In the High Court of New Zealand
Wellington Registry

CIV-2017-

Under:	the Declaratory Judgments Act 1908 and the Judicature Act 1908
Between:	[redacted] Plaintiff
And:	MINISTER OF CUSTOMS First Defendant
And:	MINISTER OF HEALTH Second defendant

AFFIDAVIT OF DR KEITH BEDFORD
Dated 6 January 2017

I, Dr Keith Richard Bedford of Auckland, Analytical Chemist, swear:

1. I am an analytical chemist and the former General Manager of the Forensic Business Group at the NZ Crown Research Institute ("CRI"), the Institute of Environmental Science and Research (known as "ESR"). I hold degrees including a PhD in physical-organic chemistry from the University of Auckland, have appeared as an expert in many cases before the New Zealand courts and have written and lectured widely on topics related to drugs, toxicology and forensic science. I have been a member of the Expert Advisory Committee on Drugs, ("the EACD") since the Committee's establishment to advise the Minister of Health on the scheduling of substances under the Misuse of Drugs Act. I have considerable experience in providing advice on issues relating to the regulation of drugs and have written and spoken internationally on the subject, most recently as the author of a chapter on "Drugs Legislation in New Zealand", for the book, *Forensic Toxicology: Drug Use and Misuse*, published by the Royal Society of Chemistry, in the UK in

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2016. Until my retirement from the position of General Manager in August 2016, I was gazetted as 'Analyst in Charge', of the Mount Albert Science Centre, ESR, for the purposes of the NZ Misuse of Drugs Act and Medicine Act, accountable for the authorisation of ESR Analysts under these Acts. A copy of my CV is annexed **marked "A"**. Information about the membership and role of the EACD taken from the Ministry of Health website is annexed **marked "B"**.

2. I am providing this affidavit as an individual, based on my scientific knowledge and professional experience of 40 years in the field, not as a representative of ESR or as a member of the EACD. I am familiar with the High Court Code of Conduct for Expert Witnesses ("the code") and have prepared this evidence in accordance with the code.

Cannabis sativa, hemp, THC and CBD

3. In the course of my professional career and expert advisory work for ESR I have researched and studied many issues relating to plants of the genus *Cannabis*; "industrial hemp" (varieties of *Cannabis* with very low THC content provided for by the Misuse of Drugs (Industrial Hemp) Regulations 2006); and various components of the Cannabis and hemp plant including Tetrahydrocannabinol ("THC"), Cannabidiol "CBD" and other natural components of the Cannabis plant (which can include up to 100 different cannabinoids, terpenes and other substances). I have particular expertise in the classification and analysis of the *Cannabis* plant, industrial hemp, THC, CBD and its other components from my time at ESR as a forensic scientist and manager.

4. The predominant psychoactive (i.e. mind altering) constituent of Cannabis plant is *delta*-9- tetrahydrocannabinol (Δ^9- THC). Although in principle other structural isomers of tetrahydrocannabinol are possible these are obscure and 'THC' is generally taken as referring to Δ^9- THC, and the abbreviation is used in this sense throughout this affidavit. The focus of ESR when analysing

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Cannabis and cannabis products has been primarily on the THC content, as this is the compound that is prohibited by the Misuse of Drugs Act in Schedule 2 and for which the prosecution must prove to be present under s29B.

5. In recent years another cannabinoid (a substance found in Cannabis) that tends to occur in elevated levels in strains of 'industrial hemp', known as "cannabidiol" or "CBD", has become of interest for a range of purported health and possible medical benefits. CBD is scheduled in the NZ Medicines Regulations 1984 in Schedule 1, Part 1 as a prescription medicine "313 Cannabidiol". Hemp products have been used for a wide range of purposes, including as a food and in medicine, by ancient civilisations in India, China and Egypt for many thousands of years, and preparations derived from Cannabis were included in many early USA and European medical texts.

6. Food Safety Australia New Zealand, "FSANZ" has recently proposed that a range of hemp seed foods be permitted for sale for human consumption in Australia and New Zealand. At present hemp seed oil may be sold for human consumption in New Zealand. A summary of the current status of hemp seeds as food and the proposed change taken from the FSANZ website is annexed marked **"C"**. An administrative assessment report- Proposal P1042 published by FSANZ on 20 May 2016 is annexed marked **"D"**. A "Cannabidiol hazard profile - Proposal P1042 Low THC Hemp Seeds as Food" published by FSANZ is annexed marked **"E"**.

7. Other hemp-sourced products (which may contain various amounts of CBD) appear to be currently sold in New Zealand for animal feed, skincare, construction and other purposes, but not for human consumption. I am not aware of any suggestion that any of these products breach the Misuse of Drugs Act because of their CBD content. To the best of my knowledge, the teams that I managed while I was at ESR were not asked to undertake any analysis of any hemp product not intended for human consumption, for CBD

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content. In the research that I have reviewed to date I have found no evidence of significant concerns in regard to harmful effects arising directly from consumption of CBD.

Status of CBD under the Misuse of Drugs Act

8. The question has arisen as to whether CBD is covered by the Misuse of Drugs Act. CBD is not specifically listed under the Misuse of Drugs Act. I have seen some documentation from the Ministry of Health that suggests that CBD is "an isomer of tetrahydrocannabinols within the same chemical designation"[1]. If this interpretation is correct, the possession, processing, use and importation of CBD and any hemp or other product that contains CBD would be restricted by the Misuse of Drugs Act Schedule 2.

9. If CBD is not an isomer within the same chemical designation as "tetrahydrocannabinols", then it is outside the scope of the Misuse of Drugs Act. None of the Misuse of Drugs Act prohibitions on import, possession or use would apply to CBD.

10. I prepared a discussion document in conjunction with my ESR colleagues "Classification of Cannabidiol" dated 17 February 2016. A copy of this discussion document is annexed **marked "F".**

11. This document was prepared in response to a document released by the medicines control division of the Ministry of Health which argued that CBD was covered by the Misuse of Drugs Act as an isomer of THC. In the ESR discussion document we explain why we do not consider that CBD is an isomer within the same specific chemical designation of THC. The conclusion

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[1] **Tetrahydrocannabinols**, except when contained in a Class C controlled drug.

The isomers of the substances mentioned in clause 1 whenever the existence of such isomers is possible within the specific chemical designation

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of myself and my expert colleagues at ESR summarised in Paragraph 6 of our "Classification of Cannabidiol" discussion document are:

- *"CBD is not a tetrahydrocannabinol*
- *CBD has the same chemical formula as THC, but it is not an isomer within the specific chemical designation of THC*
- *CBD cannot be considered as a controlled drug analogue*
- *CBD is not controlled under the MoDA*
- *CBD is listed as a prescription medicine under the Medicines Regulations 1984."*

12. In early 2016 the Expert Advisory Committee on Drugs was asked to assess and advise on the legal status of Cannabidiol ("CBD") in terms of the Misuse of Drugs Act schedules.

13. The Ministry of Health prepared a submission for the EACD dated 12 April 2016 "Cannabidiol: Submission to the Expert Advisory Committee on Drugs". A copy of the Ministry of Health Submission is annexed **marked "G"**.

14. I agree with much of the information summarised in that submission. I share the view of the author that CBD does not meet the criteria (under Section 3A of the Misuse of Drugs Act) to be scheduled as a controlled drug bearing in mind its lack of psychotropic effects, the absence of any reported serious adverse events from its use, the recent down-scoping of CBD to a prescription only medicine by the Australian Therapeutic Goods Administration (provided it contains less that 2% THC and other cannabinoid impurities), and that CBD is not specifically scheduled by the Single Convention on Narcotic Drugs 1961.

15. I disagree with the Ministry of Health's interpretation that CBD is currently caught within the Misuse of Drugs Act as an isomer of tetrahydrocannabinols

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within the same specific chemical designation, and I do not accept that the Ministry's interpretation on this is correct.

16. I was unable to attend the April 2016 meeting of the Expert Advisory Committee on Drugs ("the EACD"), so instead I prepared comments in a report headed "Interest in Medicinal Cannabis and the Classification of Cannabidiol" dated 12 April 2016, explaining why in my expert opinion CBD was not an isomer of THC and why it was not within the designation of tetrahydrocannabinols. I discussed my report with my expert colleagues in the ESR Drug Chemistry Team before I released it to the EACD, and can confirm that they share my interpretation. I acknowledge their helpful discussions at the end of my report. I was unable to come up with any interpretation from an analytical chemistry perspective that would justify treating CBD as an isomer of tetrahydrocannabinols with the same chemical designation for the purpose of the Misuse of Drugs Act, and neither were any of my colleagues. A copy of my report is annexed **marked "H".**

17. I accept that there is a separate issue, also raised by the Ministry of Health, in the argument that any amount of THC impurity in a preparation of CBD will cause it to fall under MoDA. This issue arises from the effect of clause 5 in Part 1 of Schedule 2 to the Misuse of Drugs Act, which includes within the coverage of the Schedule: "Substances containing any proportion of a substance mentioned in clause 1, clause 2, clause 3, or clause 4." CBD extracted from hemp plant material is likely to contain trace amounts of other naturally-occurring cannabinoids, including THC.

18. Tolerance levels are allowed for contamination in various regulations, standards and guidelines. For example, the Misuse of Drugs Act at Section 29A enables a defendant to put in issue whether the amount of THC in any cannabis preparation is of a usable quantity[2]. Under section 29A the court

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[2] **Misuse of Drugs Act 1975 Section 29A Issue of usable quantity**

can receive expert evidence that the amount was of useable quantity. It is accepted in the Misuse of Drugs (Industrial Hemp) Regulations that *Cannabis* with a THC concentration of less than 0.35% is excluded from coverage under the Misuse of Drugs Act and that products derived from such plant material can be used, including for hemp seed oil for human consumption. This is the basis used at ESR for assessing the permitted level of THC content in hemp plant material and hemp seed oil. Hemp seed oil that contains traces of THC below this level is not treated as if it breaches the Misuse of Drugs Act. Similarly the Australian TGA has recommended that a maximum of 2% contamination of THC and other cannabinoids be allowed.

19. One of my colleagues from ESR attended the EACD meeting to present my report. A copy of the minutes of the 27 April 2016 meeting of the EACD, available from a public website, is annexed **marked "I"**. These minutes record my apologies and the Committee's discussion. The Committee identified a series of action points and deferred its decision on CBD to its next meeting in October 2016.

20. I attended the EACD meeting of October 2016 where there was further discussion on the status of CBD. I am not authorised to speak on behalf of the Committee and it would be inappropriate of me to comment on the Committee discussion since the minutes of that meeting have not yet been made available publicly. It would be fair to say that the Committee in general seeks to arrive at a consensus view and the discussion at the meeting

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(1) On the Judge-alone trial of any person charged with an offence against this Act in which it is alleged that the defendant had in his possession any controlled drug in contravention of this Act, it shall not be necessary for the prosecution to prove that the amount of the controlled drug in the defendant's possession was of a usable quantity, unless the defendant puts the matter in issue.
(2) Where, in the course of a Judge-alone trial, the defendant puts in issue the question of whether or not the amount of any controlled drug alleged to have been in his possession was of a usable quantity, the District Court Judge shall, if requested to do so by the prosecutor, adjourn the hearing for such period as he considers sufficient to enable the prosecutor to arrange for the attendance in court of a witness or witnesses to adduce evidence that that amount was of a usable quantity; and, if the prosecutor has closed his case before the said question is put in issue, the District Court Judge shall also grant the prosecutor leave to re-open his case for the purpose of adducing evidence that the amount of the drug was of a usable quantity.

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reflected the fact that there remains disagreement within the EACD on the status of CBD, how it should be classified and resulting public policy implications.

21. Nothing that I heard at the October EACD meeting or have read since writing my earlier discussion paper has caused me to reconsider my view that CBD is currently not covered by any of the schedules in the Misuse of Drugs Act, as it is not specifically scheduled and it is not within the definition of an isomer of tetrahydrocannabinol *within the specific chemical designation of THC* (my emphasis added).

Criteria for scheduling under the Misuse of Drugs Act

22. Substances can only lawfully be scheduled under the Misuse of Drugs Act if they meet the criteria in Section 3A[3], which requires that they pose a very high, high or moderate risk of harm to individuals or to society.

23. I am familiar with much of the international research on CBD and have maintained an interest in this and recent policy developments relating to the use of CBD and other cannabinoids in New Zealand and internationally. As explained above, a useful summary was recently published by FSANZ with its proposal to legalise hemp seed foods in Australia and New Zealand for human consumption (refer annexure "E"). I am not aware of any current research or other evidence that established that CBD poses a very high, high or moderate risk of harm to individuals or to society.

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[3] Misuse of Drugs Act Section **3A Classification of drugs**

The classification of a drug under this Act is based on the risk of harm the drug poses to individuals, or to society, by its misuse; and accordingly—
(a)drugs that pose a very high risk of harm are classified as Class A drugs; and
(b)drugs that pose a high risk of harm are classified as Class B drugs; and
(c)drugs that pose a moderate risk of harm are classified as Class C drugs.
Section 3A: inserted, on 15 November 2000, by section 3 of the Misuse of Drugs Amendment Act 2000 (2000 No 47).

NZ Analysts Criteria for approving hemp and hemp seed oil

24. Hemp seed oil is legal to sell in New Zealand for human consumption if it has been certified by an approved analyst. Teams at ESR that I previously had senior management responsibility for (Illicit Drugs and Pharmaceuticals Teams) undertake such testing. The only criteria assessed for hemp seed oil is its THC content. The CBD content of hemp oil or other hemp products is not assessed.

25. To the best of my knowledge ESR does not currently have validated methodology ready for assessing the CBD content of hemp or hemp oil, because the CBD content has not hitherto been an issue. Nevertheless, such methodology could be validated to test for CBD content in due course, assuming levels are agreed.

26. If the proposed changes are made to the FSANZ Food Code then a wide range of hemp seed foods will be allowed to be sold for human consumptions in Australia and New Zealand including de-hulled hemp seed, hemp seed oil, hemp seed flour, hemp seed protein and hemp seed milk.

Incidental THC

27. It is likely that natural products that contain CBD will also contain traces of THC, as most strains of industrial hemp will still contain a trace amount of THC and some co-extraction is virtually inevitable during processing. THC of up to 0.35% is permitted in hemp plants under the Misuse of Drugs (Industrial Hemp) Regulations. This level of THC was determined by Parliament to be operationally achievable for hemp growers and to represent negligible risk of diversion of plant material for psychoactive effects. This level is in the same range as the maximum THC level allowed by a number of other jurisdictions.

28. Modern analytical methodology, as used by ESR, can potentially detect levels of THC down to 'parts per million', many orders of magnitude below levels

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