

September 11, 2017

Governor Christie and Members of the President's Commission on Combatting Drug Addiction and the Opioid Crisis (the Commission):

Quest Diagnostics applauds the Members of the Commission for your efforts and leadership in developing a comprehensive response to one of the most important public-health issues of our time – addiction and death due to the misuse of opioids. The Commission's Interim Report demonstrates the complexity of the opioid crisis and the need for a balanced health and law enforcement response.

While Quest Diagnostics agrees with the Commission's recommendations, the Company notes, however, that the role of drug testing to determine actual drug use is not mentioned. Quest Diagnostics urges the Commission to: (a) acknowledge the important role drug testing plays as part of a robust strategy to combat the opioid epidemic; (b) encourage States to adopt the *CDC's Guidelines for Prescribing Opioids for Patients in Chronic Pain* (or similar other guidelines) calling for an initial drug test (baseline) and periodic or random ongoing drug testing based on patient risk for misuse; (c) recommend States help ensure that payers properly reimburse for medically necessary drug testing; (d) include in any prescriber education initiatives training in the role, effective use and interpretation of drug tests; and (e) encourage States to explore ways to combine Prescription Drug Monitoring Program (PDMP) data with objective drug testing information.

As the leading provider of diagnostic information services, providing laboratory testing to one in three American adults each year and serving half the physicians and hospitals in the United States, Quest Diagnostics sees firsthand the value of laboratory data in addressing this societal problem. The Company just released a study, titled "Quest Diagnostics Health Trends™: Prescription Drug Misuse in America,"¹ which analyzes results of about 3.4 million prescription medication monitoring laboratory tests performed by Quest Diagnostics between 2011 and 2016. This study paints a stark picture of this health epidemic -- and the dangerous, potentially deadly, patterns of drug misuse practiced by many Americans.

Here are some of the key findings from the 2017 Quest Diagnostics Health Trends research:

- **Half of adults tested potentially misuse their prescription medication.** Based on our laboratory data, 52% of test results of patients taking prescription medications showed signs of drug misuse.

¹ To access the study, and view an interactive depiction of misuse trends by state, visit QuestPDM.com. A more detailed summary of this Study, as well as other Health Trends studies leveraging Quest Diagnostics database of 40 billion de-identified data points, is contained in Section III.

- **Nearly six in ten individuals of reproductive age potentially misuse prescription drugs.** The findings are significant because opioid and benzodiazepine use may decrease male fertility and, if taken during pregnancy, increase the risk of birth defects and other health concerns.

- **Dangerous drug combinations are not uncommon.** Of more than 33,000 patients specimens tested for opioids, benzodiazepines, and alcohol in 2016, more than 20% were positive for both opioids and benzodiazepines, 10% were positive for opioids and alcohol and 3% were positive for all three. Any one of these drug combinations can raise serious health risks, including potentially, death. **Quest Diagnostics also found that one in five (19%) specimens that was positive for heroin was also positive for non-prescribed fentanyl. Clinicians should be aware of potentially dangerous drug interactions beyond the prescription level, and the Company's data demonstrates these interactions are happening with alarming frequency.**

Objective information from laboratory drug testing is critical for monitoring and treating patients on opioid therapy, both at a patient and population level. This Quest Diagnostics study highlights the value of diagnostic information from laboratory drug testing and the objective insights it provides into potential signs of drug misuse.

I. The Utility of and Support for Drug Testing

As the Commission considers robust solutions to the opioid epidemic, it is important to understand the value of drug testing in treatment and monitoring of patients. Drug testing² provides objective information for health care providers to assess patient drug use and misuse that adds to the information provided by prescription drug monitoring programs and other tools a provider may use.

Drug testing:

- alerts providers if a patient is not taking prescribed medication and is at risk for possible drug diversion;
- augments existing subjective tools (e.g. patient medical history, risk assessment, etc.) that providers use to determine patient risk for drug use. Our information supports the observation that patient self-reporting of drug use has limited validity;
- reveals problems that may go undetected by the provider if she/he monitors only patient behavior;
- assists providers to make appropriate evidence-based decisions prior to and throughout treatment, including whether to choose non-opioid therapy or opioid therapy and referral for Substance Use Disorder treatment; and
- helps maintain the provider-patient relationship, as creating mandatory testing guidelines for all patients on opioids may help de-stigmatize the testing and help the provider maintain trust with his/her patients.

The CDC, US Department of Veterans Affairs (VA), US Department of Defense (DoD), the Federation of Medical Boards, and their medical experts all acknowledge the value of drug testing in preventing the misuse of opioids and have included references requiring drug testing in their recommendations.

² See Addenda for discussion of drug testing types

The CDC specifically refers to drug testing in Recommendation 10, as a component for Assessing Risk and Addressing Harms of Opioid Use:

“[W]hen prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.”³

As with the CDC, the Department of Veteran Affairs (VA) and the Department of Defense (DOD) have issued guidelines for prescribing opioids. The VA and DOD each call for baseline testing as part of a comprehensive plan to ensure the safe and effective use of opioid therapy. In addition to recommending baseline testing, these guidelines recommend ongoing testing throughout the course of opioid treatment. The justification for the utility of urine drug screening is that these tests can help identify patients using non-prescribed drugs and illicit substances and can assist in the diagnosis of SUD [substance abuse disorder]. They can also help identify patient adherence to opioid therapy and potential drug diversion.⁴

To date, States have taken a variety of approaches. Oregon, for example has adopted the CDC guidelines⁵, but others like Virginia have gone further requiring baseline testing and retesting for chronic pain addiction patients every three months in the first year and six months thereafter.⁶ Unfortunately, not all States have either adopted the CDC guidelines for drug testing (or adopted similar guidelines) or placed sufficient emphasis upon the utility of drug testing as part of the solution in fighting the opioid crisis.

Quest Diagnostics supports the CDC position to require initial drug testing (baseline testing) prior to prescribing opioids. Clinicians who integrate baseline drug testing along with the other CDC recommendations, such as the Prescription Drug Monitoring Program (PDMP) prescription history, patient risk assessment, and patient self-reporting into their opioid-prescribing decisions have a more complete clinical picture of the patient’s drug use that is supported by objective information from drug testing.

Quest Diagnostics also supports the CDC recommendations for follow-up drug testing (random, periodic) if a patient is prescribed opioids, in order to monitor the patient for compliance with their prescribed medications. Guidelines requiring drug testing can lead to earlier clinical interventions when clinicians are able to detect initial/early prescription misuse, potential drug diversion, dangerous drug combinations, and patients progressing to using non-prescribed or illicit drugs.

³ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>

⁴ *Id.*

⁵ <http://www.oregon.gov/obnm/rules/opioidprescribingguidelines.pdf>

⁶ <https://www.dhp.virginia.gov/medicine/>

II. Comments on Specific Recommendations

Because drug testing can be an effective additional tool for providers, Quest Diagnostics believes that the Commission's interim recommendations can be further enhanced by emphasizing the role and importance of drug testing.

Commission Recommendation: Mandate prescriber education initiatives with the assistance of medical and dental schools across the country to enhance prevention efforts. Mandate medical education training in opioid prescribing and risks of developing an SUD by amending the Controlled Substance Act to require all Drug Enforcement Administration (DEA) registrants to take a course in proper treatment of pain. HHS should work with partners to ensure additional training opportunities, including continuing education courses for professionals.

Quest Diagnostics concurs that prescriber education initiatives would enhance prevention efforts. However, any such education initiatives should include training in the role and effective use of drug tests and in interpreting drug tests. Drug testing, for the purpose of monitoring prescription drug compliance, requires specialized training for clinicians to interpret the wide range of exceptional results that may occur including but not limited to: unexpected Negative results, unexpected Positive results, and absence of drug metabolites. Drug testing interpretive skills require that clinicians understand drug metabolism and genomics as well as how some patients may try to cheat on their testing.

Quest Diagnostics provides consultative support and on-demand training to clinicians for our drug testing services and is willing to partner with the Commission or States to help develop appropriate prescriber training. Moreover, by leveraging Quest Diagnostics' largest database of de-identified clinical laboratory data, the Company can assist the Commission and governmental authorities in identifying drug use and misuse and, in turn, help better inform decisions about training.

In addition to establishing guidelines, the VA launched its Opioid Safety Initiative in 2014. The Initiative had nine goals including (1) educating prescribers of opioid medications regarding effective use of urine drug screening and (2) increasing the use of urine drug screening.⁷ This demonstrates the importance of prescriber education concerning the role of drug testing in patient assessment and monitoring. Quest Diagnostics agrees with the VA on the importance of these two goals in dealing with the opioid crisis.

Therefore, Quest Diagnostics strongly urges the Commission to include training in the role, effective use and interpretation of drug tests as part of any prescriber education initiatives.

⁷ Department of Veterans Affairs, Office of Inspector General. Report No 14-00895-165, Healthcare Inspection: VA Patterns of Dispensing Take Home Opioids and Monitoring Patients on Drug Therapy. May 14, 2014.

Commission Recommendation: Provide federal funding and technical support to States to enhance interstate data sharing among state-based prescription drug monitoring programs (PDMPs) to better track patient-specific prescription data and support regional law enforcement in cases of controlled substance diversion. Ensure federal health care systems, including Veteran's Hospitals, participate in state-based data sharing.

Quest Diagnostics whole heartedly supports the development of state-based prescription drug monitoring programs (PDMPs) and the recommendation to expand data sharing. We believe enhancing sharing PDMP data across state lines is an extremely important step in the right direction. However, we strongly believe other important steps in data sharing also need to be taken. One such step is supporting sharing PDMP data with the objective information generated by drug testing. **We believe it is critically important to understand not only prescribing patterns, but also how these patterns relate to actual patient use of prescribed and non-prescribed drugs.**

Drug testing generates critical actual drug use information that supplements PDMP prescription data so that providers and government authorities have a more complete picture of patient drug use. PDMPs facilitate the collection, analysis and reporting of information for the prescribing and dispensing of opioids. PDMP data shows only if the patient has received prescriptions from other providers, and if they refilled the prescriptions. This data on current or past prescriptions may raise questions about a patient's risk to abuse drugs, as well as identify unusual prescribing patterns. However, it is important to understand that PDMP data cannot detail what drugs the patient is actually taking, combining with other drugs or substituting for prescribed drugs. Unfortunately, PDMPs cannot tell you if the patient adhered to the drug regimen or misused or diverted the drugs. The sad truth is that unremarkable PDMP patient data cannot tell you if the patient is misusing the prescribed medication. Worse is that unremarkable PDMP patient data may give false reassurance to prescribers. Testing for drugs the patient is actually using complements PDMP information to provide a more complete picture of patient drug use that is essential when providers are making treatment and prescribing decisions.

III. Areas the Commission Highlighted for Additional Work and The Role of Drug Testing

Development of a national prevention strategy using "big data analytics" to devise targeted prevention messages that employ cutting edge methods of marketing and communications.

Targeted Data Collection and analytics need to identify most effective prevention and treatment strategies, quality treatment access programs, reimbursements, and aid to law enforcement activities. The possibility of a behavioral health surveillance system run through CDC that tracks prevalence rates, treatments modalities and comorbidities with other illnesses in real time.

Quest Diagnostics completely agrees with the important role "big data analytics" can and must play in developing a national prevention and treatment strategy to help providers, policymakers and law enforcement authorities. As a world leading provider of diagnostic information, Quest Diagnostics manages the largest database of de-identified clinical laboratory data, based on 40 billion de-identified results from clinical lab testing (and growing at a rate of 3 billion new test results per year). From this database, the company derives clinically significant insights that enable policy makers and providers to take actions to improve the health care of Americans. Quest Diagnostics

Health Trends studies⁸ are published in peer-reviewed medical journals and by the company as a public service. These reports have yielded novel insights to aid the patient and population management of allergies and asthma, chronic kidney disease, diabetes, heart disease, influence, prescription drug misuse and employer wellness.

Two annualized Health Trends Reports are dedicated to drug misuse and based on analysis of the company's de-identified laboratory data, believed to be one of the largest national representative data sets of objective laboratory information of patients prescribed opioids and other commonly abused medications. The annual Prescription Drug Monitoring Report provides an industry update of more than 3,000,000 drug test results that are focused on the clinicians who prescribe controlled medications and monitor their patients for prescription adherence.

Our 2017 Prescription Drug Monitoring Report finds that **more than half of tested patients' urine drug tests were inconsistent with the prescription information provided by the clinician.** This suggests that **a majority of tested patients misused their prescription drugs, putting their health at risk.** Other findings in our 2017 annual report include:

- 22% of all specimens tested were positive for non-prescribed or illicit drugs in addition to their prescribed drugs,
- 18% of all specimens were negative for their prescribed drugs, but positive for illicit or other non-prescribed drugs,
- 12% of all specimens tested were negative for their prescribed drug, or any other tested drug,
- 19% of specimens positive for heroin were also positive for non-prescribed fentanyl,
- among specimens tested for opioids, benzodiazepines, and alcohol,
 - more than 20% were positive for concurrent use of opioids and benzodiazepines,
 - more than 10% were positive for concurrent use of opioids and alcohol, and
 - 3% were positive for concurrent use of benzodiazepines, opioids and alcohol.

Since 1988, Quest Diagnostics has published the annual Drug Testing Index (DTI) Report (the other annualized Health Trends Report). This Report is the leading public service indicator report that provides employers and policy makers with workplace drug use among millions of workers. The DTI Report includes three categories of American workplace drug tests: federally mandated, general workforce, and the combined workforces.

- The 2017 DTI⁹ reports the highest rate of drug positivity (4.2%) over the past 12 years. Cocaine, marijuana and methamphetamine use is up among multiple specimen types and worker populations.

In addition, our information resources can be used in a variety of ways including population test result trend analysis that facilitates developing measurable prevention strategies that are adaptable to changes as the nation's epidemic evolves. Quest Diagnostics has regularly partnered with the CDC on a variety of projects that help to shape public health policy. For example, the Company has provided the CDC data related to Hepatitis C and other strains of Hepatitis, as well as liver fibrosis. Quest Diagnostics is currently exploring ways with the CDC to potentially partner to study the link of opioid use and increased risk of HIV/Hepatitis.

⁸ Quest Diagnostics Health Trend studies are performed in compliance with applicable privacy regulations, based on de-identified data, according to the company's strict privacy policies and as approved by the Western Institutional Review Board.

⁹ [The Drug Testing Index](#)

Quest Diagnostics objective drug testing information can assist in identifying trends of drug use and misuse and in turn can better inform providers' and policy makers' decisions about treatment, training and allocation of health care resources. The Company is a willing partner with the government to use Quest Diagnostics' database to assist in shaping future healthcare policies and population health messaging, and for detecting changing trends at local, state and national levels.

IV. Conclusion

As Quest Diagnostics has commented, drug testing provides objective information to help providers better (a) assess the patient risk for opioid misuse and (b) establish initial and ongoing treatment decisions. This actual drug use information can also be used to train providers, strengthen and supplement the prescribing data provided by PDMPs, and help identify trends that can shape policy and use of resource decisions.

While Quest Diagnostics agrees with the Commission's recommendations, the Company notes however, that the role of drug testing to determine actual drug use is not mentioned. Quest Diagnostics urges the Commission to: (a) acknowledge the important role drug testing plays as part of a robust strategy to combat the opioid epidemic; (b) encourage States to adopt the *CDC's Guidelines for Prescribing Opioids for Patients in Chronic Pain* (or similar other guidelines) calling for an initial drug test (baseline) and periodic or random ongoing drug testing based on patient risk for misuse; (c) recommend States help ensure that payers properly reimburse for medically necessary drug testing; (d) include in any prescriber education initiatives training in the role, effective use and interpretation of drug tests; and (e) encourage States to explore ways to combine PDMP data with objective drug testing information.

Quest Diagnostics appreciates this opportunity to highlight the role of drug testing as a valuable tool to assist in developing strategies to combat the epidemic, as well as the key role guidelines must play, and urges the Commission to do the same in its next recommendations.

Sincerely,

A handwritten signature in black ink that reads "Michael E. Prevoznik". The signature is written in a cursive, flowing style.

Michael E. Prevoznik

Addenda

Drug Testing

Drug testing is utilized to identify possible use or non-use drugs. The 2015 American Medical Association Current Procedural Terminology (CPT) publication defined standard terminology to intuitively describe drug testing methods as either ‘presumptive’ or ‘definitive’.

- Presumptive drug class testing – providers order these screening procedures to determine if specimen test results are either Negative (no drug or drug less than detection limit) or that additional testing is required to identify true positive results and what drug used. There are limitations to presumptive testing (particularly if done by point of care testing): these methods cannot rule out either false positive or false negative results; and these methods can only “screen for” a limited number of drugs/drug classes. For example, presumptive testing methods cannot detect some drugs like fentanyl.
- Definitive drug testing – providers order these procedures to confirm and identify drug(s) or drug metabolite(s) in presumptive positive specimens. Definitive testing may range from a single drug to many drugs.

A typical sequence of drug testing process includes:

Step One – perform screening (presumptive testing). When results are presumptive positive, definitive testing is necessary to identify true positive results and rule out false-negative results.

Step Two – definitive testing to identify (confirm) drug present.

Both steps one and two are essential to provide a clear clinical picture. Skipping the definitive confirmation step may lead to misinterpreting presumptive results or missing opportunities to detect potentially dangerous combinations of drug use. Additional instances where definitive testing is called for include:

- confirming unexpected presumptive Negative results; and
- where definitive testing is the only method available to detect the drug of interest.