American
Clinical Laboratory
Association

February 28, 2010

Internal Revenue Service
1111 Constitution Avenue, NW
Washington, DC 20224

Re: Notice 2010-89

Sent electronically via Notice.comments@irscounsel.treas.gov

Dear Ladies and Gentlemen:

The American Clinical Laboratory Association (ACLA), is pleased to provide these comments regarding implementation of the excise tax on medical devices in new Section 4191 of the Internal Revenue Code (the "Code"), as added by Section 1405 of the Health Care and Education Reconciliation Act of 2010, P.L. 111-152, 124 Stat. 1029 (2010), in conjunction with the Patient Protection and Affordable Care Act, P.L. 111-148, 124 Stat. 119 (2010) (collectively, "ACA"). We appreciate the opportunity to provide comments on this new tax, as well as the efforts being made by the Internal Revenue Service (IRS) and the Treasury Department to solicit views of the industry in advance of issuing guidance. We recognize the complex issues that IRS and Treasury will need to resolve in implementing this tax, particularly given that the medical device industry is diverse and innovative and includes a wide array of products and technologies, each of which may present unique issues under the excise tax. Clear guidance will be needed so that those affected will understand their responsibilities under the provision.

ACLA is a not-for-profit corporation that represents the nation's leading providers of clinical laboratory services, including local, regional and national laboratories throughout the United States. Most ACLA members offer tests that they develop "in house" (usually referred to as "Laboratory Developed Tests" or "LDTs"), which are the subject of this letter.

ACLA believes, based upon an analysis of the relevant statutory provisions, that the excise tax should be imposed as follows:

- **Reagents, equipment and other inputs used to conduct an LDT should be subject to the excise tax to the extent that these inputs constitute taxable medical devices, and**

- **LDTs should not be subject to the excise tax, because an LDT is a service, rather than a medical device.**

This result:

- is supported by the statute as well as the relevant legislative history,
- properly taxes the inputs that are devices used in performing laboratory tests, while excluding services from the tax,
- provides equal treatment between LDTs and other laboratory tests performed with a "kit", and
- avoids very complex administrative issues the resolution of which would unduly burden the IRS as well as taxpayers and would likely result in inappropriate inequities.

While we believe that this result is clear from the statute, ACLA recognizes that imposing traditional excise tax rules in the context of medical devices in general, and LDTs in particular, raises new issues. ***Therefore, ACLA requests that future guidance clarify that LDTs are not subject to the medical device tax***. One possible way to make this clear would be through an example of how the tax is to be applied.

These issues are discussed in detail below.

I. Background Information on LDTs

Clinical laboratories perform testing on human specimens ordered by physicians and other health care providers as an aid in the assessment of a patient's health and to help guide care and treatment. Laboratory tests can come to market under two different pathways – as an actual test kit or as an LDT. Under the first approach, a medical device manufacturer can develop a test as a physical product and then package all of the necessary components together in a "kit," including the necessary reagents and other materials, plus a package insert and directions for conducting the test. Manufacturers sell these kits to laboratories, hospitals, and other health care providers who then use them to perform testing. These types of kits are classified by the Food and Drug Administration (FDA) pursuant to its medical device authority as Class I, II or III devices, and the manufacturers are required to register their manufacturing establishments and list their products with the FDA. There is no question that these "kits," when sold by manufacturers to customers to perform tests, will be subject to the medical device tax (unless an exception applies, e.g., certain kits may qualify for the retail exception to the tax). The actual testing service performed with these kits, however, is not a device or regulated as such, but is a process or service and therefore would not be subject to the tax.

A second way that a test can be introduced, however, is when a laboratory develops an LDT. Laboratories are not usually regulated by the FDA, but rather are subject to a different oversight system established by the Clinical Laboratory Improvement Amendments (CLIA),[1] which is enforced and overseen by the Centers for Medicare and Medicaid Services (CMS), rather than by FDA. Unlike the commercial kits described above, LDTs are not sold to other laboratories, providers, physicians or patients. Rather, LDTs are developed "in house" by a laboratory, for use solely in the laboratory. Laboratories create LDTs by establishing a Standard

[1] 42 U.S.C. §263a.

Operating Procedure (SOP) for performing the tests and purchase reagents and other supplies in bulk to perform the LDTs. Some of these products, purchased in bulk, are taxable medical devices and, as such, should be subject to the medical device tax. Laboratories do not create a physical product like a test "kit." Instead, an LDT essentially describes a process for how a particular test service will be performed in the laboratory.

Laboratories that develop LDTs in house offer the test service to physicians and their patients. When the service is ordered, the laboratory performs the test and reports the result back to the physician. The laboratory does not use the inputs it acquires to develop a product that is sold, but rather performs a service.

Thus, in both situations – use of test kits and LDTs – there are two separate components: the inputs used to perform the test and the performance of the test itself. In both cases, the inputs would be subject to the device tax to the extent they are taxable medical devices, but the performance of the test would not be.

Laboratories choose to use LDTs for several reasons. First, there may not be a commercial test kit for a particular use available. Sometimes rare diseases affect such a small subset of the population that few incentives exist for manufacturers to develop a commercial version of a test. In other instances, the laboratory may believe that it can develop a superior version of the test as an LDT. A laboratory may have specific or proprietary clinical information that it can use to obtain clearer results. Finally, it may also decide to modify existing technology in a way that permits the test to be performed more efficiently, with clearer results, or targeted to a specific subset of the population. Any FDA-approved commercial test that a lab modifies in any way is also considered to be a laboratory-developed test under CLIA regulations. (As discussed further in this letter, any such FDA-approved kit generally would be subject to the excise tax.)

LDTs are extremely common and are performed within stand-alone clinical reference laboratories or laboratories in facilities at other locations, such as hospitals, physician pathology practices, and university medical centers. Large and small laboratories all develop some tests for their own use, in addition to purchasing test kits and equipment from medical device manufacturers.

II. Statutory Provisions

Section 4191(a) imposes on "the sale of any 'taxable medical device' by the manufacturer, producer, or importer a tax equal to 2.3 percent of the price for which so sold." Subject to certain exemptions, a "taxable medical device" is defined as "any device (as defined in section 201(h) of the Federal, Food, Drug and Cosmetic Act) intended for humans." Code §4191(b)(1). Thus, to be subject to the tax, two requirements must be met. First there must be a taxable medical device and, second, the device must be sold by a manufacturer, producer or importer.

Section 4191 was placed into Chapter 32 of the Code, which relates generally to manufacturer's excise taxes. Thus, in general, the pre-existing rules in Chapter 32 also apply to the medical device tax. It is, in fact, one of the pre-existing provisions of Chapter 32 – Section

4128 – that has created the issue discussed below. Notice 2010-89 specifically requests comments on issues relating to the application of these pre-existing rules to Section 4191.

III. Discussion and Analysis

A. Inputs Used to Perform LDTs Should be Subject to the Device Tax to the Extent They are Taxable Medical Devices

There are numerous different types of LDTs and the process for each varies. However, LDTs typically involve inputs that are needed for the laboratory to perform the test, including reagents, equipment and supplies. Many of these inputs will be "taxable medical devices" as defined in Section 4191 and ACLA expects that such inputs will be subject to the device tax when sold to a clinical laboratory. Not all inputs are taxable medical devices, and those that are not would not be subject to the excise tax.

For example, to perform even the simplest type of LDTs, the laboratory will use supplies to collect the blood or other specimens and equipment, such as a centrifuge, to prepare the blood or other specimen that is being tested. After preparation, the specimen may be mixed with other chemical reagents that react with the particular element being tested for and measured. That new mixture may then be analyzed in another instrument, that measures and reports out the level of the particular chemical for which the specimen is being tested. Or, in other events, another instrument may analyze the compound to further identify the chemical, virus, bacteria, or type of cancer or other disease that may be present. In this example, many of the inputs, such as the centrifuge and the analyzer and the chemical reagents would be taxable medical devices that would be subject to the device tax when they are purchased by the laboratory (just as a kit would be subject to the device tax). However, the actual testing service being performed by the laboratory using those devices would not be.

B. The Performance of an LDT is a Service that Should Not Be Subject to the Device Tax

As discussed above, a laboratory test kit would generally be subject to the excise tax when sold to the laboratory, because it would constitute a taxable medical device; however, the performance of the test using that kit is a service that would not be subject to the excise tax. Similarly, inputs for an LDT that are taxable medical devices, as discussed above, would be subject to the tax. However, an LDT using those taxable inputs should not be subject to the excise tax because it is a service, rather than a device.

Under Section 4191, a taxable medical device is any device as defined in Section 201(h) of the Federal Food Drug and Cosmetics Act (FFDCA) that is intended for humans. Section 201 (h) of the FFDCA defines a medical device, in pertinent part, 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 … (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."

As noted above, an LDT does not consist of a physical device or product. Rather, an LDT is a process or SOP used within the lab to perform a test. The FDA does not currently regulate LDTs as medical devices. The FDA does not require laboratories to seek approval or clearance for most LDTs. While most medical devices are classified as Class I, II or III by FDA, LDTs are not subject to this classification scheme. Further, laboratories utilizing LDTs are not required to pay user fees under the Medical Device User Fee Amendments of 2007 ("MDUFA"). In a few instances, FDA has moved to exercise enforcement authority where it believed a test offered by a laboratory did not meet the definition of an LDT. In just the past few months, FDA has announced that it is reviewing its current approach to LDTs; however, at the time the health care reform legislation was being considered and passed, FDA clearly did not regulate LDTs under its medical device authority. Indeed, just recently, the FDA described its position in the following way:

> Since the implementation of the 1976 Medical Device Amendments, the FDA has generally exercised enforcement discretion and not enforced applicable regulations with respect to LDTs, a class of in vitro diagnostics (IVDs) that are manufactured, including being developed and validated, and offered, within a single laboratory. Thus, the FDA has not actively regulated most LDTs.[2]

Further, the FDA does not subject laboratories to the fundamental registration and listing requirements of the FFDCA applicable to medical device manufacturers. Rather, the FDA considers laboratories service providers rather than device manufacturers. In exempting laboratories from the requirements applicable to medical device manufacturers, FDA regulations provide as follows: the requirements do not apply to "[p]ersons … whose major responsibility is to ***render a service*** necessary to provide the consumer (i.e., patient, physician, layman, etc.) with … the benefits to be derived from the use of a device; for example, a hearing aid dispenser, optician, ***clinical laboratory… whose primary responsibility to the ultimate consumer is to dispense or provide a service through the use of a previously manufactured device.***" 21 CFR §807.65(i) (emphasis added)

In performing LDTs, laboratories perform a service using previously manufactured devices, such as kits, supplies, reagents or instruments. Thus, ACLA believes that LDTs do not meet the requirements of a taxable device.

Additionally, in order for the tax to apply, there must be a sale of the device. In the case of LDTs, however, the LDT is not actually sold. The LDT process is performed only within the laboratory that develops it, and it is only used for services within that laboratory. Although laboratories make the results of the performance of the testing *service* available to ordering physicians, laboratories never sell the actual LDT itself in the same way that a manufacturer sells a test "kit". Thus, there is no product for sale that should be subject to tax.

The absence of any sale of a device would, ACLA believes, be determinative on this issue were it not for a pre-existing provision in Chapter 32 which creates some confusion.

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[2] http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm (last visited on February 15, 2011) (emphasis added)

Because Section 4191 added the device tax to Chapter 32 of the Code, dealing with manufacturer excise taxes, other pre-existing provisions of Chapter 32 may apply to the device tax. Section 4218 imposes a tax on the use of another otherwise taxable article. If this section applies, the tax on the article will be computed "on the price at which such or similar articles are sold, in the ordinary course of trade." As discussed below, ACLA does not believe that this provision is applicable to LDTs, but is seeking clarification out of an abundance of caution due to the newness of the tax.

Section 4218 generally operates as a backstop to the manufacturers' excise taxes in order to prevent avoidance of the tax when a manufacturer uses a taxable product itself (instead of purchasing the product subject to the tax from another manufacturer). The situations in which the tax on use applies for other manufacturers' excise taxes under Chapter 32 of the Code are far different than those at issue here. For example, the manufacturer of gasoline may actually use the gasoline in its own operation (e.g., to provide fuel for vehicles used by employees of the manufacturer in the course of business). If the use tax did not apply, the fuel would not be subject to tax in the same way as if it had been purchased from a third party. Similarly, a maker of tires might need to use some of those tires itself, rather than selling them. In those cases, Section 4218 is designed to ensure that those taxpayer uses of products become subject to the tax, even though no third-party sale occurs.

For LDTs the situation is far different. The laboratory is not producing and using for its own purposes medical devices that are normally sold and avoiding the tax by using the product in house. Therefore, the development of the LDT is not a means of avoiding payment of the tax in some way. Indeed, unlike the other situations in which the use tax is normally applied, the laboratory is purchasing products which are subject to the tax, regardless of how the product will be used by the laboratory. The laboratory then uses these taxed products to perform the test procedures. Thus, there is no avoidance of tax.

ACLA does not believe that this provision is applicable to LDTs, and seeks confirmation of this issue out of an abundance of caution.

C. Application of the Device Tax to LDTs Would Create an Unequal Playing Field in the Market

Imposing the device tax on LDTs would result in inequities in the application of the tax. As noted above, in the situation where a "kit" is used by a laboratory, hospital or other service provider to perform a test, the sale of the kit generally would be subject to the excise tax, but the testing process or service performed with the kit would not be subject to the tax. If the tax were imposed on an LDT, however, it would be imposed at a different point in the distribution process. Rather than imposing tax on the taxable inputs used to perform the test, as occurs with kits, the tax would be imposed when the test itself is performed. This would potentially impose a higher level of tax with respect to an LDT compared to other laboratory tests.

Applying the tax to the LDT would require the IRS to determine what portion of the fee paid for the testing service should be subject to the tax, an exercise that would be virtually impossible to perform. As noted, Section 4218 states that where it applies, the tax on the article is computed "on the price at which such or similar articles are sold, in the ordinary course of

trade." This formulation is relatively easy to apply in the case of gasoline, coal or tires, but is not so easy in the case of LDTs. As noted above, there is not a comparable product that is sold in commerce on which the tax can be based. Many LDTs are wholly *sui generis,* in a class by themselves.

It would be inappropriate to base the computation of the tax on the total reimbursement received from third party payers because that reimbursement is a reflection of the value of the test *service* performed by the laboratory, not what would be earned on the resale of the LDT components as medical devices. The price of the service—whether performed using a test kit or an LDT—includes additional laboratory costs, such as specimen collection, test performance, result delivery overhead, sales and marketing, regulatory compliance, personnel costs, rents, equipment and supplies, and many other expenditures. All of these expenses are added to the cost of the kit or the inputs for the LDT to develop the "price" for the service. Taxing an LDT on this price would overtax LDTs compared to laboratory testing performed with kits and create an unjustified inequity in the market.

Furthermore, notwithstanding the price charged for that service, the laboratory is reimbursed at varying levels, depending on the payor and whether the laboratory is in-network, out-of-network, and many other variables, including payment mechanisms such as capitation, where there is no "price" or even payment for the specific test, but rather a per-member, per-month payment from a health plan to the laboratory. Thus, applying the tax on LDTs at a different point in the process would involve very different, and more subjective, determinations than would occur if the tax was imposed on the inputs for the LDT, as occurs with kits.

D. Attempting to Impose the Tax on LDTs Would Raise Significant Enforcement and Interpretation Issues

The method of implementing the tax we describe here is not only the best interpretation of the statutory provisions, but also provides the most rational and administrable approach. Under this approach, there is a clear point for imposition of the tax, either when a kit is sold to a laboratory or when taxable reagents, equipment or other taxable inputs that are medical devices are sold to a laboratory that performs an LDT. This also results in the fewest potential points of collection of the tax and is consistent with how manufacturers' excise taxes are generally collected.

On the other hand, numerous enforcement and interpretative issues would arise if LDTs were considered subject to the medical device tax. First, it will be very difficult for Treasury to monitor the use of LDTs. Unlike medical devices that are subject to listing with FDA, there is no single source of information about the use of LDTs. They are simply utilized within the laboratory and there is no way to determine when they are used or how often. In fact, LDTs are used throughout the health care system, by independent clinical laboratories, hospital laboratories, academic research institutions, and medical colleges. It would be extremely difficult to determine what services are subject to the tax and to enforce the application of the tax at all of these numerous and various locations.

Yet another issue that would arise is that, if LDTs are subject to tax, then the otherwise taxable inputs that were purchased to perform the LDT should not be subject to the tax, under the

preexisting rule that provides for tax-free sales of otherwise taxable items for use in further manufacture of a taxable item under Code Section 4221. Attempting to apply that rule would raise a number of difficulties, including determining whether a particular product should be subject to tax when purchased. For example, certain taxable supplies and reagents are purchased in bulk because they are used in a variety of settings in a laboratory. A particular reagent can be used when a laboratory performs a particular test using a kit; however that same reagent might also be used in an LDT. Each of these situations involves different tax consequences. If LDTs were taxed, then each time a manufacturer sold a laboratory the taxable reagent in bulk, it would be necessary to determine what proportion of the total sale should be tax free, or in some cases to apply for refunds. This type of complexity would make application and enforcement of the tax significantly more difficult.

Moreover, there is not a single uniform definition of what constitutes an LDT. For example, in some instances, laboratories purchase "kits" and then modify them in some way, and validate the resulting test, in accordance with CLIA requirements. In that case, would the sale of the kit by the manufacturer be subject to the tax, or would the tax be imposed on the laboratory for the validated, modified test? At what point does a modification of a kit actually transform the kit into an LDT? Finally, as noted above, it will be very difficult to determine the appropriate price of the LDT, for purposes of applying the tax because price often bears no predictable relationship to payment.

E. The Legislative History Supports the Conclusion that LDTs are Not Subject to the Device Tax

Both the laboratory industry and the medical device manufacturing industry contributed in their respective ways to the funding of health care reform. The primary purpose behind imposing a medical device tax was to obtain a contribution from registered device manufacturers to help offset the costs of health care reform, because, unlike laboratories and other service providers, medical device manufacturers are not directly reimbursed by Medicare. Laboratories, on the other hand, are directly reimbursed by Medicare through the claims submitted for their services; therefore, the contribution of the laboratory industry to health care reform was made through a direct cut in their Medicare reimbursement.[3]

The laboratory industry actively and cooperatively worked with the key committees in the House and the Senate to identify cuts in laboratory reimbursement that could be used to help fund health care reform. Those cuts were implemented as reductions in the clinical laboratory fee schedule which Medicare uses to pay for clinical laboratory tests. Those cuts, totaling $10 billion over 10 years, were included in the final legislation. At no point was it ever suggested that laboratories would be responsible for providing additional savings through the medical device tax. More recently, key Committee Staff have confirmed to ACLA that no one on the Committees considered LDTs in connection with the device tax requirements.

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[3] Under PPACA, laboratories are subject to a permanent productivity adjustment, applied to the CPI update that they would otherwise receive, and an additional 1.75% cut for each of the years 2011 - 2015. *See* PPACA §3401(l).

Significantly, at one point earlier in the process, the Senate staff had proposed a separate tax on laboratory revenues, rather than a cut in reimbursement. The fact that the Senate considered a tax on laboratory revenues, at the same time that it was considering a tax on medical devices, strongly supports the view that Congress did not believe that LDTs were subject to the device tax. Had the Senate believed laboratory testing would be captured by the device tax provisions, there would have been no need to consider a separate laboratory tax. However, the proposed laboratory tax was replaced—dollar for dollar—with the cuts to the laboratory fee schedule that were ultimately enacted. Thus, there is no basis to conclude that the Senate expected to obtain any revenues from laboratories as a result of imposing the device tax on LDTs.

Other aspects of the legislative history also show that there was no intent to capture LDTs under the device tax. For example, the original provision in the Senate bill regarding medical device fees was not an excise tax, but was instead a separate "fee" that was imposed on revenues resulting from the sale of medical devices.[4] That provision would have imposed a fee based on a manufacturer's share of gross revenues from medical device sales. Of course, as noted, LDTs themselves are not sold, so this original provision would not have affected these tests. In addition, because this new fee was not an amendment to the Code, Section 4218 of the Code, discussed above, would not have applied. Thus, there would be nothing to sweep LDTs within the purview of this new device fee.

Further, in the Chairman Baucus' Committee Mark, which set out the specifications for the provisions that were ultimately included in the Senate bill, the description of the device fee states that it would apply to "medical devices ***regulated*** by the Food and Drug Administration as a medical device and ***subject to premarketing and post marketing regulatory controls***." This clearly would not have applied to LDTs because they are not regulated by the FDA and are not subject to pre- and post- market controls. It is only because the Senate language was replaced at the 11th hour by the excise tax provisions—which thus brought Code Section 4218 into play—that the current issue was created.[5]

CONCLUSION

For the foregoing reasons, ACLA requests that Treasury and IRS make clear in initial guidance on the excise tax that the tax does not apply to LDTs. If you have any questions or comments, please do not hesitate to contact me.

Sincerely yours,

Alan Mertz
President

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4 *See* PPACA §9009.

5 Early versions of the House Bill, which were not ultimately enacted, did include a medical device excise tax. However, discussions with the House staff of Ways and Means confirmed that they also did not intend for that provision to apply to LDTs.