

#### New Jersey Department of Health Medicinal Marijuana Program PO 360 Trenton, NJ 08625-0360

#### MEDICINAL MARIJUANA PETITION (N.J.A.C. 8:64-5.1 et seq.)

#### INSTRUCTIONS

This petition form is to be used <u>only</u> for requesting approval of an additional medical condition or treatment thereof as a "debilitating medical condition" pursuant to the New Jersey Compassionate Use Medical Marijuana Act, N.J.S.A. 24:61-3. Only one condition or treatment may be identified per petition form. For additional conditions or treatments, a separate petition form must be submitted.

NOTE: This Petition form tracks the requirements of N.J.A.C. 8:64-5.3. Note that if a petition does not contain all information required by N.J.A.C. 8:64-5.3, the Department will deny the petition and return it to petitioner without further review. For that reason the Department strongly encourages use of the Petition form.

This completed petition must be postmarked August 1 through August 31, 2016 and sent by certified mail to:

New Jersey Department of Health Office of Commissioner - Medicinal Marijuana Program Attention: Michele Stark 369 South Warren Street Trenton, NJ 08608

Please complete <u>each</u> section of this petition. If there are any supportive documents attached to this petition, you should reference those documents in the text of the petition. If you need additional space for any item, please use a separate piece of paper, number the item accordingly, and attach it to the petition.

1.	Petitioner Information
	Name:
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2.	Identify the medical condition or treatment thereof proposed. Please be specific. Do not submit broad categories (such as "mental illness").  FI brounds LGIA
	TIDIZUM YALGIN,
3.	Do you wish to address the Medical Marijuana Review Panel regarding your petition?
	☑ Yes, in Person
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	□ No
4.	Do you request that your personally identifiable information or health information remain confidential?
	☑Ýes
	□ No
	If you answer "Yes" to Question 4, your name, address, phone number, and email, as well as any medical or health information specific to you, will be redacted from the petition before forwarding to the panel for review.



SEP 7 2016

OFFICE OF THE CHIEF OF STAFF

### MEDICINAL MARIJUANA PETITION (Continued)

Describe the extent to which the condition is generally accepted by the medical community and other experts as a valid, existing medical condition.

SEE "THE HELLTH CARE INDUSTRY FINALLY ERCOGNIZES
FI BEOHYLLGIA"

If one or more treatments of the condition, rather than the condition itself, are alleged to be the cause of the patient's suffering, describe the extent to which the treatments causing suffering are generally accepted by the medical community and other experts as valid treatments for the condition.

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Describe the extent to which the condition itself and/or the treatments thereof cause severe suffering, such as severe
and/or chronic pain, severe nausea and/or vomiting or otherwise severely impair the patient's ability to carry on
activities of daily living.

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Describe the availability of conventional medical therapies other than those that cause suffering to alleviate suffering caused by the condition and/or the treatment thereof.

SER EXICIOSED PRINT OUTS

9. Describe the extent to which evidence that is generally accepted among the medical community and other experts supports a finding that the use of marijuana alleviates suffering caused by the condition and/or the treatment thereof. [Note: You may attach articles published in peer-reviewed scientific journals reporting the results of research on the effects of marijuana on the medical condition or treatment of the condition and supporting why the medical condition should be added to the list of debilitating medical conditions.]

SEE ENCLOSED PRINT OUT

### MEDICINAL MARIJUANA PETITION (Continued)

PETITION FOR ME AND THE LETTER FROM MY PRIMARY C.  Doctor Namey & legar is enclosed in this packet  I certify, under penalty of perjury, that I am 18 years of age or older; that the information provided in this petition is the best of my knowledge; and that the attached documents are authentic.		od identify the authors.  66 - HE IS SEMBING & BEPERSTE
I certify, under penalty of perjury, that I am 18 years of age or older; that the information provided in this petition is the best of my knowledge; and that the attached documents are authentic.	Doctor Namey Blease is	ENCLOSED IN this PACKET
	I certify, under penalty of perjury, that I am 18 years of the best of my knowledge; and tha	f age or older; that the information provided in this petition is the attached documents are authentic.
Date 8/30/16		Date 8/30/16

Draft

#### Dear Ms. Michele Stark

My name is and I am hopeful at the prospect of being able to get some much needed relief, through the Medical Marijuana Program. I have suffered from Fibromyalgia for over 15 years. I have been in Pain Management for 15 years and I want to tell you what those 15 years of Pain Management have brought and taught me. I was diagnosed in about 1999 and prior to that I had surgeries without a Fibro diagnosis yet in which the pain was so ill managed that I literally felt I was going to die. Things were pretty horrible for me at that time and I had lost my ability to work, my social circle, my selft esteem. I spent about 5 years not knowing what was wrong with me except that everything was physically wrong! I couldn't believe how sick! was with a multitude of symptoms. I got into Pain Management while in the hospital after I was hit by a drunk driver. Prior to that I was treated by my Primary Care doctor who prescribed Vicodin, Soma, Wellbutrin and Butalbital for Migraines. Not necessarily innocuous medications but I was in excruciating amounts of pain. They dimmed my pain but it was never really gone. The pain becomes background noise after awhile. In hindsight I now recognize what a fog I was in. My leg pain felt as if someone was drilling through my bones, i even thought "could this be bone cancer?" i figure pain like that only bone cancer could produce. I saw a Rheumatologist and he gave me the proper diagnosis at last. There were a handful of medications being offered that were specifically for Fibromyalgia. The first one I was on was Cymbalta and that helped a little with the Depression but eventually it stopped working. Lyrica, OMG! I gained about 20lbs on that and the side effects were horrible. My head felt like a balloon and on top of it all and I was exhausted. My muscles were beyond sore. Now I am currently on Savella and it has helped me to a degree but I have horrible nausea and headaches from it. I'm not sure it helps my pain anymore either because I've been on it for so long. I have been on many, many medications and I have to tell you the side effects have and are pretty horrific. I have had a Grand Mal Seizure from Ultram(Tramadol)! I also gained 40 lbs total from all the medications I've been prescribed. I lost the 40 lbs about 3 years ago when was diagnosed as Pre-Diabetic and am slowly trying to get better but I can't continue to live this way without the resource of MM to make the quality of my health better and therefore the quality of my life. As a Fibromyalgia sufferer I need some healthy relief! It is so amazing what Cannabis can do for the Fibromyalgia sufferer. We like anyone else deserve a decent quality of life. If you have the power to help me please find it in your heart to do so because Fibromyalgia is a "Debilitating Medica!

Condition". Science is catching up and finding out that FMS is a very serious illness and that our Brain, Spinal Cord and Nervous System are involved.

I have used CBD oil, which is legal and that gives me a little relief and I have not encountered any side effects.

I have been on a large amount of opiates for 15 years now. OxyContin 80mg. and Roxicodone 30mg. tablets and I have slowly lowered them myself and am concerned about damage these medications may have done. I am truly suffering and urgently need the benefits that Medical Marijuana can offer. I need access to safe alternative therapies such as MM.

Thank you for taking the time to consider me as a candidate for Medical Marijuana use.



#### ALATAE MEDICAL, L.L.C.

DR. NANCY ALLEGAR
DR. LARA VON BERG
390 AMWELL ROAD
BLDG. 5, SUITE 501
HILLSBOROUGH, NJ 08844
TELEPHONE: (908) 281-1077

Attn: Officer of Commissioner Medicinal Marijuana Petition- Michele Stark August 23, 2016

To Whom It May Concern:

is a patient under my care who is has been suffering from fibromyalgia and chronic fatigue for past fifteen years. She has tried assortment of therapies, alternative diet and exercises. She also has been seeing a pain specialist to supplement her medication, diet and exercise which has not really been very effective overall. I believe she would benefit from the medicinal marijuana petition If you have any further questions or concerns please feel free to contact me at my office.

Sincerely,

Nancy Allegar, MD

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# The Health Care Industry Finally Recognizes Fibromyalgia

Posted on September 30, 2015 in Fibromyalgia

On October 1, 2015, fibromyalgia will finally be recognized as an official diagnosis in the new ICD-10 list of codes being adopted across the U.S. This is the final culmination of the advances over the last decade in the medical community's understanding and acceptance of fibromyalgia as a real disease.



Ginevra Liptan, MD

For the past 30 years, every U.S. hospital and doctor's office has used the ICD-9 list of codes to indicate a diagnosis for all patient encounters. This list does not include a specific diagnosis code for fibromyalgia. Instead doctors have had to use the code "Myalgia and myositis, unspecified (729.1),"

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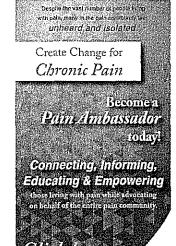
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FATIGUE AND FOGGY THINKING. IN THE NEW SASTEM FIBROMYLLEIA
TRUBUS, and roggy timiking. In the new system, including all the industry algorithms.

finally gets its own diagnostic code: "Fibromyalgia (M79.7)."

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This is a huge bureaucratic stamp of approval that legitimizes fibromyalgia as a real, distinct entity. It will make winning a disability case for fibromyalgia easier. A few years ago, I was testifying in support of one of my patients, and the opposing lawyer said to me, "How can you say fibromyalgia is real when it doesn't even have its own diagnosis code?"



The new code will also enable more accurate studies of fibromyalgia treatment outcomes, as the data for many of these observational studies are gathered by tracking diagnosis codes. Without its own diagnoses code, fibromyalgia studies have been hampered by watered down data from the inclusion of patients that did not actually have fibro, but some other illness causing muscle pain.

And most important of all, it puts the word "fibromyalgia" into the official health care lexicon, and doctors can no longer say, "Fibromyalgia does not exist."

Editor's Note: Ginevra Liptan, MD is board certified in internal medicine. She has been an associate professor at Oregon Health and Science University, her articles about fibromyalgia have been published in peer-reviewed medical journals, and she is the recipient of a Gerlinger Foundation Research Award.

Dr. Liptan has extensive clinical, personal and research experience with this illness. She has a compassionate, knowledgeable approach utilizing cutting-edge treatments, effective alternative therapies and prescription medications. Learn more about her Functional Fibro Treatment Approach by clicking here.



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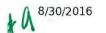


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## Marijuana Rated Most Effective for Treating Fibromyalgia

Posted on April 21, 2014 in Fibromyalgia, Pain Medication

Medical marijuana is far more effective at treating symptoms of fibromyalgia than any of the three prescription drugs approved by the Food and Drug Administration to treat the disorder.

That is one of the surprise findings in an <u>online survey</u> of over 1,300 fibromyalgia patients conducted by the <u>National Pain</u> <u>Foundation</u> and National Pain Report.

The FDA has approved only three drugs – Cymbalta, Lyrica and Savella — for the treatment of fibromyalgia. Although they generate billions of dollars in annual sales for Pfizer, Eli Lilly, Forest Laboratories and other drug makers, most who have tried the medications say they don't work.

The National How would you rate the effectiveness of Cymbalta (Duloxetine) in treating your fibromyalgia symptoms?

NOTE: SEE NEXT PAGE FOIL GRAN

Despite the visit number of people Is on with pain, many in the periodizated with beard and isolated.

Marijuana Rated Most Effective for Treating Fibromyalgia - National Pain Report

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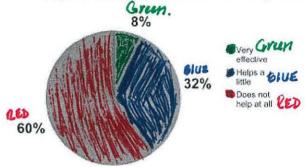
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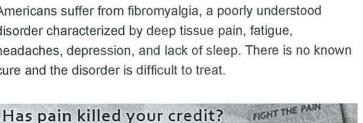
Institutes of Health estimates that 5 million



National Pain Foundation survey

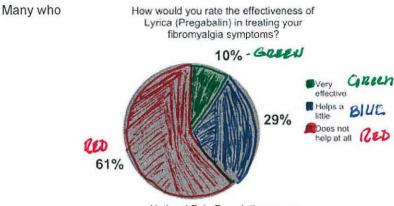
Americans suffer from fibromyalgia, a poorly understood disorder characterized by deep tissue pain, fatigue, headaches, depression, and lack of sleep. There is no known cure and the disorder is difficult to treat.

Chronic pain has a huge financial impact!



"Fibromyalgia is devastating for those who must live in its grip. There is much we do not understand. We need innovative 'out of the box' solutions that change the face of this disease," said Dan Bennett, MD, an interventional spine and pain surgical physician in Denver, Colorado, who is chairman of the National Pain Foundation.

Click to learn more



National Pain Foundation survey

responded to the survey said they had tried all three FDA approved drugs.

"The prescriptions that are available for treatment have more negative side effects than positive aspects," said one fibromyalgia sufferer.

"I haven't found anything! Please find a cure or at least a medicine that will take our pain away," said another.

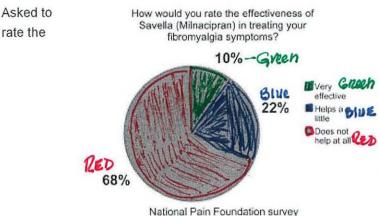
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(Duloxetine), 60% of those who tried the drug said it did not work for them. Only 8% said it was very effective and 32% said it helps a little.

Among those who tried Pfizer's Lyrica (Pregabalin), 61% said it did not work at all. Only 10% said it was very effective and 29% said it helps a little.

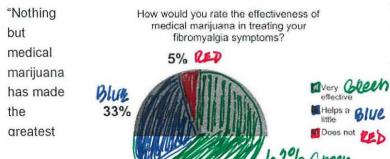


effectiveness of Forest Laboratories' Savella (Milnacipran), 68% of those who said they tried the drug said it didn't work. Only 10% said it was very effective and 22% said it helps a little.

About 70% of the people who responded to the survey said they had not tried medical marijuana – which is not surprising given that it is still illegal in most states and many countries. But those who have tried marijuana said it was far more effective than any of the FDA-approved drugs.

Sixty-two percent who have tried cannabis said it was very effective at treating their fibromyalgia symptoms. Another 33% said it helped a little and only 5% said it did not help at all.

"I've found nothing that has worked for me, apart from marijuana," said one survey respondent.



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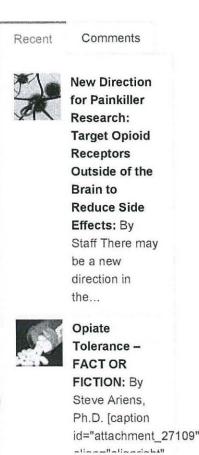
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problems," said another.

"Marijuana does help a LOT it numbs the pain. But it doesn't last long and it makes your brain foggy," wrote another fibromyalgia sufferer.

Survey respondents said massage, swimming, acupuncture, muscle relaxers and other alternative treatments also helped relieve their symptoms. Many said they take opioids to relieve their pain – although narcotic painkillers are generally not prescribed to treat fibromyalgia.

Other survey findings:

- Four out of ten (43%) fibromyalgia sufferers feel their physician is not knowledgeable about the disorder.
- Over a third (35%) feel their physician does not take their fibromyalgia seriously.
- 45% feel their family and friends do not take their fibromyalgia seriously.
- Nearly half (49%) said their fibromyalgia symptoms began at a relatively young age (18-34).
- Only 11% were diagnosed with fibromyalgia within the first year of symptoms.
- 44% said it took five or more years before they were diagnosed with fibromyalgia.

Many survey respondents lamented that the disorder had taken over their lives, leaving them socially isolated, fatigued and in constant pain.

"I was once an active person and have now virtually become a hermit due to this disease," said one.

"The worst thing about having fibromyalgia is disappointing loved ones when I can't do things with them," wrote one fibromyalgia sufferer.

"Having fibromyalgia is a life sentence. One simply cannot have a productive life living with this disease," said another

angn= angningm width="201"] Steve Ariens,...



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The 1,339 people who participated in the survey were self-selected as fibromyalgia sufferers. Ninety-six percent of them were female.

This was the <u>second online survey of pain patients</u> conducted by the National Pain Foundation and *National Pain Report*. The first survey found that over half of patients worry that they are perceived as "drug addicts" by pharmacists. Eight out of ten said they had stopped seeing a doctor because they felt they were treated poorly.

#### Share this:



Tags: Cymbalta, Fibromyalgia, Lyrica, Marijuana, National Pain Foundation, Savella

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PLoS One. 2011; 6(4): e18440.

Published online 2011 Apr 21. doi: 10.1371/journal.pone.0018440

PMCID: PMC3080871

## Cannabis Use in Patients with Fibromyalgia: Effect on Symptoms Relief and Health-Related Quality of Life

Jimena Fiz, 1,2 Marta Durán, 3 Dolors Capellà, 2,3 Jordi Carbonell, 4 and Magí Farré 1,2,\*

Antonio Verdejo García, Editor

University of Granada, Spain

Conceived and designed the experiments: JF DC MF. Performed the experiments: JF. Analyzed the data: JF MF. Wrote the paper: JF MD DC JC MF.

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Abstract Go to:

#### Background

The aim of this study was to describe the patterns of cannabis use and the associated benefits reported by patients with fibromyalgia (FM) who were consumers of this drug. In addition, the quality of life of FM patients who consumed cannabis was compared with FM subjects who were not cannabis users.

#### Methods

Information on medicinal cannabis use was recorded on a specific questionnaire as well as perceived benefits of cannabis on a range of symptoms using standard 100-mm visual analogue scales (VAS). Cannabis users and non-users completed the Fibromyalgia Impact Questionnaire (FIQ), the Pittsburgh Sleep Quality Index (PSQI) and the Short Form 36 Health Survey (SF-36).

#### Results

Twenty-eight FM patients who were cannabis users and 28 non-users were included in the study. Demographics and clinical variables were similar in both groups. Cannabis users referred different duration of drug consumption; the route of administration was smoking (54%), oral (46%) and combined (43%). The amount and frequency of cannabis use were also different among patients. After 2 hours of cannabis use, VAS scores showed a statistically significant (p<0.001) reduction of pain and stiffness, enhancement of relaxation, and an increase in somnolence and feeling of well being. The mental health component summary score of the SF-36 was

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<sup>&</sup>lt;sup>2</sup>Universitat Autònoma de Barcelona, Barcelona, Spain

<sup>&</sup>lt;sup>3</sup>Fundació Institut Català de Farmacologia, Barcelona, Spain

<sup>&</sup>lt;sup>4</sup>Rheumatology Unit, Parc Salut Mar, Barcelona, Spain

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significantly higher (p<0.05) in cannabis users than in non-users. No significant differences were found in the other SF-36 domains, in the FIQ and the PSQI.

#### Conclusions

The use of cannabis was associated with beneficial effects on some FM symptoms. Further studies on the usefulness of cannabinoids in FM patients as well as cannabinoid system involvement in the pathophysiology of this condition are warranted.

Introduction Go to:

The main complaint of patients with fibromyalgia (FM) is chronic generalized pain, although many patients suffer from concomitant symptoms, such as tiredness, morning stiffness, sleep and affective disturbances [1]. The pathophysiology of the disorder is poorly understood. Several mechanisms have been suggested including central sensitization, suppression of descending inhibitory pathways, excessive activity of glial cells, and abnormalities of neurotransmitter release [2]. In addition, blunting of the hypothalamic-pituitary-adrenal-axis (HPA-axis) and increased autonomic nervous system responsiveness have been consistently reported in FM patients. Emerging clues suggest that such dysfunction of the stress response system may be crucial in the onset of the symptoms of FM [3]. Treatment is based on the symptomatic relief of symptoms but usually modest results are obtained. The overall patient's satisfaction and the health-related quality of life are consistently poor.

Potential therapeutic uses of cannabis in different types of pain are currently extensively investigated. Data from clinical trials with synthetic and plant-based cannabinoids provide a promising approach for the management of chronic neuropathic pain of different origins [4]. Additionally, a large body of evidence currently supports the presence of cannabinoid receptors and ligands, thus an endocannabinoid neuromodulatory system appears to be involved in multiple physiological functions [5].

There is little clinical information on the effectiveness of cannabinoids in the amelioration of FM symptoms. Three clinical trials have suggested the possible benefit of cannabinoid in the management of FM [6]-[8]. Furthermore, a clinical endocannabinoid deficiency (CECD) has been hypothesized to underlie the pathophysiology of fibromyalgia, but a clear evidence to support this assumption is lacking [9].

The aim of this study was to describe the patterns of cannabis use and the associated benefits reported by patients with fibromyalgia (FM) who were consumers of this drug. In addition, the quality of life of FM patients who consumed cannabis was compared with FM subjects who were not cannabis users.

Methods Go to:

#### **Patients**

A cross-sectional survey was performed. Participants were identified through an advertisement from one Rheumatology Outpatients Unit, 15 associations of FM patients and 1 association of cannabis consumers, all of them located in the city of Barcelona, Spain. Recruitment began in August 2005, and the study was completed in April 2007. Patients were eligible if they were ≥18 years of age, had been diagnosed with FM according to the American College of Rheumatology criteria [1], had moderate to severe symptomatology, and were resistant to pharmacological treatment. Exclusion criteria were severe illness and history of abuse or dependence for cannabis or others psychoactive substances.

#### Ethics statement

The study was approved by the local Institutional Review Board (CEIC-IMAS) and all volunteers gave their written informed consent before inclusion.

#### Study procedures and evaluation

Patients were divided according their status of therapeutic cannabis use. Eligibility and exclusion criteria were checked through an accurate telephone interview. Demographic (age, gender and employment status) and clinical variables (duration of FM, number of medical consultations in the last year, associated symptoms, current pharmacological treatment, comorbid conditions, and alternative and complementary medicines) were also collected through a structured telephone interview. Patients were informed that a specific questionnaire to collect information on medicinal cannabis use will be posted to them as well as visual analogue scales (VAS) to record perceived benefits with comprehensive instructions how to fill them out.

The following variables were recorded: duration of cannabis use, previous use, cannabis derivative used (hashish or marijuana), route of administration, amount and frequency of use, supply source, physician's acknowledgement about cannabis use and changes of pharmacological treatment. Symptoms from which cannabis was used and perceived relief was recorded using 5-point Likert scale (strong relief, mild relief, not change, slight worsening, great worsening). Patients were further asked to record the perceived benefits of cannabis on a range of symptoms (pain, stiffness, relaxation, drowsiness, well-being) using 100-mm VAS scales (VAS) before and at 2 hours of cannabis consumptions. The occurrence and frequency of side effects were indicated based on a list of symptoms.

In order to compare the quality of life between users and non users of cannabis, three questionnaires were used:

The 36-item Short Form Health Survey (SF-36) is a self-administered questionnaire, validated in Spanish, in which eight dimensions of health-related quality of life are assessed: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health. Each scale is scored using norm-based methods, with higher scores indicating better health. Scores are aggregated further to produce physical and mental component summary measures of health status, using norm-based methods. The subscale scores are standardized and range from 0 to 100 with higher scores reflecting better health-related quality of life in the domain being measured [10].

The Fibromyalgia Impact Questionnaire (FIQ) is a self-administered questionnaire, validated in Spanish to assess health-related quality of life specifically in patients with fibromyalgia over the previous week. It consists of VAS and questions regarding limitations of daily living activities. The total score ranges from 0 to 80; a higher score indicates a more negative impact [11].

The Pittsburg Sleep Quality Index (PSQI) is a self-administered questionnaire, validated in Spanish, to measure the quality and patterns of sleep over the last month. It consists of 7 components that sum each other and give a total score range from 0 (no difficulties) to 21 (severe difficulties) [12].

#### Statistical analysis

Data obtained from the questionnaires were analysed using the SPSS software (version 12.0.1). Comparisons were carried out using Fisher Exact tests for categorical variables and Student t test for continuous variables. The Mann-Whitney U test was used when the size of a comparison group was too small to assume normality. Statistical significance was at the 5% level and all tests were two sided.

Results Go to:

In response to the advertisement, 70 patients contacted the researchers to inquire about the study and were screened by telephone. A total of 14 subjects, -6 cannabis users and 8 non-users-, did not meet the eligibility criteria. Therefore, 56 FM patients completed the study protocol, 28 of them were cannabis users (mainly recruited through FM association and cannabis association) and 28 were non-cannabis users (mainly recruited through FM associations and the Rheumatology Outpatients Unit of the hospital).

As shown in <u>Table 1</u>, there were no statistically significant differences between the cannabis users and non-users groups in any demographic or clinical variables. The most frequent comorbid diseases were also balanced between the study groups. No significant differences were observed for the percentage of patients with irritable bowel syndrome, chronic fatigue syndrome, restless legs syndrome, osteoarthritis, Sjögren's syndrome, and hypothyroidism (data not shown in <u>Table 1</u>). With regard to treatment based on complementary and alternative medicines, there were no significant differences between groups, neither in number (cannabis group 64%; non-users group, 75%) or modalities chosen (data not shown in <u>Table 1</u>).



<u>Table 1</u> **Patient characteristics**\*.

#### Patterns of cannabis use

Of the 28 FM patients using cannabis, 11 (40%) reported a duration of cannabis use of less than one year, 9 (32%) between 1 and 3 years, and 8 (29%) more than 3 years. Only 8 patients in the cannabis group have used cannabis recreationally before the medicinal use. Cannabis derivate used in every case was marijuana. The usual methods of administration were smoking and eating, and some patients use to combine both methods. Only smokers were 11%, only eaters were 46% and those using both methods were 43%. The amount and frequency of cannabis use were diverse among patients. The most frequent doses were between 1 and 2 cigarettes each time when patients smoked and 1 spoonful each time when eating. Most of the patients (n=12) used cannabis daily, while 5 used it 2–4 days per week, 3 used it less than twice a week and 8 patients used it only occasionally. Related amount of cannabis used in one day, 12 reported once a day, 11 reported 2–3 times a day and 3 reported more than 3 times a day. Source of supply of cannabis were from family and friends (n=14), illicit market (n=7), growing (n=5) and associations (n=2). A total of 19 patients have informed their doctor about cannabis use, and reduction of pharmacological treatment was accomplished in 19 (68%) patients as well when they started using cannabis.

#### Perceived effects of cannabis use

Main symptoms leading to cannabis use and perceived benefits is shown in <u>Figure 1</u>. Patients used cannabis not only to alleviate pain but for almost all the symptoms associated to FM, and no one reported worsening of symptoms following cannabis use. The proportion of patients who reported strong relief ranged from 81% for sleep disorders to 14% for headache.



Figure 1

Symptoms and perceived relief reported by FM patients using cannabis.

All symptoms assessed by VAS showed statistically significant improvement following 2 hours of cannabis self-administration (Figure 2). The mean reduction of pain was 37.1 mm (p<0.001, t-Test) and of stiffness 40.7 mm

(p<0.001). The change from baseline in VAS relaxation and somnolence scores also significantly increased (27.6 mm, p<0.05 and 20.0 mm, p<0.05 respectively). In addition, perception of well-being was significantly higher as compared with baseline (40.0 mm, p<0.001).

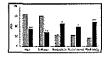


Figure 2
Perceived effects of cannabis self-administration.

#### Perceived side effects of cannabis use

At least one side effect was reported by 96% (n=27) of patients. The most frequent were somnolence (n=18), dry mouth (n=17), sedation (n=12), dizziness (n=10), high (n=9), tachycardia (n=8), conjunctival irritation (n=7) and hypotension (n=6). The frequency most commonly reported were 'sometimes' for somnolence, sedation, dizziness, high, tachycardia and conjunctival irritation, and 'always' for dry mouth, sedation and hypotension. No serious adverse events occurred.

#### Quality of life

The mental health component summary score of the SF-36 questionnaire was slightly but significantly higher in the cannabis group (mean (M)= $29.6\pm$ standard deviation (SD)=8.2) than in the non-users group (M= $24.9\pm$ SD=8.9), p<0,05, t-Test. In the physical component summary score the differences were non significant between groups (cannabis group: M= $26.29\pm$ SD=6.7; non-users group: M= $27.34\pm$ SD=5.8; p=0,53, t-Test).

No differences were found either in the Fibromyalgia Impact Questionnaire (M=65.5±SD=11.9; M=65.5±SD=12.8; p=0.36, t-Test) or in the Pittsburg Sleep Quality Index (M=14.1±SD=3.2; M=14.4±SD=3.3; p=0.73, t-Test).

**Discussion** Go to:

This observational study provides information on the patterns of cannabis use for therapeutic purposes among a group of patients with FM. Most of them were middle-aged women that did not respond to current treatment and self-administered marijuana, devoid of medical advice. Patients referred cannabis use in order to alleviate pain as well as other manifestations of FM. Significant relief of pain, stiffness, relaxation, somnolence and perception of well-being, evaluated by VAS before and 2 hours after cannabis self-administration was observed.

Although the mental health component summary score of the SF-36 questionnaire was slightly but significantly higher in the cannabis group than in the non-users group, whether these findings are clinically significant remains unclear.

The external validity of this study can be limited for some factors. The main limitation is the self-selection bias, mainly related to the fact that the majority of patients in the cannabis group were recruited from a cannabis association. It is not known how these patients are different from the ones recruited from FM associations or from the rheumatology unit. In addition the patients included in the study were all responders to cannabis self-administration. Consequently, characteristics of the patients that have used cannabis and have not obtained symptoms relief are unidentified. Others limitations were the small size of the sample and, the variability of patterns of cannabis use among FM patients.

A previous observational study of patients with chronic pain of different origins using cannabis has revealed similar results regarding symptoms relief [13]. Furthermore, significant reductions in VAS score for pain, FIQ global score and FIQ anxiety score were also seen in the first randomized controlled trial of 40 FM patients with

continued pain despite the use of other medications treated with nabilone (synthetic cannabinoid agonist) during 4 weeks [7]. In a recent randomized, equivalency and crossover trial, nabilone was found to have a greater effect on sleep than amitriptyline on the ISI (Insomnia Severity Index), and was marginally better on the restfulness based on the LSEQ (Leeds Sleep Evaluation Questionnaire) [8]. These results seem to indicate a possible role of cannabinoids on the treatment of FM, although it should be confirmed in further clinical trials.

Moreover, according to hypothetical and experimental evidence, a Clinical Endocannabinoid Deficiency has been proposed to be involved on the pathophysiology of FM and other functional conditions alleviated by cannabis [9]. The participation of the endocannabinoid system in multiple physiological functions such as pain modulation, stress response system, neuroendocrine regulation and cognitive functions among others, is well known [5]. Additionally, the innovative psychoneuro-endocrinology-inmunology (PNEI) studies have shown that chronic pain may be strongly influenced by dysfunctions of the stress system and, particularly, the HPA-axis [14]. Studies have shown that the HPA- axis and the autonomic nervous system is disturbed in patients with fibromyalgia [3] and, polymorphisms of genes in the serotoninergic, dopaminergic and catecholaminergic systems may also play a role in the pathogenesis of FM [15]. Notably, these polymorphisms all affect the metabolism or transport of monoamines, compounds that have a critical role in both sensory processing and the human stress response [16]. Endocannabinoids and cannabinoid receptors are involved in the responses of animals to acute, repeated and variable stress [17] and there is good evidence that the cannabinoid receptors play a major role in modulating neurotransmitter release such as serotonin and dopamine among others [18]. However, the endocannabinoid system and its implication in stress response in humans have not been so far investigated. Because of many methodological pitfalls in life stress research, high quality studies of the role of stress in the etiopathogenesis of unexplained chronic pain syndromes, such as fibromyalgia, are scarce.

We observe significant improvement of symptoms of FM in patients using cannabis in this study although there was a variability of patterns. This information, together with evidence of clinical trials and emerging knowledge of the endocannabinoid system and the role of the stress system in the pathopysiology of FM suggest a new approach to the suffering of these patients.

The present results together with previous evidence seem to confirm the beneficial effects of cannabinoids on FM symptoms. Further studies regarding efficacy of cannabinoids in FM as well as cannabinoid and stress response system involvement in their pathophysiology are warranted.

#### Acknowledgments

Go to:

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Footnotes Go to:

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## Marijuana/Fibromyalgia – The Data Pile Up

Posted on April 14, 2016 in Alternative Pain Therapy, Diseases & Conditions, Pain Medication with 4 Comments

By Donna Gregory Burch

Visit nearly any online fibromyalgia support group, and you'll almost always read a few testimonials from patients who say cannabis is the only thing that's ever relieved their pain.



Donna Gregory Burch

In 2014, a survey of more than

1,300 fibromyalgia patients by the National Pain Foundation and National Pain Report found medical marijuana is more effective than Lyrica, Cymbalta or Savella, the three drugs approved by the Food and Drug Administration to treat the

disorder.

Despite the vast number of people living with pain, many in the pain community feel unfleated and isolated.



There's growing anecdotal evidence that marijuana relieves fibromyalgia pain, but actual research is still scant. Cannabis remains a schedule I controlled substance in the United States, making it difficult for researchers to study the plant's pain-relieving properties. To date, there have been less than a handful of small studies using cannabis or its derivatives to treat fibromyalgia. Most of those have shown it to be beneficial, especially for pain relief.

But why does cannabis seem to work so well? Dr. Ethan Russo, medical director of PHYTECS, believes fibromyalgia's multifaceted symptoms may be caused by a deficiency in the body's endocannabinoid system (ECS), a condition he calls Clinical Endocannabinoid Deficiency (CED). Maybe the reason cannabis is so effective is because it's simply supplementing what the body needs – similar to how people take a supplement to treat vitamin D or B12 deficiency.

Russo explores the evidence behind his hypothesis in a soon-to-be published review entitled, "Clinical Endocannabinoid Deficiency Reconsidered: Current Research Supports the Theory in Migraine, Fibromyalgia, Irritable Bowel and other Treatment-Resistant Syndromes." While his idea is still theoretical, there is some early research indicating he may be onto something.

The ECS is made up of cannabinoid receptors within the brain, spinal cord, nerves, gut, organs and other locations in the body. It helps the body maintain homeostasis and is involved in a number of physiological processes, including pain sensation, mood, memory and appetite, among others.

The body naturally makes endocannabinoids – the same kinds of endocannabinoids found in cannabis – that feed the ECS and keep it functioning.



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Fibromyalgia causes symptoms throughout the body, with the primary ones being pain, fatigue and cognitive difficulties.

Certain conditions, like irritable bowel syndrome (IBS) and migraine, are extremely common among those with fibromyalgia – so much so that Russo believes they may all be connected to an ECS deficiency.

His theory makes sense. The ECS plays a role in so many of the body's major systems, so if it was indeed malfunctioning, that would account for why fibro sufferers have such varied symptoms. Supplementing the ECS with cannabinoids from the cannabis plant would, in theory, relieve symptoms because the deficiency is being treated.

Russo first posited that fibromyalgia, IBS and migraine may be caused by an ECS deficiency back in 2001. His latest review gives an update on new research that supports ECS deficiency as a possible culprit for fibromyalgia, IBS and migraine.

"Additional studies have provided a firmer foundation for the theory," he writes in the review, "while clinical data have also produced evidence for decreased pain, improved sleep and other benefits to cannabinoid treatment and adjunctive lifestyle approaches affecting the endocannabinoid system."

CED is based on the premise that many brain disorders have been linked to neurotransmitter deficiencies. For example, dopamine has been implicated in Parkinson's disease, and serotonin and norepinephrine have been associated with depression.

"If endocannabinoid function were decreased, it follows that a lowered pain threshold would be operative, along with derangements of digestion, mood and sleep among the almost universal physiological systems sub-served by the ECS," Russo writes.

That's a mouthful, but essentially it means if the ECS isn't

properly working, then it could account for the pain, sleep, digestive and other issues so common among fibromyalgia patients.

Adding cannabinoids to the body through the use of cannabis may help to bring the ECS back into balance.

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"It's a key in a lock in your body that exists for a reason," explains Dr. Jahan Marcu, chief scientist with Americans for Safe Access. "We send in cannabinoids to activate this system that's supposed to be working. It's a sort of care and feeding of the ECS so it can do its job."

The best evidence for CED comes from an Italian migraine study, which found reduced levels of an endocannabinoid known as anandamide in patients with chronic migraines versus healthy controls.

"Reduced [anandamide] levels in the cerebrospinal fluid of chronic migraine patients support the hypothesis of the failure of this endogenous cannabinoid system in chronic migraine," read the study.

Unfortunately, the Italian study will probably never be repeated in the United States because it required risky and invasive lumbar punctures.

In the gut, the ECS modulates the movement of food along the digestive tract, the release of digestive juices to break down food and inflammation.

Cannabis has long been used to treat digestive issues and was one of the first effective treatments for diarrhea caused by cholera in the 19th century.

"Unfortunately while many patient surveys have touted the benefit of cannabinoid treatment of IBS symptoms, and abundant anecdotal support is evident on the Internet, little actual clinical work has been accomplished," Russo writes.

A few studies using marijuana for fibromyalgia have had positive results. Overall, marijuana has been found to decrease pain and anxiety, and improve sleep and general well-being.

"There is actually some evidence that the levels of at least one endocannabinoid (anandamide) increase in the circulation of patients with fibromyalgia," says Prof. Roger G. Pertwee from the University of Aberdeen in Scotland. "There is also considerable evidence that anandamide is often released in a manner that reduces unwanted symptoms such as pain and spasticity in certain disorders. ... It is generally

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accepted that THC, the main psychoactive constituent of cannabis, can relieve pain, including neuropathic pain for example, by directly activating cannabinoid receptors. ...

Some non-psychoactive constituents of cannabis have also been found to relieve signs of pain, at least in animal models."

For anecdotal evidence, Russo cites the National Pain
Foundation/National Pain Report survey in his review, saying,
"The results of the survey strongly favor cannabis over the
poorly effective prescription medicines. These results certainly
support an urgent need for more definitive randomized
controlled trials of a well-formulated and standardized
cannabis-based medicine in fibromyalgia inasmuch as
existing medicines with regulatory approval seem to fall quite
short of the mark."

More research needs to be done to either prove or disprove CED's existence.

"What we really need is randomized controlled trials to look at this more carefully, and that's the only kind of evidence that the [Food and Drug Administration] and most doctors are going to find acceptable in the end," Russo says.

MRI and PET scans are not yet able to detect endocannabinoid levels in living patients, but as technology advances, that may become a possibility. The ability to actually test endocannabinoid levels in fibromyalgia patients and compare those against healthy controls would help to confirm Russo's theory.

"We're on the edge of having that capability," Russo says. "It's in my plans to look at this type of thing in the future."

Donna Gregory Burch was diagnosed with fibromyalgia in 2014 after several years of unexplained pain, fatigue and other symptoms. She covers news, treatments, research and tips for living better with fibromyalgia on her blog, FedUpwithFatigue.com. Donna is an award-winning journalist whose work has appeared online and in newspapers and magazines throughout Virginia, Delaware and Pennsylvania. She lives in Delaware with her husband and their many fur babies.

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I am a CRPS survivor. I testify to the fact that cannabis, at this time and development of our society, will not take the place of pain meds. And I can testify to the fact that cannabis will not react to the same individual the same way. Nonetheless we all, those who are in pain and those who love the ones in pain, must unite and demand the needed action that only we can demand, the Feds to listen to the people and change of classification of cannabis. Furthermore the legalization of marijuana in some states for recreational purposes has all but destroyed the medical market for those of us who desperately need it. Thanks to our state Representatives only focusing on all the tax revenue, we now have to downgrade our medical supply to unregulated polluted contaminated cr\*p. We AMERICANS must STAND up for our constitutional rights to health and prosperity!

#### Jeanie Beal

April 19, 2016 at 5:39 am

I have tried marijuana, Cymbalta and Lyrica. Cymbalta turned me into a zombie, and Lyrica caused peripheral swelling and weight gain. Marijuana, on the other hand, caused no side effects. It also allowed better control of dosing. Keeping marijuana on the Schedule 1 list is ludicrous. It is likely far more effective, with fewer side effects than the chemicals currently sanctioned by the FDA.

#### **Katherine Johnson**

April 15, 2016 at 12:52 pm

This is why it's so important for cannabis to be reclassified. The only reason it was classified as schedule 1 in the first place is because Nixon was angry at the "hippies" that were challenging him on the war and thought this was a way to "get them out of the way". The most comprehensive research ever done on cannabis in this country was done on his request, when it showed that cannabis was fairly benign especially in comparison to other illegal drugs, was given to Nixon, he threw it in a drawer and made it a schedule 1 drug so that no one else could studied and find out the truth. It's time to quit indulging political lies in an attempt at social engineering and reschedule to allow science to do it's job. Many who are dying of drug overdoses today, might still be alive if cannabis was

available as an option. Cannabis is far more effective on nerve pain than opiod pain medication.

#### Nancy R

April 14, 2016 at 3:31 pm

They need to test it against opioids as well to see an accurate result. The standard available treatments help some, some of the time. Adding cannabis to the mix of acceptable drugs is fine but it is not a replacement for pain medications. It helps some, to some degree. For some, like the approved meds, make things worse.

We need more research and we need more relief. We are trying to function out here....more normal-like. Thanks

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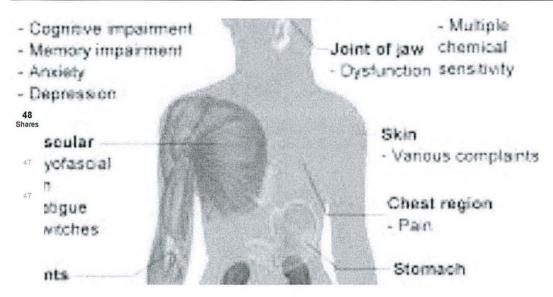
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#### Fibromyalgia – Medical Marijuana Research Overview

28 September, 2015

The following information is presented for educational purposes only. Medical Marijuana Inc. provides this information to provide an understanding of the potential applications of cannabidiol. Links to third party websites do not constitute an endorsement of these organizations by Medical Marijuana Inc. and none should be inferred.

Fibromyalgia is a disorder characterized by intense musculoskeletal pain that affects 5 million Americans. Studies have shown marijuana effectively lowers pain levels and improves quality of sleep in patients.

#### Overview of Fibromyalgia

Fibromyalgia is a common disorder characterized by widespread pain and fatigue that primarily affects women. The disorder can greatly affect a person's abilities to perform daily activities and causes sleep problems. According to Mayo Clinic, having fibromyalgia affects the way the brain processes pain signals and makes painful sensations feel amplified.

In addition to pain, fatigue and sleep problems, those with fibromyalgia may also experience cognitive and memory problems, headaches, morning stiffness, painful menstrual periods, numbness or tingling, restless legs syndrome, temperature to sensitivity, irritable bowel syndrome, and depression.

The causes of fibromyalgia remain unknown, but the National Institute of Arthritis and Musculoskeletal and Skin Diseases notes that many people associate their fibromyalgia to a physically or emotionally stressful or traumatic event. Repetitive injuries or illnesses are also commonly associated to fibromyalgia by patients. Others claim the disorder developed spontaneously.

There is no cure of fibromyalgia, so treatment focus is on controlling symptoms with pain relievers, antidepressants, exercise and therapy.

#### Findings: Effects of Cannabis on Fibromyalgia

The cannabinoids contained in cannabis have both analgesic and sleep-promoting effects to help fibromyalgia patients manage symptoms. Studies have found that cannabis is effective at improving sleep disruption, pain, depression, joint stiffness, anxiety, physical function and quality of life in individuals with fibromyalgia (de Souza Nascimento, et al., 2013) (Russo, 2004).

While fibromyalgia is known for causing intense and unrelenting musculoskeletal pain, cannabls has proven effective at offering fibromyalgia patients relief. Fibromyalgia patients treated with cannabls and assessed over a seven-month period experienced significant pain intensity improvements and were able to reduce their doses of opioids (Weber, et al., 2009). One study discovered that after four

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Canadian Medical Marijuana Pati Allowed to Grow Own Cannabis weeks of cannabis treatment, fibromyalgia patients experienced significantly less pain and anxiety whereas a piacebo group saw no improvements (Skrabek, Galimova, Ethans & Perry, 2008). Another study reported significant reductions in pain and stiffness, an enhancement of relaxation and an increase in somnolence and feeling of well being in fibromyalgia patients two hours after they smoked or orally consumed cannabis (Fiz, et al., 2011).

Cannable has also been found to be effective at improving sleep quality in patients with fibromyalgia (Ware, Fitzcharles, Joseph & Shir, 2010).

#### States That Have Approved Medical Marijuana for Fibromyalgia

Only the states of Illinois and Ohio have approved medical marijuana specifically for the treatment of fibromyalgia.

However, several states have approved medical marijuana specifically to treat "chronic pain," a symptom commonly associated with fibromyalgia. These states include: Alaska, Arizona, California, Colorado, Delaware, Hawaii, Maine, Maryland, Michigan, Montana, New Mexico, Ohio, Oregon, Pennsylvania, Rhode Island and Vermont. The states of Nevada, New Hampshire, Ohio and Vermont allow medical marijuana to treat "severe pain." The states of Minnesota, Ohio, Pennsylvania and Washington have approved cannabis for the treatment of "intractable pain."

Fifteen states have approved medical marijuana for the treatment of spasms. These states include: Arizona, California, Colorado, Delaware, Florida, Hawaii, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, Oregon, Rhode Island and Washington.

A number of other states will consider allowing medical marijuana to be used for the treatment of fibromyalgia with the recommendation by a physician. These states include: California (any debilitating illness where the medical use of marijuana has been recommended by a physician), Connecticut (other medical conditions may be approved by the Department of Consumer Protection), Massachusetts (other conditions as determined in writing by a qualifying patient's physician), Nevada (other conditions subject to approval), Oregon (other conditions subject to approval), Rhode Island (other conditions subject to approval), and Washington (any "terminal or debilitating condition").

In Washington D.C., any condition can be approved for medical marijuana as long as a DC-licensed physician recommends the treatment.

#### Recent Studies on Cannabis' Effect on Fibromyalgia

Fibromyalgia patients experienced significant reductions in pain and stiffness, an enhancement of relaxation, and an increase in somnolence and feeling of well being, two hours after smoking or orally consuming cannabis.

Cannabls use in patients with fibromyalgia: effect on symptoms relief and health-related quality of life. (http://www.ncbi.nim.nih.gov/pubmed/21533029)

Cannabis medication found effective at improving sleep quality and was well tolerated by fibromyalgla patients.

The effects of nabilione on sleep in fibromyalgia: results of a randomized controlled trial.

(http://www.ncbi.nlm.nlh.gov/pubmed/20007734)

Four weeks of cannabis treatment caused significant decreases in pain and anxiety in patients with fibromyalgia.

Nabilone for the treatment of pain in fibromyalgia.

(http://www.ncbi.nlm.nlh.gov/pubmed/17974490)

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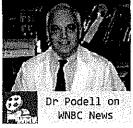
## The Podell Medical Practice Integrative Medical Care for Complex Health Problems

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Home >>Fibromyalgia Diagnosis

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## Fibromyalgia and Its Causes: Special Attention to Severe Fibromyalgia

To Treat Fibromyalgia Syndrome (FMS), First Understand It's Cause: Increased Sensitization of the Central Nervous System's Pain Signaling Pathways

#### CONTENTS:

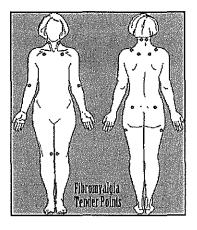
- Migraine/Tension Headaches 1. What Is Fibromyalgia Syndrome (FMS) and Why We Suffer from Fibromyalgia Pain
  - 2. Dr. Podell, One of the Nation's Leading Fibromyalgia Doctors
  - 3. Confirming a Severe Fibromyalgia Diagnosis
  - 4. The Fibromyalgia Impact Questionnaire Revised (FIQR)

See also: Fibromyalgia Treatments | Fibromyalgia and Holistic
Therapies | Fibromyalgia Disability |
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## What Is Fibromyalgia Syndrome (FMS) and Why We Suffer from Fibromyalgia Pain

Fibromyalgia causes sore and tender muscles. But it's now clear that Fibromyalgia means much more than just pain. Persons with moderate or severe Fibromyalgia almost always suffer from additional symptoms—not only pain! For example: poor memory and concentration, chronic fatigue and poor sleep. Other frequent symptoms include headache, numbness, feeling light headed, irritable bowel, and irritable bladder. To optimize your health we have to address these "co-morbidities" also, along with your pain.

Fibromyalgia specialists report that most patients with severe FMS also qualify for the diagnosis of <u>Chronic Fatigue Syndrome</u> (CFS). Until recently many physicians believed that Fibromyalgia was a psychological diagnosis-



as if FMS were a disguised form of mental distress. Today Fibromyalgia doctors agree that Fibromyalgia is both real and mainly physical. Psychological support helps, but physical measures are required to relieve pain and to treat the whole person.

A key mechanism of Fibromyalgia is "Central Sensitization"—an abnormal increase of pain sensitivity within the brain and spinal cord. Sophisticated research studies prove that when Fibromyalgia patients report feeling pain, the pain centers in their brain actually "light up". This confirms that people with

Fibromyalgia accurately report the pain that they feel.

#### Dr. Podell is Among the Nation's Leading Fibromyalgia Doctors

Our New Jersey Fibromyalgia Clinic has helped more than 1,000 persons find relief for Fibromyalgia pain. Richard Podell, M.D. has lectured on Fibromyalgia to many medical and professional groups including the Association of Administrative Law Judges, who decide Fibromyalgia's social security disability claims, and the National Organization of Social Security Claimants



Representatives (NOSSCR). Dr. Podell has testified in court as a medical expert on Fibromyalgia. Since 2012 the federal government's Center for Disease Control (CDC) has recognized Dr. Podell as one of a select group of chronic fatigue syndrome specialists for an ongoing research project. Nearly all the research patients in this study are also treated for severe Fibromyalgia.

A clinical professor at Robert Wood Johnson Medical School, the New Jersey Chronic Fatigue Syndrome Association awarded Dr. Podell their annual Achievement Award. He has co-authored a textbook for physicians on Chronic Fatigue Syndrome and has written extensively about both Fibromyalgia and chronic fatigue.

Our Fibromyalgia Treatment Philosophy: We seek to combine the best of standard medical therapies with alternative medicine and holistic support for the body's natural healing systems. Fibromyalgia relief medicines can be valuable but the relief they provide is often only partial. To treat FMS best we must also provide holistic support. This includes improving sleep quality, better nutrition, biochemical metabolic support, carefully graded exercise and positive coping skills.

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#### To Relieve Fibromyalgia Pain, First Confirm the Diagnosis

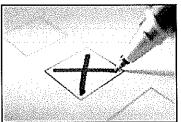
Fibromyalgia doctors have found that dozens of common ailments can mimic Fibromyalgia pain and fatigue. So before focusing on relief for Fibromyalgia, we must first be sure:

- 1. that we have the correct diagnosis and
- 2. that we also identify and address co-existing complications.

This requires a very careful and detailed review of your history. That's why we ask you to complete a comprehensive <u>history questionnaire</u> which we always review in preparing for your visit. That's also why we typically spend at least 1.5 hours with you at your first visit. Our nurse educator may spend additional time to help you with the practical points of our recommendations.

#### ▶back to top

## Help Your Doctor Document Your Illness: The Fibromyalgia Impact Questionnaire Revised (FIQR)



Fibromyalgia specialists report that most patients with severe FMS also qualify for the diagnosis of <u>Chronic Fatigue Syndrome</u>. It's difficult to explain all your symptoms and limitations within the limited time of most medical visits. This is especially so if your Fibromyalgia is severe. The FIQR can help your physicians better understand both you

and your illness. You can complete the FIQR in less than 5 minutes.

Consider giving your doctor an updated copy of your FIQR before each and every visit. The FIQR also helps you keep track of your Fibromyalgia pain relief and treatments.

Review and download the  $\underline{\text{FIQR}}$  or read more on the benefits of using this simple  $\underline{\text{questionnaire}}$ .

Contact us to get your Fibromyalgia diagnosis today.

See also: Fibromyalgia Treatments | Fibromyalgia and Holistic Therapies |
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## ★ Medical Marijuana Rated Much More Effective in Treating Fibromyalgia Symptoms Than Drugs

#### Synopsis:

**Published** 2014-04-21 (*Rev.* 2016-01-04) -- Survey of people with fibromyalgia revealed those who used marijuana to treat symptoms find it significantly more effective than the 3 drugs approved by the FDA to treat the disorder.

Author: The National Pain Foundation - Contact: www.thenationalpainfoundation.org



**Quote:** "Nothing but medical marijuana has made the greatest dent in the pain and mental problems."

#### Main Document

The three drugs approved for the treatment of fibromyalgia are Cymbalta (Duloxetine); Lyrica (Pregabalin); and Savella (Milnacipran).

How Cymbalta Performs for Fibromyalgia Sufferers (N=960)

- 60% say Cymbalta does not work at all
- 32% say Cymbalta helps a little
- 8% say Cymbalta was very effective

#### How Lyrica Performs for Fibromyalgia Sufferers (N=860)

- 61% say Lyrica does not work at all
- 29% say Lyrica helps a little
- 10% say Lyrica was very effective

#### How Savella Performs for Fibromyalgia Sufferers (N=387)

- 68% say it does not work at all
- 22% say it helps a little
- 10% say it was very effective

#### How Marijuana Performs for Fibromyalgia Sufferers (N=379)

- 5% say it does not work at all
- 33% marijuana helps a little
- 62% say marijuana was very effective

#### Comments from survey respondents regarding the use of marijuana to treat Fibromyalgia:

- "I've found nothing that has worked for me, apart from marijuana."
- "Nothing but medical marijuana has made the greatest dent in the pain and mental problems."
- "Marijuana does help a LOT, it numbs the pain. But, it doesn't last long and it makes your brain foggy."

#### About The Survey:

- Ninety-six percent (96%) of survey respondents were females.
- About half (49%) were diagnosed between the ages of 18 and 34, while 38% were diagnosed between the ages of 35 to 49.
- Only 12% were diagnosed at the age of 50 or older.
- Forty-four percent (44%) lived with Fibromyalgia for more than five years before receiving a diagnosis.
- Only 11% were diagnosed within one year of experiencing symptoms.
- Four out of ten (43%) of fibromyalgia sufferers feel their physician is not knowledgeable about

A long

the disorder.

- Over a third (35%) feel their physician does not take their fibromyalgia seriously.
- And 45% feel their family and friends do not take their fibromyalgia seriously.

The National Pain Foundation is a 501(c)(3), not-for-profit organization that is addressing the critical public health challenges attributed to pain on a global basis.

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#### Comments and Discussion:



Have Your Say: We welcome relevant discussions, advice, criticism and your unique insights. To ask a specific question see our <u>Disability Q&A Community</u>. All comments are moderated and will not appear until approved. NOTE: We do not verify any information posted in the comment section.

#### **Further Information:**



Fibromyalgia: Pain, Causes, Symptoms & Treatment - Disabled World



Fibromyalgia Pain and the Weather - *Ian Langtree - (Nov 14, 2011)* http://www.disabled-world.com/health/fibromyalgia/weather-pain.php



First treatment for Fibromyalgia Pain now Available in Canada - PFIZER CANADA INC. - (May 12, 2009)

http://www.disabled-world.com/health/fibromyalgia/fibromyalgia-lyrica.php



Medical Marijuana for Pain and Depression // medical/pharmaceutical/marijuana/



Medical Marijuana not Recommended for Rheumatoid Arthritis, Lupus, or Fibromyalgia Symptoms - *Wiley - (Mar 09, 2014)* 

http://www.disabled-world.com/medical/pharmaceutical/marijuana/ra-herbal.php



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#### Synopsis:

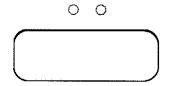
**Published** 2010-06-26 (*Rev.* 2013-06-16) -- Information for people suffering from Fibromyalgia and Chronic Fatigue Syndrome in regards to applying and obtaining Social Security Disability Benefit Payments.

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Author: Jeffrey A. Rabin & Assoc

# Apply For Disability

(Recommended) 100% Accepted. No Need to Wait — Free Evaluation!



**Quote:** "Many claims for SSDI and SSI benefits are approved for persons with Fibromyalgia and Chronic Fatigue Syndrome."

#### Main Document

Social Security Disability And Fibromyalgia - Information for people suffering from Fibromyalgia and Chronic Fatigue Syndrome in regards to applying and obtaining Social Security Disability Benefit Payments.

Social Security disability benefits are often the ultimate safety net for persons suffering from medical impairments that make it impossible for them to work. For many people, however,

struggling through the Social Security Administration's bureaucracy is frustrating, confusing and slow. For people suffering from conditions such as <u>Fibromyalgia</u> and <u>Chronic Fatigue Syndrome</u>, the requirements of the Social Security Act can become overwhelming. This article will explain and simplify in general terms the requirements of the Social Security disability program and describe the application and appeals process.

#### Two Different Programs - SSDI and SSI

There are two programs under the Social Security Act providing benefits for persons who are unable to work. The first is the Social Security Disability Insurance (SSDI) program found in Title II of the Social Security Act. The second is the Supplemental Security Income program contained in Title XVI of the Social Security Act. The medical test for both programs is identical. The differences are in the non-medical eligibility requirements.

#### **Non-Medical Requirements**

SSDI benefits are paid to totally disabled individuals who have worked and paid into the Social Security system with the FICA taxes that are deducted from paychecks. These FICA taxes are analogous to insurance premiums paid for automobile, homeowners or other private insurance. The FICA payments, which are matched by employers, buy coverage under the Social Security Retirement, Disability and Medicare programs. For SSDI, there are two requirements: a worker must have worked and paid FICA taxes for at least 40 quarters lifetime (10 years) and, also 20 quarters had to have been paid in during the ten years prior to the date of becoming totally disabled. For example, a 40 year-old Claimant who became disabled in 2003 would have had to have worked and paid FICA taxes for at least 10 years during his lifetime, and for at least 5 years between 1992 and 2002.

If approved for SSDI the Social Security Administration pays a monthly benefit based upon how much was earned and paid into the Social Security system. Benefits are also paid to dependent children who are under 16 years old, or who are under 18 years old and still in high school. Medicare eligibility begins twenty-nine months after the onset date of total disability.

The SSI program requires that an individual be totally disabled and "indigent." "Indigent" basically means that a single Claimant has little or no income and less than \$2,000.00 in non-exempt assets. A home and furniture are not counted. One car is exempt. Bank accounts, IRAs, profit sharing plans, cash value life insurance and similar assets are all included in determining assets, even if penalties and taxes would be incurred if the asset were converted to cash. In addition, a spouse's assets and income are "deemed" to the disabled Claimant - this deeming rule wreaks havoc on many disabled persons, particularly the stay-at-home parent.

In 2004 SSI will pay a basic monthly benefit of \$564.00 which may be supplemented by some states. A disabled person receiving SSI will also be eligible for food stamps and a Medicaid card from the state.

The Social Security disability program is designed to pay benefits to claimants suffering from medical problems causing symptoms so severe that it becomes impossible to sustain function at

any type of work. Issues of employability, job existence, insurability and location or desirability of alternative work will not be considered, although age and education are often important factors. The fact that a person can not do the work performed in the past is usually not determinative. This is a medical program that focuses upon medically proven symptoms and their impact on the ability to perform work activities.

Therefore, the focus in on function, not on diagnosis; SSA often admits that Claimants have medical problems and are "impaired," but denies that they are "totally disabled." The debate is over what the Claimant can "do" despite the medical problems.

The Social Security Administration's Regulations require determination of disability be based upon on "objective proof" of both the medical problem and of the severity of the symptoms. "Objective proof" means the findings contained in medical tests that are not dependent on the patient's subjective responses. A MRI, a cardiac treadmill test, an x-ray and a pulmonary function test are all "objective" tests. Asking a patient if she is in pain is "subjective." In Fibromyalgia and CFS claims, it is often difficult to objectively prove either the existence of the disease, or the severity of the symptoms. This has caused many claims based upon these conditions to be denied especially at the first two levels of review.

The focus in all disability claims is upon the medical evidence, i.e. the treating physicians' clinical findings, office notes, reports, and medical test results. This evidence is primary and is often more important than the testimony of the Claimant. While a Claimant's description of the impact on daily activities, social functioning and concentration must be considered by SSA, the content of the medical documentation is the most important source of evidence in deciding the claim.

In Fibromyalgia claims the clinical notes and a report of the treating rheumatologist are most important. A 1996 decision by the Seventh Circuit Court of Appeals established that a rheumatologist is the primary source for proof of this disease. Office notes from the rheumatologist should consistently document the positive findings for the tender points which are diagnostic for this disease. In addition, the patient should be complaining at each office visit of the fatigue and pain that are consistent with this condition. A report that establishes that all other causes for the symptoms have been ruled out helps establish the existence of the disease.

Since the extent of fatigue and pain can not be measured, consistency of complaints in the various medical records will be important. The use of pain medications, even if just for trial periods is an important consideration in evaluating the severity of pain. Use of mild analgesics indicates less severe symptoms; prescription of stronger narcotics indicates that the treating specialist felt the pain problems more severe. Also, documentation by the physicians of concentration impairments, and the inability to perform routine daily activities such as housework, shopping, and social functioning, are also factors considered by Social Security Administration decision makers.

Chronic Fatigue Syndrome claims have been made clearer by the adoption of Social Security Ruling 99-2p. This Ruling finally acknowledges that CFS is a medically determinable impairment and describes the various findings that can establish the diagnosis. This Ruling is quite useful and can be found at the SSA's website, www.ssa.gov. Generally, the focus is on a longitudinal view of

the medical evidence and the extent and nature of the treatment provided by the various physicians. The clinical findings and summaries of the patient's complaints in the office notes are critical in terms of establishing the existence of a medical impairment. As to whether the symptoms are totally disabling, SSA will consider the medical opinions, as well as the statements of the Claimant and third parties, as in any other disability claim.

Claimants who suffer from depression should also seek treatment from a mental health professional. Whether the depression is a symptom of the disease, or results from the significant impact on a Claimant's lifestyle, or is a separate disabling medical condition, the treatment notes and histories often lend credibility to the claim. However, SSA will generally not give significant weight to depression treated by a family doctor or social worker - emphasis will always be given to the records and reports of an M.D. psychiatrist or Ph.D. psychologist. Depression does not usually negate the existence of other underlying impairments but instead confirms the severity of their impact. On occasion, this diagnosis provides an alternative theory for an Administrative Law Judge who wishes to award benefits but will not approve a claim based on CFS or Fibromyalgia.

#### The Application Process

There are multiple levels of review of an application filed under the Social Security Act. In an effort to increase productivity, and decrease processing time, the Social Security Administration is testing different review models across the country. This article will describe the basic system which is still in place throughout most of the United States.

A claim is initiated by filing an application. This can be done over the telephone, on SSA's web site at www.ssa.gov (for SSDI claims only) or, preferably, in person at the local Social Security Administration District Office. The application will require a list of all of the jobs performed during the last 15 years, a list of all medical providers, a list of current medications, names and dates of all prior marriages and divorces, and a copy of the Claimant's birth certificate. Generally our practice is to recommend as much be done with Social Security face to face at the District Offices - this decreases the chance for errors. At the time of this writing, only SSDI claims can be filed over SSA's web site.

After the application is filed, the Social Security Administration will send the file to a Disability Determination Service (DDS) administered by that State. Each state has a contract with SSA to perform the first two levels of review. At the DDS the file will be assigned to an adjudicator who will be responsible for gathering medical documentation, getting any additional information from the Claimant, arranging for consultative examinations and obtaining medical and vocational opinions from the DDS's internal experts. A written decision is issued in about 90 days on average, although the time frame can vary widely. Historically only about 36% of claims are paid at this level.

If denied, the second step is the filing of a Request for Reconsideration at the SSA District Office. A Claimant is allowed 60 days from the date of the initial denial to file this appeal, although there is usually little to gain by waiting. The Request for Reconsideration is also processed by the state DDS. Historically only about 17% of claims are approved at this level and SSA is testing

elimination of this step.

The third level of review, for those claims denied at Reconsideration, is the hearing before the Administrative Law Judge (ALJ). These are informal administrative hearings held before independent judges who hear testimony, review the medical records and issue written decisions. While progress had been made in reducing the backlog in setting hearing dates, the delays have been increasing once more. Time frames vary widely across the nation, many hearing offices now take at least twelve months from the date the Request for Hearing is filed to set a hearing date.

The hearing is critical to the review process because it is the only time that a Claimant has the opportunity to see, and talk to, the decision maker. Up until this time all decisions are based upon paper, i.e. medical reports and written questionnaires. This is the only time in the process where the decision maker gets to see and question the Claimant. That face to face observation is critical and in this author's experience is one of the factors causing ALJs to reverse many reconsideration denials.

While all Social Security cases first focus on medical proof, the testimony at an administrative law judge hearing may tip the scale in favor of a sympathetic and credible Claimant. It is important that a Claimant fully explain the limitations and the effects of the disease on their daily activities. Testimony, which is consistent with the medical evidence and credible, can persuade a Social Security judge to award benefits in a claim based upon Fibromyalgia or CFS.

The final two steps in the review process are the Appeals Council, and if unsuccessful, the United States District Court. These reviews are primarily based upon the medical evidence and testimony from the ALJ hearing. Since there is no additional testimony, and very little additional medical evidence can be supplied, these two levels of review are helpful in only a small percentage of claims. The backlog at the Appeals Council is now almost two years.

NOTE: SSA has begun testing different application processes in different parts of the nation. Some Claimants will not have a reconsideration stage; some will not have Appeals Council review. All Claimants will have an opportunity for an Administrative Law Judge hearing.

#### Representation

This Social Security disability application and appeals process was designed so that Claimants are not required to obtain representation. However, people with representation have much higher success rates. Familiarity with SSA's Regulations, Rulings, the federal caselaw interpreting the Act, and with SSA's internal guidelines called the POMS and HALLEX, help guide preparation of a claim. Representatives do not have to be licensed attorneys and there are paralegals and other non-attorneys who do provide representation.

This author's strong preference is to become involved in a claim as early in the process as possible. The earlier a Claimant understands the issues in her particular situation, and the earlier the review of the existing available medical proof, the greater the chance the assistance will be granted at some point in the process. In addition, care needs to be exercised in the completion of many of the early questionnaires sent by the DDS adjudicators - many answers on these forms end up being

twisted and serving as the basis for denials by adjudicators and ALJs.

Almost all attorneys who focus in this area of the law will agree to representation on a contingency fee basis - that means that fees are only awarded in the event of a favorable outcome. In addition, the Social Security Administration always retains the right to review attorney fees.

#### Conclusion

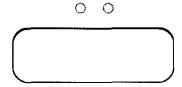
Many claims for SSDI and SSI benefits are approved for persons with <u>Fibromyalgia and Chronic Fatigue Syndrome</u>. Claimants must have the support of their treating specialists - especially the rheumatologist and/or pain specialist and must maintain good communication regarding their symptoms and limitations. If depression has become an issue then treatment with either a Ph.D. psychologist or M.D. psychiatrist is important. The earlier a Claimant obtains experienced representation the greater the chance for success, and the less stressful the battle through the various levels of appeal and review. Perseverance will prevail and disabled persons can obtain this much needed assistance.

Nothing in this article is intended to be specific legal advice or to create an actual or implied attorney-client relationship. This article has been a brief summary of the basic law and persons seeking benefits should contact experienced representatives for advice upon which they can rely. Hopefully, however, this brief analysis will provide some insight into the disability system.

Article provided by Jeffrey A. Rabin & Assoc - Visit us at www.rabinsslaw.com

## Social Security Benefits

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#### **Comments and Discussion:**



**Have Your Say:** We welcome relevant discussions, advice, criticism and your unique insights. To ask a specific question see our <u>Disability Q&A Community</u>. All comments are moderated and will not appear until approved. NOTE: We do not verify any information posted in the comment section.