Cooley

Proposed Rule on Laboratory-Developed Tests Takes Center Stage

November 29, 2023

The US Food and Drug Administration (FDA) is resolute in its quest to phase out its enforcement-discretion approach for laboratory-developed tests (LDTs). On October 3, 2023, FDA published a proposed rule to confirm that LDTs are devices under the Federal Food, Drug, and Cosmetic Act (FDCA) and to describe FDA's phase-out policy.[1] At the subsequent webinar on October 31, 2023, FDA reiterated its rationale for initiating this rulemaking and clarified certain issues. Despite FDA's clarifications, uncertainty remains. This alert provides a brief background on LDTs, discusses the proposed rule, summarizes FDA's recent clarifications and offers insights into the road ahead as FDA seeks to finalize the rule.[2]

Background on LDTs

FDA regulation defines in vitro diagnostic products (IVDs)[3] but not LDTs.[4] FDA has viewed LDTs as a subset of IVDs and expressed that there is no legal distinction between "test kits" made by conventional manufacturers and "LDTs" made by laboratories for their own use or another laboratory's use.[5] In FDA's view, both IVDs and LDTs are "devices" under section 201(h) of the FDCA.[6]

Circumstances at the time of implementation of the Medical Device Amendments of 1976 led FDA to adopt a general enforcement-discretion approach for LDTs, such that FDA generally has not enforced applicable requirements for most LDTs.[7] Specifically, back then, LDTs were mostly manufactured in small volumes by local laboratories for use in diagnosing rare diseases or for other uses in the local patient population.[8] These tests demonstrated characteristics of well-characterized, standard tests with components legally marketed for clinical use and tended to employ manual techniques performed by specialized laboratory personnel.[9]

Since 1976, the landscape for LDTs has changed significantly.[10] Today's tests often use automation and rely on complex, software-based systems to generate and interpret laboratory results.[11] Such tests are often used in laboratories outside the patient healthcare setting and are manufactured by laboratory corporations in high volume for diverse patients nationwide.[12] FDA believes that these LDTs are commonly manufactured with instruments or other components not legally marketed for clinical use and are more often used to inform or direct critical treatment decisions concerning a wide range of serious medical conditions.[13]

FDA also believes that many laboratory-made test systems today are functionally the same as those made by conventional IVD manufacturers, and thus have a similarly significant impact on patient care.[14] Yet, according to FDA, there are serious concerns about whether patients can rely on IVDs offered as LDTs.[15] These concerns arose from information suggesting that laboratories have not been conducting adequate validation studies, and that there have been high rates of false positive and false negative results that have caused, or may cause, patient harm.[16] FDA also believes that more recent evidence – including scientific literature, allegations of problematic tests reported to FDA, FDA's own experience in reviewing IVDs offered as LDTs, news articles, and class action lawsuits – suggests that the situation is getting worse.[17]

Given these changed circumstances, FDA is proposing to change its approach to regulating LDTs, and thus has initiated the current rulemaking.

Main elements of the proposed rule

In essence, FDA proposes to amend the definition of "in vitro diagnostic products" in 21 CFR § 809.3(a), which

states, “[t]hese products are devices as defined under section 201(h) of the [FDCA].” To make clear that LDTs are devices under the FDCA, FDA proposes to add to the end of this definition the language “including when the manufacturer of these products is a laboratory.”[18]

In the preamble to the proposed rule, FDA articulates a proposed phase-out approach for its current enforcement-discretion policy. This approach is designed to increase FDA oversight in five stages over four years, beginning on the date the final rule is published, as described in Table 1.

Table 1: FDA’s proposed phase-out of enforcement-discretion approach

Stage	Time from when final rule (final phase-out policy) is published	Requirements under which general enforcement-discretion approach will be phased out
1	One year	Requirements for medical device reporting (MDR) and corrections and removals
2	Two years	Requirements other than MDR requirements, correction-and-removal reporting requirements, quality system (QS) requirements, and premarket review requirements[19]
3	Three years	QS requirements[20]
4	Three and a half years (but not before October 1, 2027)	Premarket approval (PMA) application requirements for high-risk LDTs (class III devices)[21]
5	Four years (but not before April 1, 2028)	Premarket review requirements for low-risk (nonexempt class I devices) and moderate-risk (nonexempt class II devices) LDTs that require premarket submissions (510(k) or De Novo)[22]

Categories of tests excluded from general enforcement-discretion approach

For the following categories of tests, FDA will continue to expect immediate compliance with the FDCA, Public Health Service Act and implementing regulations:

- Blood donor screening tests, or human cells, tissues, and cellular- and tissue-based product (HCT/P) donor screening tests, required for infectious disease testing under 21 CFR § 610.40 and § 1271.80(c), respectively, or tests for the determination of blood group and Rh factors required under 21 CFR § 640.5.
- Tests intended for actual or potential emergencies or material threats declared under section 564 of the FDCA.
- Direct-to-consumer tests (i.e., tests intended for consumer use without meaningful involvement by a licensed healthcare professional).

Categories of tests not affected by the phase-out policy

The proposed rule states that the following categories of tests are not affected by the proposed phase-out policy, meaning that FDA will continue to exercise enforcement discretion with respect to these tests:

- 1976-type LDTs, which have certain characteristics that were commonly associated with LDTs offered in 1976, including:
  - Use of manual techniques (without automation) performed by laboratory personnel with specialized expertise.
  - Use of components legally marketed for clinical use.
  - Design, manufacture and use within a single CLIA-certified laboratory that meets the requirements under CLIA for high-complexity testing.
- Human leukocyte antigen (HLA) tests for transplantation used in histocompatibility laboratories that meet the regulatory requirements under CLIA to perform high-complexity histocompatibility testing, when used in connection with organ, stem cell and tissue transplantation to perform HLA allele typing, for HLA antibody screening and monitoring, or for conducting real and "virtual" HLA crossmatch testing.
- Forensic tests (i.e., tests intended solely for law enforcement purposes).
- Public health surveillance tests, which are intended solely for use on systematically collected samples for analysis and interpretation of health data in connection with disease prevention and control, and test results are not reported to patients or their healthcare providers.

FDA seeks comments on certain issues

FDA highlighted certain topics on which it would like to receive comments, including:

- Whether specific enforcement-discretion policies would be appropriate for IVDs offered as LDTs for other public health scenarios (i.e., beyond immediate response to emerging outbreaks).
- Whether IVDs offered as LDTs by academic medical centers (AMCs) should be treated differently.
- Whether a longer phase-out period should be applied to IVDs offered as LDTs by small laboratories (i.e., those with annual receipts below a certain threshold, such as $150,000).
- What, if any, unintended consequences may result from the proposed phase-out policy to certain patient populations (e.g., Medicare beneficiaries and rural populations).
- Whether currently marketed IVDs offered as LDTs should be exempted in some fashion, if no modifications to the LDTs are made.
- To what extent FDA should leverage outside programs – such as the New York State Department of Health Clinical Laboratory Evaluation Program or those within the Veterans Health Administration.

FDA's clarification of certain issues at the October 31 webinar

At the October 31, 2023, webinar, FDA made the following key clarifications based on questions submitted in advance.

Interplay between FDCA and CLIA. FDA regulates devices, including IVDs, under the FDCA, whereas the CLIA program falls under the Public Health Service Act. The FDA's device program focuses on the devices themselves, including IVDs, whereas the CLIA program focuses on laboratory operations. The two frameworks are different in focus, scope and purpose, but are intended to be complementary. FDA proposes to leverage CLIA where appropriate. Specifically, FDA proposes to enforce a subset of QS requirements, rather than all, for laboratories, when all manufacturing activities within a single CLIA-certified laboratory meet the regulatory requirements to perform high-complexity testing and where the IVD is not distributed outside of that laboratory. The proposed rulemaking would not change requirements for laboratory certification under CLIA.

Premarket review pathways for LDTs. FDA estimates that only about 5% of LDTs would undergo review through the PMA pathway and expects that most LDTs subject to premarket review requirements would be eligible for either the 510(k) pathway or De Novo pathway. Also, FDA has a breakthrough devices program, which is a voluntary program for certain devices meeting the criteria of breakthrough designation. This program is intended to speed up development of certain devices and would be available to LDTs that now must go through premarket

review.

Deadline for submitting comments. FDA is firm on the December 4, 2023, deadline and will not extend it.

Applicability of proposed rule to screening tests. The proposed rule applies to screening tests (e.g., cholesterol and diabetes screening tests), as FDA does not propose to exclude screening tests from the phase-out policy.

Bioinformatics and other software. Bioinformatics and other software that meet the definition of device under section 201(h) of the FDCA must comply with applicable device requirements.

Examples of "1976-type LDTs." These LDTs include various stains for cytology, hematology, and bacterial infections, cystic fibrosis sweat tests, certain colorimetric newborn screening tests, and certain tests that are based on immunohistochemistry or karyotyping or fluorescence in situ hybridization (FISH).

Applicability of investigational device exemption (IDE) requirements. LDTs used in clinical investigations are subject to the IDE requirements.[23] These include LDTs used for making treatment decisions about drugs or other medical products (e.g., LDTs used to evaluate pharmacodynamics or monitor for safety biomarkers). However, in recognition that there has been some confusion about FDA's enforcement approach in this area, FDA will include compliance with IDE requirements in stage 4 of the proposed phase-out policy.

"Manufacturer" and "laboratory." The term "manufacturer" includes any entity that engages in various activities that constitute manufacturing as described in FDA regulations,[24] such as design, preparation, propagation, assembly and processing. FDA intends to phase out its general enforcement-discretion approach for LDTs, so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as IVDs manufactured by non-laboratories. FDA recognizes that there is not a definition of "laboratory" in the FDCA, FDA regulations or the proposed rule.

Meaning of "IVDs offered as LDTs." FDA has generally considered the term "laboratory-developed test" to mean an IVD that is intended for clinical use, and that is designed, manufactured and used within a single CLIA-certified laboratory that meets the regulatory requirements under CLIA to perform high-complexity testing. FDA recognizes, however, that not all laboratories have understood that definition and the limited nature of FDA's general enforcement-discretion approach, and some have been offering IVDs based on that approach even when they do not fit what the FDA generally considers to be an LDT. Thus, FDA proposes to apply the phase-out policy to IVDs that are manufactured and offered as LDTs by laboratories that are certified under CLIA and meet the regulatory requirements under CLIA to perform high-complexity testing – **even if those IVDs do not fall within FDA's traditional understanding of an LDT (e.g., they are not designed, manufactured and used within a single laboratory). Thus, throughout the proposed rule, these IVDs are referred to as "IVDs offered as LDTs."**

Research use only (RUO) components and kits. RUO components and kits can be incorporated into an IVD where the manufacturer ensures that the test complies with applicable requirements. Since the proposed phase-out policy would apply to all IVDs offered as LDTs – **except as noted in the proposed rule, IVDs with components or kits that were previously labeled as RUO would be treated the same as tests manufactured by conventional manufacturers where the manufacturer is responsible for overall compliance**, including incorporating into their quality system any components previously labeled as RUO.

Modifications of LDTs. FDA does not propose to change the legal requirements that apply to modifications of FDA-authorized IVDs. If a laboratory modifies an FDA-authorized IVD in a way that is considered "manufacturing" an IVD, then the laboratory and IVD must comply with applicable requirements in the FDCA and implementing regulations. Under FDA regulations, a manufacturer includes a "remanufacturer" – which does any act to a finished device that significantly changes the device's performance, safety specifications or intended use.[25] A laboratory is a device remanufacturer if it modifies an existing IVD that it did not develop itself in a way that significantly changes the device's performance, safety specifications or intended use, and the modified IVD is expected to comply with applicable device requirements, as outlined in the phase-out policy, if finalized.

Timing of different phase-out stages. The general enforcement-discretion approach for LDTs would be phased out over four years after FDA publishes a final phase-out policy. Thus, the timing for each stage is based on the date FDA publishes the final phase-out policy and is not based on when the previous stage ends.

Laboratory inspection. Laboratories that manufacture IVDs are subject to inspection under the FDA's inspection

authority (codified in the FDCA, 21 USC § 374).

Treatment of modular PMA. Under FDA's proposed phase-out policy, FDA generally would not intend to enforce against IVDs offered as LDTs after a PMA has been submitted, within the three-and-a-half-year time frame, which includes all modular PMA submissions if a manufacturer is pursuing the modular PMA approach.

Enforcement discretion exercised after LDTs are submitted for premarket review. Under FDA's proposed policy, FDA generally would not intend to enforce premarket review requirements against IVDs offered as LDTs after a PMA, 510(k) or De Novo request has been submitted within the appropriate time frame until FDA completes its review.

Fees associated with premarket review. There are user fees associated with stage 2 (registration and listing) and stages 4 and 5 (premarket review). The current user fee program includes considerations for small business.

Applicability of the least burdensome approach. FDA considers the least burdensome approach when evaluating premarket submissions consistent with applicable requirements. Provided that available literature is adequate to demonstrate the test is clinically valid, FDA would not expect laboratories to generate additional clinical validity data. FDA's current practice in review of IVDs is to leverage information from the literature when it's available and applicable. Further, FDA also has established a recognition program for databases of human genetic variants that provides a mechanism for test manufacturers to leverage information in FDA-recognized databases to support clinical validity of their tests (see 'the road ahead' section below for further discussion of this program).

Predetermined change control plan (PCCP). A PCCP is a means to manage certain device modifications, where regulatory authorization before marketing is typically required, particularly in the context of artificial intelligence/machine learning-enabled medical devices. FDA is open to the use of PCCPs for LDTs.

Design controls. IVDs and LDTs are subject to applicable device requirements, so QS requirements, including design controls, apply, but commenters also can comment on how design controls should be enforced for marketed LDTs. This is an area where more guidance from FDA may be helpful for labs, so FDA will make more resources available in this area.

Labeling requirements. Many LDTs do not have package inserts like those in IVD kits, but the LDTs still must meet labeling requirements for IVDs under 21 CFR § 809.10, including specific information that must be included. Laboratories may comment on how they meet these requirements – including how the information might be encompassed in more than one document, such as the test protocol, test report templates or a test menu. FDA intends to issue more guidance on this topic over the course of the phase-out period.

Engagement and interactions with stakeholders. During the COVID-19 pandemic, FDA learned new ways to engage and interact with stakeholders, such as through townhalls and FAQs. FDA plans to build on this approach going forward and also will provide additional guidance documents to clarify its policy – such as guidance on appropriate validation, particularly with respect to clinical validity.

The road ahead

1. FDA is determined to phase out its long-standing enforcement-discretion approach for LDTs.

FDA has expressed significant concerns about IVDs offered as LDTs. Informed by its recent experience reviewing LDT validation and performance information during the COVID-19 pandemic, FDA treats this issue with renewed urgency and is moving forward on its own after recent legislative failures. For that reason, FDA seeks to finalize the proposed rule expeditiously, declining to extend the December 4, 2023, deadline for comments. Although it remains to be seen whether Congress will respond to FDA's proposed rule, FDA's action may put pressure on Congress to act. Given FDA's significant concerns in this area in recent years, the issues will not go away any time soon.

2. FDA's efforts to finalize and implement any proposed phase-out policy will likely face obstacles.

Despite FDA's determination, the road to implementation seems rocky.

First, it is no secret that FDA has faced industry opposition in its efforts to phase out the enforcement-discretion policy for LDTs. Thus, a potential legal challenge from industry remains probable. Any legal challenge would present obstacles to FDA's action in terms of timing and implementation of the new rule.

Second, even if the proposed rule and phase-out policy were to become final without being challenged, it is unclear whether the time frame proposed would provide sufficient time for industry to transition. In the draft 2014 LDT guidance documents, FDA proposed a phase-out time frame about twice as long as the current proposal. As a practical matter, many issues will still need to be worked out – including after FDA receives public comments, which will need to be digested and considered.

Third, in response to FDA's proposed rule, Congress may decide to intervene, which would affect FDA's timing and policy trajectory.

Fourth, any proposed policy would need support from the presidential administration after the 2024 elections. Without such support, it would be difficult to make LDTs a top priority for implementation, from both policy and resource perspectives.

Finally, FDA will need resources to implement the proposed phase-out policy successfully. It is unclear what level of user fee resources and associated fee structure will be available for LDTs. Moreover, although FDA also is looking at ways to reduce its resource needs – such as by working to enhance its third-party review program – it is unclear what the structure of that program will look like and how it will work in practice.

3. The risk-based approach will continue to drive how FDA regulates LDTs, regardless of whether the proposed rule and phase-out policy become final.

Not all LDTs are similarly situated. Based on the proposed rule and FDA's actions in recent years, some types of LDTs will garner more attention from FDA than others. Generally, the higher the risks that LDTs pose to public health based on their intended uses, the more attention they will receive. For example, FDA recently raised concerns about certain pharmacogenetic tests that reference drugs. LDT developers have increasingly offered tests that reference drugs and provide information and specific treatment recommendations concerning the drugs. In FDA's view, some of these tests make claims that may be outside of, or inconsistent with, FDA-approved drug labeling. Thus, FDA warned against the use of certain pharmacogenetic tests in 2018[26] and – despite its long-standing enforcement-discretion approach for LDTs – took regulatory actions against certain LDTs based on its belief that the LDTs were being offered with claims stating or suggesting that they may be used to manage therapeutic treatment of patients in a manner not consistent with the approved drug's labeling and not supported by sufficient clinical evidence.[27]

FDA also has stated that certain LDTs will not get the benefit of any gradual phasing out based on the inherent risks they pose, including:

- Direct-to-consumer tests.
- Blood donor screening tests or HCT/P donor screening tests under 21 CFR § 610.40, § 640.5 and § 1271.80(c).
- Tests intended for actual or potential emergencies or material threats declared under section 564 of the FDCA.

In addition, FDA has stated that IVD manufacturing activities occurring outside of a CLIA-certified laboratory are not the types of activities for which FDA's enforcement-discretion approach would apply.

By contrast, as discussed above, FDA has stated that it will continue to apply the enforcement-discretion approach for certain tests, because of the relatively low risk that they pose to public health or because they have additional safeguards. These tests include 1976-type LDTs, certain HLA tests, forensic tests and public health surveillance tests.

FDA also will likely use the risk-based approach to evaluate whether LDTs made by certain groups, such as AMCs and small laboratories, should be treated differently based on the characteristics of those tests, including how they are made and used, along with their risk profiles.

4. Even under its new proposed approach, FDA acknowledges that CLIA-certified LDTs require special

consideration.

FDA understands the practical interplay between the FDCA and CLIA regulatory schemes. Although FDA has explained that the two frameworks are different in focus, scope and purpose, it has recognized the complementary nature of the frameworks and has thus proposed a policy that leverages CLIA where appropriate. Specifically, FDA has proposed to enforce a subset of QS requirements, rather than all, for laboratories, when all manufacturing activities within a single CLIA-certified laboratory meet the regulatory requirements to perform high-complexity testing and where the IVD is not distributed outside of that laboratory.

Moreover, FDA understands that it needs to address CLIA-certified laboratories differently as it winds down its enforcement-discretion approach to regulation across the industry. Perhaps recognizing that its general enforcement-discretion approach has led to confusion across the industry, FDA is proposing to apply the phase-out policy to IVDs that are offered as LDTs by laboratories that are certified under CLIA and meet the regulatory requirements under CLIA to perform high-complexity testing, even if those IVDs are not designed, manufactured and used within a single laboratory (i.e., they do not fall within FDA's traditional understanding of an LDT).

5. FDA acknowledges that existing data sources can provide a viable option for test manufacturers to demonstrate clinical validity.

During the October 31 webinar, FDA reiterated its current practice to allow IVD sponsors to leverage information from the literature when it is available and applicable. Specifically, FDA stated that it would not expect laboratories to generate additional clinical validity data if available literature is adequate to demonstrate the test is clinically valid.

Moreover, FDA has created a mechanism for test manufacturers to leverage information on human genetic variants in certain databases to support clinical validity of their tests through FDA's recognition of such databases.[28] After a database containing information about genetic variants is established, researchers submit data to the database, which collects, organizes and publicly documents the evidence supporting the links between a human genetic variant and a disease or condition. For example, FDA recognized two databases in 2018 and 2021, respectively – Clinical Genome (ClinGen) Resource Consortium's ClinGen Expert Curated Human Genetic Data and Memorial Sloan Kettering Cancer Center's Oncology Knowledge Base.[29]

The scientific information in such databases, including informed assessments of the correlation (or lack of correlation) between a disease or condition and a genetic variant based on the current state of knowledge, can aid in the diagnosis and treatment of individuals with genetic conditions. FDA's recognition of such databases means that developers of genetic tests can use the information in such databases to support the clinical validity of their tests without the need for additional FDA review to confirm the suitability of the databases.[30]

Finally, FDA recently created a Table of Pharmacogenetic Associations to share information about certain pharmacogenetic associations that "FDA has evaluated and believes there is sufficient scientific evidence to suggest that subgroups of patients with certain genetic variants … or genetic variant-inferred phenotypes … are likely to have altered drug metabolism, and in certain cases, differential therapeutic effects, including differences in risks of adverse events."[31] FDA recognized that "[p]harmacogenetic tests, along with other information about patients and their disease or condition, can play an important role in drug therapy."[32]

Notes

1. See Medical Devices; Laboratory Developed Tests, 88 FR at 68006 (October 3, 2023).
2. This article is for general information purposes only. It is not intended to be, and should not be taken as, legal advice.
3. FDA's regulation defines "in vitro diagnostic products" as "reagents, instruments, and systems intended for use in the diagnosis of disease and other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae," and "intended for use in the collection, preparation, and examination of specimens taken from the human body" 21 CFR § 809.3(a).
4. The proposed rule states that "FDA has generally considered an LDT to be an IVD that is intended for clinical use and that is designed, manufactured and used within a single laboratory that is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and meets the regulatory requirements under CLIA to perform high-complexity testing" 88 FR at 68009.
5. Id. at 68009-68012.
6. Id.

7. Id.
8. Id.
9. Id.
10. Id. at 68009.
11. Id.
12. Id.
13. Id.
14. Id. at 68009-68010.
15. Id.
16. Id.
17. Id.
18. With the proposed amendment, the regulation would read: "These products are devices as defined in section 201(h) of the [FDCA], and may also be biological products subject to section 351 of the Public Health Service Act, **including when the manufacturer of these products is a laboratory**" 88 FR at 68031 (emphasis added).
19. In other words, in this stage, requirements that would begin to apply include: (1) establishment registration and device listing requirements (21 USC § 360 and 21 CFR Part 807); (2) labeling requirements (21 USC § 352 and 21 CFR Parts 801 and 809); and (3) investigational use requirements (21 USC § 360j(g) and 21 CFR Part 812).
20. For LDTs designed, manufactured and used in the same laboratory that is CLIA-certified for high-complexity testing, the QS requirements are limited to design controls (21 CFR § 820.30), purchasing controls (21 CFR § 820.50), acceptance activities (21 CFR § 820.80 and 820.86), corrective and preventive actions (21 CFR § 820.100) and records requirements (21 CFR Part 820, Subpart M).
21. LDTs may continue to be offered after this date while a PMA is under review by FDA.
22. LDTs may continue to be offered after this date while a 510(k) or De Novo is under review by FDA.
23. See 21 CFR Part 812.
24. See, e.g., 21 CFR § 807.3(d) and § 820.3(o).
25. See 21 CFR § 820.3(o) and § 820.3(w).
26. See a statement from Jeffrey Shuren, MD, JD, director of the FDA's Center for Devices and Radiological Health, and Janet Woodcock, MD, director of the FDA's Center for Drug Evaluation and Research, on the agency's warning to consumers about genetic tests that claim to predict patients' responses to specific medications.
27. See the FDA's April 4, 2019, warning letter related to the Inova Genomics Laboratory.
28. See FDA's April 2018 final guidance, Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics.
29. See FDA Recognition of Public Human Genetic Variant Databases.
30. In the oncology field, FDA took a similar practical approach by issuing guidance to announce and describe a voluntary program for certain oncology drug products that are regulated by the Center for Drug Evaluation and Research (CDER) and used with certain corresponding IVDs. See FDA's June 2023 guidance, Oncology Drug Products Used with Certain In Vitro Diagnostics: Pilot Program (Oncology Drug Pilot Guidance). In that pilot, "FDA seeks to support better and more consistent performance of certain LDTs used to identify patients for treatment with certain oncology drug products, resulting in better drug selection and improved care for patients with cancer" (Oncology Drug Pilot Guidance, at 2 – 3). The upside of this practical approach: "Test developers would be able to leverage the clinical validity of the [clinical trial assays] established through the drug trial to help streamline validation of additional tests for the same use. Ultimately, this may bring new treatment options to appropriate patients sooner" (Id. at 4).
31. See Table of Pharmacogenetic Associations.
32. Id.

This content is provided for general informational purposes only, and your access or use of the content does not create an attorney-client relationship between you or your organization and Cooley LLP, Cooley (UK) LLP, or any other affiliated practice or entity (collectively referred to as "Cooley"). By accessing this content, you agree that the information provided does not constitute legal or other professional advice. This content is not a substitute for obtaining legal advice from a qualified attorney licensed in your jurisdiction, and you should not act or refrain from acting based on this content. This content may be changed without notice. It is not guaranteed to be complete, correct or up to date, and it may not reflect the most current legal developments. Prior results do not guarantee a similar outcome. Do not send any confidential information to Cooley, as we do not have any duty to keep any information you provide to us confidential. When advising companies, our attorney-client relationship is with the company, not with any individual. This content may have been generated with the assistance of artificial intelligence (AI) in accordance with our AI Principles, may be considered Attorney Advertising and is subject to our legal notices.

Key Contacts

Sonia Nath Washington, DC	snath@cooley.com +1 202 776 2120
Son Nguyen Washington, DC	snguyen@cooley.com +1 202 728 7100

This information is a general description of the law; it is not intended to provide specific legal advice nor is it intended to create an attorney-client relationship with Cooley LLP. Before taking any action on this information you should seek professional counsel.

Copyright © 2023 Cooley LLP, 3175 Hanover Street, Palo Alto, CA 94304; Cooley (UK) LLP, 22 Bishopsgate, London, UK EC2N 4BQ. Permission is granted to make and redistribute, without charge, copies of this entire document provided that such copies are complete and unaltered and identify Cooley LLP as the author. All other rights reserved.