From: Charles Casimaty
Sent: Tuesday, 3 July 2012 3:40 PM
To: Scott Hennessy
Subject: FW: Submission to the Tasmanian Hemp Industry Inquiry

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From: Andrew Kavasilas [mailto:akavasilas@hotmail.com]
Sent: Tuesday, 3 July 2012 3:11 PM
To: Charles Casimaty
Cc: samantha.torres@foodauthority.nsw.gov.au; myles.parker@dpi.nsw.gov.au; jonathon.kite@foodstandards.gov.au; DPI Phil Blackmore
Subject: Submission to the Tasmanian Hemp Industry Inquiry

Dear Mr Hennessy

Thank you for your call yesterday to confirm our interest in the Tasmanian Government inquiry into the States' Hemp Industry.
I have been speaking with Insp Boorman from Vic Police for quite some time now. Insp Boorman is credited with the introduction of Random Roadside Saliva Testing (RRST) in Australia and remains the only reliable information point for all research in the field, he can be contacted on 03 93807212.
RRST was introduced in Australia under the corporate funded Rosita Project based in the EU.
The Rosita Project Final Report states "At the end of the study, no device was considered to be reliable enough in order to be recommended for roadside screening of drivers".
Insp Boorman has since discounted this report and advised that the most recent, reliable studies are available on the DRUID Project site.
We can only assume that the Insp has not read these articles as the evidence against the reliability of RRST becomes indisputable.
Additionally, the follow up from Clinical Chemistry indicates the extremely low cut-offs applied to THC (1mg/L) confirmation in Australia, compared to Belgium (10mg/L). Screening cut-offs for France and Belgium are 15 and 25 mg/L respectively.
Moreover, findings point to the fact that all research in relation to THC detection was carried out in a non-scientific environment and should be viewed as such. There's some extracts added and links to both reports below.

With Australian Police now confusing the unnecessarily complex issue around hemp seed foods and RRST, it could be very simply put to Enforcement agencies that as research has been effective in lowering Delta 9 in modern industrial hemp cultivars, analytical confirmatory testing to detect minute trace elements has developed as well.

Other concerns raised by Australian Police and some politicians mirror those of the United States Drug Enforcement Agency (DEA) whose rationale involved concerns as to whether commercial cultivation of industrial hemp would increase the likelihood of covert production of high-THC marijuana cultivars, while complicating detection and enforcement activities. There were also concerns that supporting industrial hemp would “send the wrong message to the American public concerning the government’s position on drugs.”
Rather than supporting the growth of an industrial hemp sector, the DEA made a concerted effort beginning in late 1999 to ban hemp food products that might contain even trace amounts of THC. They acted administratively to demand that the US Customs Service enforce a zero-tolerance standard for the THC content of all forms of imported hemp, and hemp foods in particular.
The DEA held that when Congress wrote the statutory definition of marijuana in 1937, it exempted certain portions of the Cannabis plant from the definition in the belief that the non flower (stems and leaves) portion of the plant contained no THC whatsoever. With minute amounts of THC detectable throughout the hemp plant, it felt justified in treating all hemp material as a controlled substance.
In the resulting free trade dispute, a coalition of hemp industry trade groups, retailers, and a major

Canadian exporter brought the DEA to court, arguing that Congress clearly intended to allow industrial uses of hemp when the material contained non-psychoactive levels of THC, citing the precedent whereby poppy seeds are permitted, despite trace amounts of naturally occurring opiates. On February 6, 2004, the US Court of Appeals ruled that “the DEA’s definition of ‘THC’ contravenes the unambiguously expressed intent of Congress in the CSA and cannot be upheld.” This ruling was not appealed, re-opening the market for imported hemp material and products. While ultimately unsuccessful, the DEA’s actions did serve to significantly set back the development of US domestic hemp product processing, and by extension the Canadian industrial hemp sector.
It is reported that some State Police in Australia have acted in a similar 'administrative' manner to ensure that whole of Government submissions reflect negatively on the issue.
Offhandedly it could be noted that Police oppose everything before it's made legal, by nature they do respond conservatively. On the other hand some think the police doth protest too much.

With the Canadian hemp industry and EU hemp production subsidised, hemp seed food imports to Australia have grown considerably. It would be of more interest to understand what measures Enforcement Agencies believe would be appropriate to stop imports and stop Australians from ordering hemp seed food products via the web.
Internationally, the Australian market is viewed as untouched, open, expanding and protected by the fact that Australian hemp growers would not risk the possibility of losing their license by allowing locally produced hemp seeds to enter the Australian food supply.

Furthermore, I note that NSW Food Authority and many other Australian Government departments are not aware of an exemption to the Australian New Zealand food regulations. The exemption allows New Zealand the use of hemp seed oil in foods. In effect, Australian produced hemp seed oil and foods could be exported to New Zealand for human consumption, while New Zealand's hemp seed products imported to Australia must state on the label that the product is unlawful to be consumed in Australia.

I believe there is additional information of critical nature that should be used to accurately clarify unfounded concerns and accurately scrutinise contributions made to this and other inquiries.

Vitahemp is a developing export company that could give expert advise in relation to current Australian hemp production, imports of seed products entering the local market and endeavours being undertaken by foreign companies selling and marketing hemp seed food products in Australia.

I can be contacted at home on 02 66891998 or Mobile 0427891968.

Many thanks for the opportunity.
Andrew Kavasilas
Vitahemp Pty Ltd.

From Druid.
Executive Summary This analytical evaluation of oral fluid screening devices and preceding selection procedures was carried out as an integral part of the DRUID project (Work package 3, Task 2). The duration of the evaluation was from October 2007 to December 2009. The study was carried out by the Faculty of medicine and health sciences, Department of clinical chemistry, microbiology and immunology, Ghent University (UGent) in Belgium, the Alcohol and Drugs Analytics Unit, National Institute for Health and Welfare (THL) in Finland and the SWOV Institute for Road Safety Research in the Netherlands. The Department of Transport, Technical University of Denmark (DTU) was responsible for leading the task due to its connection to the road side survey (Work package 2, Task 2.2a1) for which DTU was Work package leader. THL was responsible for finalising the deliverable. Eight on-site tests were evaluated: BIOSENS Dynamic (Biosensor Applications Sweden AB), Cozart DDS (Cozart Bioscience Ltd.), DrugWipe 5+ (Securetec Detections-Systeme AG),

Dräger DrugTest 5000 (Dräger Safety), OraLab6 (Varian), OrAlert (Innovacon), Oratect III (Branan Medical Corporation) and Rapid STAT (Mavand Solutions GmBH). Rapid STAT was tested in all three countries and DrugTest 5000 in Belgium and the Netherlands. All other devices were tested in only one country. Tested substance classes were amphetamine(s), methamphetamine, MDMA, cannabis, cocaine, opiates, benzodiazepines and PCP. A checklist for clinical signs of impairment (CSI) was also evaluated in order to see if visible signs of impairment can be used as preceding selection criteria for performing an on-site test. The checklist was based on several existing checklists, e.g. one developed for the German police and previously used in the European IMMORTAL (Impaired Motorists, Methods Of Roadside Testing and Assessment for Licensing) project. Study populations consisted of randomly selected drivers from the roadside survey for DRUID (Work package 2, Task 2.2a1), drivers suspected of driving under the influence of drugs, patients of treatment centres and rehabilitation clinics and customers of coffeeshops. Oral fluid was collected as the reference sample. For some cases, in the Netherlands, whole blood samples were also collected. The performance of the tests was assessed based on sensitivity, specificity, accuracy, positive predictive value and negative predictive value for the individual substance tests of the device. These were assessed based on both DRUID and manufacturer cut-offs. Sensitivity, specificity and accuracy performance values of 80% or more were set as a desirable target value. The analytical evaluation of the amphetamine test showed sensitivity varying from 0% to 87 %. Specificity values were from 91% to 100% and accuracy values from 84% to 98%. For cannabis tests, sensitivities ranged from 11% to 59%. Specificities were between 90% and 100% and accuracies from 41% to 82%. Cocaine tests scored sensitivities of between 13% and 50%, specificities of 99% to 100% and accuracies from 86% to 100%. Sensitivities of opiate tests ranged from 69% to 90%. Specificities were between 81% and 100% and accuracies between 75% and 99%. Benzodiazepine tests had sensitivities from 48% to 67%. Specificities were from 94% to 100% and accuracies from 77% to 100%. Not enough positive cases were gathered to successfully evaluate any of the methamphetamine, MDMA or PCP tests for the devices in which these were included.
None of the tests reached the target value of 80% for sensitivity, specificity and accuracy for all the separate tests they comprised. An overall evaluation, wherein any positive drug screening result was viewed as valid providing that the confirmation sample contained one of the DRUID substances analysed, was performed as a measure of the usefulness of the devices in police controls. Three of the devices performed at >80% for sensitivity, specificity and accuracy in the overall evaluation. Prevalence of drugs in the study population needs to be considered when assessing the evaluation results. In addition, the type and prevalence of drugs within the population for which the device is intended to be used needs to be taken into account when considering the suitability of the device based on the results presented in this report. Some device failures were noted in the study. For one of the tests, 15 individual tests (12%) failed. For other tests, 5 or less tests failed. In the Netherlands the evaluation of Oratect III was stopped because the devices frequently failed to collect oral fluid in a sufficiently short time.. All countries took their own approach to the evaluation of the checklist for clinical signs of impairment. The results of the evaluations were not very promising. The checklist scored a low sensitivity value (Dutch study), low correlation of symptoms and actual presence of drugs (Belgian study) or there were difficulties in correlating the symptoms to actual drug use due to the insufficient data collection (Finnish study).

Figure 44. Sensitivity vs. specificity for each device.

The findings of this overall evaluation largely reflect the results discussed in the previous sections, nonetheless as a means of assessing the devices it should be remembered that the results from this analysis may rely, to some extent, on chance. A device which falsely detects one substance whilst missing another cannot be said to be analytically reliable.

As previously noted, the overall evaluation performance of the DrugWipe 5+ can be largely attributed

to the strong individual performance of the device‟s amphetamines test and the prevalence of these substances in the study population. Similarly, it is worth reflecting upon the fact that the overall sensitivity results for devices in the Belgian study are significantly reduced when the opiates screening

results are not considered. The sensitivity of each of these devices is therefore enhanced, to some extent, by the fact that the Belgian study was largely carried out with samples collected from drug addiction centres with a high prevalence of opiates. A similar outcome can also be expected to be true

for devices tested in coffeeshops in the Netherlands, due to the high prevalence and sample concentrations for cannabis as mentioned above. While a high prevalence of an individual substance,

or group of substances, in the sampling group should be considered it would be extremely difficult, or
impossible, to test all the devices on a study population with a high prevalence of all the substances concerned, even more so since this study was carried out in three countries.

From Clinical Chemistry.

Oral Fluid Testing: Promises and Pitfalls

Marilyn A. Huestis, Moderators[1],*,
Alain Verstraete, Experts[2],
Tai C. Kwong, Experts[3],
Jorg Morland, Experts[4],
Michael J. Vincent, Experts[5] and
Raphael de la Torre, Experts[6]

Oral fluid is a promising new matrix for drug-testing programs for drug treatment, the workplace, pain management, and driving under the influence of drugs (DUID)[7]. As with any new technology, there are strengths and limitations. We discuss with international experts the role this new alternative matrix will play in diverse drug-monitoring settings, and the research, development, and legislation needed to permit oral fluid testing to best take its place in the modern laboratory armamentarium.[8]

What is needed to improve interpretation of oral fluid drug test results?

Alain Verstraete: Further research on: (1) passive smoking and external contamination; (2) adulteration and THC washout from the mouth; (3) development of on-site devices with a small sample volume (like the DrugWipe) and results in <5 min (the DrugWipe in Belgium requires 12 min, but 5 min in Australia for only 2 analytes and with lower THC sensitivity); (4) reproducibility of multiple sampling; (5) finding a marker for concentration normalization, similar to creatinine measurements in urine; (6) more toxicokinetic controlled-administration studies to provide concentration–time data and detection windows (concentrations are sampling dependent, with results from one sampling method not necessarily representative for another method); and (7) more studies on the relationship between oral fluid drug concentrations and impairment, or crash risk.

Tai Kwong: Our ability to interpret urine drug test results is based on published controlled drug-administration studies. We need similar studies on oral fluid before we can interpret oral fluid drug test results properly.

Jorg Morland: An oral fluid test tells us that a particular drug was recently used, but no interpretation of blood or brain concentrations can be made. Oral fluid pH and secretion rate markedly influence drug concentrations. A reference substance (similar to creatinine in urine) for normalization of oral fluid results is needed. This could at least be helpful when serial samples from a single individual are evaluated over time to detect new drug intake.

Michael Vincent: Currently, most work has focused on analytical-method development, rather than result interpretation. Pain-management and DUID testing are areas where drug and metabolite concentrations can provide valuable information. Further research is needed for oral fluid and blood concentration correlations and for correlations with motor skill impairment and brain activity. Another area of concern with interpretation is the presence of

multiple drugs in numerous cases. Most research involves single-drug administration in a controlled environment, making it difficult to predict effects when multiple drugs are present with and without alcohol.

Raphael de la Torre: Oral fluid drug testing was approached as urine drug testing, with some cosmetic changes. Most companies forgot that there is strong science and experience behind urine drug testing. In this context, it has been possible over time to define new target biomarkers and change cutoff concentrations based on scientific evidence. In the case of oral fluid testing, we need to follow the same approach. Manufacturers developed oral fluid analytical devices (particularly for on-site analysis) without knowing sensitivity and performance requirements. As the market was not yet mature, many initiatives were halted. There is a need for well-designed controlled clinical studies to guide selection of target biomarkers and cutoff concentrations (in the context of a given application). This is relevant not only for diagnostic companies, but also for law-enforcement authorities and clinicians. Interpretation of results is at an early stage.

www.**druid**-project.eu/.../**Druid**/.../Deliverable_3_2_2.pdf

http://www.clinchem.org/content/57/6/805.full

http://www.votehemp.com/PDF/National_Industrial_Hemp_Strategy_Final_Complete2.pdf

The Rosita-2 project was carried out in 2003-2005 in order to evaluate the usability and analytical reliability of the onsite oral fluid (saliva) drug testing devices.

The study was carried out by National Institute for Criminalistics and Criminology in Brussels, Belgium, the National Public Health Institute in Helsinki, Finland, the Institute for Legal Medicine in Strasbourg, France, the Institute for Legal Medicine in Homburg/Saar, Germany, the Division of Forensic Toxicology and Drug Abuse, Norwegian Institute of Public Health, Oslo, Norway and Institute of Legal Medicine, University of Santiago de Compostela, Spain. It was coordinated by Ghent University, Ghent, Belgium.

The study was performed in cooperation with the Unites States, where it is funded by The National Institute on Drug Abuse (NIDA), National Institutes of Health, US Department of Health and Human Services, the National Highway Traffic Safety Administration (NHTSA), US Department of Transportation and the Office of National Drug Control Policy Executive Office of the President. The US part is coordinated by The Walsh Group (Bethesda, Maryland). The study is carried out in the following states: Florida (Hillsborough County Sheriff's Office, Florida Department of Law Enforcement, Manatee County Sheriff's Office), Washington (Washington State Police, Washington State Toxicology Lab), Utah (Salt Lake City Police Department, Center for Human Toxicology) and Wisconsin (12 Police Jurisdictions, Wisconsin State Lab of Hygiene).

In the US, the study continues until the end of 2006. The complete results for the European part and the partial results of the US parts are presented here.

2046 Subjects were included in the study and 2605 device evaluations were performed.

Nine devices were evaluated: American Biomedica Oralstat, Branan Medical Oratect, Cozart Bioscience RapiScan (only in the USA), Dräger/Orasure DrugTest/Uplink, Lifepoint Impact,

Securetec Drugwipe, Sun Biomedical Oraline, Ultimed Salivascreen and Varian OraLab.

The devices had tests for the following drugs: amphetamines, methamphetamine, cannabis, cocaine and opiates. Three devices also had a test for benzodiazepines.

During the study, two devices were withdrawn form the market: Dräger/Orasure DrugTest/Uplink and Lifepoint Impact.

Subjects for whom a suspicion of driving under the influence of drugs existed were asked to participate in the study on a voluntary basis. In most cases the following samples were taken: a blood sample and an oral fluid sample with the Intercept™ sampler for analysis in the lab with reference techniques (gas or liquid chromatography coupled to mass spectrometry, sometimes after screening with an immunoassay), and one (or two) oral fluid sample for analysis with the onsite device.

For some devices, a very high percentage of failures was observed. Depending on the type of device, this was apparently due to too little or too viscous saliva (the fluid didn't migrate until the control line, or it caused smears), or to a malfunctioning of the instrument that read the results. For six devices (Varian Oralab, Lifepoint Impact, Branan Oratect 2nd generation, Sun Oraline, Ultimed Salivascreen and Branan Oratect 1st generation), more than 25% of the devices failed to run. For the other devices, the number of failures was less than 10 % (American Biomedica Oralstat and Dräger DrugTest/Orasure Uplink) or less than 5% (Cozart Rapiscan and Securetec Drugwipe). The evaluators considered that a failure rate of maximum 5-10% was acceptable.

The number of evaluations per device varied widely, with two devices evaluated more than 500 times, one 190 times and 6 less than 50 times. The explanation lies in the large number of failures for Branan Medical Oratect, Ultimed Salivascreen and Varian OraLab, which led to their exclusion from the study and the late start of the evaluation of the American Biomedica Oralstat, Lifepoint Impact and Sun Biomedical Oraline.

The percentages of positive samples were: amphetamines (including methamphetamine, ecstasy and analogues) 20 %, benzodiazepines 32 %, cannabinoids 36%, cocaine 19% and opiates 8%.

The analytical evaluation of the amphetamine and methamphetamine tests (in comparison to the reference method in oral fluid) showed a sensitivity (percentage of the true positive samples that tested positive with the onsite assay) varying between 40% and 83% and a specificity (percentage of the negative samples that tested negative with the onsite assay) between 80% and 100%.

The analytical evaluation of the benzodiazepine tests (in comparison to the reference method in oral fluid) showed a sensitivity varying between 33% and 69% and a specificity between 85% and 94%.

The analytical evaluation of the cannabis tests (in comparison to the reference method in oral fluid) showed a sensitivity varying between 0% and 74% and a specificity between 70% and 100%. Detailed analysis of the data for cannabis showed that some devices (e.g. Drugwipe) gave a negative result even when very high concentrations of THC were found with the Intercept. The reason is unknown, but one hypothesis is that with an improved (more thorough) sampling technique more THC could be captured, resulting in more positive results.

The analytical evaluation of the cocaine tests (in comparison to the reference method in oral fluid) showed a sensitivity varying between 0% and 97% and a specificity between 91% and 100%.

The analytical evaluation of the opiate tests (in comparison to the reference method in oral fluid) showed a sensitivity varying between 51% and 100% and a specificity between 86% and 100%.

No device met the criteria proposed during the Rosita-1 project (sensitivity and specificity > 90%,

accuracy > 95%) for the amphetamines, benzodiazepines and cannabis. The Varian Oralab met these criteria for cocaine and opiates, but it gave 26% failures, so it cannot be recommended.

The operational evaluation of the Drugwipe showed that the sampling technique was well accepted by the police and the subjects, but the results, particularly for cannabis, were difficult to read. There were also problems when using it in cold weather.

The operational evaluation of the Dräger DrugTest/Orasure Uplink showed that sample collection was easy and hygienic, but that the procedure was long and complicated. The test must be read by an instrument, so it cannot be used in remote areas or when no instrument is available.

The operational evaluation of the American Biomedica Oralstat showed that the collection stick lost one of its collection sponges in some cases. This test could also be read with or without the reading unit, but the scanning of the test strip by the electronic reader was sometimes difficult.

The operational evaluation of the Branan Medical Oratect showed that the test was liked by the police officers, because it is very small and portable and no additional equipment is needed, but the sample collection was too complicated, it could be outsmarted by the tested persons and it took too much time. The number of failures was too high.

The operating procedure of the RapiScan was fairly direct, but was found to intimidate officers if they were not able to use it soon after training. Many officers were uncomfortable using the instrument, stating that it was difficult to remember the procedure.

The operational evaluation of the Lifepoint Impact showed that in many cases the collected sample volume was not sufficient because the instrument stopped the sampling automatically after a preset time.

The test procedure of the Sun Biomedical Oraline was simple with few steps but a rather large sample volume was needed and it took too much time. There were problems to use it in cold and rainy weather. The lines indicating positive or negative results were too pale.

The operational evaluation of the Ultimed Salivascreen showed that the device gave more invalid than valid tests. Officers reported smearing of the result bands or not enough saliva collected by the device to give a reading.

The operational evaluation of the Varian OraLab showed that subjects were often unable to provide sufficient oral fluid during specimen collection, resulting in many invalid tests. Officers also experienced difficulty observing the presence or absence of the test lines making interpretation of results inconsistent.

At the end of the study, no device was considered to be reliable enough in order to be recommended for roadside screening of drivers. However, the experience in the state of Victoria in Australia shows that random roadside oral fluid testing of drivers for methamphetamine and cannabis (using the Securetec Drugwipe followed by the Cozart Rapiscan and chromatographic analysis in the lab) has a deterrent effect. Government officials should carefully weigh the pros (deterrent effect) and the cons (risk that drivers will realise that they often test negative after having used drugs due to the limited sensitivity of the test) of introducing random drug testing with the currently available devices.