issues of coding, coverage, and payment that must be dealt with at CMS, but it is also due to the lack of a clearly defined relationship in the agency’s statute. At FDA, there is a well-defined system which includes an ombudsman to mediate difficult issues between the manufacturer and agency. No such position is existent at CMS. The value of an ombudsman at FDA is significant in mediating disputes that can hold up a final decision by the agency. Given the limited staff at CMS, it is most likely that one individual from that agency will be responsible to interact with FDA. This person will be very involved with the protocol and have significant ownership of the clinical trial. It is more likely than not that this will result in CMS also having an “ombudsman.”
Voluntary Process

The most significant advantage of parallel review stems from the volunteer nature of the process. Both agencies continue to review public comments collected last year, and will use this information to develop the parallel review system. The fact that FDA and CMS continue to review these comments and have not yet issued regulations implies that the agencies are trying to ensure that volunteer participants not be subjected to a prejudicial process. Once the agencies do their part, the value of parallel review will only be appreciated by industry when a few brave and enlightened companies use the process and end up with favorable end results. Should the contrary occur, the role of parallel review will be doomed. It is probable that with the amount of scrutiny that has been placed on this program, viable early adopters will likely receive support from the agencies to ensure that successful outcomes are achieved.

Clarification of Code Issuance Process

The issuance of procedure, diagnostic, equipment, and supply codes is controlled by CMS. Often, the code application procedures can become an obstacle to market entry. Physician services provided in clinics and offices, as well as supplies, require codes governed by the American Medical Association Current Procedural Terminology (CPT) Editorial Panel. The CPT Panel takes time to evaluate FDA decisions as well as its own level of evidence criteria before granting codes—further extending a product's time to market. In addition, the type of codes granted (i.e., Category III codes) can cause problems for CMS coverage and reimbursement down the road. Category III codes are often referred to as “experimental” by payers when in reality they are intended to be tracking codes for new and emerging technologies. Because parallel review will require the same level of information for both agencies at the outset, this roadblock theoretically can be avoided. Parallel review by the agencies would also save time on this months-to-year-long process, providing the committee with the data it needs at the outset of its deliberations.
As a corollary to the coding and coverage process, CMS and its contractors want to see a product’s utilization before it will be covered and valued, in particular for Category III codes. The “chicken and egg” problem is a common one when dealing with CMS. How widely utilized is the product? It is likely low because it has no reimbursement. If utilization is low, MACs reason that they should not reimburse for the product and that it should not provide a value to the Category III code. With parallel review, the CMS decision should accompany FDA approval, giving MACs additional guidance on their coverage decisions regardless of local utilization.

**Market Success and Pricing**

Parallel review could affect market success and pricing. CMS establishment of payment rules is both complex and frequently protracted based on the need for cost data. This information is often obtainable during clinical trials if the proper protocol elements are included. Coordination of this function through parallel review could speed the process of successful marketing and overcome many early product pricing obstacles.

**Improved Payment for New Technologies**

CMS has numerous payment policies that may apply to new products. For example, a new product used in hospital outpatient settings may be eligible for a “new technology-add on” payment. Many other special payments can be made, and the early involvement of CMS during the FDA approval process could lead to earlier access to such incentive payments.

**Predictable and Stable Coverage Environment**

Finally, and most importantly, in our current economic state, parallel review can lead to a coverage environment that is predictable and stable. Does this mean an NCD? Yes, it probably does. But if it can be obtained without the additional year of delay, it is an advantage. An NCD that spells out positive a coverage position is uniform and manageable. It is often feared that an NCD will produce limited product coverage and
not be amenable to new, or in the case of drugs or biologics, compendia covered or non-covered uses, which will be “non-covered.” However, a company does not have to halt a pending NCD and delay its coverage and reimbursement timeline if it turns out that the FDA comes out with new data that may benefit the company in the NCD process. This information will be proactively shared between the agencies, reducing not only the lag time, but also the burden on the corporation to act as the liaison between the agencies, assuming the joint process allows for this seamless communication. In many cases, CMS leaves coverage decisions to the local Medicare contractors. Depending on the expected coverage scenarios, this can be disadvantageous to companies, as it can result in inconsistent coverage decisions.

**Concerns With Parallel Review**

It may seem that a determination of safety and effectiveness is sufficient to obtain coverage, but it is not. CMS’ determination of whether or not items are reasonable and necessary goes beyond the requirement that the product have FDA approval. The evidence must support the finding that there is an “overall health benefit” in order to procure coverage. This often requires evidence that is quite different from FDA. The FDA is often most concerned with measurable endpoints; when these parameters are used, they bear directly on the claimed effectiveness. On the other hand, CMS wants to see outcome-based measures that directly represent health status. FDA frequently avoids outcome assessments in favor of quantifiable measures of the drug’s or device’s effects. The difference in focus of the two agencies is by no means inevitable. The goal of parallel review is to engage in discussions that will resolve these issues early in the product life cycle. If this is successful, there is the potential that trials undertaken for FDA review can also be the basis for CMS evaluation.

The first problem to overcome is not with the agencies, but rather, it is with most companies’ organization and structure. Most companies have distinct teams to communicate with each agency: a regulatory affairs team whose role it is to act as a liaison to the FDA, and a policy/reimbursement staff or business unit whose role is to
manage reimbursement matters, serving as a liaison to CMS. The organizational separation of these functions leads to a lack of coordination, which can prove detrimental in certain circumstances where inline or pipeline products demand a collaborative representation on a parallel path.

For example, a drug or device may receive FDA approval at the beginning of a year; however, CMS review may not begin until months later. In a company where there is no synergy between the regulatory affairs and reimbursement teams, FDA approval may be interpreted as the “green light” that gives the public open access to the drug or device. This may be the case for some, but for those companies that have a high-cost product; FDA approval should be taken as a “yellow light.” Without the subsequent CMS review and decision, the hands of healthcare entities and providers are tied because they cannot risk paying out-of-pocket for a new product—no matter how effective it may be—if they cannot guarantee that they will be reimbursed. Parallel review will encourage teams within a company to work simultaneously to gather data to meet the end goal of both FDA approval and CMS coverage, working to avoid access problems that may result when FDA approval is granted long before a CMS decision is issued clarifying coverage and coding.

There are several types of issues that are best identified and dealt with early and in concert by both staffs: when the product has limited clinical utility; when trial design or evidence is not high on the evidentiary hierarchy accepted by CMS or private payors; or when it is difficult to determine whether the product fits in a defined benefit category.

**Conclusion**

For all of the aforementioned reasons, it is very reasonable to believe that parallel review could be a worthwhile venture, particularly for those products/services with expected unclear Medicare coverage. Both federal agencies are ready to work together to combine their efforts and staff expertise to create efficiency on their end. This
process offers the opportunity to reduce time to beneficiary access, consistent national Medicare coverage (often a marker for commercial and Medicaid payers), and more fair pricing for new services based on experience in clinical trial data. However, it should be repeated that manufacturer participation in parallel review will be voluntary. Many companies appear hesitant to step forward as one of the first to undergo parallel review. For years, these same companies have placed the blame on the slow approval process on the agencies. How long will it take them to realize that it may now be their own fears that are keeping beneficiaries from expedited access to new treatments?

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Parallel Review: Not for Everyone, Useful for Some, and Additional Considerations for Improvement

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On September 17, 2010, the Centers for Medicare & Medicaid Services (CMS) and the U.S. Food and Drug Administration (FDA) announced their intent to establish a formal, voluntary parallel review process for medical products.¹ The agencies followed up with an October 11, 2011, notice outlining procedures for parallel review of medical devices.² The process is intended to help expedite the current framework whereby manufacturers obtain approval in a serial manner with products first reviewed by FDA for marketing approval or clearance and then reviewed by CMS for coverage under the Medicare program.

Because FDA and CMS apply different statutory standards when considering marketing and coverage applications,³ the agencies often require different data. Thus, a manufacturer that fails to consult with CMS when designing its clinical studies for FDA approval may miss an opportunity to ensure that such studies are also appropriate for obtaining a Medicare national coverage determination (NCD) from CMS or local coverage determinations (LCDs) from Medicare Administrative Contractors (MACs). An NCD binds all Medicare contractors and leads to consistent coverage throughout the country, while LCDs are effective within a MAC’s region.⁴ An affirmative coverage determination is critical to many manufacturers because Medicare is the largest

healthcare payor in the United States and a benchmark for many third-party payor coverage determinations.\textsuperscript{5}

To address these issues, the proposed parallel review process would allow CMS to conduct NCDs for new products at the same time that FDA considers whether to approve or clear the product.\textsuperscript{6} The agencies expect this formal process to reduce the time between FDA regulatory review and CMS coverage determinations.\textsuperscript{7}

Parallel review is not a new concept for FDA and CMS. The agencies have been talking about establishing this formal program as early as 2005, and they engage in informal parallel review at a manufacturer’s request.\textsuperscript{8} Indeed, manufacturers have long had the option to approach CMS about the amount and kind of information needed to support coverage.\textsuperscript{9} In any case, CMS generally requires FDA approval or clearance for an NCD and, thus, typically does not issue an NCD until after FDA has conducted its review.\textsuperscript{10} Accordingly, final CMS decisions by the two agencies will likely continue in a serial manner even under formal parallel review.

Although informal parallel review is already available and regulatory decisions will continue to be serial, the development of a formal parallel review process represents a shift in FDA and CMS policy that requires, as the agencies say, “important issues [to] be resolved” before such a process is designed and implemented.\textsuperscript{11}


\textsuperscript{6} 75 Fed. Reg. at 57045.

\textsuperscript{7} Id.


\textsuperscript{10} Innovators’ Guide, supra note 5, at 5 (noting that “CMS will not generally accept a coverage determination request for a device or pharmaceutical that is not approved or cleared for marketing by the Food and Drug Administration”); see 75 Fed. Reg. at 57047 (characterizing the proposed parallel review process as “a variation of the usual serial review process”).

\textsuperscript{11} See 75 Fed. Reg. at 57047.
consideration from the agencies and stakeholders, the proposed process could exacerbate delays in obtaining regulatory approval rather than achieving its goal of promoting access to medical technology. Further, the majority of manufacturers are unlikely to benefit from the development of a formal parallel review process.

This article first discusses the types of products and circumstances under which parallel review would—and would not—be useful for a manufacturer. The article then identifies areas where additional consideration is needed by the agencies and stakeholders to ensure the implementation of a successful parallel review process.

Proposed Parallel Review Process: Not for Everyone
A manufacturer’s regulatory situation can vary greatly. Because a formal parallel review process may be useful only under certain circumstances, this section discusses which manufacturers would—and would not—likely benefit from such a process.

Parallel Review: Who Shouldn’t Get Too Excited
The majority of manufacturers are unlikely to participate in the proposed parallel review process as it currently stands. First, the coverage of many products is relatively clear and therefore they do not require an NCD and do not stand to benefit from parallel review. Second, requesting an NCD is not without risk and an adverse determination from CMS could significantly hinder a manufacturer’s ability to obtain coverage and reimbursement for its product. Third, parallel review might delay the FDA approval process and, thus, cause more harm to manufacturers than good.

No NCD Is Needed
For many products, an NCD is not necessary and may even be undesirable. Many new devices can be reimbursed under existing codes or covered through LCDs that avoid
the need for an NCD or any specific, affirmative decision by CMS to cover a product.¹²
Because products can be covered by Medicare without affirmative CMS action, device
manufacturers may conclude that the benefits of a favorable NCD are a secondary
consideration to FDA approval and that the proposed parallel review process is
therefore unnecessary given the resources involved and potential for an adverse
outcome. In addition, some products—such as laboratory-developed tests—generally
do not require FDA approval before CMS makes a coverage determination and parallel
review may again be unnecessary.

NCDs have been rare for drugs and biologics and are generally only available for those
covered under Medicare Part B.¹³ Parallel review for new drugs and biologics under
Medicare Part B may be of limited usefulness because FDA-approved drugs and
biologics are likely to be covered for at least their on-label indication unless a local
contractor or CMS issues a non-coverage decision. In the case of off-label use, a
manufacturer with enough evidence to meet CMS’ standard is likely to either have a
product that has been in clinical use for so long that an NCD would be superfluous
(given CMS’ coverage of drugs in compendia), or may be able to get FDA approval for
the indication or use, making an NCD unlikely to be helpful. The same principles apply
generally with respect to devices, which is the initial focus of the formal parallel review
pilot.

Risk of Adverse Coverage Determinations

Participating in parallel review carries the risk of an adverse determination by CMS that
could result in the loss of Medicare and third-party payor coverage. Many manufacturers
are not prepared to submit data justifying an NCD at the same time the FDA review
process is ongoing. For example, this data may come from post-approval studies and is,

¹² See Innovators’ Guide, supra note 5, at 14 (“LCDs may be developed in the absence of an NCD or as a
supplement to an NCD as long as the LCD policy does not conflict with national policy.”); see also 42
benefits under part A, or enrolled under part B, or both”); see also 68 Fed. Reg. at 55636.
thus, unavailable to the manufacturer until after FDA approval. The submission of premature data could result in a negative or limited NCD for a product that may be a strong candidate for coverage but does not have sufficient clinical support.\textsuperscript{14} These adverse determinations are binding on all MACs and could prevent the product from being covered by Medicare.\textsuperscript{15} Because third-party payors generally follow CMS' coverage determinations, an adverse NCD could also limit access for non-Medicare patients. Getting CMS to change its mind after issuing an adverse NCD is likely to be more difficult than drawing on a blank slate, as the agency will not likely have firm preconceived notions in a new decision.

Manufacturers may also be unable to obtain Medicare coverage through LCDs if local MACs choose to delay a coverage determination until the NCD has been completed. Avoiding the risk of an adverse determination will likely be critical to manufacturers, especially if an NCD is not otherwise needed or data is insufficient to support an NCD.

\textit{Delays in FDA Review}

Parallel review may delay the FDA approval process even if it speeds the process of review by both FDA and CMS. Any agency collaboration—even mere consultation—could slow FDA’s progress in approving or clearing a device. Consultation with CMS could delay the FDA review process by forcing manufacturers to conduct longer and more costly clinical trials that meet both FDA and CMS standards.

In addition, Medicare often covers off-label indications that have not yet been approved by FDA. If FDA became aware of a manufacturer’s goal to obtain Medicare coverage of


\footnote{\textsuperscript{15} See Innovators’ Guide, supra note 5, at 11.}
an indication not likely to be approved by the agency, the product might receive greater scrutiny by FDA resulting in a delay in approval.\(^\text{16}\) Conversely, CMS might be less inclined to allow reimbursement for an off-label indication if FDA declined to approve that indication and specifically communicated its denial to CMS and the two agencies discussed the matter. These risks must be addressed by the agencies, especially because most manufacturers may be unwilling to trade quicker CMS coverage decisions for slower FDA regulatory determinations.

**Parallel Review: It May Be for You**

Though most manufacturers will likely not take advantage of the proposed parallel review process, some manufacturers—particularly those that face coverage difficulties or develop high-cost products or screening tests—are likely to participate. Parallel review is most likely to be used for new technologies that face Medicare coverage issues such as a national non-coverage determination, a limited NCD, or widespread local non-coverage determinations.

Manufacturers may also consider participating in parallel review for high-cost products. Such products could garner sufficient CMS attention to attract a national coverage analysis (NCA), which is a formal review initiated by CMS to determine if a treatment is “reasonable and necessary” and, thus, warrants a new NCD. Manufacturers of screening tests must utilize the NCD process and, thus, are likely to benefit from a formal parallel review process. The law prohibits Medicare from paying for “items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury . . . .”\(^\text{17}\) Because screening tests do not involve “diagnosis or treatment,” such tests cannot be subject to individual LCDs and must utilize the NCD process to

\(^{16}\) A manufacturer’s efforts to obtain coverage for an off-label indication might also generate emails and activities not directly related to the communications with FDA or CMS but could be used later by the FDA to argue that the manufacturer has impermissibly established a new intended use for the product.

obtain Medicare coverage.\textsuperscript{18} Thus, a formal parallel review process could help ensure that screening technology is available quickly for large segments of the population.

**Proposed Parallel Review Process: The Need for Additional Consideration**

In developing and implementing the proposed parallel review process, FDA, CMS, and stakeholders must address important issues—such as the scope of parallel review and the relationship between the two agencies—to avoid unintended consequences such as increasing regulatory delays. With additional consideration and stakeholder engagement, the agencies could develop a parallel review process that promotes access to all types of medical technology.

**Scope of Parallel Review**

A formal parallel review process may not be very meaningful for device manufacturers who would rather start coverage discussions in the context of LCDs and do not wish to seek Medicare coverage under an NCD at all or until building a broader base of coverage experience under LCDs. Thus, many manufacturers will derive no benefit from this formal process that expedites only NCDs.

**No Clarification on Coding and Reimbursement**

In addition, parallel review is more likely to be used if the process also expedites coding and reimbursement. The proposed parallel review process does not address coding or reimbursement.\textsuperscript{19} Indeed, many Medicare-related delays are caused by a manufacturer’s inability to obtain a timely coding and reimbursement decision,\textsuperscript{20} which are often made only annually or quarterly and further increase the delay between an

\textsuperscript{19} 75 Fed. Reg. at 57047 (“Parallel review . . . would include only CMS coverage determination reviews and not any reviews of payment mechanisms.”).
\textsuperscript{20} In the absence of an appropriate code, a new product will be reimbursed under an existing code with a lower reimbursement rate, entered manually with repeated processing delays, or negotiated on an ad hoc basis with individual Medicare contractors sometimes on a patient-by-patient basis. Innovators’ Guide, \textit{supra} note 5, at 17.
NCD or LCD and reimbursement.\textsuperscript{21} Thus, even if CMS issues a favorable NCD under the proposed parallel review process, manufacturers will continue to face delays in obtaining reimbursement codes for its new technology. As an alternative, CMS could establish codes in a timelier manner by using parallel review to identify technologies that will need codes prior to their approval.

The agencies may also wish to address reimbursement in clinical settings where new technology costs are generally not reflected in Medicare’s payments until the technology is widely adopted, which can take years even if a product has an NCD.\textsuperscript{22} This lag in reimbursement is addressed in the inpatient and outpatient prospective payment systems through special add-on or pass through payments for new technologies.\textsuperscript{23} Qualifying for such special payments, however, is difficult and medical devices are rarely eligible. Without these payment options, manufacturers can face a significant delay in reimbursement even with an NCD. Unless the process for assigning new codes and obtaining timely reimbursement is also addressed, expedited approval under the parallel review process could be meaningless because of the delay in obtaining coding and reimbursement for a new technology.

\textit{Relationship Between FDA and CMS}

Without additional consideration, the proposed parallel review process could result in inappropriate overlap between FDA and CMS during the agencies’ individual evaluations, the transfer of proprietary information, and the failure to meet regulatory review requirements because of delays at the other agency.

First, the agencies have distinct statutory responsibilities and, thus, apply different standards of review to medical products. To be approved by FDA, a product must be

\textsuperscript{21} Id. at 18, 27.
\textsuperscript{22} Id. at 34.
\textsuperscript{23} See 42 C.F.R. §§ 412.87-.88, 419.66 (2009).
shown to be “safe” and “effective” while CMS can approve on- and off-label uses that are “reasonable and necessary” for the Medicare population. Despite assurances that each agency would continue to apply its own standards, the agencies may blur their respective standards, leading to FDA review that incorrectly considers a product’s cost and effectiveness during market review. An example of this blurring can be seen in the Memorandum of Understanding signed by the two agencies in 2010, which includes the goal of “meet[ing] the common needs for evaluating the safety, efficacy, utilization, coverage, payment, and clinical benefit of drugs, biologics and medical devices.”

In addition to the potential for overlapping standards, parallel review could complicate the protection of proprietary information held by FDA for approval or clearance. Though CMS can “receive and consider proprietary data” while protecting such data from improper disclosure, the parallel review process could result in a substantial increase in the amount of proprietary data exchanged between the two agencies and, thus, the risk of inadvertent chatter that could affect a company’s financial status.

Finally, a parallel review process must contemplate both agencies’ statutory timelines for decisions. As discussed above, decisions will likely continue in a serial manner because CMS generally requires FDA approval or clearance for an NCD. Thus, to be useful, CMS’ review must be late enough so that FDA is fairly confident it will approve a product but also early enough to ensure that the manufacturer receives some benefit over the current serial review process. FDA’s review schedule also varies on a case-by-

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26 75 Fed. Reg. at 57047 (“The regulatory standards and evidentiary standards used by FDA and CMS for decision-making would not change; under any review scenario, each agency would continue to make its decision under its respective authority and with its own standards, independent of the other.”).
27 FDA and CMS, Memorandum of Understanding Between United States Food and Drug Administration and Centers for Medicare & Medicaid Services, MOU-225-10-0010, at ¶ 2(c) (June 2010), available at www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/u cm217585.htm.
29 Innovators’ Guide, supra note 5, at 5 (noting that CMS will “not generally accept a coverage determination request for a device or pharmaceutical that is not approved or cleared for marketing by the Food and Drug Administration (FDA)”)

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case basis, which further complicates CMS’ review and ability to meet its regulatory timeline requirements. Though FDA is obligated to meet review deadlines under the Medical Device User Fee and Modernization Act, the agency can freeze its review clock to request additional information. In contrast, NCDs are issued pursuant to a process that generally takes about nine months and must be completed by twelve months. These timing decisions will be critical in ensuring that both agencies comply with their independent statutory requirements without needless delay at either agency.

Other Issues Associated With Parallel Review

A host of concerns remain about the agencies’ proposed parallel review process. Though significant, these concerns require additional consideration and can likely be addressed through sustained efforts by the agencies to engage stakeholders.

First, stakeholders must address the costs of parallel review and whether the agencies will seek legislative action to apply a user fee to parallel review. If the user fee is not increased because of parallel review, those manufacturers that decide to participate in such a process may receive additional “value” for their user fee dollars. However, the vast majority of manufacturers are unlikely to use the proposed process and, thus, increased user fees to support parallel review would likely be unpopular.

Second, CMS may not have the resources and expertise to conduct frequent NCDs, and NCD reviews could skew CMS priorities towards new technologies. For example, the proposed process could cause CMS to focus on new technologies subject to FDA regulation while excluding products that are not approved by FDA. This process could lead to a misallocation of CMS’ limited resources by focusing on new, high-cost technologies to the detriment of other successful therapies that do not require such rigorous FDA review. In addition, CMS may lack the methodological expertise needed

31 See 75 Fed. Reg. at 57048.
for clinical trial development of premarket products. In addition to these issues, FDA and CMS may also want to assure that any parallel review process will avoid the expectation that an NCD is required before Medicare covers FDA-approved drug uses.

**Conclusion**

Parallel review is not new for FDA and CMS. However, the majority of manufacturers are unlikely to benefit from the proposed parallel review process. With so much at stake, the agencies and stakeholders must give additional consideration to parallel review to ensure that such a process succeeds in its goal of promoting access to medical technology.

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