



Quest Diagnostics Health Trends™ Prescription Drug Monitoring Report 2015

Prescription Drug Misuse in America

Diagnostic Insights in the Continuing Drug Epidemic Battle

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Prescription Drug Misuse in the U.S. is Widespread

Summary

In May, 2014, Dr. Nora Volker, the long-term Director of the National Institute on Drug Abuse (NIDA) at the National Institutes of Health, testified in front of the United States Senate Caucus on International Narcotics Control. She stated, "the abuse of and addiction to opioids such as heroin, morphine, and prescription pain relievers is a serious global problem that affects the health, social, and economic welfare of all societies.... An estimated 2.1 million people in the United States (suffer) from substance use disorders related to prescription opioid pain relievers in 2012 and an estimated 467,000 addicted to heroin.2 The consequences of this abuse have been devastating and are on the rise.... There is also growing evidence to suggest a relationship between increased non-medical use of opioid analgesics and heroin abuse in the United States.3"

Opioid abusers generate, on average, annual direct healthcare costs 8.7 times higher than non-abusers.⁴ Quest Diagnostics believes that laboratory testing is a crucial tool that healthcare professionals use to identify non-medical use of opioid analgesics and non-use when prescribed.

This fourth annual *Prescription Drug Monitoring Report* from Quest Diagnostics Health Trends™ examines some of the disturbing patterns and trends observed based upon testing performed at our laboratories. Healthcare providers are increasingly using laboratory tests to uncover compliance with prescribed medications and the misuse of drugs not

prescribed. These tests detect commonly prescribed drugs including pain medications, central nervous system medications, marijuana which is illegal in many states, and certain illicit drugs such as cocaine and heroin.

This Quest Diagnostics Health Trends series of reports produced by Quest Diagnostics are based on our database of laboratory testing of patients from across the U.S. For 2015, we have updated the information and provided the trends over the four-year period from 2011 to 2014. In 2012, the first report was "Prescription Drug Misuse in America: Laboratory Insights into the New Drug Epidemic, ⁵" in 2013 the report was "Prescription Drug Misuse in America: A Report on Marijuana and Prescription Drugs, ⁶" and in 2014 the report was "Prescription Drug Misuse in America: Diagnostic Insights into Managing the Drug Epidemic. ⁷"

Our 2015 report builds on our prior research and continues to confirm high rates of inconsistent test results among patients prescribed pain medications, spanning all age ranges and both genders. This report also looks at specimen validity testing and the leading drug groups associated with inconsistent results by age range. Together, these reports reflect analysis of more than 2.5 million patient test results over the four-year period.

Urine specimens are screened by immunoassaybased methods and all positive results are confirmed by mass spectrometry, the most sensitive and specific drug testing method. Quest Diagnostics



Health Trends studies are performed in compliance with applicable privacy regulations, the company's strict privacy policies, and are deemed exempt by the Western Institutional Review Board.

with no prescribed drugs listed who tested positive for one or more drugs, the abnormal rate was 2.4%—twice as high as the group with no drugs listed.

Key Findings

Prescription Drug Misuse in the U.S. is Widespread Regardless of Age Range, Gender, Geographic Region, and Payer Type

A majority of de-identified patient test results from 2011 through 2014 were inconsistent, suggesting that many patients continued misusing prescription drugs, putting their health at risk. While high, the rate of inconsistency declined from 63% in 2011 to 53% in 2014, suggesting signs of progress in combatting prescription drug misuse. The percent decline from 2013 to 2014 (2%) was the smallest observed in the three annual intervals from 2011 to 2014.

Drug Groups Associated with Inconsistency by Age Range

In adults thirty years and older, the two drug groups associated with the highest number of inconsistent test results were opiates and oxycodone. Among children less than 10 years old, the most common inconsistent drug groups were amphetamines and opiates. Among patients ten through twenty-nine years of age, the leading drug groups associated with inconsistency were marijuana and opiates.

Specimen Validity Testing is Important for Improving the Reliability of Laboratory Test Results

The present Quest Diagnostics Health Trends Report describes the results from 2,188,639 patient test reports from 2011 through 2014 that includes specimen validity testing (SVT) along with drug testing. The number of abnormal, i.e., invalid, SVT patient test reports was 33,396 (1.5%). Although the percentage of abnormal SVT reports was similar among patients with one or more prescribed drugs listed (1.5%) or no drugs listed (1.2%), for patients

About This Study

The objectives of this study were to assess the scope and demographic drivers of prescription drug misuse in America. As with our earlier Reports, from 2012 – 2014, we looked at the influences of age, gender, payer type, and geography on inconsistent rates. As in the previous Report, we examined the importance of specimen validity testing when included in the drug testing. New to this Report is a look into the most common drugs associated with inconsistency test reports by age ranges. These studies have allowed us to examine temporal trends on prescription medication abuse.

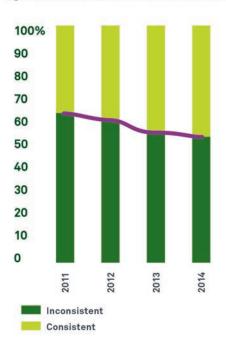
As the leading diagnostic information services provider, Quest Diagnostics is well positioned to identify trends in prescription drug monitoring and misuse. Our comprehensive prescription drug testing services build on our long-standing leadership in workplace drug testing for employers. For information about the use of drugs by American workers, refer to Quest Diagnostics Drug Testing Index™ reports at QuestDiagnostics.com/DTI.

For the current report, Quest Diagnostics medical and scientific experts analyzed a national sample of 2,551,611 de-identified patient test results performed over a recent four-year period, 2011 – 2014. The study included test results of patients of both genders, wide age spectrum, and 48 states and the District of Columbia. The analysis was of results of patient testing performed by Quest Diagnostics and as ordered by healthcare providers serving patients in a spectrum of practice settings. For the evaluation of the inconsistency rates, we excluded testing from drug rehabilitation clinics and addiction specialists, given the higher rates of testing and potentially higher rates of inconsistency in populations served in these clinical segments.

Prescription Drug Misuse in the U.S. is Widespread

A key finding from our earlier reports was the high inconsistency rates observed overall and in every sector of the population. In 2014, we again found the majority of patients tested (53%) misused their prescription medications, potentially putting their health at risk. By every means of slicing the data—by age, gender, geography, and payer type—patients were at a high risk for misuse.

Fig. 1 Distribution of Patient Test Results, 2011 - 2014



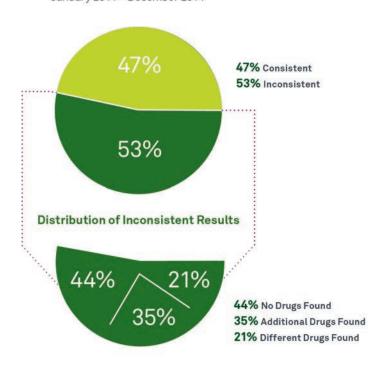
Source Quest Diagnostics, January 2011 - December 2014

With the results of 2014, we are pleased to see a continued progressive decline in the overall inconsistency rate, although it remains high. The overall inconsistency rate decreased from 63% in 2011 to 53% in 2014, a 10% absolute decrease or 16% relative decrease (Fig. 1).

The declining trend in prescription drug misuse suggests better provision of information of prescribed drugs (better matching between what we are told and what we detect), less misuse of additional drugs

other than those prescribed, better compliance with prescriptions, or a combination of these factors. This likely represents improved education of and use of available tools by physicians and patients as awareness of this epidemic increases. Additionally, more states have required continuing medical education in prescription control and have developed programs to combat drug misuse.

Fig. 2 Distribution of Patient Test Results, January 2014 – December 2014

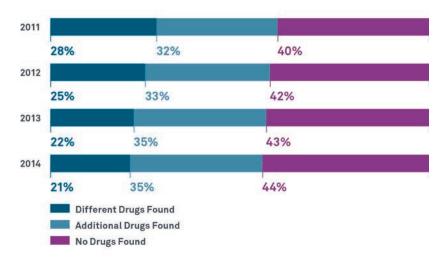


Source Quest Diagnostics, January 2014 - December 2014

The distribution of the three categories for inconsistency is shown in Fig. 2. We also found that the results for inconsistent testing reports have shifted over the four years (Fig. 3). We found a downward trend of different drugs found than those that are prescribed and upward trends in having additional and no drugs found. These findings may reflect improved collection of information of drugs prescribed, decreased use of different drugs, or a combination of these factors.



Fig. 3 Distribution of Cause of Inconsistent Patient Test Reports, 2011 - 2014



Source Quest Diagnostics, January 2011 - December 2014

In particular, among patient test results reported with inconsistent test results, the percentage that indicated different drugs were found than those prescribed decreased from 28% in 2011 to 21% in 2014, a relative decrease of 25%.

Among patient test reports with inconsistent test results, the percentage that indicated the patient tested positive for the prescribed drug(s) and additional drug(s) for which the patient was not prescribed, increased slightly from 32% in 2011 to 35% in 2014. This is worrisome as it suggests high rates of potentially dangerous drug combinations. For some patients, the inconsistency may have reflected incomplete information provided by the healthcare provider.

Finally, the percentage of inconsistent test results due to no drugs found that were expected, increased from 40% in 2011 to 44% in 2014, a 10% relative increase. Why would a prescribed drug not be detected? Many patients do not take their prescribed drugs. Patients may cease taking a prescribed drug due to concerns of side effects or because their pain subsided. A small number of patients may be rapid metabolizers of the prescribed drug and the drug or metabolite is undetectable at the time of testing. Others may not take their drugs perhaps due to financial constraints or through sale of their medication.

Causes for Inconsistency

Different Drugs Found

Prescribed drug(s) was not detected, but at least one other drug, non-prescribed or illicit, was detected

Additional Drugs Found

Prescribed drug(s) was detected, but at least one other drug, nonprescribed or illicit, was also detected

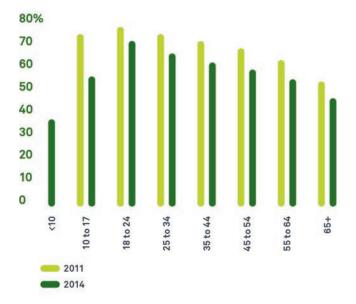
No Drugs Found

Prescribed drug(s) was not detected; non-prescribed or illicit drug(s) was also not detected.

Inconsistency Rates by Age and Gender

Inconsistency rates were greater than 50% for all age ranges 10 and older except patients 65 years and older, which was 43%. Inconsistency rates improved for all age range groups between 2011 and 2014 (Fig. 4A). The largest improvement was seen in the 10 – 17 age group, which decreased from 70% to 52%. For the first time we are sharing the inconsistency rate for children younger than ten years; the rate was 34%. This lower rate for these young children may be reflective of the responsibility of parents or guardians.

Fig. 4A Inconsistency Rates by Age, 2011 Versus 2014



Source Quest Diagnostics, January 2011 - December 2014

The inconsistency rates decreased for both genders between 2011 and 2014 (Fig. 4B). In the four years, women had slightly higher inconsistency rates than that of men. This difference in inconsistency rates between women and men decreased from approximately 2% in 2011, 1% in 2012, and to a similar rate of 0.5% in 2013 and 0.6% in 2014. It is noteworthy that the rates of the annual declines were similar for women and men.

Fig. 4B Inconsistency Rates by Gender, 2011 - 2014



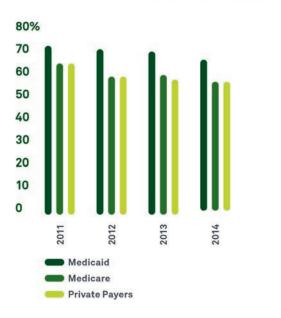
Source Quest Diagnostics, January 2011 - December 2014

Inconsistency Rates by Payer Type

We continued to observe that test reports of patients insured by Medicaid had the highest inconsistency rate of the three major payer groups (Fig. 5). This higher rate among Medicaid insured patients may reflect differences in the quality of care and coordination among healthcare providers, medical conditions being treated, or of the patients themselves. The differences in inconsistency rates among patients insured by private payers and Medicare were small. Although inconsistency rates remained relatively high, decreases were observed in each of the three major payer groups from 2011 through 2013. The causes for the differences in the changes in the inconsistency rates among the major payer groups may reflect similar factors, as discussed above.



Fig. 5 Inconsistency Rates by Major Payer Type, 2011 - 2014



Source Quest Diagnostics, January 2011 - December 2014

Definition of Health and Human Services Regions

Region 1 CT, ME, MA, NH, RI, VT

Region 2 NJ, NY

Region 3 DE, DC, MD, PA, VA, WV

Region 4 AL, FL, GA, KY, MS, NC, SC, TN

Region 5 IL, IN, MI, MN, OH, WI

Region 6 AR, LA, NM, OK, TX

Region 7 IA, KS, MO, NE

Region 8 CO, MT, ND, SD, UT, WY

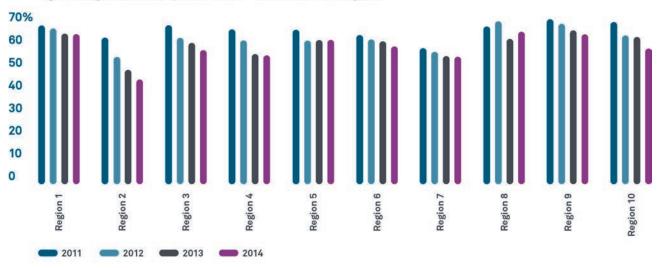
Region 9 AZ, CA, HI, NV

Region 10 AK, ID, OR, WA

Inconsistency Rates by Geography

We found that there is a broad range in the inconsistency rates across the U.S., as well as a wide variation in the inconsistency rate changes between 2011 and 2014 (Fig. 6). In 2011, all U.S. Health and Human Services (HHS) Regions had inconsistency rates greater than 54.1%. In 2014, only five of ten HHS regions had inconsistency rates greater than 54.1%. Region 2 had the lowest inconsistency rate (41.1%) and Region 8 had the highest inconsistency rate (61.1%) in 2014 (Fig. 7).





Another way to look at this data is to categorize inconsistency rate ranges by color (Table 1). Regions 1 and 8 stayed within the same category with relative reductions in the inconsistency rate of only 5.6% and 3.5%, respectively, over the four-year period. Region 8 had a significant increase in the inconsistency rate, from 2013 to 2014. In contrast, Region 2 had a nearly 30% relative reduction in the inconsistency rate, over the four-year period. From 2013 to 2014, Regions 2 and 10 had a relative decline in the inconsistency rate of 8.9% and 8.3%, respectively.

This analysis shows that when we look at the large HHS regions, there are sharp distinctions in the pattern of the inconsistency rates and the changes over time. The differences in the changes in the inconsistency rates across the HHS Regions may relate to differences in efforts to address pain medication misuse, changes in prescription patterns, changes in test ordering patterns among the HHS regions or an artifact of the inclusion criteria (testing performed by Quest Diagnostics).

Marked Improvements in Seven States

Many states showed improvement in inconsistency rates. There are likely different dynamics within each state that drove these observed differences. While most states have implemented a prescription drug monitoring program (PDMP) for practitioners, providing access to prescription drug databases, other states have supplemented the database with guidance and regulations on use of controlled medications.

California, Florida, Georgia, Kentucky, New York, Pennsylvania, and Tennessee all showed marked improvement from 2011 – 2014 in their inconsistency rates, displayed in Fig. 8. These states are highlighted because they are driving change through various approaches, including but not limited to state legislation, practitioner education requirements, public awareness campaigns, and utilization of law enforcement. All the states highlighted have an active PDMP with a state prescription database.

Pennsylvania enacted a bill that will take effect in mid-2015 that is scheduled to provide physicians with a prescription drug database. Pennsylvania has shown steady year-to-year improvement prior to the start of their prescription drug database. We observed a slight reversal in downward trend in Tennessee in 2014 versus 2013, but overall 2014 rates remain lower than 2011.

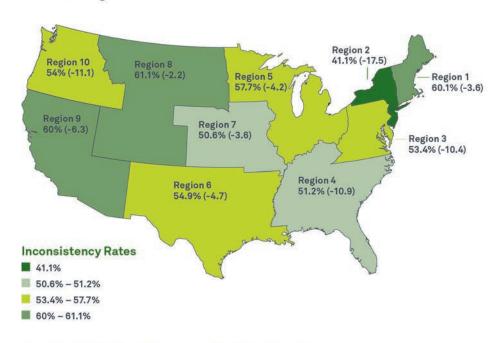
Table 1 Average Inconsistency Rates (Percent) 2011 – 2014 in U.S. HHS Regions

Year	2011	2012	2013	2014
HHS Region				
1	63.7			
2		50.5	45.1	41.1
3	63.8	58.5	56.4	53.4
4		57.4	51.7	51.2
5		57.4	57.6	57.7
6		57.9	57.1	54.9
7	54.2	52.7	50.9	50.6
8	63.3	65.4	58.1	61.1
9	66.3	64.4	61.7	60.0
10	65.1	59.5	58.9	54.0





Fig. 7 Average Inconsistency Rates in 2014 (and Change from 2011) in HHS Regions in the U.S.



Source Quest Diagnostics, January 2011 - December 2014

Fig. 8 Seven States with Improvements in Inconsistency Rates



Source Quest Diagnostics, January 2011 - December 2014

Drug Groups Associated with Inconsistent Test Results, by Age Ranges

This report examined the drug groups associated with the highest number of inconsistencies from 2011 – 2014. We also looked at these results for various age groups (Table 2).

Among the youngest patients, under ten years of age, amphetamines were associated with the most inconsistent results, followed by opiates. Stimulants like amphetamines are frequently prescribed to treat children with attention-deficit hyperactivity disorder (ADHD). Opiates, including codeine, morphine, hydromorphone, and hydrocodone, are prescribed as pain relievers. Among the next age group, ages 10-19, marijuana and opiates were associated with the largest number of inconsistent results. The CDC reports that since 1999 the rate of youth drug abuse has decreased across all measured categories; however, there has been an increase in marijuana use from 2009 – 2013.8

In 2013, an estimated 24.6 million Americans aged 12 or older (9.4% of the population) had used an illicit drug or abused a psychotherapeutic medication (such as a pain reliever, stimulant, or tranquilizer) in the past month. In our study, in ages 20 and above, opiates had the highest number of inconsistent test results. In patients aged 20 – 29, opiates is followed by marijuana. However, in patients 30 and older, opiates is followed by oxycodone.* Oxycodone has been in clinical use since 1916. These results highlight a troubling pattern of opioid misuse nationally, with over 2 million people estimated to have a substance use disorder related to prescription opioid pain relievers.

Table 2 Most Common Drug Groups Associated with Inconsistent Test Results, by Age Ranges, 2011 – 2014

Age Range (Years)	Most Common	Second Most Common	
<10	Amphetamines		
10-19	Marijuana Metabolite	Opiates	
20-29	Opiates	Marijuana Metabolite	
30-39	Opiates	Oxycodone	
40-49	Opiates	Oxycodone	
50-64	Opiates	Oxycodone	
>64	Opiates	Oxycodone	

[&]quot;Oxycodone is defined as a separate group from opiates due to use of a dedicated oxycodone immunoassay screen.



Specimen Validity Testing to Increase Reliability of Drug Testing

The basis of interpreting any laboratory test is assurance that the specimen is reflective of the natural state of the person being tested and testing is reliable. Patients who are tested for opioids, and other drugs of potential abuse, are more likely to intentionally alter the specimen, prior to or during collection. Specimens can be diluted by consuming large quantities of liquid prior to testing or adding fluid to the specimen. Adulterants are foreign substances that are added directly to a urine specimen during the collection process to prevent the detection of drug use. Promoted as "cleansing agents," these substances range from everyday household items to specific chemical additives easily obtained through the internet.

Specimen validity tests determine whether a urine specimen has been diluted, adulterated, or substituted to obtain a negative drug test result. A specimen validity test can compare urine specimen characteristics with acceptable density and composition ranges for human urine, detect the effects of many adulterants (e.g., abnormal pH, oxidizing compounds), or test for a specific compound (e.g., nitrite, chromium VI) at concentrations indicative of adulteration (Table 3).

Industry standards for specimen validity testing have been established by the Substance Abuse and Mental Health Services Administration (SAMHSA), Division of Workplace Programs. "Invalid" has a very specific definition. In our clinical testing program, we adopted many features of the federal SAMHSA program and use "abnormal" when we encounter specimen validity results out of range. Quest Diagnostics provides several tests to establish specimen validity focusing on detecting dilution and addition of adulterants.

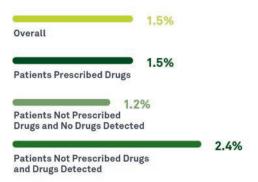
Table 3 Criteria for Abnormal Specimen Validity Test Result

Test	Objective		
Creatinine of <2 mg/dL Or	Creatinine and specific gravity are two ways to check for dilution and flushing which are the most common		
Creatinine >2 mg/dL and <20 mg/dL with a specific gravity <1.003	mechanisms used in an attempt to circumvent drug testing		
pH of <4.5 or >9.0	Tests for the presence of acidic or alkaline adulterants in urine		
Oxidants >200 mcg/mL	Tests for the presence of oxidizing agents such as nitrite bleach, hydrogen peroxide, and chromate VI		

As part of our Quest Diagnostics Health Trends analyses, we reviewed more than 2.1 million patient test reports from 2011 to 2014 that included specimen validity testing along with drug testing. Overall, 33,396 (1.5%) patient test reports had abnormal specimen validity results (Fig. 9). This percentage was relatively constant over the four years. The abnormal rate was similar among patients prescribed one or more drugs (1.5%) and patients not prescribed drugs and no drugs detected (1.2%). This 1.2% may represent successful attempts to mask inappropriate drug use. Moreover, we observed that among the 433,438 patients with no prescribed drugs listed who tested positive for one or more drugs, the abnormal rate was 2.4%—twice as high as the group with no drugs detected. The patients in this group of 2.4% may represent unsuccessful attempts to mask inappropriate drug use. This suggests that patients with inconsistent test results, based on having no prescribed drug listed and detection of a non-prescribed drug, are most likely to have a specimen with abnormal specimen validity testing results. Patient awareness of the effectiveness of specimen validity testing may limit attempts to manipulate the specimen.

The observed 1.5% of test reports flagged as abnormal is substantial. Given the importance of drug testing, the role of testing for specimen validity is significant, as this step assures the treating healthcare provider about how to interpret the test results and take appropriate follow-up for patient management.

Fig. 9 Abnormal Rates Based on Specimen Validity Testing, 2011 - 2014



Source Quest Diagnostics, January 2011 - December 2014

Finally, we analyzed the causes for abnormal test reports and there was extremely little overlap. Three in five test reports with failed specimen validity test results were attributed to dilute urine (Fig. 10). One in five tests with failed specimen validity test results were attributed to detection of oxidants and the remainder were split between low creatinine (12.0%) and likely the addition of adulterants (7.4%).

Fig. 10 Distribution of Causes for Abnormal Test Reports with Specimen Validity Testing, 2014



59.7% Creatinine >2 mg/dL and <20 mg/dL with a Specific Gravity <1.003

20.9% Oxidants >200 mcg/mL 12% Creatinine <2 mg/dL

7.4% pH of <4.5 or >9.0



Research Methodology

Study Objectives

The objectives of our study were to assess and identify the scope of prescription drug misuse in America, and identify patterns of misuse over time in a large nationwide population. We also examined the pattern of abnormal laboratory test results based on specimen validity testing.

We assessed:

- Inconsistency rate by age, drug group, gender, by health plan payer group (Medicaid, Private Payer, and Medicare), and by geography (state and HHS regions).
- The patterns of misuse, including:
 - The use of different drug groups (illicit or controlled) other than those prescribed (i.e., different drug groups found)
 - The use of additional, non-prescribed (illicit or controlled) medications (i.e., additional drug groups found), and
 - 3) The failure to use or detect prescribed drugs (i.e., no drugs found)
- The scope and pattern of abnormal test reports with specimen validity testing.

Testing Methodology

All patients were tested using our proprietary prescription drug monitoring service and medMATCH® reporting methodology for tests of up to 26 commonly prescribed and abused drugs, including pain medications, central nervous system medications, and amphetamines, as well as certain illicit drugs such as marijuana, and cocaine. Our medMATCH® service reports if prescribed drug(s), drug metabolite(s), and other drugs are in a specimen, as indicated by the ordering healthcare provider. All specimens were screened by immunoassay-based methods and all positive results were confirmed by mass spectrometry, the most sensitive and specific drug testing method. The mass spectrometry definitive methods of analysis included liquid chromatography-tandem mass spectrometry (LC/MS/MS) performed in our clinical laboratories. Specimen validity testing included analysis for creatinine, pH, oxidants (and depending upon creatinine results, specific gravity).

Strengths and Limitations

Our study's strengths include its size, geographic scope, multiple years of test results, and its use of validated testing by the highly reliable mass spectrometry method. Its limitations include the geographic disparities (nearly 80% of testing came from 12 states) and the inability to validate or contextualize test results with medical records. Like any laboratory test, a clinical determination of drug misuse requires consideration of several factors, including test results, patient history, and symptoms, made in the context of a complete medical assessment.

The procedures used to de-identify the test results and analyze the data were approved and determined to be exempt by the Western Institutional Review Board.

Laboratory testing does not identify addiction or impairment due to drug use. Patient variations, including hydration state, time since last drug use, and genetic differences in drug metabolism, as well as methodology limitations, can contribute to a failure to detect drugs in a small minority of specimens.

Moreover, it is possible that in some cases, patients in our study were referred to testing because their healthcare providers suspected a high probability of misuse, while the index of suspicion was lower for others who were not tested. In addition, some physicians may have neglected to indicate all prescribed drugs a patient was taking when submitting the test request. These dynamics may have changed over time.

Our analysis assessed patterns of prescription drug misuse for the population served by physicians ordering testing from Quest Diagnostics. Quest Diagnostics provides testing services to approximately half of all physicians and hospitals in the United States. Quest Diagnostics does not serve all healthcare providers and these insights may not accurately be reflective of the entire population. Again, dynamics in our client base may have changed over time and affected our observations.

Quest Diagnostics Health Trends Reports

Quest Diagnostics maintains the largest private clinical laboratory database in the United States. Consisting of de-identified data on nearly two billion patient encounters since 2000, the database provides laboratory information on the vast majority of conditions and diseases affecting Americans. Quest Diagnostics Health Trends reports are designed to identify and track disease and wellness benchmarks to inform patients, healthcare professionals, and policymakers about the current status of the nation's health. Quest Diagnostics Health Trends reports include Allergies Across America,™ the largest study ever conducted on allergy and asthma testing in the United States (2011), as well as peer-reviewed and publicly available reports on hypothyroidism in pregnancy, gestational diabetes, cardiovascular disease (247 million LDL cholesterol results over 11 years), chronic kidney disease, H1N1 influenza and rotavirus. For more information, visit QuestDiagnostics.com/HealthTrends.

Contributors

This report was developed by a team of Quest Diagnostics medical, technical, and informatics experts including Amy J. Blatt, Ph.D., Zhen Chen, Leland McClure, Ph.D., Justin Niles, and Harvey W. Kaufman, M.D. We also wish to acknowledge the contributions of Nancy Lavon and support from Kathleen Valentine.

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Quest Diagnostics (NYSE:DGX) is the leading provider of diagnostic information services that patients and healthcare professionals need to make better healthcare decisions.

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Notes		

