

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at LEXINGTON
No. 5:14-CR-74-6-DCR

UNITED STATES OF AMERICA,)	
)	
Plaintiff)	Defendant's Memorandum
)	Regarding PharmChem
vs.)	Sweat patch
)	
KATHERINE MICHELLE JONES,)	
)	
Defendant)	
)	e-filed

Defendant Katherine Michelle Jones tenders this memorandum regarding the reliability of the PharmChem sweat patch.

Statement of the Case

On November 18, 2016, a Pharmchek “sweat patch” manufactured by PharmChem, Inc. was applied to defendant’s arm, where it remained until November 28, 2016. Defendant was subjected to a urine drug screen on November 28, which results, it is understood, were negative. The “sweat patch” was then sent to Clinical Reference Laboratory for analysis. The results were reported positive for cocaine and marijuana.

While the sweat patch was on her arm, defendant was subjected to drug tests administered through her doctor’s office (defendant is a Suboxone patient and therefore subject to regular urinalysis testing) and at the Montgomery County Detention Center, which was part of the ongoing requirements for judicial proceedings related to defendant’s relationship with her child. These tests yielded negative results. *See Notice of Filing* (DE 414).

The “sweat patch” is a gauze pad covered by a protective membrane and has an appearance similar to a bandage. The official trade name of the sweatpants is the “PharmChek Drugs of Abuse Patch”; it is marketed by PharmChem, Inc., a private corporation with Texas headquarters.

Typically, and it is understood was done in this case, the sweat patch is worn on the subject’s upper arm and an adhesive perimeter bonds it to the individual’s skin. PharmChem directs that the subject’s arm be swabbed with isopropyl alcohol prior to application of the sweat patch;¹ it is understood that this procedure was followed with respect to defendant. According to PharmChem, the patch can be worn by “most people ... for 7 to 10 days.” *PharmChem Technical Manual* at 5. Why the length of time varies from “person-to-person and skin type to skin type” is unknown; how this variable may have impacted defendant’s sweat patch results is not known.

PharmChem has a contract with the Administrative Office of the Federal Courts, a relationship that dates back to the mid-1990s. It is unknown to defendant if any government entity requires PharmChem to use any particular collection techniques, chain of custody procedures, quality control mechanisms, or testing procedures. It appears that all aspects of PharmChem’s sweat testing program are designed and operated by private corporation. It does not appear that any government entity certifies that PharmChem is spending the money necessary to ensure accurate test results. It is largely unknown what, if any,

¹ *PharmChek Drugs of Abuse Patch: Technical Questions & Answers* at 14 (Feb. 2015 rev.)(PharmChem Technical Manual), available at https://www.pharmchem.com/files/download_files/patch-tech-qa-2-15.pdf (last visited Feb. 22, 2017).

problems PharmChem itself has unearthed regarding the accuracy and/or reliability of its sweat patch. The same is true with regard to the Clinical Reference Laboratory: what measures it takes to ensure the accuracy and reliability of its staff and the testing procedures they follow is unknown to defendant.

Overview of Scientific Literature Regarding Reliability of the Sweat patch

Scientific research indicates that the “sweat patch” is prone to yielding a “false positive” drug test results at a rate of at least 7%. D. Kidwell, et al, “Comparison of Daily Urine, Sweat, and Skin Swabs Among Cocaine Users,” 133 *Forensic Science International* 63 (2003)(hereinafter “2003 Kidwell Report”).²

The false positives appear to result from environmental contamination of the sweat patch that can occur in two ways: (1) a subject’s skin can be contaminated with drugs prior to application of the patch; and/or, (2) drugs can pass directly through the membrane that covers the patch. *See* D. Kidwell, F. Smith, “Susceptibility of PharmChek Drugs of Abuse Patch to Environmental Contamination,” 116 *Forensic Science International* 89 (2001)(hereinafter “2001 Kidwell Report”).³ At least two of these sources are “(1) an individual’s own previous drug use or (2) an individual’s being ‘around drugs’ unrelated to intentional use by the individual in question.” 2003 Kidwell Report at 64.

The cleaning of a subject’s skin with isopropyl alcohol prior to application of the patch does not cure or eliminate contamination of the patch by drug residue already on the subject’s skin. Research has shown that after application

² As this report is in the public domain, a copy is tendered as Ex. 1 hereto.

³ This report is also in the public domain and is tendered as Ex. 2 hereto.

of a minuscule amount of drugs to the skin “(an amount equivalent to 0.1 – 0.01% of a dose), 6 days of regular hygiene followed by ‘cleaning’ with isopropanol wipes (as recommended by the manufacturer) does not prevent positive patch results.” *Id.* It appears that PharmChem once performed a similar study and it yielded false positive results at a 40% rate. L. Bazelon, “Testing Testing: The Sweat Patch Was Supposed to Solve the Problems of Urinalysis, But It Created A Host of Its Own,” *Legal Affairs* (July/August 2003).⁴ It is unknown what, if any, ameliorative steps or measures PharmChem took in response.

Research also indicates that drugs can be stored in the skin for long periods of time and then released into the sweat patch and thus yielding a “false positive.” *See* Levisky, Bowerman, Jenkins & Karch, “Drug Deposition in Adipose Tissue and Skin: Evidence for an Alternative Source of Positive Sweat Patches,” 110 *Forensic Science International* 35 (2000). It is unknown how, if at all, PharmChem, which markets the sweat patch as a reliable indicator of recent drug use, has responded to this research. What research, if any, PharmChem has undertaken regarding how long drugs can be stored in the body before they are excreted in sweat is unknown.

A study published in 1996 discussed that “cocaine may be an unknowing contaminant from contact with the sweat of a user, or residue from another’s drug use. Once cocaine is deposited onto hair, the previous drug-free individual need only sweater otherwise moisten their hair to form a solution of the drug.” F. Smith, D. Kidwell, “Cocaine in Hair, Saliva, Skin Swabs, and Urine of Cocaine

⁴ Accessed at https://www.legalaffairs.org/issues/July-August-2003/review_bazelon_julaug03.msp (last visited February 22, 2017).

Users' Children," 83 *Forensic Science International* 179, 180 (1996).⁵ The same study also reported that forehead swabs for most of the children involved in the study indicated measurable quantities of cocaine. *Id.* at 179. Notably, the study found that "in several households the child's hair contained quantities [of cocaine and related compounds] greater than the adult users' hair." *Id.* at 186.

Furthermore, the study offered that benzoylecgonine (BE), a cocaine metabolite, "may not be a marker of cocaine use." *Id.* In sum, research indicates that the hair of nonusers can in essence store drug residue that is then released by the person perspiring; similarly, research indicates that a skin swab of non-drug users can yield a positive result for the presence of cocaine.

A 2001 study concluded that drugs can pass through the sweat patch membrane and contaminate it from an external source. *See* Kidwell 2001 Report at 89. Three sources identified as increasing the likelihood of this type of environmental contamination include: (1) the tested individual actively perspiring; (2) the exterior of the patch becoming wet; and, (3) the exterior of the patch being exposed to a material with a pH level greater than seven, such as many common soaps and shampoos. *Id.* at 94. All of these sources are common in everyday living.

There does not appear to have been performed much research regarding the sweat patch and marijuana. Researchers called in 2004 for further investigation because three issues "may limit the application of THC sweat testing." R. Torre, S. Pichini, "Usefulness of Sweat Testing for the Detection of

⁵ This report is also in the public domain and is tendered as Ex. 3 hereto.

Cannabis Smoke,” 50 *Clinical Chemistry* 1961 (2004).⁶ Those three issues were (1) environmental skin contamination, (2) drug absorption/loss through patch membrane, and, (3) drug reabsorption from patches. *Id.* However, at least one study reported similar effects on the children of marijuana smokers as reported for the children of cocaine users. *See* <https://www.statnews.com/2016/04/30/marijuana-smoke-children/> (last visited February 22, 2017).

PharmChem states that the sweat patch can detect drug use occurring 24-48 hours prior to its application and/or up to 24 hours prior to its removal. Cocaine use should show up on a urinalysis four days after its use. 2003 report at 66. THC is detectable in urine for even a first-time user for 5-8 days. *See* <https://www.addict-help.com/cannabis/how-long-does-weed-stay-in-your-urine-system/> (last visited February 22, 2017). That defendant is overweight and has hepatitis C would weigh against a shorter period of time for her to retain THC in her urine. A timeline for possible use does not preclude defendant’s use prior to application of the patch; it would seem to preclude use after the urinalyses done on November 21 and 22.

The sweat patch has been accepted by some courts as generally reliable, the Eighth Circuit being foremost. *United States v. Meyer*, 483 F.3d 865 (8th Cir. 2006). A district court rejected sweat patch as prone to external contamination. *United States v. Snyder*, 187 F.Supp.2d 52 (N.D.N.Y. 2002).

⁶ This article is in the public domain and is tendered as Ex. 4 hereto.

Conclusion

The sweat patch is too unreliable for the Court to rely on as a basis for revoking defendant's supervised release.

Respectfully submitted,

BY: s/Robert L. Abell
ROBERT L. ABELL
120 N. Upper St.
Lexington, KY 40507
859-254-7076 (phone)
859-281-6541 (fax)
E-mail: Robert@RobertAbellLaw.com
COUNSEL FOR DEFENDANT

Certificate of Service

I certify that on February 22, 2017, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system, which will send notice of electronic filing to the following: All Counsel of Record.

BY: s/Robert L. Abell
Robert L. Abell
COUNSEL FOR DEFENDANT