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Senate Bill 9 Opponent Testimony
Ohio Senate General Government Committee
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Chairman Rulli, Vice Chairman Schuring, Ranking Member DeMora and members of the Senate General Government Committee, thank you for the opportunity to provide opponent testimony on Senate Bill 9. My name is Bob Miller and I am the Chief Scientific Officer for ACT Laboratories, a licensed Ohio medical marijuana testing laboratory.

ACT has an extensive presence in the Cannabis Testing arena. We are actively licensed in 5 states (Ohio, Michigan, Pennsylvania, New York and Illinois) with ongoing plans to be licensed in 3 more states this year (Massachusetts, Florida and New Jersey). I personally am involved with state regulators in all states we do business with as each of these states have either recently modified their regulators, or are in the process of doing so. Because of this vast experience we are ideally situated to work with you to develop a sound program to ensure that patients/consumers receive safe and effective medicines.

First, I want to take this opportunity to thank the bill's co-sponsors, Senator Steve Huffman and Senator Kirk Schuring, for their effort to include language in the bill that seeks to improve the uniformity of testing results across Ohio's licensed testing laboratories. While I am here today testifying in opposition to the inclusion of specific testing standards in the bill, I want to ensure the Committee that ACT Labs supports the goal of ensuring Ohio's patients are provided with accurate test results and safe medical marijuana products.

We are familiar with the history of cannabis in the US. In 1970, the Controlled substances Act was implemented and Cannabis was placed on the Schedule 1 list of controlled substances, the most restrictive class, codifying a belief that cannabis has no potential for medical application. The substance remains on the federal Schedule 1 list to this day. In retrospect, this was likely more of a political statement rather than a medical or scientific one, due to the turbulence of the Viet Nam era political climate at the time.

The scientific and medical truth is that this plant has been used for hundreds of years as a medicine, across many cultures and is worthy, in fact it is imperative, that we apply modern knowledge and technology to study the material to understand and develop the beneficial uses that certainly exist. Unfortunately the legal status of the plant has sharply suppressed scientific and medical study until very recently. In the past few years, many individual states have bravely created a legal climate in which study can be legitimately conducted to find the answers.

Analytical cannabis science was one of the research areas that has been largely suppressed for the past 40+ years and is now rapidly developing with new and exciting knowledge about cannabis testing emerging at an astounding pace. There are currently no published (USP or otherwise) federal analytical

standard methods for cannabis which differs from that for pharmaceuticals, its closest neighbor. Analytical scientific innovation is being driven by those on the front lines of the Cannabis industry and in Ohio – the licensed cannabis testing laboratories. We work with the analytical testing methods and emerging technology each and every day and are continuously seeking and finding sometimes elusive and subtle ways to improve the accuracy and reliability of the data that we generate to benefit patients who find relief from cannabis. It is imperative that legislation enacted to ensure data accuracy and reliability does not suppress this critical innovation. States that implement scientifically suppressive legislation have and will very likely continue to fall behind as time progresses. The actions being proposed mirrors that previously in place in NY, where the state mandated methods to be used. This limited lab's ability to innovate and resulted in extensive delays in lab testing and testing cost. Last fall, the OCM changed their position allowing for the labs to implement best available technology which has been very welcomed.

As written, lines 2161 – 2176 of Senate Bill 9 requires testing laboratories to use a list of specific testing procedures and standards from two different organizations: Six from AOAC International, Six from ASTM International. The proposed standard testing methods reflect only the science that was available, known to, and evaluated by the organizations that have endorsed them. AOAC or ASTM endorsement only confirms that the methods that were studied work as claimed by the inventors. These endorsements do not ensure that these methods are the best available, that they are the most accurate, or that they are reliable on a long-term basis.

When the testing language was added as an amendment to last year's Senate Bill 261 and then, again, when it was incorporated into Senate Bill 9, I had the opportunity to work with my colleagues in Ohio's testing industry to discuss how the language could be written to more effectively address accuracy and safety, while strongly supporting innovation and scientific advancement. As a result the labs have developed amendment language, which I believe has been shared with the co-sponsors. We recommend striking the language as written and instead including the following two provisions.

First, the labs strongly believe regulatory oversight by scientific experts is the best way to prevent Ohio's program from experiencing unethical test result inflation and recalls that we see in the media. As you probably know, there have been several lawsuits issued by patients and consumer groups claiming that this potency inflation has caused economic and safety concerns. To reduce the chances of potency inflation and other testing issues, the division of marijuana control should have at least two full-time scientific experts on staff who can regulate the laboratory industry based on experience and knowledge. These regulators should have an advanced degree in chemical, environmental or biological sciences and a background in laboratory testing in a regulated industry. These experts can use data analytics, targeted auditing, and a structured blind, round-robin proficiency test program to reveal data that implies a pattern of questionable data reliability. Certainly, standardized test methods, as currently proposed, do not prevent unethical data, but a robust oversight environment will be a strong deterrent.

Second, the language related to standards should allow testing labs to use the best, most innovative methods available to the marijuana industry and firmly promote continued innovation. Many excellent test methods have been published to test cannabis. Often, the best testing methods are developed by

laboratory equipment manufacturers for their clients to use. An informed study confirms that the proposed standard AOAC and ASTM testing methods, although they undoubtedly will work, are inferior to test methods that have been otherwise published, and are certainly inferior to the proprietary, state-of-the-art methods currently used by licensed Ohio testing laboratories. Imposing the proposed mandatory standard testing methods will have the opposite of the intended impact – results that are generated according to these methods will be less accurate, less precise, and less reliable. Scientific advancement achieved by Ohio’s labs will be cast aside, and patients will have less reliable information. The ability for Ohio’s labs to accommodate new analytes (such as the more exotic synthetic cannabinoids) and to engage new technology will be sharply limited. Additionally, the cost to Ohio labs to implement these methods is substantial, requiring purchase of very expensive instrumentation in some cases, lengthy and costly method verification and training to gain ISO 17025 accreditation for the standard methods, and the daily struggle to verify and evaluate questionable results generated according to the inferior methodology.

We recommend replacing this language with comprehensive, proven method validation standards that have been used for decades by the US Pharma and Environmental industries. Unlike specific test methods, we do have well-established method validation standards from nationally and internationally reputable organizations to draw upon, supplemented by standard performance requirements set forth by the division as necessary to protect the health and safety of Ohio’s patients. This approach would give the division’s scientific experts the ability to regulate the labs according to validated methods while being nimble enough to allow innovation.

I appreciate the opportunity to provide my perspective regarding laboratory standards to the committee and I welcome any questions you may have at this time.

Respectfully,

Bob Miller
Chief Scientific Officer
ACT Laboratories