

**Report to the Utah State Legislature
Health and Human Services Interim Committee**

**Hemp Extract Registration Act
2017 Implementation and Study Update**

**Prepared by the Utah Department of Health
Office of Vital Records and Statistics**

November 2017



INTRODUCTION

The Utah Department of Health (UDOH), Office of Vital Records and Statistics (OVRs) is pleased to report on its implementation of the Hemp Extract Registration Act (Utah Code 26-56). This report includes a legislative background of the Act, an update regarding a study of hemp extract requested by the Utah Legislature, and information about issuance of hemp extract registration cards. This report is submitted in compliance with Utah Code 26-56-103 (9)(d) and is current as of October 31, 2017.

LEGISLATIVE BACKGROUND

Lawmakers approved H.B. 105: Plant Extract Amendments during the 2014 General Legislative Session. H.B. 105 created the Hemp Extract Registration Act (Utah Code 26-56) and granted authority to UDOH to adopt Utah Admin. Rule R436-55. Pursuant to H.B. 105, UDOH issues hemp extract registration cards to qualified applicants who are being treated by a licensed neurologist for intractable epilepsy.

In 2016, lawmakers approved H.B. 58 which made certain amendments to the Hemp Extract Registration Act. H.B. 58 required that UDOH request proposals to conduct a study of hemp extract.

HEMP EXTRACT STUDY UPDATE

Pursuant to H.B. 58, UDOH issued a Request for Proposals (RFP) for the purpose of entering into a contract with researchers at a higher education institution to conduct a study of hemp extract. In July 2016, the RFP was awarded to researchers at the University of Utah School of Medicine, Division of Pediatric Neurology. The principal investigator on the study is Dr. Francis Filloux and Dr. Carey Wilson is the co-principal investigator. The overall purpose of the study is to analyze experiences of patients who obtained hemp extract registration cards in Utah. The RFP awarded \$40,000 to the University to help fund the study.

After contracting with UDOH, the University prepared and submitted a study protocol for review by the University of Utah Institutional Review Board (IRB). In March 2017, the IRB gave the protocol an IRB exemption determination, authorizing the University to begin the research procedures outlined in the protocol. UDOH mailed study questionnaires to 138 individuals who had held hemp extract registration cards for at least 6 months. A copy of the study questionnaire that was mailed is provided as *Attachment A*. Preliminary results from the questionnaire are included as *Attachment B*. The University is on schedule to release a final executive summary outlining the study findings in February 2018.

NUMBER OF CARDS ISSUED

The first hemp extract registration card was issued in July 2014. As of October 31, 2017, cards have been issued to 231 patients.

CARD RENEWAL

Hemp extract registration cards expire one year from the issuance date. 76 of the 166 patients who were issued cards before October 31, 2016 have renewed their cards for a renewal rate of 45%. As of October 31, 2017, 119 patients hold active cards.

CARD HOLDER DEMOGRAPHICS

Basic demographic and contact information is collected from each applicant. This information includes the patient's name, mailing address, telephone number, email address, date of birth and sex. If one or both parents of the patient are listed on the record, the parent name, mailing address, telephone number, date of birth, and email address are collected.

- 134 cards were issued to patients under the age of 18. 97 cards were issued to patients 18 and over.
- 120 patients with the card are female and 111 are male.

NEUROLOGIST INFORMATION

The 231 patients who have been issued cards had neurologist evaluations from 23 physicians. Of the 23, 16 are affiliated with the University of Utah. Of the 231 patients, 171 had a physician affiliated with the University of Utah. Information in the neurologist certification and patient evaluation forms are the only information about patients that physicians provide OVRs.

REGISTRATION DATABASE

OVRs uses a database called the Utah Plant Extract Registry (UPER) to electronically store information about each card issued. The Utah Department of Public Safety has access to UPER so it can electronically verify the card of an individual found in possession of hemp extract.

For more information about the hemp extract registration program, please visit the registry website at hemp.utah.gov/hempregistry or contact Richard J. Oborn, OVRs Director, at (801) 538-6262 or roborn@utah.gov.

Attachment A

Hemp Study Questionnaire

HEMP EXTRACT

Registration Card

QUESTIONNAIRE

Card Number _____

Patient Name _____

Who is completing this questionnaire?

Applicant Parent/Guardian

Other (*specify relationship*): _____

Name (*if not applicant*) _____

Q1

Have you actually started treatment with hemp extract for yourself, your child, or a family member?

- Yes
 No

If you answered **YES**, what product(s) have you used?

★ *Please provide details about the products you have used below (you may need to look at the label or internet information provided about the products).*

a) Name of Product(s), Manufacturer(s):

If you answered **NO**, why not?

★ *Check all that apply.*

- Too Expensive
 Could not figure out what product to buy
 Could not figure out where/how to get the product
 Could not figure out the dose
 Other (explain below):

Q2

Do you know the concentration of the product(s) you have used?

Concentration will appear as a number of milligrams or grams of cannabidiol, cannabinoids, or cannabis product per volume of the solution.

(Ex: 50 mg CBD/milliliter, 40 mg cannabinoids/milliliter)

- Yes
 No

★ If you answered **YES**, please specify the **CONCENTRATION** of the product(s) below:

Q3

What is the maximum amount (dose) of the product(s) you have ever administered?

a) Name of Product:

Maximum amount given at a time:

How often per day?

b) Name of Product:

Maximum amount given at a time:

How often per day?

Q4

What is the maximum amount of time (in months) you have continuously given a hemp extract product to yourself, your child, or a family member?

★

If you have decided to continue an amount that is **LESS** than the maximum amount you ever gave yourself, your child, or a family member, what is the amount that you decided to give?

Q5

Do you plan to continue the hemp extract?

- Yes
 No

Q6

Has the hemp extract been helpful?

- Yes
 No

★

If you answered **YES**, has it reduced the frequency of the seizures (how often the seizures happen)?

- Yes
 No

If you answered **YES** to the previous question, by how much did it reduce **HOW OFTEN** the seizures happen?

Choose the answer that best describes the situation for you, your child, or the family member.

- A little better
- Less than ½ as many seizures as before
- Almost completely controlled
- Seizures are completely gone

Q7

If the hemp extract has reduced the **SEVERITY** of the seizures (how bad they are), how much better are they?

Choose the answer that best describes the situation for you, your child, or the family member.

- A little better
- Quite a bit better
- A whole lot better

Q8

Has the hemp extract caused any side effects?

- Yes
- No

★ If you answered **YES**, check all that apply.

- Tiredness
- Increased Appetite
- Decreased Appetite
- Diarrhea
- Vomiting
- Irritability/Moodiness
- Balance or Coordination Problems
- Increased Seizures
- Other (explain below):

★ Has the hemp extract caused any **SEVERE** or **SERIOUS** side effects?

- Yes
- No

★ If you answered YES, what **SERIOUS** or **SEVERE** side effects occurred?

Q9

Has the hemp extract been helpful in any other way than helping with seizures?

- Yes
- No

★ If you answered **YES**, please check all that apply:

Thank you very much for completing this questionnaire and returning it to us. We are hopeful this will help us to better understand which patients may benefit from treatment with “hemp extract”.

- More Alert
- More Happy
- Sleeps Better
- More Social
- Speech/Language Improvement
- Other (explain below):

Q10

Are you planning to continue the hemp extract?

- Yes
- No

★ If you answered **NO**, why not?

Check all that apply.

- Too Expensive
- Did not work
- Too difficult to get
- Other (explain below):

Q11

How much do you pay for the hemp extract on average per month?

THE NEXT QUESTION IS ONLY FOR FAMILIES WHO HAVE HAD THE REGISTRATION CARD FOR MORE THAN A YEAR:

Q12

If you have had the Hemp Extract Registration Card for more than a year, Utah law requires that you renew the card.

Have you renewed?

- Yes
- No

★ If you answered **NO**, why?

Check all that apply.

- We no longer plan to administer hemp extract
- We did not realize that we needed to renew
- We have tried to renew, but it is confusing how to do that
- It is too expensive
- It is too difficult
- Other (explain below):

Attachment B

Hemp Study Questionnaire Results

Artisanal “Hemp Extract” Experience in Utah Epilepsy Cohort: Self-Reported Survey Results 2017

Requisitioned Report to Legislative Committee

Presented by Francis Filloux, MD* of the University of Utah on November 15, 2017

OBJECTIVE: To better understand patterns of use, challenges, and effects of artisanal “hemp extract” on Utah patients with intractable epilepsy. This may help improve patient care and inform decision makers regarding use of cannabidiol for epilepsy.

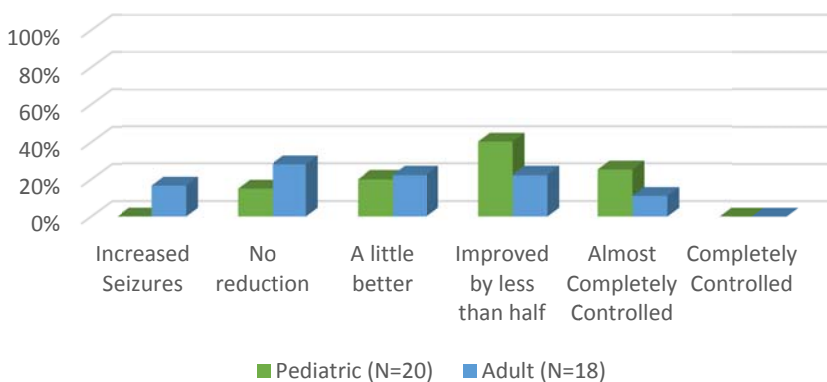
BACKGROUND: Utah House Bill 105 authorized Utah patients with uncontrolled epilepsy to use “hemp extract” to try to better control their seizures. The law requires these patients or caregivers to apply for and obtain a “hemp extract” registration card via the Utah Department of Health. The law also specifies that the “effects of hemp extract” be studied. This document and associated discussion briefly summarizes early descriptive, self-reported outcomes in these registrants.

DESIGN/METHODS: In the Spring of 2017, all 139 patients with intractable epilepsy enrolled in the hemp extract registration program as of October 31, 2016 received a voluntary 12 item questionnaire by US postal mail. Information was abstracted from the questionnaires and preliminary, patient or caregiver reported results are summarized below.

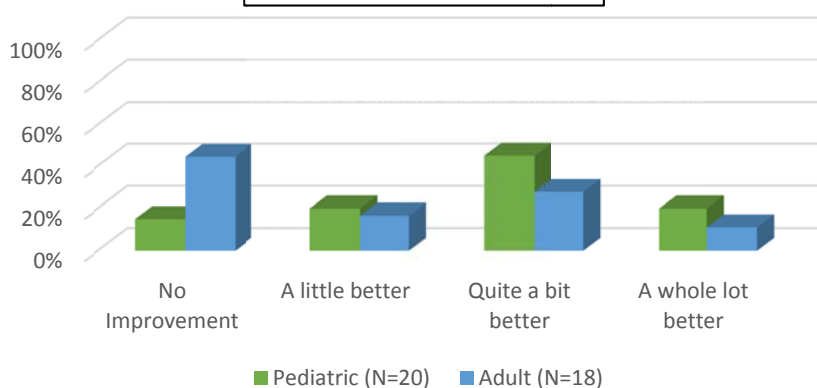
PRELIMINARY PATIENT/CAREGIVER REPORTED SURVEY RESULTS:

- 139 patients obtained hemp registration cards from July 2014 - October 2016.
- 46 (33%) responded to survey; 41 (89%) of respondents had started taking “hemp extract” and provided additional data.
- 20/41 (49%) of respondents were <18 years of age (no age data provided on 3 respondents).
- 85% of pediatric and 56% of adult patients reported some improvement in seizure burden.
- Challenges in choosing, obtaining, or dosing a product were top reasons for not using.
- 31% (13) of eligible users had renewed their card at time of survey. Those who did not cited lack of efficacy, cost, or difficulties accessing product.
- 80% (33) of users reported knowing product concentration, but could only provide an actual daily dosage 64% (23/36) of the time.
- Most prevalent product: Charlotte’s Web (78%).
- Most common dosing: Twice daily (54%).
- Average usage duration: 14 months (range 1-36m).
- Average cost: \$177/month (range \$40-500/mo).

Self-reported effect on SEIZURE FREQUENCY



Self-reported effect on SEIZURE SEVERITY



Self-reported Adverse Effects	Number (% of 41)
Any other adverse effect?	9 (22%)
Tired	3 (7%)
Diarrhea	3 (7%)
Decreased Appetite	2 (5%)
Increased Appetite	1 (2%)
Coordination Problems	1 (2%)
Moody	1 (2%)
Vomiting	0 (0%)
Self-reported Beneficial Effects	Number (% of 41)
Any other beneficial effect?	27 (66%)
Improved Sleep	16 (39%)
More Alert	14 (34%)
Happier	11 (27%)
Improved Speech	7 (17%)
More Social	6 (15%)

PRELIMINARY ASSESSMENT OF DATA

Many reported improvement in seizure burden (frequency and severity) while using hemp extract, though this was reported more often in children versus adult respondents.

Few reported adverse effects, and many reported other beneficial effects.

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