

## Drug Testing, Chronic Pain, and Financial Conflicts of Interest

### TO THE EDITORS:

In their article entitled “Healthcare Costs and Nonadherence Among Chronic Opioid Users,” published in January of this year, the authors did not mention that the efficacy of drug testing people with chronic pain remains unproven<sup>1</sup> and that in certain cases it may be unconstitutional.<sup>2</sup> In addition, the fact that the article’s 2 lead authors are employees of Ameritox, Ltd, the research was funded by Ameritox, and the results may financially benefit Ameritox requires increased scrutiny of the study. As one reads through the article it becomes apparent there is a fatal flaw in the data. Patients’ non-adherence to opioid therapy was determined by Ameritox’s “proprietary algorithm”—“Rx Guardian,” which has not been peer-reviewed and was only briefly mentioned in the article. The authors cite 4 studies when mentioning Rx Guardian but only 1 looks at the accuracy of Ameritox’s proprietary algorithm, and that is with OxyContin and no other opioids.<sup>3</sup> Moreover, in that particular study the sample size was 36—far too small to apply the article’s conclusions to any global applications. In the current study—a global application—the authors evaluated nonadherence with 19 different opioids, not just OxyContin. What peer-reviewed evidence exists for the accuracy of Ameritox’s proprietary algorithm for the other 18 opioids?

This study is dependent upon data generated from the non-peer-reviewed proprietary algorithm of a drug testing company, which indicates that most people using opioids do not comply with opioid therapy, nonadherence increases healthcare costs, and more drug testing should be conducted. Each of these suggestions may ultimately benefit Ameritox, the company who funded the study with employees who authored it by using data generated from a secret algorithm created by the same company. Nowhere in the study was Rx Guardian questioned for accuracy even though there is a dearth of evidence as to its effectiveness. The lack of transparency and peer-reviewed

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science behind Rx Guardian combined with the conflicts of interest make the findings of this study highly suspect.

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**Author Disclosures:** The author reports no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this letter.

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### IN REPLY:

The authors are pleased to respond to comments to the editor by Mr Collen. Multiple professional societies and healthcare organizations support the use of urine drug testing for patients on chronic opioid therapy (COT) based on their review of the scientific evidence as well as expert opinion. The American Pain Society, the American Academy of Pain Medicine, the American Society of Interventional Pain Physicians, the Department of Veterans Affairs, and the American College of Occupational and Environmental Medicine each have endorsed this technology as an important tool to ensure safe prescribing of opioids in a manner that reduces the risk of drug misuse, abuse, and diversion.

The objectives of this study were to examine: the prevalence of COT, the total annual medical costs for patients on COT, and the healthcare costs associated with likely nonadherence to the pain medication regimen in a large insured population. The authors believe that the study accomplished these goals in a non-biased manner. While the research leading to this publication was sponsored by Ameritox, it was conducted in collaboration with Innovus (previously i3 Innovus), which is an independent research organization. Innovus authors have no financial relationship with Ameritox and all data management and analysis were conducted by Innovus.

With respect to possible bias introduced by use of data from the proprietary Rx Guardian algorithm that adjusts urine drug levels for physiologic variation such as hydration and body weight, these data were used only as an element of the analyses related to the last study objective. The second multivariate model (Table 4) in the study shows that healthcare costs were significantly associated with patient urine drug test results. Specifically, results indicative of illegal drug use and medication levels above expected ranges, as determined using the Rx Guardian tool, were associated with significant differences in total healthcare costs.

In addition to the 1 study<sup>1</sup> referenced by Mr Collen, the Rx Guardian technology is supported by 3 additional peer-reviewed studies.<sup>2-4</sup> These studies explore the use of this tool in patients and subjects taking methadone, OxyContin, and hydrocodone, some of the most common opioids prescribed by physicians. Assessment of drug levels within expected ranges using Rx Guardian was conducted only for these 3 opioids and morphine. The authors agree that there are numerous opioids available, and in fact, the presence of claims for all 19 opioids was used to identify the population of patients from the claims database who were chronic opioid users.

Finally, with respect to concerns expressed about the constitutionality of urine drug testing, we are not aware of any court of law in this country that has prohibited a clinician from using pain management agreements to obtain patient consent for urine drug testing for COT. From a practical standpoint, this is standard in the industry. Use of this type of agreement is recommended by all of the previously referenced guidelines and commits a patient to obtaining opioids from only 1 clinician and 1 pharmacy and establishes consent to periodic urine drug testing. If a patient refuses to sign the agreement, there is no obligation to have urine drug testing performed, but the clinician has the prerogative to not prescribe or to discontinue opioids and offer other modalities of pain management.

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## ■ LETTERS TO THE EDITORS ■

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