DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
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Pre-Decisional

MEMORANDUM

TO: Stephen Hahn, M.D., Commissioner of Food and Drugs

CC: Eric D. Hargan, Deputy Secretary
Brian Harrison, Chief of Staff
Stacy Amin, Deputy General Counsel & Chief Counsel
Anand Shah, M.D., Deputy Commissioner of Food and Drugs
Keagan Lenihan, Chief of Staff FDA
Danielle Steele, Counselor to the Secretary

FROM: Robert Charrow, General Counsel

SUBJECT: Federal Authority to Regulate Laboratory Developed Tests

DATE: June 22, 2020

Introduction

We have been asked by departmental leadership to review the legal bases—both substantive and procedural—for FDA's regulation of laboratory developed tests ("LDT").[1] This memorandum summarizes the results of our analyses.

Since 1992, FDA has taken the position in draft guidances, manuals, and web postings that LDTs are devices within the meaning of the Food, Drug, and Cosmetic Act ("FDCA" or "Act") § 201(h) and subject to the Agency's jurisdiction. Most recently, FDA announced on its website that

> FDA generally has not enforced premarket review and other legal requirements [with respect to LDTs]. However, LDTs for which an HHS [Emergency Use Authorization] declaration justifies a need (and that potentially meet the EUA criteria) present a higher risk. This is because they are developed to diagnose serious or life-threatening diseases or conditions that not only have serious implications for individual patient care, but also for analyses of disease progression and public health decision-making. Thus, FDA requests that developers of such LDTs submit information about their tests to help FDA better understand their design, validation, and performance characteristics.

[1] "A laboratory developed test (LDT) is a type of in vitro diagnostic test that is designed, manufactured and used within a single laboratory." https://www.fda.gov/medical-devices/vitro-diagnostics/laboratory-developed-tests (Sept. 27, 2018).

https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua (March 1, 2020) (last viewed June 15, 2020). We understand that some stakeholders, including many state university laboratories, have complained that this policy hindered their ability to develop and use LDTs to detect the virus that causes COVID-19.

We have undertaken a review of the relevant legal authorities and regulatory processes so as to advise departmental leadership, FDA, and other policymakers of FDA's authority in this area, especially in light of COVID-19. Specifically this memorandum addresses: (i) whether an LDT is a medical device; (ii) if so, under what circumstances, if any, does FDA have the jurisdiction to regulate LDTs; and (iii) whether FDA can properly regulate in this area without notice and comment rulemaking. We also discuss a potential re-assessment of relevant delegations in light of the foregoing analysis.

Summary of Conclusions

We believe that the Medical Device Amendments of 1976 ("MDA"), Pub. L. No. 94-295, may be broad enough, in certain settings, to accommodate FDA's view that LDTs, as opposed to the procedures used to run those tests, are "devices," within the meaning of section 201(h) of the FDCA.[2] However, the Agency's jurisdiction to regulate these devices is not uniform and not as plenary as it is for a traditional device; this lack of jurisdictional uniformity is dictated by the FDCA itself. FDA relies on FDCA section 301(k) and the premarket review regime in sections 510(k) and 515 as the primary means of exercising authority over LDTs. This theory has several potential weaknesses. First, it appears likely that LDTs, even if they satisfy the constitutional and statutory "interstate commerce" requirements of the FDCA, would likely not satisfy the separate "commercial distribution" requirement of the premarket review provisions at sections 510(k) and 515. Section 301(k), the primary provision dealing with prohibited acts, turns on whether the device is "held for sale." While courts in the past have given that term a broad reading to include devices that never leave a physician's office, a plain meaning assessment may not be as agency-friendly. Second, many first-line sophisticated laboratories are operated by state public health departments or academic medical centers at large state universities. These laboratories, by definition, are not "persons," within the meaning of the Act, and not subject to many of the Act's requirements, including registration (§ 510(c)), premarket review (§§ 510(k), 515), and adverse event reporting (21 C.F.R. pt. 803).

Third, the process that FDA used to ordain that LDTs are devices subject to the usual breadth and depth of FDA regulation is, in my view, inconsistent with the rulemaking provisions of the Administrative Procedure Act ("APA"), 5 U.S.C. § 553. Although the FDCA does not mention laboratory tests, FDA's various issuances have sought to fill this gap. However, where that gap-filling binds the Agency and has significant legal, regulatory and financial implications for those outside of the Agency, it is a legislative rule. This is especially the case, here, where as recently as last year, FDA has taken quasi-enforcement action on the basis of its determination that an LDT is a device, and where the FDA determination is inconsistent with the Secretary's existing regulations. The APA requires that legislative rules be issued through notice and

[2] Given that FDA has not expressed its view in a rule subject to notice and comment rulemaking, its determination that an LTD is a medical device would not enjoy *Chevron* deference, but rather lesser *Skidmore* deference.

comment rulemaking coupled with a Regulatory Flexibility Act ("RFA") analysis. *See* 5 U.S.C. § 601 *et seq*. Here, FDA did neither.[3]

All of this is not to say that during a national public health emergency, FDA would lack authority to seize or take other appropriate action against fraudulent or dangerous LDTs. Its authority, though, would not derive from the FDCA. Under the Public Health Service Act § 361(a), 42 U.S.C. § 264(a), the Public Health Service agencies, including FDA and CDC, have authority "to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession." FDA has used this authority to enjoin facilities that transplant stem cells and it could be used in those rare cases when an LDT poses undue risk. There may also be other federal agencies with authority to take action in such circumstances.

Background

When the MDA amended the FDCA, Congress authorized the then-Secretary of Health, Education, and Welfare to regulate medical devices through, among other things, premarket review—notification and approval—and the imposition of sanctions on those that failed to heed FDA's regulations or orders. The MDA broadly defined "device" to include, among other things, an "in vitro reagent . . . intended for use in the diagnosis of disease." MDA § 3(a)(1)(A). Laboratory developed tests—tests developed in a single clinical laboratory and used exclusively in that laboratory—were never mentioned in the MDA, in the House Report accompanying it, or during the floor debates.

In 1988, though, Congress addressed clinical laboratory testing when it enacted CLIA, codified at 42 U.S.C. § 263a, which among other things, instructed the Secretary of Health and Human Services to "issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures." 42 U.S.C. § 263a(f)(1). CLIA also required the Secretary to conduct inspections of laboratories to ensure compliance with established standards. *See* 42 U.S.C. § 263a(g). Since CLIA certification is a prerequisite to receiving Medicare payment, it was viewed primarily as Spending Clause legislation and delegated to CMS for enforcement. Thereafter, the Secretary issued comprehensive rules governing clinical laboratories. *See* 42 C.F.R. pt. 493. With respect to laboratory developed tests, those regulations provide as follows:

> Each laboratory that modifies an FDA-cleared or approved test system, or <u>introduces a test system not subject to FDA clearance or approval</u> (including methods developed in-house and standardized methods such as textbook procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable:
>
> (i) Accuracy.
> (ii) Precision.
> (iii) Analytical sensitivity.

[3] 21st Century Cures: Examining the Regulation of Laboratory Developed Tests, Before the H. Comm. on Energy and Commerce Health Subcomm. 113 Cong. 91 (2014) (preliminary transcript) ("21st Century Cures hearing") (statement of Dr. Jeffrey Shuren, Director, CDRH. FDA); *see also id*. at 68.

(iv) Analytical specificity to include interfering substances.
(v) Reportable range of test results for the test system.
(vi) Reference intervals (normal values).
(vii) Any other performance characteristic

42 C.F.R. § 493.1253(b)(2) (2019) (emphasis added). To perform LDTs, laboratories have to be certified under CLIA to perform highly complex tests. *See id.* § 493.17(c)(4). These tests can usually only be performed under the supervision of a board certified pathologist. *See id.* § 493.1443(b)(3) (noting that some with Ph.Ds may be grandfathered and medical doctors may satisfy the certification requirement in other ways). CLIA appeared to have occupied the field for regulating LDTs.[4]

FDA seems to have first suggested that LDTs are subject to its jurisdiction in a 1992 draft compliance policy guide aimed at regulating products sold to laboratories for research use only. The draft compliance guide stated that "laboratories have been manufacturing 'home brew' products, either from products already on the market, or from components, and utilizing these unapproved products for diagnostic purposes" and asserted that "[t]hese products are subject to the same regulatory requirements as any unapproved medical device." FDA, *Draft Compliance Policy Guide: Commercialization of Unapproved In Vitro Diagnostic Devices Labeled for Research and Investigation* at 4 (Aug. 1992).

In 1997, FDA issued a final rule regulating analyte specific reagents ("ASR"), the type frequently sold to commercial laboratories. In the preamble to the final ASR rule, FDA expressly stated that LDTs were devices subject to FDA jurisdiction: "FDA believes that clinical laboratories that develop [LDTs] are acting as manufacturers of medical devices and are subject to FDA jurisdiction under the act."[5] 62 Fed. Reg. 62,243, 62,249 (col. b) (Nov. 21, 1997).

During the intervening seventeen years, FDA did little to regulate LDTs, although it did issue a draft guidance for certain high-risk LDTs known as "in vitro diagnostic multivariate index assays" in 2007.[6] Things changed, though, in 2014, when FDA issued two draft

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[4] Pursuant to a delegation of authority from the Secretary of HHS, FDA is delegated limited authority under CLIA, to "implement CLIA's complexity categorization provisions as they apply to *commercially available tests* . . ." https://www.govinfo.gov/content/pkg/FR-2004-04-27/pdf/04-9527.pdf (emphasis added). This authority pertains to categorizing the complexity of such tests for purposes of CLIA. As discussed below, this involves physical test kits that are "commercially available" in interstate commerce, and not the type of laboratory developed testing at issue in this memorandum. This delegation of authority was recognized in statutory language in section 3057 of the 21st Century Cures Act. The Centers for Disease Control and Prevention (CDC) also provides analysis, research, and technical assistance with respect to CLIA and manages the Clinical Laboratory Improvement Advisory Committee (CLIAC).

[5] Statements in preamble which are not mirrored in the text of the rule are treated as interpretive rules, at best. *See Wyeth v. Levine*, 555 U.S. 555 (2009).

[6] See: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/vitro-diagnostic-multivariate-index-assays-draft-guidance-industry-clinical-laboratories-and-fda . In addition, in 2010, FDA held a widely-attended public meeting to solicit feedback from stakeholders on LDTs.

guidances.[7] Not only did the Agency continue to assert its authority under the FDCA to regulate LDTs, but it noted that, as part of that authority, it was going to require registration for all LDTs, to classify LDTs under section 513, and to require premarket notification or approval under sections 510(k) or 515, respectively, for certain LDTs.

The draft guidances' legal justification for treating LDTs as devices subject to FDA jurisdiction relied on the FDCA definitions of "device" and "manufacturer." A "device" under FDCA § 201(h) is defined as:

> an instrument, apparatus, implement, machine, contrivance, implant, *in vitro reagent*, or other similar or related article, including any component, part, or accessory, which is—(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. (emphasis added)

A "manufacturer" is defined as any person who owns or operates any establishment engaged in the "manufacture, preparation, propagation, compounding, assembly, or processing of a device" is required to register that establishment with FDA. FDCA § 510(b), (c).[8] Under FDA's logic, because an LDT is system using one or more *in vitro* reagents, and hence a "device," that is assembled or prepared in the clinical laboratory, and hence "manufactured," it is, in the Agency's view, subject to its regulatory jurisdiction. Most of the draft guidance is a lengthy justification as to why regulation is warranted and how that regulation would be implemented.

FDA received more than 50 comments in response to the draft guidances. Some were supportive, but many questioned the Agency's legal authority, questioned the absence of any documentation to support its claim that LDTs posed a risk, and questioned whether agency action of this magnitude could be undertaken without going through notice and comment rulemaking. On November 18, 2016, following the Presidential election, FDA announced that it would not finalize the two guidance documents. Notwithstanding this decision, FDA's position—announced initially in a compliance policy guide, later in a preamble to a regulation, and most recently in the web posting—that LDTs are medical devices within its jurisdiction remains in place. At issue is whether that decision is legally viable.

Analysis

I. Many LDTs Are Likely Medical Devices, But Even Those That Are May Fall Outside of FDA's Full Regulatory Regime

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[7] *See FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)* (Oct. 3, 2014) and *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* (Oct. 3, 2014).

[8] The regulation would not reach state public health laboratories or state university laboratories, since they are not "persons" within the meaning of the law. *See* FDCA § 201(e).

FDA maintains that LDTs are systems that include *in vitro* reagents intended to diagnose disease in humans and therefore are medical devices subject to FDA jurisdiction. Those opposing this position argue that LDTs are not physical embodiments, *e.g.*, "contraptions," but rather are processes or services, and therefore not devices. FDA is correct that, by definition, *in vitro* reagents are devices, but that does not necessarily lead to the conclusion that LDTs fall within FDA's jurisdiction. For purposes of this memorandum, we assume that had FDA made that determination through notice and comment rulemaking, it would be entitled to *Chevron* deference and would likely withstand scrutiny under that standard. However, even assuming that LDTs are medical devices, three additional requirements must be satisfied before FDA can implement its most significant regulatory authorities: (i) the "device" must satisfy the constitutional and statutory "interstate commerce" requirements; (ii) the device itself must be in commercial distribution or held for sale; and (iii) the laboratory must be a "person." We believe that the first requirement may be easy to establish with respect to certain authorities; the second more difficult to establish; and the third one cannot be established, as a matter of law, in many significant instances.

A. Statutory Interstate Commerce Requirement

The Constitution grants Congress power "[t]o regulate commerce with foreign nations, and among the several States, and with the Indian tribes." U.S. Const., art. I, § 8, cl. 3. Since the 1940s, the Supreme Court has construed the Commerce Clause broadly. *See, e.g.*, *Wickard v. Filburn*, 317 U.S. 111 (1942). In addition to regulating the channels of interstate commerce, and persons and things therein, Congress has authority to regulate activities that "substantially affect" interstate commerce. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 2578 (2012). The Court's current constitutional interpretation provides Congress wide berth to regulate local, noncommercial activities that have only a nominal or indirect connection to interstate commerce. *See, e.g.*, *Gonzales v. Raich*, 545 U.S. 1, 22 (2005); *Katzenbach v. McClung*, 379 U.S. 294, 300-01 (1964); *United States v. Wrightwood Dairy Co.*, 315 U.S. 110, 121 (1942); *Wickard*, 317 U.S. at 128-29;. Given the breadth of the Court's interpretation, the Commerce Clause poses no barrier to FDA's theory of jurisdiction.

In the years since *Wickard*, Congress also expanded FDA's statutory jurisdiction to cover some intrastate activities. Congress revised the FDCA in 1948 to clarify that its prohibitions against adulteration and misbranding apply to articles that are held for sale within a state after being shipped in interstate commerce.[9] Amendments in 1976 authorized FDA to seize misbranded or adulterated medical devices without proof that they have traveled in interstate commerce. *See* FDCA § 304(a)(2). FDA also has authority under the Public Health Service Act ("PHSA") to prohibit false labeling of biological products whether or not they move in interstate commerce, and section 361 of the PHSA authorizes FDA regulation to prevent the spread of communicable disease without any interstate commerce limitations. However, despite

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[9] As enacted in 1938, section 304(a) of the FDCA authorized the seizure of articles that were adulterated or misbranded "when introduced into or when in interstate commerce." 52 Stat. 1040, 1044. In 1946, the Ninth Circuit Court of Appeals held that this provision did not empower the government to seize adulterated pasta that was sitting in a warehouse after traveling in interstate commerce. *United States v. Phelps Dodge Mercantile Co.*, 157 F.2d 453 (9th Cir. 1946). In response, Congress amended section 304(a) in 1948 to also permit the seizure of an article that is adulterated or misbranded "while held for sale (whether or not the first sale) after shipment in interstate commerce." *See also* FDCA § 301(k) (prohibiting any act that results in an article being adulterated or misbranded "if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce").

these extensions of FDA jurisdiction, the Agency still lacks statutory authority to regulate a large segment of wholly intrastate conduct. Nonetheless, as those regulated by FDA have generally engaged in interstate commerce in some fashion, courts have tended to make statements regarding FDA's statutory jurisdiction as broad as the Commerce Clause, and the Agency prevails in the overwhelming majority of cases where its jurisdiction is challenged because a component of the drug or device was transmitted in interstate commerce. We offer below, in case a litigant were to assert that their conduct is wholly intrastate, advice regarding how FDA can successfully assert that its regulation of LDTs satisfies the statutory interstate commerce requirement in section 301(k) and otherwise consider its litigation position or review its regulations in light thereof.

1. Section 301(k)

Section 301(k) of the FDCA (21 U.S.C. § 331(k)) prohibits:

> The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, tobacco product, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) <u>after shipment in interstate commerce</u> and results in such article being adulterated or misbranded. (emphasis added).

The ability of the Agency to satisfy the statutory interstate commerce requirement in section 301(k)[10] hinges on whether a laboratory can show that everything used in its tests came from within the state.[11] In *United States v. Regenerative Sciences, LLC*, 878 F.Supp.2d 248 (D.D.C. 2012), *aff'd*, 741 F.3d 1314, 1326 (D.C. Cir. 2014),[12] two Colorado physicians developed a cellular therapy for orthopedic patients that involved harvesting stem cells from a patient's bone marrow or synovial fluid, culturing those cells for several weeks in a laboratory with growth factors from the patient's blood, placing the cultured cells into a syringe along with the antibiotic doxycycline and other additives, and injecting the contents of the syringe into the patient's injured area. The doctors formed Regenerative Sciences LLC ("Regenerative") to commercialize this practice. FDA officials inspected Regenerative's facilities in 2009 and 2010 and found that its laboratory operations did not conform to FDA manufacturing regulations. When FDA charged Regenerative with manufacturing and distributing adulterated and misbranded biological drug products in violation of section 301(k) of the FDCA and section 351(k) of the PHSA, the defendant physicians responded that they were lawfully practicing medicine within the state of Colorado and that their procedure fell outside FDA's regulatory purview.

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[10] We believe that section 301(k) is the FDA's most viable avenue for regulating LDTs. The Agency would face an uphill challenge if it used the adulteration and misbranding provisions at FDCA sections 301(a) or 301(b). The former requires the "introduction . . . into interstate commerce . . . . of the device" while the latter requires the "adulteration or misbranding . . . of any . . . device . . . in interstate commerce." Since the LDT never leaves the laboratory, it would be difficult for FDA to establish a violation of either subsection.

[11] The Act presumes, through a rebuttable presumption, that the Agency has jurisdiction. *See* FDCA § 709.

[12] Our discussion of *Regenerative Sciences* borrows from an outstanding article by Dr. Anna Laakmann. *See* Anna Laakmann, *Customized Medicine and the Limits of Federal Regulatory Power*, 19 VAND. J. ENT. & TECH. L. 285 (2016).

The district court focused on whether defendants' actions were directly connected to interstate commerce. FDCA section 301(k) prohibits any act "with respect to, a . . . drug . . . if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded." The court held that the manipulated cellular brew was "held for sale," a fact not contested by defendants. The court further went on to hold that

> [d]efendants do not dispute that the doxycycline is shipped from out of state to their facilities in Colorado. *Id.* Therefore, because a component of the drug in this case is shipped through interstate commerce prior to its administration to the patient, the "interstate commerce" requirement [of section 301(k)] is also met.

878 F.Supp.2d at 259.

The defendants' conduct satisfied the statutory interstate commerce requirement only because the doxycycline was shipped into Colorado from out of state and added to the stem cells prior to the mixture's administration to patients. Had the doxycycline been manufactured in Colorado and shipped intrastate, FDA would have lacked a jurisdictional hook. Alternatively, suppose the defendants had administered the doxycycline separately rather than mixing it with the stem cells in a single syringe. If the procedure were modified to comprise two separate injections—a first syringe of stem cells and a second syringe of doxycycline—FDA presumably would lose its regulatory authority under the FDCA, even if the doxycycline were shipped from out of state. In this case, the defendants would be prescribing doxycycline for off-label use, an activity that FDA lacks power to regulate regardless of its connection to interstate commerce. It was the mixing of the doxycycline, an approved drug, with other material that created FDA's jurisdictional hook.

Thus, under the terms of *U.S. v. Regenerative Sciences, LLC*, in order for FDA to satisfy the statutory interstate commerce requirement in section 301(k), at least one element of an LDT must come from outside the state.[13] With the exception of some academic medical centers, most laboratories use LDTs that have at least one component that came from out-of-state, so we believe FDA can usually successfully defend its jurisdiction in this regard.

2. Section 510(k)

Premarket review, which is set out in section 510(k), was central to the 2014 guidances and is the primary difference between regulation under CLIA and regulation under the FDCA. FDCA section 510(k) (21 U.S.C. § 360(k)) provides:

> Each person who is required to register under this section and who proposes to begin *the introduction or delivery for introduction into interstate commerce* for commercial distribution of a device intended for human use shall, at least ninety days before making such introduction or delivery, report to the Secretary . . . action taken by such person to comply with requirements under section 514 [related to performance standards] or 515 [related to premarket approval] which are applicable to the device. (emphasis added).

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13 The Act presumes, through a rebuttable presumption, that the Agency has jurisdiction. *See* FDCA § 709.

Section 510(k) has a meaningful grammatical difference from section 301(k). Section 301(k) prohibits the sale in interstate commerce of a component or other aspect of a device that is then altered or manipulated. Hence, if a laboratory were to purchase in interstate commerce any of its reagents, which it then modified or used to modify other reagents, it would satisfy the jurisdictional prerequisite in section 301(k). However, under section 510(k), the premarket review requirements are only triggered when one proposes to introduce or deliver the device into interstate commerce, even if the reagents were purchased from another state. The typical LDT, though, never physically leaves the laboratory. There is no "introduction" and no "delivery."

Thus, while the actions of the laboratory operator may have been sufficient to support regulation under the Commerce Clause, as having a substantial effect on interstate commerce, those actions may not be sufficient, if challenged by a savvy litigant, to satisfy the statutory requirements of section 510(k) or section 515 (premarket approval), which uses identical language.

B. "Held for Sale" or "Commercial Distribution" Requirement

1. Section 301(k)

Section 301(k) only applies if an article is "held for sale . . . after shipment." Courts have tended to interpret section 301(k)'s "held for sale" requirement very broadly—far broader than the plain meaning of the statutory text. But it is unclear whether the current Supreme Court would ignore the plain meaning of the text and affirm these expansive readings.

Case law supports the assertion that the "held for sale" standard of section 301(k) has long been afforded a liberal reading, encompassing "[a]ll articles, compound or single, not intended for consumption by the producer." *United States v. Cassaro, Inc.*, 443 F.2d 153, 156 (1st Cir. 1971)(citing *Hipolite Egg Company v. United States*, 220 U.S. 45, 54 (1911)). The Supreme Court has explained that that 301(k)'s "held for sale" requirement is "designed . . . to extend the [FDCA's] coverage to every article that had gone through interstate commerce until it finally reached the ultimate consumer." *United States v. Sullivan*, 332 U.S. 689, 697 (1948). The United States government has repeatedly advocated for this expansive reading of "held for sale," and stated that the requirement is satisfied if the product can be shown to have been used for any purpose other than personal consumption. *See, e.g.*, *United States v. Rhody Dairy, L.L.C.*, 812 F.Supp.2d 1239 (E.D. Wash. 2011); *United States v. Scenic Dairy, L.L.C.*, 2011 WL 3879490 at *14 (W.D. Mich. Sep. 1, 2011); *United States v. Torigian Labs., Inc.*, 577 F. Supp. 1514, 1521 (E.D.N.Y. 1984); *Articles of Animal Drug Containing Diethylstilbestrol,* 528 F. Supp. 202, 205 (D. Neb. 1981); *United States v. Articles of Device (Acuflex; Pro–Med),* 426 F. Supp. 366, 368 n.3 (W.D. Penn. 1977).

Several courts have held that the phrase "held for sale" extends to physicians using devices in the treatment of patients. *See, e.g.*, *United States v. Kaplan*, 836 F.3d 1199, 1208 (9th Cir. 2016). In *Kaplan*, the Ninth Circuit held that a doctor's use of a device (in that case, single-use plastic needle guides used during prostate biopsy exams) in the course of treating a patient is considered a "sale" within the meaning of "held for sale" in section 301(k). 836 F.3d at 1208. This makes sense—the single-use medical device is being consumed (i.e., sold) when used by the doctor, because the doctor is using the item with the patient during the course of a service. In contrast, LDTs usually involve the development of technologies and processes to conduct

testing activities. For example, Medicare does not pay for the physical embodiment of any LDT or any other laboratory test. LDTs are more analogous to a doctor who creates and develops a replicable procedure, rather than a doctor who uses a medical device during an ordinary course of treatment. Just as the doctor's development and use of a medical procedure would not be considered to be "held for sale," the development and use of LDTs would also not be considered "held for sale" under the common meaning of that term.

In short, even though courts have given a liberal reading to the "held for sale" requirement, it is unclear whether that reading is sufficient to support liability under section 301(k) with respect to LDTs. Even in light of this uncertainty, we assume for purposes of our analysis that courts would adopt a liberal reading and apply that section to LDTs such that FDA could defend its current position.

2. Sections 510(k), 513(f), and 515

Similar to section 301(k)'s "held for sale" requirement, section 510(k) requires that persons subject to it "begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device . . . ." Similar language is used in section 513(f) and 515(b). There do not appear to be any judicial interpretations of "commercial distribution" as used in these classification and premarket review sections. But this phrase is used in the grandfathering provision of the FDCA, and with respect to that provision, FDA has interpreted "commercial distribution" to mean "on the market" or "actively promoted" for a specific purpose. *See, e.g.*, *United States v. An Article of Device Consisting of 1,217 Cardboard Boxes*, 607 F. Supp. 990, 994 (W.D. Mich. 1985); *see also Northwest Tissue Center v. Shalala*, 1 F.3d 522, 535 (7th Cir. 1993).

The plain meaning of this phrase makes it much narrower than section 301(k)'s "held for sale" requirement. First, the term "commercial" relates to "commerce" which means the "buying or selling of commodities on a large scale involving transportation from place to place." WEBSTER'S NEW COLLEGIATE DICTIONARY 223-24 (1980). Second, the term "distribution" means to "supply." *Id.* at 330. This means that if LDTs are to satisfy the "commercial distribution" standard, they must be viewed as goods or commodities that are sold and dispersed beyond the laboratory. This, of course, does not occur. Each LDT remains *in situ*, and is not treated as merchandise by the Secretary for payment purposes, but rather as a service. For example, under Medicare part B, the Secretary only pays for clinical laboratory services. *See* Social Security Act § 1861(s) (defining "medical and other health services" as including diagnostic laboratory tests); § 1834A (referring to the information generated by laboratory tests). Thus, the Secretary does not purchase the physical embodiment of any LDT or any other laboratory test, for that matter.

The FDA definition of "commercial distribution" appears to be to be in keeping with the phrase's plain meaning, namely, "any distribution of a device intended for human use which is held or offered for sale but does not include . . . "[i]nternal or interplant transfer of a device between establishments within the same parent, subsidiary, and/or affiliate company." 21 C.F.R. § 807.3. The development and use of LDTs involves purely internal transfers of LDTs because payors or clinicians are not paying for the LDT itself. Thus, even if LDTs could be viewed as being "held for sale," they certainly almost always involve only internal transfers, or no transfers at all, and thus would not, if challenged by a savvy litigant, satisfy the plain meaning

of FDA's regulation.

To marginalize the importance of movement outside the walls of the laboratory is to equate "held for sale" and "commercial distribution," which would be inconsistent with both its plain meaning and the well-established canon of statutory interpretation that the use of different words or terms within a statute demonstrates that Congress intended to convey a different meaning for those words. *See Russello v. United States*, 464 U.S. 16, 23 (1983); *Persinger v. Islamic Republic of Iran*, 729 F.2d 835, 843 (D.C. Cir. 1984) ("When Congress uses explicit language in one part of a statute to cover a particular situation and then uses different language in another part of the same statute, a strong inference arises that the two provisions do not mean the same thing."); *Nat'l Insulation Transp. Comm. v. ICC*, 683 F.2d 533, 537 (D.C. Cir. 1982); *Russell v. Law Enforcement Assistance Admin.*, 637 F.2d 354, 356 (5th Cir. 1981) (stating the "well settled rule of statutory construction that where different language is used in the same connection in different parts of a statute it is presumed that the Legislature intended a different meaning and effect") (internal quotation marks omitted); *NLRB v. Food Fair Stores, Inc.*, 307 F.2d 3, 10 (3rd Cir. 1962) (stating the rule of statutory construction which holds that different words appearing in the same statute are presumed to have different meanings). Even words with remarkably similar definitions can still convey a unique or distinct meaning or flavor from words that are similar or even synonymous in nature because of their differing tone or usage within a sentence.

C. The "Person" Requirement—Sections 510(c), 510(k), 515(c), and 21 C.F.R. pt. 803

In addition to the statutory commerce clause, the "held for sale," and the "commercial distribution" requirements of the FDCA, portions of the Act only apply to a "person." Thus, the registration and premarket review requirements of section 510(c) and 510(k), premarket application requirement of section 515(c),[14] and the adverse event reporting requirements of 21 C.F.R. pt. 803 apply only to "persons." *See* 21 C.F.R. § 803.3(1) (stating that a "*Manufacturer* means any person"). Under the Act, though, a "state" is not "person."

1. State is Not a "Person"

Many of the more sophisticated laboratories that are the ones most likely to first develop LDTs in response to an infectious disease are located in state public health departments and academic medical centers at state universities. A state, including its departments and state-owned universities, is presumed by definition not to be a "person." *See Vt. Agency for Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765 (2000) (applying its "longstanding interpretive presumption that 'person' does not include the sovereign" to find that a state is not a "person" within the meaning of the False Claims Act).[15] That presumption is not necessary here because the Act defines "person" to "include[] [an] individual, partnership, corporation, and association."

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[14] The term "person" is defined in the Agency's premarket application rules as including "any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity." 21 C.F.R. § 814.2. Inasmuch as the regulation is inconsistent with the definition of "person" in the Act, as including governmental entities, we believe that definition is invalid.

[15] Counties and local governmental entities are "persons" under the FDCA. *See, e.g.*, *Cook County, Ill. v. U.S. ex rel. Chandler*, 538 U.S. 119 (2003) (holding that a county is a "person" under the False Claims Act).

FDCA § 201(e). The Act separately defines "State," "except as used in the last sentence of section 372(a) of this title, [to] mean[] any State or Territory of the United States, the District of Columbia, and the Commonwealth of Puerto Rico." *Id.* § 201(a). The two definitions are not linked or cross-referenced. Thus, a "person" is not a "State."

2. Premarket Review, Registration, and Related Provisions Only Apply to "Persons" and Not States

Section 510(c) requires "[e]very person upon first engaging in manufacture . . . of . . . a device . . . shall register with the Secretary . . . ." The premarket notification provision of section 510(k) applies to "[e]ach person who is required to register under this section . . . ." Inasmuch as a state would not be required to register, it is also not required to file a premarket notification under section 510(k). If a device manufacturer does not take advantage of this pathway, it is generally subject to review under other the more rigorous premarket review pathways in the Act, such as the premarket approval in section 515 or the *de novo* review in section 513(f)(2). For most manufacturers, this is true by operation of two provisions in the statute. First, under section 513(f)(1) of the FDCA, a non-grandfathered device is automatically classified in class III unless the device "is substantially equivalent to another device" or has been classified pursuant to a petition or request, such as a *de novo* request. If such a device cannot be found to be substantially equivalent under the 510(k) pathway and if it has not been classified through another process, such as the *de novo* process, it is automatically classified in class III. Second, under section 515(a)(2), a device that is in class III by virtue of section 513(f) is "required to have … an approval under this section of an application for premarket approval." Devices that are subject to these provisions and that lack premarket approval are adulterated. *See* FDCA § 501(f)(1)(B).

In the case of a state actor, though, the normal interplay between sections 501, 510, 513, and 515 breaks down. First, a state is not required to file a premarket notification under section 510(k) or to register under section 510(c). Second, to avoid being automatically treated as a class III device, section 513(f) merely requires that the device is "substantial[ly] equivalen[t]" to another lawfully marketed device. The section does not require that the Secretary make this finding or receive a report under section 510(k). Even assuming that section 513(f) applied and the device were by default classified into class III, that would still not impose any burdens on a state because it is likely that the premarket approval provision of section 515 does not apply to states and may not apply to LDTs, at all, and the adulteration provision also does not apply to states.

A device is adulterated if it were classified under section 513(f) into class III; a class III device, under section 515(a) "is required to have an approval under this section of an application for premarket approval . . . ." This presupposes that the state actor is required to file such an application. Section 515(c), though, limits those who may file applications to "persons:" "[a]ny <u>person</u> may file with the Secretary an application for premarket approval for a class III device." FDCA § 515(c)(1) (emphasis added). It would be anomalous to require an approved application from an entity not required to file an application. One could argue that the phrase "any person may file" does not foreclose a state from filing a PMA. Courts, though, have viewed similar or identical phrases in other statutes as restricting the class that can file. Thus, under the False Claims Act, "[a] person may bring a civil action for a violation of section 3729

for the person and for the United States Government." 31 U.S.C. § 3730(b). No one has suggested, following the Court's decision in *ex rel. Stevens*, that a state could act as a relator and file a qui tam suit under section 3730(b). We believe the most natural way to read these provisions is recognize that when the FDCA and MDA were enacted and amended no one contemplated that they would apply to states. This is especially so given that the penalty provisions of the FDCA only apply to "persons." *See* FDCA § 303. The fact that state public health and academic medical center laboratories appear to fall between the regulatory cracks in the case of LDTs, strongly suggests that the Act was never intended to reach these services.

As a result, FDA's registration, premarket review, and adverse event reporting requirements would not, if challenged by a sophisticated litigant, likely apply, as a matter of law, to any state-owned laboratory, whether in a state department of public health or university.

In sum, although it appears that FDA was acting within its discretion by treating LDTs as medical devices and that section 301(k) could be applied, its premarket review authority would not apply to LDTs, because the provisions require the device itself (*i.e.*, the reagent) to be placed into commercial distribution. Further, the registration, premarket review and adverse event reporting requirements only apply to "persons." State laboratories are unlikely to be considered persons within the meaning of the FDCA.

II. FDA's Policy that LDTs Are Devices Was Adopted Without Notice and Comment Rulemaking or a Regulatory Flexibility Analysis and Is Therefore Void

The APA establishes the procedures federal administrative agencies must use for "rule making," defined as the process of "formulating, amending, or repealing a rule."[16] 5 U.S.C. § 551(5). "Rule," in turn, is defined broadly to include "statement[s] of general or particular applicability and future effect" that are designed to "implement, interpret, or prescribe law or policy." *Id.* § 551(4); *see Perez v. Mortgage Bankers Ass'n*, 575 U.S. 92, 95–96 (2015). Rules fall into two broad categories—legislative rules and interpretive rules. Legislative rules can only be issued through notice and comment rulemaking, formal rulemaking or negotiated rulemaking; interpretive rules can be issued unilaterally. *See* 5 U.S.C. § 553(b). Therefore, whether an agency's issuance is a legislative rule or interpretive rule can have major consequences. Differentiating between the two, though, is complicated.

We believe that FDA's determination that an LDT is a device is a legislative rule for at least three independent reasons: (1) it fills a gap in the Act; (2) the Agency has treated its determination as legally binding forming the basis of enforcement and the exercise of enforcement discretion; and (3) the Agency's determination is inconsistent with an extant legislative rule of the Department.

A. FDA's Guidances and Determinations Are "Gap Filling" and Therefore Legislative Rules

First, a legislative rule "performs a legislative function when it makes 'reasonable but arbitrary (not in the "arbitrary and capricious" sense) rules that are consistent with the statute or regulation under which the rules are promulgated but not derived from it, because they represent

16 A stricter standard applies to Medicare under Social Security Act § 1871, where policy statements that affect substantive rights are subject to notice and comment, even if they would not qualify as legislative rules.

an arbitrary choice among methods of implementation.'" *Catholic Health Initiatives v. Sebelius*, 617 F.3d 490, 495 (D.C. Cir. 2010) (citing *Hoctor v. USDA*, 82 F.3d 165, 170 (7th Cir. 1996)). Gap-filling is a quintessential characteristic of a legislative rule.

FDA's determination starting in 1992, confirmed in 1997, reconfirmed in the 2014 draft guidances, and reconfirmed in its January 13, 2017 White Paper that LDTs are devices were all gap-filling policy determinations with significant economic and regulatory implications. The proposed LDT framework in the 2014 draft guidances would have required FDA to review virtually all LDTs. Under the White Paper, FDA review would be limited to "new and significantly modified high and moderate risk LDTs." White Paper at 4–5. As a result, FDA envisions that the process could be completed in four years, rather than the rather prolonged nine-year period originally envisioned in the draft guidances. In the White Paper, the Agency also stated that "[t]o protect patients from tests that could lead to harm, the Agency would retain its ability to enforce premarket review, quality systems, and other applicable requirements for any LDT, including those listed above, if the agency identified one or more of the following, taking into account all available evidence." *Id.* at 4. It also represents a clear choice, opting to define an LDT as a device; it thereby filled a gap in the statute, a quintessential characteristic of a legislative rule.

Nor is this a case where one can argue that the organic legislation unmistakably leads to the conclusion that LDTs are devices and an enforcement action can be based solely on the statute. Laboratory developed tests are not mentioned in the FDCA nor are they defined in it. Rather, they are only defined in FDA guidances and similar issuances. *See, e.g.*, *Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)* at 5 (Oct. 3, 2014) (defining LDT) ("Guidance Document"). It would be difficult to argue that FDA regulation of LDTs is so inherent in the FDCA that no regulation is necessary. This is especially so where the Secretary has issued rules implementing Medicare and CLIA that strongly suggest that LDTs are not devices and not within FDA's jurisdiction.

The argument that LDTs could be regulated without a regulation is also belied by the public comments submitted in response to the 2014 draft guidances which challenged FDA's contention that an LDT is a device. One commenter argued that

> [i]t is far-fetched to suppose that laboratory-developed testing services become medical devices in their own right merely because they sometimes utilize other medical devices. FDA's own regulations recognize the distinction between a service that uses devices and a device itself. For example, the FDA regulation excluding laboratories from device registration requirements specifically recognizes that laboratories' "primary responsibility to the ultimate consumer is to … provide a service through the use of a previously manufactured device." 21 C.F.R. §807.65(i) (emphasis added). Laboratories may well draw on both reagents and laboratory equipment of many kinds in executing their clinical testing services, but that plainly does not render the services these laboratories perform themselves "medical devices."

Comment submitted by Paul D. Clement & Laurence H. Tribe on Behalf of the American Clinical Laboratory Association at 9.

FDA's ability to regulate LDTs is not inherent in the language of the Act, which is silent

on the point. When, as here, the statute is silent, an agency's attempt to describe the contours of its authority is "gap-filling." Gap-filling, though, can only occur through notice and comment rulemaking. *See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843–44 (1984).

B. FDA's Determinations Were Intended to Be Binding and Have the Force and Effect of Law

Second, an agency action that purports to impose legally binding obligations or prohibitions on regulated parties—and that would be the basis for an enforcement action for violations of those obligations or requirements—is a legislative rule. An agency action that sets forth legally binding requirements for a private party to obtain a permit or license is a legislative rule." *National Min. Ass'n v. McCarthy*, 758 F.3d 243, 251–52 (D.C. Cir. 2014); *see also Appalachian Power Co. v. E.P.A.*, 208 F.3d 1015, 1021 (D.C. Cir. 2000). Correspondingly, legislative rules, as opposed to interpretive rules, "'grant rights, impose obligations, or produce other significant effects on private interests;' 'narrowly constrict the discretion of agency officials by largely determining the issue addressed;' and '[has] substantive legal effect.'" *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 35 (D.C. Cir. 2005) (quoting *Batterton v. Marshall*, 648 F.2d 694, 701–02 (D.C. Cir. 1980)).

The finding that an LDT is a device is a sentinel determination enabling the Agency, at any time, to take enforcement action, to require registration, listing, compliance with quality systems, and premarket review and clearance or approval, at the Agency's discretion. Because this finding has significant economic effects on private interests, it raises the specter that the Agency, exercising discretion that is arguably not reviewable, could require laboratories to comply with any or all of these requisites that govern ordinary devices, the determination fits the profile of a legislative rule.[17] The Agency's determination that an LDT is a device "would be the basis for an enforcement action for violations of those obligations." *National Min. Ass'n, supra*. Consistent with that description, the Agency recently took action in the form of a Warning Letter against a laboratory based on its determination that an LDT is a device. *See* Warning Letter to Inova Genomics Laboratory (April 4, 2019). That Warning Letter is, to a reviewing court, convincing evidence that the decision to treat an LDT as a device was intended to have the force and effect of law and has been treated as such by the Agency.[18] Since the determination was issued without the benefit of notice and comment rulemaking, it is likely to be

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[17] The Agency's ever changing views of whether and when to exercise enforcement discretion could itself be viewed as a legislative rule. *See Am. Academy of Pediatrics v. F.D.A.*, 379 F.Supp.3d 461, 494 (D. Md. 2019), *affirmed on other grounds, sub nom. In re Cigar Association of America*, 2020 WL 2116554, at *3 (4th Cir. 2020).

[18] Whether a Warning Letter is an enforcement action or merely the first step in a compliance process is open to question in light of *Ipsen Biopharmaceuticals, Inc. v. Azar*, No. 18-5299 (D.C. Cir. Dec. 3, 2019). There are some who argue that FDA warning letters could be viewed as final agency action. Michelle Yeary, *Could FDA Warning Letters Be Final Agency Action*, DRUG & DEVICE LAW (Dec. 10, 2019), https://www.druganddevicelawblog.com/2019/12/could-fda-warning-letters-be-final-agency-action.html.

considered void if challenged.[19]

FDA has acknowledged that its issuances have the force and effect of law, even though its guidance documents trumpet the opposite in boilerplate. The Agency noted that it had exercised enforcement discretion with respect to LDTs, but that the 2014 draft guidances, when finalized, would have ended that. *See* Guidance Document at 6. Two years later, when abandoning the 2014 draft guidances, the Agency indicated its intent to continue extending enforcement discretion to LDTs, except in the event of a pandemic. See https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/information-laboratories-implementing-ivd-tests-under-eua (March 1, 2020) (last viewed June 15, 2020) ("FDA generally has not enforced premarket review and other legal requirements [with respect to LDTs]."). Obviously, an agency can only exercise enforcement discretion if it believes that it has the authority to enforce its determination, in this case that an LDT is a device.

C. FDA's Determination Is Inconsistent with Extant Departmental Regulations and Is Therefore Void Absent Notice and Comment Rulemaking

Third, if an agency adopts a position that is "inconsistent with an existing regulation, or effects 'a substantive change in the regulation,' notice and comment are required." *U.S. Telecom Ass'n v. F.C.C.*, 400 F.3d 29, 35 (D.C. Cir. 2005) (quoting *Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 100 (1995)). Here, before FDA's initial determination in 1992 that LDTs are devices, the Secretary issued a comprehensive regulation implementing CLIA that expressly recognized three classes of laboratory tests—(i) those purchased by a laboratory that were FDA cleared or approved, (ii) those that are modifications of FDA cleared or approved tests, or (iii) "test system[s] not subject to FDA clearance or approval (including methods developed in-house [*i.e.*, LDTs] and standardized methods such as text book procedures . . .)." 42 C.F.R. § 493.1253(b) (2019) (adopted 68 Fed. Reg. 3640, 3707 (Jan. 24, 2003), previously codified at 42 C.F.R. 493.1213(b), 57 Fed. Reg. 7163 (Feb. 28, 1992)).[20] Those laboratories that use FDA cleared or approved tests are required to employ fewer quality controls than those laboratories that use modified tests or LDTs.

At bottom, the 1992 CLIA regulation recognizes LDTs as a separate class of tests not subject to FDA clearance or review, and by implication, FDA jurisdiction. That regulation is

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[19] Correspondingly, FDA has never performed a Regulatory Flexibility Act analysis, as would be required of significant substantive rules. FDA acknowledges that it did not perform any economic analyses of its guidances or of its determination that an LDT is a medical device. Dr. Shuren stated during the September 9, 2014, 21st Century Cures Act hearing that while the Agency had not conducted a formal economic impact analysis, and had no "hard numbers" of the cost to laboratories, the cost to laboratories should be manageable because laboratories should already have the clinical data in hand and the cost should primarily be sending in the data to FDA. 21st Century Cures hearing) (statement of Dr. Jeffrey Shuren, Director, CDRH, FDA); *see also id.* at 68.

[20] FDA's determination is also inconsistent with the Secretary's Medicare rules holding that a diagnostic laboratory test is a "service." *See, e.g.*, 42 C.F.R. § 410.32(d)(1). We understand that CMS has issued FAQs stating that LDTs are subject to FDA regulation. The FAQ is irrelevant as it is inconsistent with the plain language of CMS' 1992 and 2003 regulations, and potentially inconsistent with the Court's recent decision in *Azar v. Allina Health Services*, 139 S.Ct. 1804 (2019), requiring notice and comment rulemaking, rather than FAQs, with respect to any policy that may affect Medicare payment or eligibility to receive benefits or provide services or payment. *Allina* requires notice and comment rulemaking even in situations where the APA would not.

consistent with the legislative history underlying the 1988 amendments to the original Clinical Laboratory Improvement Act of 1967, which was limited to specimens traveling in interstate commerce. In supporting the 1988 amendments, Chairman Waxman noted the complete absence of federal regulation in certain instances: "many laboratories, particularly physicians' offices and smaller laboratories not accepting specimens in interstate commerce, are not subject to such Federal regulations."[21] FDA's determinations that LDTs are devices, none of which was published for notice and comment rulemaking, are inconsistent with this CLIA rule and the legislative history surrounding the 1988 amendments.

This inconsistency leads to one outcome for two alternative reasons. An interpretive rule or other policy issued without the benefit of notice and comment is *void ab initio* if it is inconsistent with an existing legislative rule. The legislative rule takes precedence over the interpretive one. *See F.C.C. v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009) ("An agency may not, for example, depart from a prior policy *sub silentio* or simply disregard rules that are still on the books."); *Berkovitz v. United States*, 486 U.S. 531 (1988) (HHS is not free to ignore its own legislative rules); *Gunderson v. Hood*, 268 F.3d 1149, 1154 (9th Cir. 2001) (If a rule is inconsistent with or amends an existing legislative rule, then it cannot be interpretive."). Alternatively, the Agency determinations are void because they seek to modify or repeal an existing legislative rule which can only be accomplished through notice and comment rulemaking. *See Perez*, 575 U.S. at 105 ("APA rulemaking would still be required if [an agency] adopted a new position inconsistent with . . . existing regulations."); *Motor Vehicle Manufacturers Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29 (1983).

Thus, even if none of the statutory impediments noted above existed, the Agency's determination that an LDT is a "device" would still falter for want of notice and comment rulemaking.

III. CLIA and Other Provisions in the PHS Act Can Provide Appropriate Safeguards

Regardless of the advice outlined above, we note, in light of concerns raised by some regarding dual regulation by FDA and CMS in this space, that the Secretary retains authority to ensure administrative efficiency by channeling regulation of LDTs through one agency and to determine which agency should exercise that authority. Policymakers may wish to consider whether CMS, which regulates through the Spending Clause and already regulates the actual use of tests in the laboratory, is better suited legally and logistically to regulate LDTs than is FDA, which is tethered by the Commerce Clause and by statutory commerce clause requirements.

One might take the position that Congress has addressed the federal regulation of laboratory testing in CLIA, and the Secretary has determined or can determine that CMS is the agency within HHS to regulate clinical laboratories. This is not to say that by enacting CLIA Congress expressed an intent that no further regulation was necessary. Rather, CLIA's comprehensive scheme arguably makes regulation by another HHS agency less essential. That is especially the case where the second agency's authority is relatively limited or vulnerable to legal challenge. In such situations, the other agency often provides technical assistance and that could be a model in this instance as well.

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[21] Clinical Laboratory Improvement Act, Hearing Before the Subcomm. on Health and the Environment, 100 Cong. 167, at 1 (1988). Representative Waxman's statement does not recognize any post-1976 role for FDA in the regulation of laboratories.