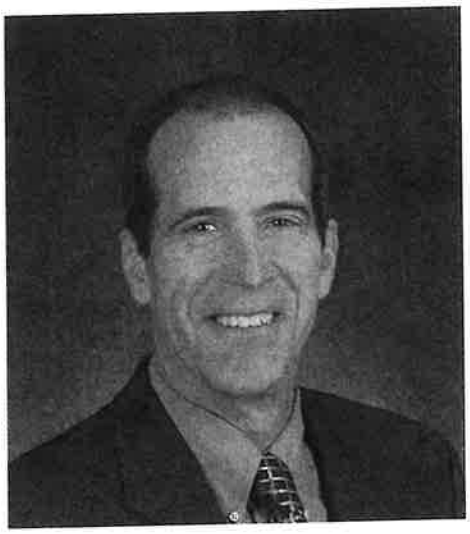
ACT LAB



Dr. Robert Miller
Chief Scientific Officer
ACT Lab

As Chief Scientific Officer, Dr. Bob Miller is focused on the rigorous pursuit of excellence in applying the most advanced and trusted scientific methods. He joined ACT as COO in 2019. He took on the role of Chief Scientific Officer in 2023. Dr. Miller has over 35 years in Pharmaceuticals, which included oversite of diverse product portfolios for global Pharma and Generic companies such as Bayer Pharmaceutical, Pfizer/Warner-Lambert, and Johnson & Johnson.

Prior to joining ACT, Dr. Miller was SVP of Quality at Gilead Sciences Inc. He has a wealth of experience in the design and implementation of quality systems and guiding companies through compliance enhancements in response to FDA and other global regulatory agencies. Prior to his role at Gilead, Dr. Miller was the head of Quality at Johnson & Johnson and Pfizer.

Dr. Miller holds a B.S. in Pharmacy and a Ph.D. in Pharmaceutical Chemistry from Rutgers University College of Pharmacy.

2023 Green Market Report
NOTABLE LEADERS
IN CANNABIS

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ACT \ laboratories

To: Representative Dan Frankel
Chairman House Health Committee

Representative Rick Trajewski
Subcommittee Chair on Health Care

From: Bob Miller, Ph.D
Chief Science Officer
ACT Laboratories

Date: February 5, 2024

RE: Testimony for Hearing on Adult-Use Cannabis

Dear Chairman Frankel:

I want to thank you for the opportunity to be part of the Laboratory Panel focused on how we can all work together to ensure a successful launch of an Adult Use program in Pennsylvania. As you may know, ACT Laboratories perform Cannabis testing in western PA and has been in operation for 5 years. More importantly, as the Chief Science Officer (CSO) of ACT, which is located in 6 states, I have been actively and personally involved in working with state agencies, most notably in NY and Ohio, who have recently implemented an Adult Use program or are considering such a launch. In addition, I have worked with state agencies in Michigan and Illinois as they continue to make changes to their existing programs.

Based on my experiences, there are three keys to a successful AU program;

- Ensuring the creation of appropriate lab regulations driven by science,
- Development of the necessary controls to enable the marketing of infused products
- Greater focus on data integrity coupled with empowered regulators.

When looking at successful regulatory bodies in the states that ACT operates in, there is a need to have laboratory expertise to both develop and regulate the program. In addition, the regulatory body needs to have real enforcement power and the tools necessary to investigate the irregularities found. We have seen this as an issue in a number of states that we operate in. In addition, the underlying statute for labs should allow for flexibility to change through regulation and not be prescribed in statute limiting flexibility.

This flexibility will enable the regulatory agency to react to the science and best standards constantly being developed and innovated. This has been a significant challenge in Illinois, where the state acknowledges that some of the tests required can not be implemented as written. However, they are unable to make the necessary changes.

In AU markets, infused products are the fastest-growing products. As you may know, infused products are all over Pennsylvania right now. They are being sold by unregulated hemp producers that are selling gummies, candies, etc., everywhere. It has been seen that some patients have mistakenly turned to this market because of the rigidity of the current medical program not meeting patients' needs for chewable products. It is clear that infused products must be allowed in the regulated program. Otherwise, a gray market will continue with PA patients buying these unregulated hemp products in gas stations or going across state lines to get approved infused products resulting in a loss of PA revenue.

With the introduction of the AU market in Pa., it is expected that there will be an increase in product production. Making it even more critical that there is a greater focus on data integrity by an empowered regulatory body. Data is currently available at the state level with the seed-to-sale system to identify atypical results being generated, yet it is not being utilized.

In summary, ACT is committed to working with state regulators in the launch of an AU program in PA. We are very grateful for the opportunity to offer this testimony and look forward to continuing the conversation on lab integrity with you soon.

Additionally, I offer additional examples of some challenges that other states have seen below.

Sincerely,

Bob Miller, Ph.D.
Chief Science Officer
ACT Laboratories

Examples of Laboratory Testing Issues in other States

Current issues with cannabis testing laboratories that have made headlines:

Cannabis shoppers use THC percentages like nutritional labels, purchasing products based on THC content, yet the lab system entrusted with measuring the compound is vulnerable to corruption. Some unscrupulous laboratories have been caught inflating THC potency levels, passing moldy cannabis as safe, and even making up results entirely. In several other states with medical/adult use programs, testing issues have come to surface which has disrupted those markets and potentially caused patient safety risks. In some of the worst cases in other states, laboratories have falsified results or incentives have been created for companies to "laboratory shop" for results that yield desired results.

Lab tests have other impacts too. If a sample fails its quality assurance test, a grower might need to destroy an entire crop of cannabis. And, corrupt labs are cheating customers out of the potency they think they're buying.

Experts say that lab corruption is widespread because the incentives to cheat are too high and enforcement is mostly ineffective.

What is the solution or potential solutions?

To ensure consistency, we should clarify what types of testing methods are allowed and which ones are not as well as what laboratories should be testing for. It is believed that in PA, not all laboratories are using the same testing methods and that many are not using uniform nomenclature to report results which could be confusing for patients. The granularities of testing and its concomitant practices should be standardized or formalized in an effort to strengthen laboratory integrity.

To ensure consistency we should also endeavor to clarify what types of testing methods are permitted in an effort to strengthen laboratory integrity. Stakeholders have expressed the need for the permissibility of formal proficiency testing among labs and accountability to meet program standards. This could include blind "round-robin" style testing, where labs test products which have been tested previously on a peer-to-peer level, or the utilization of trend analysis to ensure accurate and reliable testing data is being generated. This could be a meaningful next step as it relates to the development of formal laboratory oversight from the PA DoH and as well in an eventual adult-use program.

How have other states tried to tackle this issue and what has worked in addressing the problem?

The strictest lab regulations in the country are likely in Oklahoma, where a booming pot economy worth $800 million a year has sprung up on the edge of the American South. Pot labs face regular proficiency tests and the state requires labs to collect two samples for every test and then hold a reserve sample, which is used to investigate complaints. The second sample is also used as a calibration tool, with the state randomly retesting reserve samples. The lab must answer for any deviations between the first and second tests.

A blistering 2019 audit of Oregon's testing system found that the state's testing program "cannot ensure that test results are reliable and products are safe" and said the state regulatory program had "limited authority, inadequate staffing and inefficient processes."

Allegations of lab fraud have dogged the legal cannabis industry from the beginning of commercial pot sales, especially in Washington state, where recreational pot has been legally sold since 2014. Observers have known about the problem in part because lab data is public in Washington, allowing data scientists to analyze the test results of individual labs.

In late 2015, MacRae published data showing that, in a three-month period, four of Washington state's 14 certified labs had tested tens of thousands of samples without ever failing a sample for microbial contamination, while other labs failed as many as 45 percent of samples. Four months later, the state suspended one of those four labs for six months, finding the lab had given the highest THC averages in the state and "put the public health and safety at risk by exposing the public to ... marijuana products that have not been properly or accurately tested for microbial contamination and other risks."

Other states have similar issues. In 2019, MacRae analyzed the cannabis market in Nevada, which has publicly struggled to regulate their industry. (In one five-month period, the state suspended the licenses of nearly half of all of its certified labs.) MacRae's analysis found that the average THC potency in the state had steadily increased from 19 percent to almost 22 percent between 2018 and 2019, and multiple labs were appearing to release fraudulently inflated THC potencies and rarely failing samples for safety standards. Within days of MacRae presenting his findings to the state, Nevada's government warned the lab industry that they were actively investigating THC inflation, and within weeks the state had fined a lab for "unsound testing practices."

Additional References

America's Pot Labs Have A THC Problem | FiveThirtyEight

Lack of standards, dubious business practices threaten to upend cannabis testing industry

False test results, lab shopping put cannabis consumers at risk

Lab Shopping: Highlighting the Need for Checks and Balances in Cannabis

Ethics or Profits: Lab Shopping in the Cannabis Industry