Alfred E. Staubus, PharmD, PhD
Forensic Toxicologist
1015 Kenway Court
Columbus, Ohio 43220

February 21, 2023

To Members of the Senate Committee at the Hearing on Senate Bill No. 26:

Introduction:

I am an independent forensic toxicologist who has testified in criminal cases involving marijuana for both the defense and the prosecution. I have testified since 1985 throughout the state of Ohio and in some twenty other states as a recognized expert in the area of forensic toxicology. I have two doctoral degrees, a Doctor of Pharmacy degree (a PharmD in clinical pharmacy) and a PhD in Pharmaceutical Chemistry. I was a full-time faculty member in The Ohio State University College of Pharmacy, providing teaching, research, and public functions for 30 years. Currently I hold an Emeritus Faculty appointment with The Ohio State University College of Pharmacy. Upon my retirement from OSU in 2004, I expanded to full time my consulting activities in forensic toxicology, although since the pandemic, I have reduced my work hours in this area.

Issue No. 1 - *per se* limits for the inactive metabolite (carboxy-THC) in blood and urine:

I was one of the forensic toxicologists who testified on March 8, 2005, at the Ohio House of Representatives Senate Bill 8 hearing. The drug *per se* sections of the Ohio Revised Code became law following the passing of Senate Bill 8. Within footnote 2 of the Ohio First District Court of Appeals opinion in *State v. Whalen* is the following statement:

> *The General Assembly, in constructing the per se statute, expressly considered the arguments of those who claimed that the law lacked a direct correlation between the prohibited amount of marihuana and its metabolite in a driver's system and impairment. Senators Steve Austria and Patricia Clancy, two of the bill's sponsors, noted during deliberations on the bill that they had worked closely with forensic toxicologists to establish the precise levels at which driving is prohibited in the statute and that the levels in the bill were not only consistent with federal standards, but that the forensic toxicologists who had participated in setting those levels had unanimously agreed that anyone driving with the levels of the substance listed in the bill definitely would be impaired. See 2005 OH Sub.S.B. 8, Third Consideration, available at http://www.ohiochannel.org, Ohio Senate Session (February 16, 2005) 14:15:57 (accessed May 1, 2013).*

It would appear that the opinion by the Ohio First District Court of Appeals in *State v. Whalen* relied upon the statements made by Senators Steve Austria and Patricia Clancy that they had worked closely with forensic toxicologists who had unanimously testified that anyone driving with the levels of the substances listed in Senate Bill 8 definitely would be impaired (see footnote 2 in *State v. Whalen*). As a forensic toxicologist who testified at the Senate Bill hearing and who has reviewed the written materials/testimonies provided by others during the Senate Bill

8 hearings, I can definitively state that the alleged statements made by Senators Steve Austria and Patricia Clancy are false and inaccurate with regard to forensic toxicologists unanimously testifying that anyone driving with the levels of the substances listed in Senate Bill 8 definitely would be impaired. I have provided a summary of the materials supplied by the testifying forensic toxicologists in Appendix A of my materials today.

As a result of the misrepresentation of the testimony by forensic toxicologists, people have been falsely convicted in the state of Ohio as being *per se* impaired while having the inactive marijuana metabolite in their urine above the *per se* limits. These people have suffered a great injustice caused by the inactive marijuana metabolite *per se* law of Ohio due to the inactive marijuana metabolite's prolonged duration of days and even weeks after last use of marijuana, long after any impairing effects have dissipated.

This fact is recognized by experts who testify for the prosecution:

When Dr. John F. Wyman was hired by the Guernsey County Prosecuting Attorney Daniel G. Padden to prepare an opinion letter to evaluate the defendant's urine marijuana metabolite level of over 200 ng/mL in a MVA case involving the death of two individuals (*State of Ohio v. Razel Sheppard*, Guernsey County Common Pleas Court, Case No. 14CR212), Dr. Wyman opined the following:

> "*The marijuana metabolite detected in urine is carboxy-THC; THC and 11-hydroxy THC are typically not detected in urine.* ***The concentration of drugs in urine cannot be used to interpret effects on behavior, since the drugs are no longer available to receptor sites. For pharmacological purposes, drugs in urine only indicate exposure to the drug or agent.***" and
>
> "*Ms. Sheppard stated that she smoked marijuana before she left Cleveland at approximately 10:00 a.m. It is not possible to know whether Ms. Sheppard's ability to drive at the time of the accident (approximately 2:00 p.m.) was impaired by the effects of marijuana because the specimen collected for Ms. Sheppard was urine. The level of carboxy-THC measured was > 200 ng/mL. As stated above, carboxy-THC is pharmacologically inactive and a drug in urine cannot be used to interpret effects on behavior.*"

It is time for the state of Ohio to stop prosecuting people for having the inactive marijuana metabolite in their blood or urine.

The proposed Senate Bill No. 26 thankfully removes the *per se* limits for the inactive marijuana metabolite thereby preventing prosecutions and false convictions for those having the inactive marijuana metabolite in their blood or urine.

Issue No. 2 - *per se* limits for marijuana's active compound (THC) in blood, serum/plasma and urine:

1. Both the Society of Forensic Toxicologists (SOFT) and the American Academy of Forensic Sciences (AAFS) on page 8 in the 2006 SOFT/AAFS Forensic Toxicology Laboratory Guidelines (http://www.soft-tox.org/files/Guidelines_2006_Final.pdf) have taken a position on the interpretative use of drugs and/or metabolites in urine on human behavior:

> "*Urine may also be submitted for testing; a minimum volume of 30 mL is recommended. It must be emphasized that neither qualitative nor quantitative analysis of urine permits an evaluation of the effect of the drug or chemical on human behaviour. If other specimens are submitted and analyzed, any conclusions regarding drug use or effects on human behavior should be based only on appropriate validated scientific studies.*"

I, therefore, recommend that all references to THC and other drugs in urine at any *per se* limit be removed from Senate Bill No. 26.

2. THC is not similar in its pharmacokinetics behavior or in its pharmacodynamics behavior to that of alcohol. Alcohol is eliminated from the body by a saturated zero-elimination process that allows for possible back extrapolation to the time of the incident, and the blood-alcohol concentration has some direct correlation to the level of alcohol concentration in the brain and, therefore, some correlation to the degree of impairment. However, THC is eliminated from the body by a tri-phasic first-order process that does not permit back extrapolation to the time of the incident, and the THC-blood concentration does not have a direct correlation to the level of THC concentration in the brain and, therefore, lacks any direct correlation to the degree of impairment.

3. The federal government's National Highway Traffic Safety Administration (NHTSA) has studied the effects of marijuana and other drugs on driving performance and has published a set of fact sheets for various drugs including marijuana. Even the National Highway Traffic Safety Administration's Drugs and Human Performance Fact Sheet on Marijuana clearly states under the section titled "Duration of Effects":

> "*Typical marijuana smokers experience a high that lasts approximately 2 hours. Most behavioral and physiological effects return to baseline levels within 3-5 hours after drug use, ...*"

This same fact sheet states under the section titled "Effects on Driving":

> "*Marijuana has been shown to impair performance on driving simulator tasks and on open and closed driving courses for up to approximately 3 hours. Decreased car handling performance, increased reaction times, impaired time and distance estimation, inability to maintain headway, lateral travel, subjective sleepiness, motor incoordination, and impaired sustained vigilance have all been reported. Some drivers may actually be able to improve performance for brief*

periods by overcompensating for self-perceived impairment. The greater the demands placed on the driver, however, the more critical the likely impairment. Marijuana may particularly impair monotonous and prolonged driving."

4. The NHTSA fact sheet on marijuana states:

"*It is difficult to establish a relationship between a person's THC blood or plasma concentration and performance impairing effects. Concentrations of parent drug and metabolite are very dependent on pattern of use as well as dose.*" and

"*It is inadvisable to try and predict effects based on blood THC concentrations alone, and currently impossible to predict specific effects based on THC-COOH concentrations.*"

5. In addition, the May 2016 AAA Foundation for Traffic Safety's report and fact sheet "An Evaluation of Data from Drivers Arrested for Driving Under the Influence in Relation to *Per se* Limits for Cannabis" makes the following conclusions:

"*All of the candidate THC concentration thresholds examined would have misclassified a substantial number of drivers as impaired who did not demonstrate impairment on the SFST, and would have misclassified a substantial number of drivers as unimpaired who did demonstrate impairment on the SFST.*" and

"*Based on this analysis, a quantitative threshold for per se laws for THC following cannabis use* ***cannot*** *be scientifically supported*."

6. There is no agreement among the experts with regard to a suggested *per se* limit for THC in blood or plasma/serum:

a) One early literature report made a preliminary suggestion that THC concentrations in serum of 7 to 10 ng/mL (in blood of 3.5 to 5 ng/mL) has the driving impairment equivalent of a 0.05 g/dL blood-alcohol concentration ("Developing Limits for Driving Under Cannabis," Franjo Grotenhermen, et al., *Addiction*, 102, 1910-1917, 2008).

b) Another literature report from Marilyn Huestis' lab at the National Institute on Drug Abuse, NIH, used lane weave (standard deviations of lateral position, SDLP) in driving simulators as the measure of impaired driving and found that blood THC concentrations of 8.2 ng/mL (serum/plasma THC concentrations of about 16.4 ng/mL) increased SDLP similar to 0.05 g/210 L breath alcohol concentration and that blood THC concentrations of 13.1 ng/mL (serum/plasma THC concentrations of about 26.2 ng/mL) increased SDLP similar to 0.08 g/210 L breath alcohol concentration ("Cannabis Effects on Driving Lateral Control With and Without Alcohol," Rebecca L. Hartman, et al, *Drug Alcohol Depend.,*154: 25-37, 2015).

c) However, the most recent (2021) literature report concludes that "There appears to be a poor and inconsistent relationship between magnitude of impairment and THC concentrations in

biological samples meaning that *per se* limits cannot reliably discriminate between impaired from unimpaired drivers." ("The Failings of *per se* Limits to Detect Cannabis-induced Driving Impairment: Results from a Simulated Driving Study," Thomas R. Arkell, et al., *Traffic Injury Prevention*, 22: 102-107, 2021).

.

d) The recent 2021 literature report by Arkell, et al., supports the positions of the National Highway Traffic Safety Administration and the AAA Foundation for Traffic Safety.

7. I have been asked to give my opinion as a forensic toxicologist with regard to what *per se* limits for THC should be included in Senate Bill No. 26.

a) Based upon the total inability to correlate THC concentrations in urine with marijuana driving impairment, I strongly recommend removing any and all *per se* limits for THC concentrations in urine.

b) However, if political considerations require the establishment of *per* se limits in Senate Bill No. 26, I strongly recommend a rebuttable *per se* limit for THC in blood of 15 ng/mL and a rebuttal *per se* limit for THC in serum/plasma of 30 ng/mL. For purposes of prosecution under these *per se* limits for THC in blood and serum/plasma, support of marijuana driving impairment should be obtained by direct observation of the subject's impaired driving (for example, lane weaving) and/or by a confirmatory finding from a Drug Recognition Evaluation (DRE) examination.

8. In order to reliably establish impairing effects of drugs in suspected impaired drivers, the Drug Recognition Evaluation (DRE) protocol has been developed. The DRE evaluation is a systematic, standardized twelve-step method. The DRE evaluation yields information that is the basis for a DRE-trained officer's opinion 1) that a suspect is/is not impaired, 2) (if impaired) that the impairment is/is not drug related, and 3) (if drug related) that a specific drug category (or categories) is present. The Los Angeles Police Department (LAPD) originated the DRE program in the 1970s and attracted the attention of the National Highway Traffic Safety Administration (NHTSA) in the early 1980s. The two agencies collaborated to develop a standardized DRE evaluation protocol, which led to the development of the Drug Evaluation and Classification (DEC) program. In 1989, the International Association of Chiefs of Police (IACP) and NHTSA joined together to implement the DEC program across the country. Ohio participates in the DEC program.

Issue No. 3 - THC-blood concentrations are about half that of THC-plasma concentrations:

1. It should be noted that other parts of R.C. 4511.19(A)(1) take into consideration the recognized 20% difference in alcohol concentrations between blood and serum/plasma by having different *per se* alcohol levels for blood (0.080 g/dL and 0.170 g/dL) versus serum/plasma (0.096 g/dL and 0.204 g/dL):

R.C. 4511.19(A)(1)

> *(b) The person has a concentration of eight-hundredths of one per cent or more but less than seventeen-hundredths of one per cent by weight per unit volume of alcohol in the person's whole blood.*
>
> *(c) The person has a concentration of ninety-six-thousandths of one per cent or more but less than two hundred four-thousandths of one per cent by weight per unit volume of alcohol in the person's blood serum or plasma.*

2. However, the marijuana *per se* section does not distinguish the 50% to 55% difference in THC concentrations between blood and serum/plasma. Despite, the fact that THC concentrations in plasma or serum are about twofold greater than the corresponding THC concentrations in blood. R.C. 4511.19(A)(1)(vii) has the same THC ("marihuana") *per se* levels for whole blood, plasma, and serum. This is another technical fault that reflected the lack of understanding of forensic toxicology of marijuana in the writing and passing of Senate Bill 8 by our state lawmakers back in 2005. This should be corrected in Senate Bill No. 26 within draft section (F)(1)(b):

(b) The person has a concentration of at least 10 nanograms of delta-9-tetrahydrocannibinol per milliliter of the person's whole blood, or of at least 5 nanograms of delta-9-tetrahydrocannibinol per milliliter of the person's blood serum or plasma.

Or, if my recommended *per se* limits are adopted:

(b) The person has a concentration of at least 30 nanograms of delta-9-tetrahydrocannibinol per milliliter of the person's whole blood, or of at least 15 nanograms of delta-9-tetrahydrocannibinol per milliliter of the person's blood serum or plasma.

Appendix A

Examples of testimonies and/or supporting documentation that were provided to the Senate Bill 8 committee hearings included the following:

A. Nationally known forensic toxicologist Dr. Arthur J. McBay (the chief toxicologist in the Office of the Chief Medical Examiner for North Carolina and a professor at the University of North Carolina in Chapel Hill) provided his input in the form of a literature review with a clear summary statement of the research on marijuana and driving impairment (see first page of McBay material marked 8c):

> "*Several studies came to the conclusion that it appears to be impossible to conclude anything about a driver's impairment based on THC and THC-COOH blood concentrations.*"

B. Dr. McBay's review included referencing the 1985 Consensus Report "Drug Concentrations and Driving Impairment" published in JAMA (vol. 254, pages 2618-2621, Nov. 8, 1985). The Consensus Report concluded with respect to blood concentrations of drugs:

> "*One difficulty is that the blood concentration-impairment relation is more complex with other drugs than it is with the relatively simple drug ethanol. Conservatively, a per se drug concentration might be selected that could be expected to produce impairment in virtually all cases. The problem with this approach would be that many drivers impaired at lower concentrations would not be caught in this net. On the other hand, if a minimum concentration is chosen, below which impaired driving is unlikely in virtually all cases, the system might net too many unimpaired drivers. If both minimal and maximal concentrations could be defined, the intermediate gray area would still have to be resolved by clinical evidence of impairment. Thus, relatively little would be gained by a per se approach based on arbitrary data.*"

The Consensus Report concluded with respect to urine concentrations of drugs:

> "*Testing of drugs or drug metabolites in urine is only of qualitative value in indicating some prior exposure to specified drugs. Inferences regarding the presence or systemic concentration of the drug at the time of driving or impairment from drug use are generally unwarranted. The presence of an illicit substance in urine that may indicate prior illegal action can, however, add a dimension to probable cause of observed driving performance.*"

C. Dr. McBay's review also included a reference to the NHTSA's 1993 Final Report "Marijuana and Actual Driving Performance" (DOT HS 808 078). The NHTSA's 1993 Final Report concluded with respect to drug plasma concentrations and driving performance:

> "*It is not possible to conclude anything about a driver's impairment on the basis of his/her plasma concentrations of THC and THC-COOH determined in a single sample.*"

D. The Ohio Department of Public Safety provided the recommendations of the Governor's Task Force on Impaired Driving, the Drugged Driving: Linking the Science Committee, members of which included law enforcement, forensic scientists, treatment professionals, prosecutors, and the judiciary. Members of the Drugged Driving: Linking the Science Committee were all in agreement on a number of basic facts with respect to urine drug levels:

> *"A urine level of a drug or its metabolite is proof of prior exposure to that drug or chemical."*
>
> *"The presence of a drug or its metabolite in urine does not relate directly to a level of active drug in the blood."*
>
> *"The presence of an inactive metabolite or derivative of a drug in urine does not rule out the possibility of active drug in the blood since both moieties may exist in the body simultaneously."*
>
> *"Metabolites may be excreted and detected in urine several days after use of a legal or illegal drug."*
>
> *"Schedule I and II drugs and or metabolites may be detected in urine after eating a food or health preparation."*

E. Edward J. Orlett of the Drug Policy Alliance (DPA) in Ohio testified and provided both written and electronic support at the February 16, 2005, Senate Bill 8 hearing before the Ohio Senate Judiciary Criminal Justice Committee. The Drug Policy Alliance (DPA) is the nation's leading organization promoting drug policies that are grounded in science, compassion, health and human rights. Mr. Orlett presented the DPA recommendation to delete the language on marijuana metabolites from Senate Bill 8. Mr. Orlett provided the Ohio Senate Judiciary Criminal Justice Committee with an electronic copy of the 2003 Final Report of "State of Knowledge of Drug-Impaired Driving" (NHTSA DOT HS 809 642). On page 13 of this 2003 Final Report are comments pertaining to urine drug testing and behavioral impairment:

> *"Urinalysis*
>
> *The drug testing methodology for urinalysis is well established. With the advent of workplace testing, where large numbers of drug tests are conducted daily in the United States, urinalysis methods have become the standard by which other technologies are being compared. Drugs and drug metabolites are detectable in urine for several days after the drug has been used. This several-day window of detection can overlap with intoxication, impairment, and being "under the influence," and can extend even beyond these states of behavioral impairment. Therefore, while a positive urine test is solid proof of drug use within the last few days, it cannot be used by itself to prove behavioral impairment during a focal event."*

F. In addition, in my March 8, 2005, Ohio House of Representatives Senate Bill 8 hearing testimony and supporting documentation, I clearly testified that:

> *"Mr. Chairman and Members of the Committee:*
>
> *We can all agree that we do not want alcohol and/or drug impaired drivers on the roads of Ohio. While the goal of Senate Bill 8 is intended to establish legal procedures for effective detection and removal of drug impaired drivers, the bill as written will not reliably accomplish this goal.*
>
> *In addition to a number of technical faults, such as the lack of appropriate scientific terminology for the specific compounds and metabolites to be measured for detection of marijuana and cocaine, there is the general lack of scientific reliability in establishing per se limits for drugs other than alcohol, particularly in urine. With rare exceptions, such as alcohol, the forensic science field, including governmental agencies, such as the National Institute for Drug Abuse (NIDA), are in agreement that drug and metabolite concentrations cannot be correlated with driving-related impairment.*"

G. At the same March 8, 2005, Ohio House of Representatives Senate Bill 8 hearing, there was also testimony and documentation from Edward J. Orlett who again was representing the Drug Policy Alliance in Ohio. At the Ohio House of Representatives hearing, Mr. Orlett discussed and provided a copy of the article by Dr. Marilyn Huestis of the NIDA titled "Blood Cannabinoids. I. Absorption of THC and Formation of 11-OH-THC and THCCOOH During and After Smoking Marijuana," (Journal of Analytical Toxicology, vol. 16, pages 276-282, 1992). This same article was also previously cited by Captain J.D. Brink, PhD, Commander of the Ohio State Highway Patrol Crime Laboratory. Captain Brink had testified that all metabolites are gone from the body in 6 to 10 hours based upon the 1992 article by Dr. Huestis. The article by Dr. Huestis does show that from the smoking of a single marijuana cigarette, the marijuana metabolite (carboxy-THC or THC-COOH) concentrations drop below the 50 ng/mL *per se* level in plasma found in ORC 4511.19 (A)(1)(j)(viii)(II) within 6 to 10 hours. However, the marijuana metabolite (carboxy-THC or THC-COOH) from the smoking of a single marijuana cigarette is detectable above the 5 ng/mL *per se* level in plasma found in ORC 4511.19 (A)(1)(j)(viii)(I) for 6 to 48 hours at the low dose (1.75% THC) and for 27 to 72 hours at the high dose (3.55% THC)–see pages 277-279 of the 1992 article. It should be noted that currently available marijuana (having higher THC concentrations than were used in the 1992 study) would have marijuana metabolite concentrations above the *per se* limits for even longer periods of time following the smoking of a single marijuana cigarette. In addition, because of the long half-life in the body of the marijuana metabolite, concentrations of the inactive marijuana metabolite above the *per se* limits can be detected in chronic users for many days following last use.

As can be seen in the above-cited statements from the testimonies of forensic experts at the committee hearings and/or from the submitted documents, none of the forensic toxicologists testified that anyone driving with the levels of the inactive metabolite (carboxy-THC) of marijuana in blood or urine, as specified in Senate Bill 8, definitely would be impaired. There was, in fact, no unanimous testimony that anyone driving with the levels of the marijuana

metabolite at any concentration listed in Senate Bill 8 definitely would be impaired. To the contrary, the testimonies from these forensic toxicologists clearly indicated that the presence of the inactive metabolite of marijuana in blood or urine only establishes that the subject had been exposed to or had used marijuana some time in the past and does not establish that the subject was impaired by marijuana.

Consequently, the Ohio rulings that have upheld the *per se* levels for the marijuana metabolite in R.C. 4511.19(A)(1)(j)(viii)(II) are based upon misunderstanding of the actual committee hearing testimony and documentation from forensic toxicologists. This misunderstanding was caused by the false and inaccurate statements made during the Ohio Senate session on February 16, 2005, by Senators Steve Austria and Patricia Clancy with regard to forensic toxicologists unanimously testifying that anyone driving with the levels of the substances listed in Senate Bill 8 definitely would be impaired.