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New FDA Guidance Aims to Ease Approval for New NGS Tests—But It Probably Won't Work

Test makers have long complained about the FDA's unwillingness to embrace technology and diagnostics advances. But on April 13, the agency took steps to address those concerns by issuing a pair of final guidances designed to make the process for securing approval of new next-generation sequencing (NGS) tests quicker and easier. Here is the lowdown on each guidance and what it might portend for NGS test development going forward.

Guidance 1: Use of Public Genetic Variant Repositories to Show Clinical Validity

The first final guidance, which bears the catchy title "Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic & Genomic-Based In Vitro Diagnostics," explains how NGS test developers can rely on FDA-recognized public genetic variant repositories to support the accuracy of their tests and related marketing claims.

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Medicaid Fraud: Enforcement Continues to Trend Down as Labs Drift Deeper into the Background

Last month, the OIG published its annual summary of Medicaid Fraud Control Unit (MCFU) activity for FY 2017. Here is a summary of the key findings, trends and impact on labs.

Background

The 50 MCFUs are essentially the state arm of the OIG in charge of investigating and prosecuting provider Medicaid fraud and patient abuse violations. Each year, the OIG issues a report documenting aggregate MCFU case outcomes for the prior year including convictions, civil settlements, judgments and recoveries.

Criminal Convictions

At 1,528, total MCFU convictions remain flat over a five-year period with fraud accounting for 73% of all convictions.

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New FDA Guidance Aims to Ease Approval for New NGS Tests, *from page 1*

A "genetic variant database" means a publicly accessible database of human genetic variants that aggregates and curates reports of human genotypephenotype relationships to a disease or condition with publicly available documentation of evidence supporting those linkages, the guidance explains. While following an open-access model is a best practice for databases that may be used to support clinical validity of genetic or genomic tests, the guidance adds that databases which use licensing models and charge fees for commercial use may also qualify for such uses.

The guidance lists the criteria of reliability for a genetic variant database. It should:

- Operate so as to provide sufficient information and assurances regarding the quality of source data and its evidence review and variant assertions;
- Offer transparency regarding its data sources and operations, particularly on how variant evidence is evaluated;
- Collect, store and report data and conclusions in compliance with all applicable requirements regarding protected health information, patient privacy, research subject protections and data security; and
- House genetic variant information generated by validated methods.

Guidance 2: Design of NGS Tests for Diagnosing Germline Diseases

The other final guidance ("Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing–Based In Vitro Diagnostics Intended to Aid in the Diagnosis of Suspected Germline Diseases") explains to test developers the types of data the FDA is looking for in premarket submissions for such tests.

The guidance then lists recommendations covering different aspects of NGS test development and quality including:

- NGS test design considerations;
- Test performance and accuracy;
- Test run quality metrics;
- Performance and evaluation studies;
- Supplemental procedures;
- Variant annotation and filtering;
- Presentation of test performance in labeling; and
- Test reports.

Why Guidance Probably Won't Have Much Practical Impact on NGS Test Development

The self-stated objective of the guidance is to "help ensure patients receive accurate, reliable, and clinically meaningful test results, while promoting innovation in test development." According to Jeffrey Shuren MD, director of the FDA's Center for Devices and Radiological Health, the new final guid-

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ance on genetic variant databases "will change the paradigm" of NGS development "by encouraging data sharing and the accumulation in public databases of evidence supporting the clinical validity of genomic tests to help provide an even more efficient path to market."

But while certainly well-intentioned and constructive, the new guidances will have a hard time living up to the "paradigm changing" expectation that FDA officials are fostering.

Too Limited in Scope

For one thing, the guidances apply to new tests that are undergoing premarket review. But premarket review is not required to secure FDA approval of lab developed tests (LDTs). Accordingly, NGS test makers typically treat their NGS-based tests as LDTs to get around the need for premarket review. Result: The guidance will have minimal practical impact on LDTs development, at least for the near future.

The related problem is that the guidance expressly excludes many kinds of NGS-based tests, including:

- Companion or complementary diagnostic testing;
- Cell-free DNA testing;
- Microbial infection diagnosis;
- Microbial genome identification;
- Detection of antimicrobial resistance and virulence markers;
- Pre-implantation embryo testing; and
- RNA sequencing.

Draft Guidance on Determining Risk of Investigational Oncology IVDs

On the same day it issued the NGS testing final guidance, the FDA published new draft guidance laying out a streamlined process for evaluating investigational *in vitro* devices (IVDs) in oncology drug trials, specifically addressing whether the investigational IVD is considered significant risk (SR), nonsignificant risk (NSR) or exempt. The draft guidance says that the FDA device division will make this risk determination alongside the drug division's evaluation of the investigational new drug application. It also calls on sponsors to submit information on how the test results will be used in the clinical trial, discuss the prevalence of the biomarker in the patient population and any risks the biopsy collection process has on study subjects.

If the drug and device divisions find that an investigational IVD in a particular study confers non-significant risk, the FDA will issue a letter instructing sponsors to proceed with the trial ensuring that biopsy procedures do not carry significant risks and report any unanticipated adverse events. If the test is found to carry significant risks, FDA will tell the sponsor to submit an IVD exemption application and wait to start the trial until it is approved. Trials of invasive biopsy procedure presenting serious health risk to study participants would not be eligible for the new streamlined submission process, the guidance notes.

The deadline to comment on the draft guidance is June 12, or roughly 60 days from the April 13 publication date.

PAMA Reimbursement:
CMS Explains How to Get ADLT Status for New Lab Tests

Although the 2018 market-based Clinical Laboratory Fee Schedule (CLFS) is officially in effect, implementation of the new PAMA Part B payment rules for lab tests remains a work in progress. On March 23, CMS filled in some of the missing details by issuing guidance for labs seeking ADLT status for newly developed tests.

What Are ADLTs

ADLTs, or Advanced Diagnostic Laboratory Tests, are a new classification of tests created by PAMA. To qualify as an ADLT, a new test must:

- Be covered under Medicare Part B;
- Be offered, furnished and sold only by the single lab that develops the test (or a successor owner); and
- Meet either of the following:
  - *Criterion A:* The test is an analysis of multiple biomarkers of DNA, RNA or protein combined with a unique algorithm to yield a single patient-specific result predicting if a patient will develop a condition(s), how the patient will respond to a therapy(ies) or providing new clinical diagnostic information that cannot be obtained from another test(s); or
  - *Criterion B:* The test receives FDA clearance or approval.

What's At Stake

Securing ADLT status for a new test is a big deal because it means the test is subject to separate pricing rules. Specifically, prices of new ADLTs are the actual list charge for the test over the first three quarters that the test is available on the market. Labs are required to report the prices of their ADLTs during that period. When the initial period ends, CMS will use this pricing data to determine the test's weighted median rate. If the list charge turns out to be more than 130% of the median, CMS can make the lab repay the difference.

By contrast, pricing of new tests that are not ADLTs is based on current CMS cross-walking or gap-filling methods:

- Cross-walking to an existing HCPCS code is used if CMS determines that the new test is comparable to an existing test, multiple existing test codes or a portion of an existing test code;
- Gap-filling is used for tests that have no existing HCPCS analog and is based not on a HCPCS code but charges for the test, routine discounts, resources required to perform the test, payment amount set by other payors, input from the clinical lab payment advisory committee and other factors.

What the Guidance Says

Labs must apply to CMS to secure ADLT status for their tests. The significance of the new guidance is that it explains the application process in specific detail.

Information Required to Apply for ADLT Status

First, the guidance specifies the information the lab must furnish to show that the test meets each element of the ADLT definition explained above:

Information Labs Must Submit to CMS to Get ADLT Approval

Element of ADLT Definition	Required Documentation to Prove
Test is covered by Medicare Part B	Evidence of coverage includes (but isn't limited to): ■ Payment for test by a Medicare Administrative Contractor (MAC) based on a reasonable and necessary determination, e.g., MAC remittance notice for test ■ Molecular Diagnostic Services program coverage determination for test ■ Local coverage determination (LCD) for test ■ National coverage determination (NCD) for test
Test is furnished, sold and offered by single lab that develops (or successor)	Information that may be required includes: ■ Name & address of all lab components furnishing test ■ Name, address & role of entity(ies) that owns lab which may offer, sell or design test ■ Name, address & role of entity(ies) that lab owns which may offer, sell or design test ■ Indication of whether applying lab is a successor owner ■ All of single lab's Tax Identification Number(s), NPI(s) and CMS Certification Number(s)
Pricing and payment information	Current coding payment info for test which may include (for all payors to which test is billed): ■ Any existing HCPCS code or identifier used to bill test ■ Descriptor used to bill test ■ MAC's local payment amount for test and date of payment determination
Pricing information about new ADLTs to be paid at actual list charge over initial period	If test hasn't been paid under CLFS before Jan. 1, 2018: ■ First date on which test is obtainable by patient or marketed to public ■ All amounts charged covered by private insurance or listed in marketing on such first date ■ Actual list charge for test based on publicly available rate ■ If available, publicly available source(s) that report actual list charge & all other amounts charged on such first date
Test meets Criterion A (described above)	■ Identification of DNA, RNA or protein biomarkers analyzed by test ■ Description of test's unique algorithm ■ Summary showing that analysis of biomarkers combined with unique algorithm yields result predicting patient condition, response to therapy and delivers new info not obtainable from existing tests on market ■ List of potential comparative tests ■ Comparison between test & other similar tests
Test meets Criterion B, i.e., has received FDA clearance or approval	Documentation must include: ■ FDA premarket approval or notification number ■ Date of FDA clearance or approval ■ Name and branch of FDA reviewer

The lab must also agree to notify CMS of any changes to the information in the application it submits within 30 days of the change.

Additional Information Required If Lab Is Also Applying for Unique HCPCS Code

Each ADLT must have a "unique" HCPCS code, i.e., a code that describes that particular test and only that particular test. If the would-be ADLT does not have a unique HCPCS, the lab must tell CMS if it has applied (or is in the process of applying) to the AMA for a unique level 1 HCPCS code for the test along with the date and status of the application. If not, the lab must include in its ADLT application a request for CMS to assign the test a unique level II HCPCS code when and if it okays ADLT status for the test.

ADLT Application Process

CMS will make ADLT status determinations (and, if necessary, accompanying HCPCS code assignments) on a quarterly basis based on the following calendar:

Quarterly ADLT Application Filing Window

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Dates on which CMS must Receive ADLT Application	Jan. 1 to Jan. 31	April 1 to April 30	July 1 to July 31	Oct. 1 to Oct. 31

CMS' review of ADLT applications will result in one of three possible outcomes:

- Approval of the test for ADLT status (which may include assignment of a unique level II HCPCS code;
- Denial of ADLT status for test via email notification to the lab contact person; or
- Request for lab to supply additional information.

Takeaway: Along with the new guidance, CMS published the actual form that labs are supposed to use when applying for ADLT status. The good news is that breezing through this overview and carefully following the instructions set out in the application should spare you the agony of having to read all 30 pages of the guidance.

Labs IN COURT

A roundup of recent cases and enforcement actions involving the diagnostics industry

Lab Forks Over $525K to Settle Claims of Inflating Specimen Travel Mileage

Case: The feds accused a Missouri lab of submitting false claims to Medicare for travel fees in transporting specimens from April 2011 to December 2014. In addition to a $525K fine, the lab had to sign a five-year corporate integrity agreement to settle the case.

Significance: The lab allegedly committed two violations of Medicare travel allowance billing rules that caused its mileage claims to be deemed false:

- Logging mileage for specimens transported collectively in a single trip separately rather than prorating the miles among each specimen; and
- Charging for mileage traveled by a non-medical driver rather than by a lab technician.

Breast Cancer Recurrence Test Billing Case Ends in $2 Million Settlement

Case: BioTheranostics has agreed to shell out $2 million to settle claims of falsely billing Medicare for its molecular Breast Cancer Index (BCI) test. BCI, which determines the risk of breast cancer recurrence beyond five years, is used to guide treatment decisions regarding the value of extended endocrine therapy. But the DOJ claimed that BioTheranostics promoted and performed BCI on breast cancer patients who had not been in remission for five years and who had not been taking tamoxifen. In so doing, the San Diego-based company flew in the face of not only Medicare coverage rules but published practice guidelines and clinical trial data finding BCI medically unnecessary for such patients.

Significance: So far, FCA cases targeting billing of medically unnecessary gene expression tests have been relatively rare. Of course, that is bound to change as Medicare broadens its coverage rules for such tests. The BCI case may thus prove to be a harbinger of things to come.

Self-Disclosed Sleep Study Billing Violations Cost Hospital $252K+

Case: A North Carolina hospital has agreed to fork over $252,455 for improper billing of Medicare and TRICARE for sleep testing and treatment services committed by its sleep center, an amount that might have been higher had the hospital not self-disclosed the violations.

Significance: The OIG does not provide any details about the case or what the hospital did wrong. However, sleep testing by independent and hospital labs has become a high priority of OIG enforcement in recent months, particularly polysomnography, a sleep study in which patients sleep overnight while connected to sensors measuring brain waves, blood oxygen flow and other parameters. The study is commonly used to diagnose obstructive sleep apnea and evaluate the effectiveness of using positive airway pressure (PAP) devices to manage the condition and PAP titration may also be done when the test indicates that a patient has a sleep disorder. (To find out about the billing pitfalls of polysomnography and how to avoid them, see *GCA*, Jan. 6, 2017.)

Pennsylvania Drug Testing Lab at Center of Alleged Stark Scam

Case: What do Dr. Robert Fetchero of Jeannette, Pennsylvania, Dr. Sridhar Pinnamaneni of Windermere, Florida, and Dr. Thelma Green-Mack of Zionsville, Indiana, have in common—other than being physicians? Answer: All three settled charges of accepting payments for Medicare referrals to Universal Oral Fluid Laboratories (UFOL), a Pennsylvania drug testing lab with which they had an improper financial relationship in violation of the Stark and anti-kickback laws. The price of settlement:

- Dr. Fetchero: $200K;
- Dr. Pinnamaneni: $370K; and
- Dr. Green-Mack

UFOL's medical director also pled guilty to charges for his role in the scheme which unfolded over a roughly three-year period.

Significance: While drug testing has been the hottest trend in lab enforcement, this case is an old-fashioned kickback scheme rather than the opioid-related abuses that have become so common over the past 18 months.

Enforcement Trends: Private Insurers Are Cracking Down on the Labs that Scam Them

Once the almost exclusive domain of federal law enforcers and inside whistleblowers, the lucrative industry of going after labs for improper billing has opened to a wide range of players encompassing just about everyone from shareholders to consumers. But of all these new private sector nemeses, none is more formidable than the insurance company. And among the insurance companies trying to force labs to cough up their ill-gotten gains, none has been more aggressive than UnitedHealthcare.

Don't Mess With UnitedHealthcare

A pair of Texas labs are learning this lesson the hard way. UnitedHealthcare is suing Sun Clinical Laboratories and Mission Toxicology (and their owners) for allegedly "conning" it into paying $44 million worth of bogus toxicology and allergy lab testing claims. Paying physicians kickbacks for referrals is just the tip of the iceberg. The insurance giant is claiming that the labs, who are not part of its network, set up testing centers inside in-network rural hospitals to make it look like the bills came from the hospitals. Then when the United payments came in, the labs allegedly had hospital employees transfer 95% of the money to the labs and their owners. Hiding behind the hospital's persona, the suit charges that the two labs inflated claims to 50 times the actual cost of testing, charged for tests not performed or ordered and billed for tests already billed by another provider.

The Next Health Case

Aggressive legal action against labs that "con" them is hardly a new policy for UnitedHealthcare. Last January, the insurer filed a massive lawsuit against Next Health LLC claiming that the Dallas-based provider and its subsidiaries scammed it for over $100 million in drug and genetic tests. The allegations sound like they came right out of the DOJ's own script:

- Improper utilization of standing orders for tests administered to patients regardless of actual medical history or conditions;
- Payment of kickbacks to physicians in exchange for referrals;
- Illegal recruitment of insured patients to participate in "wellness studies" in exchange for $50 gift cards;
- Billing for tests that were never actually ordered or performed.

Other Insurers Join the Fray

Of course, UnitedHealthcare is not the only private insurer to take on labs for improper billing. Last fall, Aetna filed suits against the same two Texas labs that UnitedHealthcare is suing, i.e., Sun Clinical Laboratories and Mission Toxicology, for an alleged fraudulent billing scheme costing Aetna $21 million.

Those same two labs are also at the center of a lawsuit by Blue Cross & Blue Shield of Mississippi. The accusations in both cases follow the same pattern as the alleged violations against UnitedHealthcare—payment of kickbacks and misrepresenting claims as coming from an in-network hospital.

Industry Trends: Small Labs Relying on Antitrust Laws to Protect Their Market Position

Frustrated by the consolidation taking place within the medical lab testing market, small and mid-sized labs that have not been swallowed up are fighting back by filing antitrust lawsuits against the giants they believe are squeezing them out.

The St. Joseph Hospital Case

The most recent proponent of this last-ditch legal strategy is Wahidullah Medical Corp., the Eureka, California-based owner of Redwood Urgent Care and its affiliated lab which is asking a federal court to issue an injunction barring St. Joseph Hospital from seeking to monopolize outpatient lab testing within the Eureka market. Redwood claims that St. Joseph tarnished its reputation, misled consumers and implemented an EMR that was incompatible with the lab's systems in a deliberate attempt to stifle competition. The suit contends that St. Joseph charges nearly10 times more than Redwood for outpatient tests, citing the example of a vitamin D test costing $36 at Redwood and $327 at St. Joseph.

LabCorp & Quest Also on the Firing Line

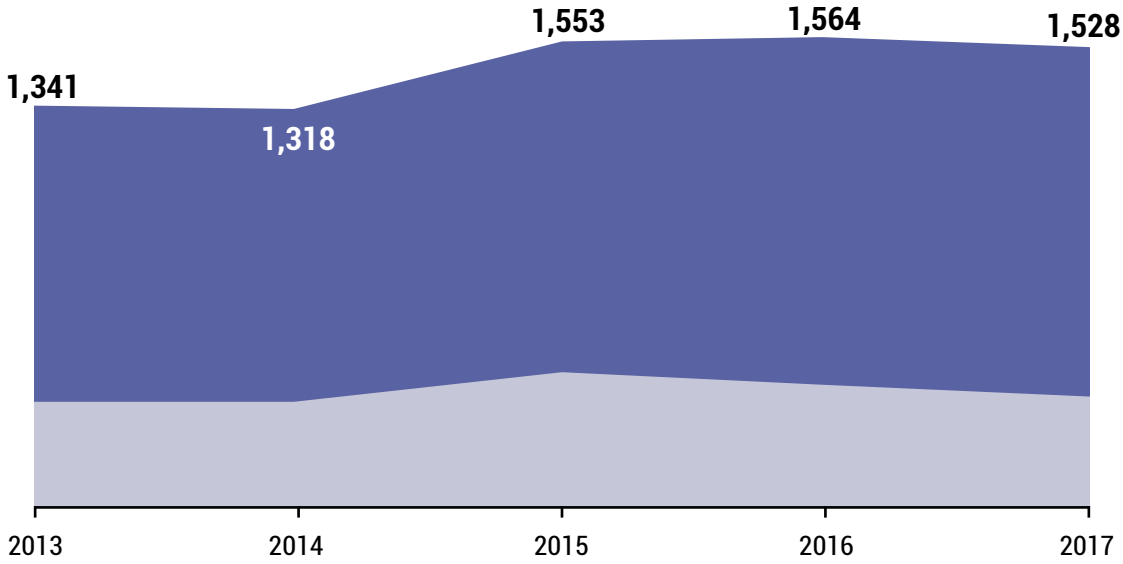
And the St. Joseph case is only the most recent illustration of a larger trend. Two of the lab industry's biggest players have been targeted for civil lawsuits for allegedly crowding smaller labs out of the market in violation of antitrust laws including:

- Laboratory Corporation of America which is being sued by Prescient Medicine for colluding with AmeriHealth on an illegal contract making LabCorp the exclusive provider of Medicaid lab services in the state of Delaware; and
- Quest Diagnostics which is defendant in a lawsuit brought by Texas-based United Allergy Services (UAS) for conspiring with Thermo Fisher Scientific's Phadia business (among others) to squeeze UAS out of the allergy testing market.

Takeaway: Private antitrust litigation is a high-risk strategy typically borne of frustration. While the potential penalties are staggering, including treble damages, antitrust claims are also extremely hard to prove. Quest itself has been down this road before beating back antitrust claims in northern California, the same market at the center of the claims against St. Joseph Hospital.

Enforcement Continues to Trend Down as Labs Drift Deeper into the Background, *from page 1*

Table 1: MCFU Convictions FY 2013-2017



Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

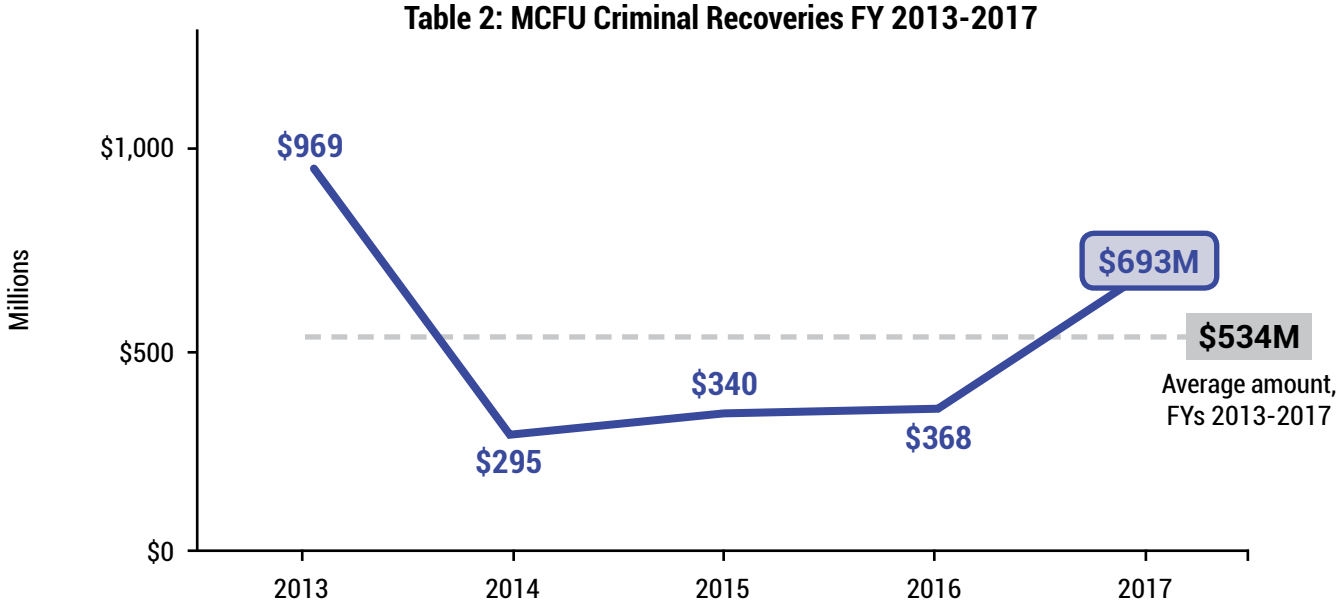
Of last year's 1,157 fraud convictions, 523 (45%) involved personal care service (PSC) attendants and agencies, by far the highest of any provider group, followed by nurses (88), home health agencies (54) and family practice physicians (36).

Labs were down on the list, accounting for only 12 convictions (8 clinical labs and 4 radiology and physiology labs).

Criminal Recoveries

While the number of convictions was consistent with previous years, *criminal recoveries* were $693 million, nearly double FY 2016 levels.

Table 2: MCFU Criminal Recoveries FY 2013-2017



Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

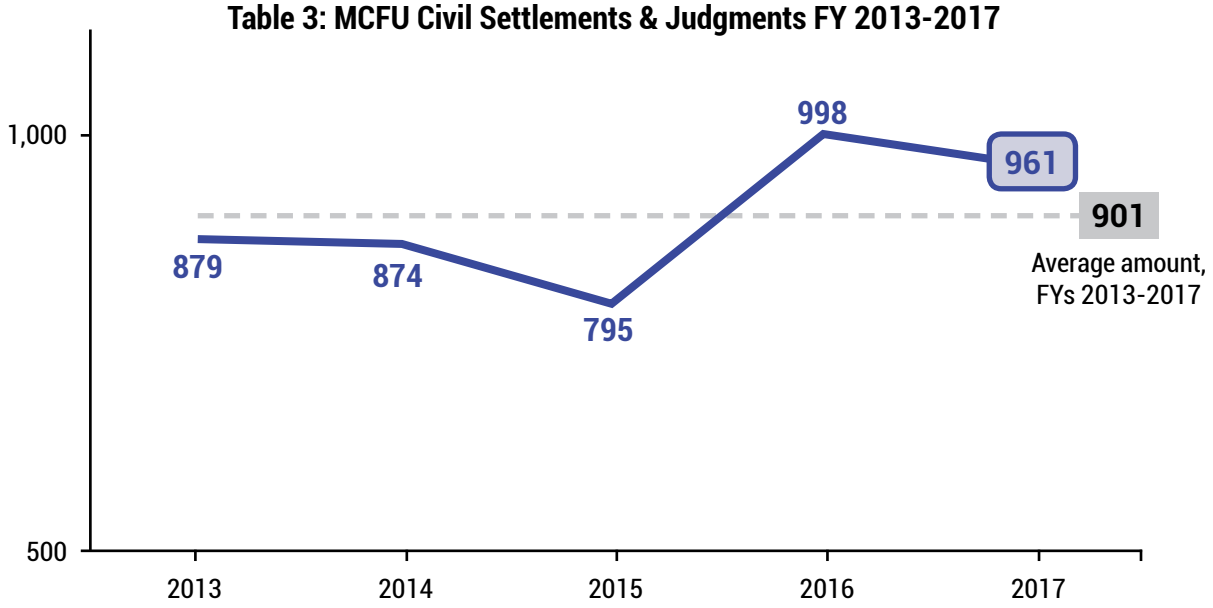
Most of this money—about $519 million—came from one big case in Texas involving a doctor and other codefendants who defrauded Medicaid and Medicare by improperly recruiting individuals and falsifying medical documents.

Labs contributed roughly $5.443 million to total criminal recoveries with $3.396 coming from the 8 convicted clinical labs and the remaining $2.047 million from the 4 convicted radiology and physiology labs.

Civil Settlements & Judgments

Continuing recent trends, the number of civil settlements and judgments was slightly down at 961.

Table 3: MCFU Civil Settlements & Judgments FY 2013-2017



Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

Pharmaceutical makers was the segment with the most settlements and judgements in with 426 (44%) followed by pharmacies (137), DME suppliers (37), PCS attendants and agencies (34) and medical device makers (28).

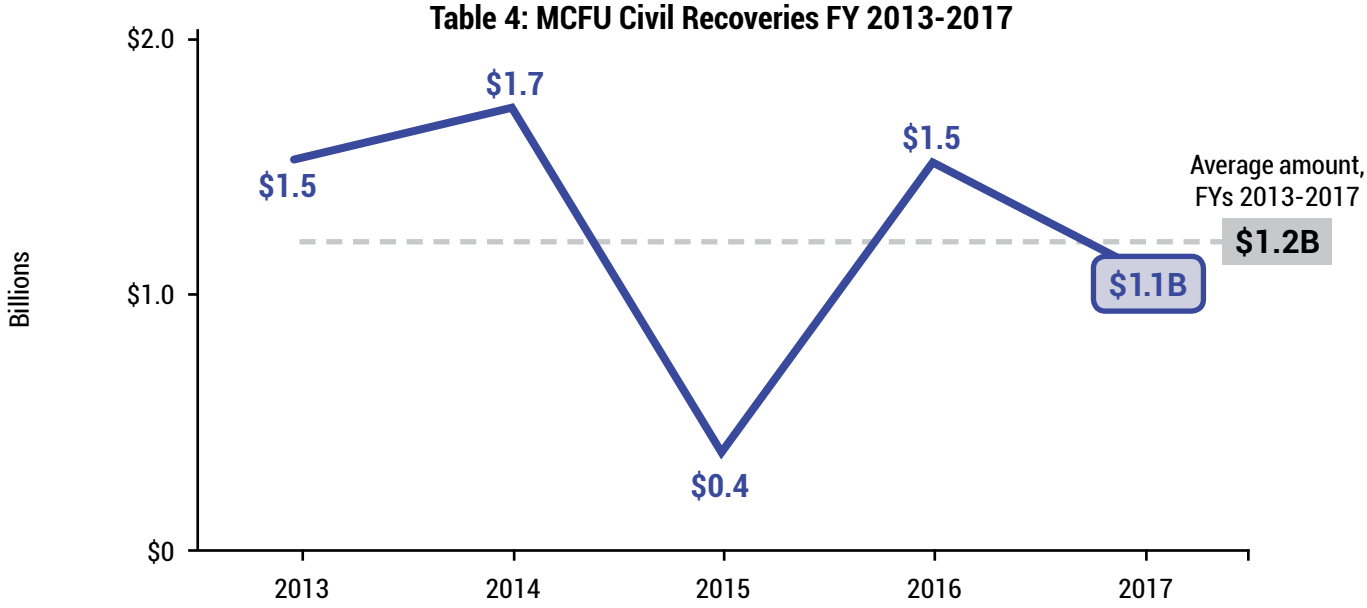
Labs accounted for 10 settlements and judgments, 8 involving clinical labs and 2 involving radiology and physiology labs.

Civil Recoveries

Unlike the criminal side where the decline in convictions belied the spike in recoveries, civil recoveries mirrored the decrease in settlements and judgments dipping to $1.1 billion, as compared to $1.5 billion in FY 2016 and below the annual $1.2 billion average during the overall five-year period.

Labs paid out just over $13 million in civil recoveries, with 8 clinical labs contributing roughly $6.268 million and 2 radiology and physiology labs another $6.750 million.

Table 4: MCFU Civil Recoveries FY 2013-2017



Source: OIG analysis of Quarterly Statistical Reports for FYs 2013-2014 and Annual Statistical Reports for FYs 2015-2017.

Takeaway: Medicaid fraud enforcement at the MCFU level remains steady and even in modest decline. And while labs are still drawing attention, they appear to be becoming a relatively marginal target as MCFUs focus more on the PCS and pharmaceutical sector. However, the opioid imperative is likely to turn those trends around given the lab's role in urine drug testing.