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The FDA Drops a Bombshell: No More EUA Review of COVID-19 LDTs

Perhaps one of the only positive things to come out of the COVID-19 crisis has been its exposure of the flaws in the FDA's ham-handed system (if it can be called a system) of premarket regulation of laboratory developed tests (LDTs). The seeming moment of decision came in August, when HHS announced that the FDA will no longer be able to regulate by informal decrees but will have to go through the customary notice and comment rulemaking process required for new regulations to regulate LDTs. However, things have now taken another unexpected, and this time unwelcome turn with the agency announcing that it will no longer review applications for Emergency Use Authorization of COVID-19 LDTs.

The Controversy Over FDA LDTs Regulation

Lab tests weren't included in the original legislation that created the FDA and current regulatory system of medical drug and device

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Enforcement Trends: Whistleblowing Activity Continues to Grow Despite the Pandemic

Even during a pandemic, False Claims Act whistleblower litigation against labs and other health providers continues to be a highly profitable business for both whistleblowers and the federal government alike. However, while uptick in whistleblower activity is par for the course, new takedowns and fishing expedition information gathering practice by the federal government may betoken potentially disturbing new trends that drive up both compliance costs and risks.

The Thriving Whistleblower Industry

First things first. It takes enormous courage to be a whistleblower and the vast majority of individuals willing to stake their careers

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The FDA Drops a Bombshell: No More EUA Review of COVID-19 LDTs, *from page 1*

regulation. So, the agency has relied on its powers to regulate devices to exert oversight of lab tests. Accordingly, LDTs must obtain premarket approval through the 510(k) pathway for medical devices.

In addition to challenging the FDA's authority over LDTs, the lab industry has long objected to the agency's practice of skirting the regulatory process and relying on guidance, website statements and other informal issuances to make regulatory policy.

The HHS Decision

On Aug. 19, HHS raised eyebrows by taking the same position and essentially stripping the agency of its authority to regulate LDTs via website pronouncement, guidance and other informal methods. From now on, the FDA rules over LDTs would have to go through the normal notice and comment rulemaking process required to establish new federal regulations.

One result of the HHS decision, which is part of the Administration's broader policy to cut government regulation over business, was to enable labs to offer LDTs for SARS-CoV-2 without going through the EUA process. "Those with an active EUA to use an LDT to detect the virus causing COVID-19 or its antibodies are unaffected by this announcement," HHS added.

The FDA Abdication

So far, so good. But on Oct. 7, during its weekly virtual town hall briefings, the FDA dropped a bombshell by announcing that it will longer review COVID EUA submissions for LDTs. Whether deliberately spiteful or not—so, you want us to go through formal rulemaking, then we'll show you—the agency said that dropping EUAs for LDTs was consistent with the recent HHS announcement and necessary to prioritize its scarce review resources.

"We are currently in a different phase of the pandemic with respect to tests," explained **Timothy Stenzel**, director of the Office of In Vitro Diagnostics and Radiological Health at FDA's Center for Devices and Radiological Health, noting that the FDA has authorized more than 250 tests to be run in labs. Stenzel also clarified that the agency would prioritize review of EUA requests for point-of-care tests, home collection tests, at-home tests, tests that reduce reliance on certain types of test supplies and high-throughput, widely distributed tests.

The new approach applies not only to new EUA submissions but also to those already submitted for review, although Stenzel offered assurances that the agency had made last-ditch efforts to wrap up review of submissions "close to the finish line" in the interest of fairness. But LDTs that were "further out from potentially being authorized" will progress no further through the pipeline. And no new submissions will be accepted.

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The Aftershocks

The announcement caught the industry off-guard. The American Clinical Lab Association (ACLA), which had generally supported the HHS announcement, criticized the FDA's decision. In a statement, ACLA president **Julie Khani** called on the FDA to continue to let labs voluntarily submit EUAs for COVID-19 LDTs, noting that many of the tests that have received EUA are precisely the kinds of "innovative, high-throughput [tests] that have reduced reliance on supplies and been integral to expanding testing capacity" that the new FDA policy is purportedly designed to promote.

The FDA decision to stop reviewing LDTs may thwart development of innovative tests. Specifically, it gives test makers three good reasons not to launch new COVID-19 LDTs:

1. Reimbursement Uncertainty

One problem is the new uncertainty it creates over reimbursement. That's because the Family First Coronavirus Act (FFCRA) requires commercial payors to cover medically necessary SARS-CoV-2 testing without cost sharing, but only if they have EUA from the FDA. Consequently, labs developing new SARS-CoV-2 LDTs face the prospect of not being reimbursed for their tests.

2. Liability Risks

In addition to reimbursement risk, taking EUA off the table heightens test makers' liability exposure by stripping away the immunity protections afforded by the Public Readiness and Emergency Preparedness (PREP) Act. Like reimbursement under FFCRA, immunity from claims for use of tests during the public health emergency under PREP applies only to tests with EUA. And because of the urgency of the situation and need to get tests out faster than normal, test makers need these liability protections in case things go wrong. COVID-19 litigation has already become big business for trial lawyers and labs that develop inaccurate or faulty LDTs will be a sitting duck.

3. Harm to Competitiveness

While it's not full FDA approval, EUA status raises the credibility of a lab test product in the eyes of payors, clinicians and even patients. So, taking EUA off the table may make it harder for new LDTs to compete in the market, particularly against tests that have EUA.

Takeaway

While deregulation of LDTs has long been an industry goal, the FDA's new policy of completely bowing out of EUA review of new SARS-CoV-2 tests is a wrong-headed and perhaps even spiteful decision that works against the very goals it's purported to promote.

Letter to Pence: Leading Lab Organizations Ask White House to Resolve COVID-19 Testing Supplies Shortages

COVID-19 lab testing supplies have been a bottleneck from the moment the public health emergency began. But what's less well understood is that the supplies problems stem not just from the lack of volume but also transparency with regard to allocation. With that in mind, a group of leading lab organizations have appealed directly to the Vice President of the U.S. for help.

The Letter to Pence

The Oct. 6 letter to Vice-President **Mike Pence** asking for the White House to play a more active role in promoting transparency on the allocation of COVID-19 testing supplies was signed by six organizations representing lab professionals from across the country, including:

- The American Association of Bioanalysts;
- The American Association for Clinical Chemistry;
- American Medical Technologists;
- The American Society for Microbiology;
- The Association for Molecular Pathology; and
- The National Independent Laboratory Association.

The organizations also directed copies of the letter to HHS Secretary **Alex Azar**, White House Coronavirus Response Co-ordinator **Dr. Deborah Birx** and White House Coronavirus Testing Co-ordinator **Dr. Brett Giroir**.

Testing Supplies Challenges

The letter's signatories provide SARS-CoV-2 RT-PCR, antibody, and antigen testing using a variety of platforms. These tests, the letter stated, require supplies that are currently in severe shortage, including pipette tips, reagents, and test kits. Because of shortages, these organizations stated that they're operating below their potential testing capacity and below the capacity that their communities demand. As a result, COVID-19 test volume is lower and turnaround time is longer than it should be. As an example, the letter cites one lab that's currently processing only 500 tests per day, far below its capacity to provide at least 3,000 tests per day.

Compounding this problem, the letter continues, is the lack of transparency into the federal government's acquisition and distribution of testing supplies to states and private labs. According to the letter, current efforts to share information on supply availability, such as the FDA's Medical Device Shortage listing, lack the specificity necessary to enable labs to understand what supplies are in production, where the supplies can be procured and when they will be available.

"Nearly eight months into the COVID-19 public health emergency, the medical supply chain remains weak and laboratories still do not have

the supplies needed to meet the testing needs of their communities," the letter states. "Until the federal government takes action, these shortages will persist, future surges in the pandemic will occur, and patients will continue to suffer."

What the Organizations Want

Of course, the letter writers asked the White House to encourage production of the supplies and reagents which are in short supply. But the crux of their message focuses on transparency and logistics. The letter urged the White House Coronavirus Task Force to lead a coordinated federal effort to transparently communicate information on the availability of COVID-19 testing supplies and to do everything possible to encourage the production of sufficient testing supplies to meet the needs of every state.

"Our organizations would like to offer our partnership in that pursuit, but believe your leadership is greatly needed," according to the letter. "We cannot rely on one test platform or two or three large manufacturers to increase our testing capacity to the level our country demands." A coordinated national response spearheaded by the White House "would enhance our nation's response to the pandemic, reduce wait time for COVID-19 test results, and permit our members to operate closer to the needed testing capacity," the letter states.

Takeaway

The six signatory organizations have asked for a meeting to discuss the supplies issues that their letter documents. As of yet, no such meeting has been scheduled and it's unclear if one will ever be. Of course, that doesn't necessarily mean that no one's listening. Other letters from the lab industry to the Vice President asking for help with the supplies situation have had at least some impact on the White House. It remains to be seen if this one will as well.

Reimbursement: New Medicare 2021 Pay Rule Penalizes Labs for Long COVID-19 Test Turnaround Times

On Oct. 15, CMS announced new Medicare reimbursement policies designed to cut turnaround time and speed up processing of COVID-19 tests.

Medicare Reimbursement of COVID-19 Testing

When the public health emergency first began, Medicare paid labs $51 per test for high throughput COVID-19 diagnostic

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Reimbursement: New Medicare 2021 Pay Rule Penalizes Labs for Long COVID-19 Test Turnaround Times, *from page 5*

tests. Recognizing that the rate was inadequate, CMS raised it to $100 per test. However, new effective Jan. 1, 2021, labs will only qualify for the $100 payment rate if they complete the test within two calendar days of collecting the specimen. Labs that take longer than two days will be paid only $75 per test.

The Way It Works

Technically, the amended Administrative Ruling (CMS 2020-1-R2) lowers the base rate payment amount for COVID-19 diagnostic tests run on high throughput technology to $75. However, labs will qualify for a $25 add-on payment if:

- They complete the billed test in two calendar days or less; AND
- They complete the majority of high throughput COVID-19 tests in two calendar days or less for **all** of their patients (not just their Medicare patients) in the previous month.

Labs that qualify will use HCPCS code U0005 to bill for the add-on payment. Labs that fail to meet the add-on payment criteria will receive only the $75 base pay rate.

The new payment policy "supports faster high throughput testing, which will allow patients and physicians to act quickly and decisively with respect to treatment decisions, physical isolation, and contact tracing," notes CMS Administrator **Seema Verma** in the announcement press release.

Takeaway

Really, CMS? Nobody disagrees that rapid COVID-19 testing is essential and that turnaround times are far too long. However, the implication that a 25 percent add-on payment will get labs to speed up the process is ill-informed and even downright insulting. Further adding insult to the injury is that what's being presented as an incentive is actually a price cut, just the same way it would be if your boss cut your salary by 25 percent and offered you the opportunity to earn a "raise" by working faster.

Reporting Trends: Lack of Reporting, Not Tests, Is the Bar to Mass Utilization of COVID-19 Antigen Testing

Because of their low costs, scalability and speed, antigen tests may play a crucial role in meeting the unprecedented level of demand for point of care COVID-19 screening tests, particularly in nursing home, educational and workplace settings. However, if antigen testing is to be the answer, there's one significant problem that will need to be addressed: lack of reliable and consistent test data reporting.

Could Antigen Testing Be the Answer?

There's a desperate need for point of care tests for screening asymptomatic populations that can deliver accurate results at cost-effective prices While accurate, RT PCR tests are performed at offsite labs which undermines their effectiveness for widespread and rapid screening. Blood-based serology tests that detect SARS-CoV-2 antibodies can be performed at the point of care but lack the specificity and sensitivity of RT PCR assays.

Tests that detect viruses by identifying the presence of antigens or toxins a virus produces that cause the body to produce antibodies are relatively inexpensive to produce and generate results rapidly at the point of care. And while its relative lack of sensitivity creates the risk of false negatives and need for confirmatory testing, antigen testing may still be appropriate for applications like screening health care workers and other high-risk groups and triaging patients during peak outbreak periods.

Moreover, developers and manufacturers of rapid antigen tests have declared that they're ready and able to meet demand for increased testing in the coming months. On Aug. 26, the FDA granted Emergency Use Authorization to Abbott Laboratories' BinaxNow COVID-19 Ag Card, a SARS-CoV-2 antigen test that doesn't require an analyzer to read the results and works like a home pregnancy test. Other companies like Roche, Quidel, AccessBio and LumiraDx have or soon plan to launch rapid and scalable SARS-CoV antigen tests.

The Potential Stumbling Block

The cloud to the antigen testing silver lining is lack of an adequate data reporting infrastructure to support it. The same features that make antigen testing so scalable also complicate reporting of test data to public health authorities. By contrast, testing labs have the equipment, skills and experience to report data electronically. Accordingly, more than 20 states either don't release or have incomplete data on rapid antigen testing, according to a new report from Kaiser Health News (KHN). Key findings:

- 21 states and the District of Columbia do not report all antigen test results;

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Reporting Trends: Lack of Reporting, Not Tests, Is the Bar to Mass Utilization of COVID-19 Antigen Testing, *from page 7*

- 15 states and D.C. do not count positive results from antigen tests as COVID cases;
- Two states do not require antigen test providers to report results;
- Five states require only positive results to be reported; and
- Nearly half of states believe their antigen test results are underreported.

This resulting lack of data bedevils the efforts of public health officials and policy makers charged with monitoring the scope of the pandemic and making crucial decisions about reopening schools and other forms of public activity. It also artificially deflates the number of COVID-19 cases, potentially creating the dangerously false impression that the infection rate is declining when the virus is actually spreading on a continued or even accelerated rate. And as utilization of antigen testing continues to expand, this blind spot will only continue to grow.

States that Don't Report Antigen Test Results or Don't Count Antigen Positives as COVID-19 Cases

California, Colorado, District of Columbia, Georgia, Illinois, Maryland, Minnesota, Missouri, Montana, New Hampshire, New Jersey, North Carolina, North Dakota, Ohio, Pennsylvania, South Dakota, Tennessee, Texas, Vermont, Virginia, Washington, Wisconsin, Wyoming

Source: Kaiser Health News

What Counts as a COVID-19 Case

Part of the problems with antigen test reporting is that under CDC guidance, a case must be determined from a RT PCR test to be considered a "confirmed" case of COVID-19. Positive antigen tests are considered "probable" COVID-19 cases because the tests are less accurate. In early August, the CDC revised its guidelines to allow a positive antigen test to count as a probable case without assessing whether the person has COVID-19 symptoms or close contact with a person confirmed as having the virus.

This asterisk placed by the CDC on antigen positives has led to a disconnect among state reporting rules, with some states requiring reporting of only "confirmed" COVID-19 cases while others require reporting of both "confirmed" and "probable" cases.

Takeaway

Reporting of test data will be crucial to contain the spread of COVID-19 and make scientifically sound decisions about the pace and scope of reopening. In recognition of this, CMS recently imposed draconian new

testing requirements on skilled nursing facilities and stepped up the penalties for violations of existing reporting rules for hospital and other laboratories. As the use of rapid antigen testing proliferates, policy makers at both the federal and state levels will have to confront and resolve the problems that are currently preventing full, consistent and accurate reporting of antigen test results.

Testing Trends: Total Shipments of Molecular COVID-19 Tests Top 200 Million Mark

As of Oct. 16, total U.S. shipments of COVID-19 molecular diagnostic tests have topped 200 million, according to the AdvaMed COVID-19 Diagnostic Supply Registry (Registry). On average, diagnostics companies are shipping over 1.4 million molecular tests every day. Registry data also show that approximately 121 million COVID-19 molecular tests have been administered.

The AdvaMed Registry

Since the pandemic began, federal and state government response actions have been impaired by the lack of widely available national data on COVID-19 and supplies has been a problem impairing since the pandemic began. On July 21, with that problem in mind, the Advanced Medical Technology Association (AdvaMed) launched a national COVID-19 diagnostic supply registry compiling information from diagnostic companies with publicly available daily test data. The Registry provides weekly state and national updates on the number testing of molecular and serology (antibody) tests shipped in the U.S. AdvaMed and AdvaMedDx, the association's diagnostics division, developed the Registry in partnership with 13 commercial diagnostics manufacturers:

- Abbott;
- Becton Dickinson;
- bioMérieux;
- Bio-Rad;
- Beckman Coulter;
- Cepheid;
- Hologic;
- Ortho Clinical Diagnostics;
- QIAGEN;
- Roche Diagnostics;
- Sekisui Diagnostics;
- Siemens Healthineers; and
- Thermo Fisher Scientific.

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Testing Trends: Total Shipments of Molecular COVID-19 Tests Top 200 Million Mark, *from page 9*

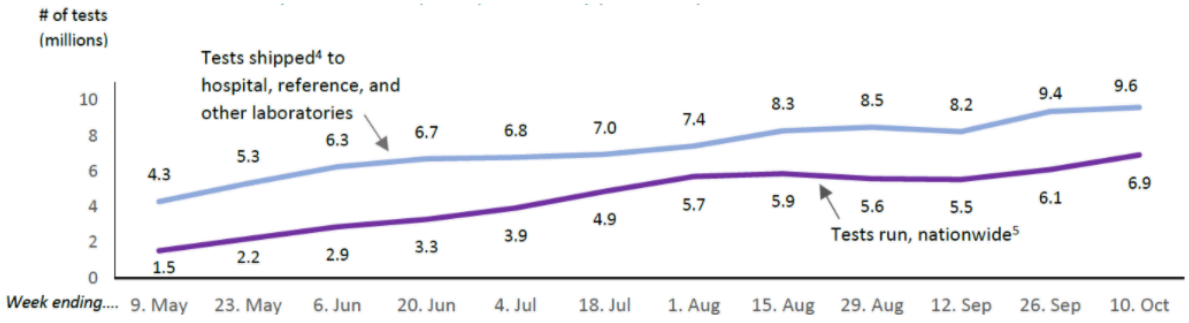
Key Registry Findings

According to the Registry, as of Oct. 16:

- The 13 Registry participants have shipped over 200 million cumulative molecular COVID-19 tests nationwide since March 2020, including approximately 145 million commercial tests and 55 million extraction reagents;
- On a week to week basis, the number of daily molecular tests run increased approximately 5 percent compared to the previous week (Oct. 9), up to an average of approximately 1.1 million tests per day;
- High-quality serology testing authorized by the U.S. Food and Drug Administration remains available at scale with industry capacity to manufacture 100 million tests per month.

Registry participants are also bringing antigen testing to the market with significant manufacturing capacity, the Oct. 16 report notes.

Weekly Molecular (MDx) tests shipped & reported test results nationwide[3]



Source: AdvaMed COVID-19 Diagnostic Supply Registry

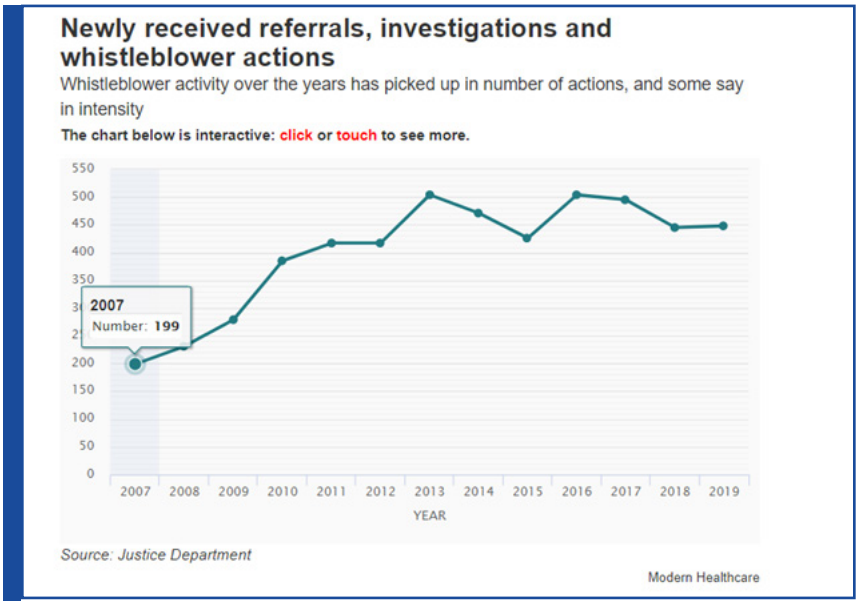
Takeaway

"For the past few months, our diagnostics companies have made it clear they'll do whatever it takes to stay ahead of COVID-19 testing demand to help bring this pandemic under control," Scott Whitaker, president and CEO of AdvaMed said in a press release, "200 million molecular tests shipped nationwide since the beginning of the pandemic is a remarkable testament to their commitment to saving lives."

Enforcement Trends: Whistleblowing Activity Continues to Grow Despite the Pandemic, *from page 1*

and reputations on suing their employers don't do it for the money. But having said that, it's also true that winning a *qui tam* whistleblower lawsuit can net a whistleblower, aka relator, a fortune, including up to 25 percent of whatever the government recovers from the action if it chooses to intervene.

While growth rates have tailed off somewhat since 2010, the federal government still recovers billions of dollars from whistleblowing activity targeting the health care sector each year—including $3.6 billion in 2019—with relators enjoying a big chunk of the profits. And those figures belie the true costs labs and other providers incur in defending claims that turn out to be baseless.



The 'Takedown' Effect

The pandemic has done little to blunt whistleblowing investigations and litigation. On the contrary, 2020 and 2021 are shaping up to be record years for recoveries due, in part, to the Department of Justice's (DOJ) massive healthcare takedown initiatives. In 2019, it was Operation Double Helix targeting genetic testing fraud.

And lest anybody thought 2020 might bring a lull, in late September, the DOJ unveiled Operation Rubber Stamp, the largest healthcare takedown in the agency's history charging more than 345 people across 51 federal districts, including 100 doctors, with submitting over $6 billion(!) in false claims to public and private insurers, mostly for telemedicine services. Numbers like that are likely to fuel even more and bigger probes in the future, experts say.

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From Investigation to Fishing Expedition

The step-up in enforcement is reflected not only in the higher numbers of charges and recovery amounts but also the aggressiveness of investigators' tactics. "Burdensome investigative demands for documents seem to be on the rise," notes Hogan Lovells' attorney **Craig Smith** quoted in a recent article from *Modern Healthcare*. Other attorneys cited in the excellent piece note that investigators often start with broad demands and may ask a provider for five to 10 years worth of data, requests that can cost providers tens or even hundreds of thousands of dollars to fulfill.

The investigators' role is to gather evidence and root out wrongdoing. But investigators are, in essence, flipping the script, counting on the providers to do the extensive data analysis and prove that they did nothing wrong. And as enforcement budgets continue to tighten, lawyers expect such fishing expedition tactics to continue and grow more common.

Takeaway

Whistleblowing remains a major concern not just for labs that do ill but those that work like heck to do right. But the fishing expedition type of investigation does represent something of a novel, and hopefully, short-lived phenomenon. The good news is that attorneys say that if you cooperate and work with investigators, whether state or federal, you can often get them to agree to narrow the scope of their requests for records and data.