

Declaration on the 40th ECDD Conference 2018 in Geneva

Why cannabis must be taken from the 1961 Single Convention

Presented by

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by Christoph Rossner

The first International Conference on Health Promotion adopted a Charter in Ottawa on 21 November 1986. It thus calls for active action to achieve the goal of "health for all" by the year 2000 and beyond. This goal can only be achieved by mankind if the hemp plants *Cannabis sativa L.*, *Cannabis Indica* and *Cannabis Ruderalis* are put on an equal footing with all other nutrient and crop plants.

The international ban on hemp, which was implemented during the 1st and 2nd opium conferences and the Single Convention of 1961, must finally be lifted in the health interests of the entire world population. The goal of humanity and the WHO must be to develop a symbiotic and nature-compatible way of life in order to achieve the long-term use of our planet's natural resources by the beings living on it.

Hemp offers the cost-effective possibility to realize a medicine with few side effects for everyone, which is cost and energy efficient due to its production method. Hemp provides relief and healing from depression, pain, cancer, asthma and many other diseases, and is both food and energy. Hemp can be used to produce 80% of all petroleum products in an ecological way without poisoning groundwater and polluting the seas.

80 years ago, the founders of the oil industry had a very great economic interest in banning hemp. As a life-threatening result of this lobbying we have a CO₂ pollution of our atmosphere, a resulting greenhouse gas effect and the pollution of the seas with non-degradable, petroleum-based microplastics; the health of the entire world population is thus endangered by the hemp ban. The same applies to the pharmaceutical industry, 80 years ago 80% of all medicines and remedies on the market were based on hemp. However, these drugs with few side effects disappeared from the market in the course of the condemnation by the Single Convention of 1961 and were partially replaced by significantly more problematic substances, such as opiates. The current "opiate epidemic" in the USA is also at the expense of the devastating effect of the cannabis ban (source:

<https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>).

The reduction of CO₂ through coupled combined heat and power plants, which generate electricity and heat with biodiesel produced from hemp, is another important use of hemp, whose research and further development is currently being hindered. This form of energy production has a thermo-electric efficiency of 93%, which means that with this form of energy production we can directly convert 93% of the biomass carbon used into energy, actively removing CO₂ from our atmosphere while generating electricity, water and heat (see appendix). With this method it would be possible to give mankind a realizable, long-term and ecological perspective for the future.

It is due to the international ban on hemp, which makes its research and exploitation almost impossible for an enormous scientific and technological backlog to exist worldwide (see appendix: Model project "Cannabis as Medicine" from Prof. Dr. phil. habil. Gundula Barsch).

This plant must be removed immediately from the 1961 Single Convention.

Erklärung zur 40. ECDD Konferenz 2018 in Genf
Warum Cannabis aus der Single Convention von 1961 entnommen werden muss

von Christoph Rossner

Die erste Internationale Konferenz zur Gesundheitsförderung hat am 21. November 1986 in Ottawa eine Charta verabschiedet. Sie ruft damit auf zu aktivem Handeln für das Ziel „Gesundheit für alle“ bis zum Jahr 2000 und darüber hinaus. Dieses Ziel ist für die Menschheit nur erreichbar, wenn die Hanfpflanzen *Cannabis sativa* L., *Cannabis Indica* und *Cannabis Ruderalis* wieder allen anderen Nähr- und Nutzpflanzen gleichgestellt werden.

Das internationale Verbot von Hanf, das im Rahmen der 1. bzw. 2. Opiumkonferenz und der Single Convention von 1961 durchgesetzt wurde, muss endlich im Gesundheitsinteresse der gesamten Weltbevölkerung aufgehoben werden. Das Ziel der Menschheit und der WHO muss es sein, eine symbiotische und naturverträgliche Lebensweise zu entwickeln, um auf lange Sicht eine Nutzung der natürlichen Ressourcen unseres Planeten durch die darauf lebenden Lebewesen erreichen zu können.

Hanf bietet die kostengünstige Möglichkeit, eine nebenwirkungsarme Medizin für alle zu realisieren, die aufgrund ihrer Herstellungsweise kosten- und energieeffizient ist. Hanf ermöglicht Linderung und Heilung von Depression, Schmerz und Krebs genauso wie von Asthma und vielen anderen Erkrankungen, ist Nahrungsmittel und Energieträger zugleich. Mit Hanf können 80% aller Erdölprodukte auf ökologische Weise hergestellt werden, ohne eine Vergiftung von Grundwasser und eine Verschmutzung der Meere in Kauf zu nehmen.

Die Begründer der Erdölindustrie hatten vor 80 Jahren ein sehr großes wirtschaftliches Interesse daran, Hanf zu verbieten. Als lebensbedrohliches Ergebnis dieser Lobbyarbeit haben wir eine CO₂ Belastung unserer Atmosphäre, einen daraus resultierenden Treibhausgaseneffekt und die Belastung der Meere mit nicht abbaubarem, auf Erdöl basierendem Mikroplastik zu verbuchen; die Gesundheit der gesamten Weltbevölkerung ist somit durch das Hanfverbot gefährdet. Gleiches gilt für die Pharmaindustrie, noch vor 80 Jahren basierten 80% aller auf dem Markt befindlichen Medikamente und Heilmittel auf Hanf. Diese nebenwirkungsarmen Medikamente verschwanden jedoch im Zuge der Verdammung durch die Single Convention von 1961 vom Markt und wurden teilweise durch deutlich problematischere Stoffe, wie z.B. Opiate, ersetzt. So geht auch die aktuelle "Opiat-Epidemie" in den USA zu Lasten der verheerenden Wirkung des Cannabisverbots (Quelle: <https://www.drugabuse.gov/drugs-abuse/opioids/opioid-overdose-crisis>).

Die CO₂-Reduktion durch gekoppelte Blockheizkraftwerke, die mit aus Hanf produziertem Biodiesel Strom und Wärme erzeugen, stellt eine weitere wichtige Nutzungsmöglichkeit von Hanf dar, deren Erforschung und Weiterentwicklung aktuell behindert wird. Diese Form der Energieerzeugung hat einen thermo-elektrischen Wirkungsgrad von 93 %, was bedeutet, dass wir mit dieser Form der Energieerzeugung 93% des eingesetzten Biomassenkohlenstoffs direkt zu Energie umwandeln und unsere Atmosphäre dabei aktiv von CO₂ befreien können, während wir Strom, Wasser und Wärme erzeugen (siehe Anhang). Mit dieser Methode wäre es möglich, der Menschheit eine realisierbare, langfristige und ökologische Zukunftsperspektive zu geben.

Es ist dem internationalen Verbot von Hanf geschuldet, welches seine Erforschung und Nutzbarmachung fast unmöglich macht, dass weltweit ein enormer wissenschaftlicher und

nd technologischer Rückstand besteht (siehe Anhang: Model project "Cannabis as Medicine" von Prof. Dr. phil. habil. Gundula Barsch).

Diese Pflanze muss sofort aus der Single Convention von 1961 entnommen werden.

Memmingen, den 28.05.2018

Biotechnological process for energy production and long-term binding of CO₂ from the atmosphere

by Christoph Rossner

Introduction:

Reducing greenhouse gases is one way of positively influencing climate change in our atmosphere. A frequent greenhouse gas is carbon dioxide (CO₂), which is produced by thermal combustion. Since people all over the planet use thermal burns with CO₂ emissions, the best approach to reducing the greenhouse gas CO₂ is possible.

Problem solving:

In order to solve the problem of energy supply sustainably, it is necessary to use a process that generates heat and electricity, but at the same time reduces and binds the amount of harmful CO₂ produced in the long term. In order to achieve this, a biotechnological process must be used, since a process based purely on industrial and technical processes cannot be implemented for energy-related reasons. Phytology and biotechnology can be used to derive the greatest possible energy benefits from the metabolic energy storage of crops.

Claim of the invention:

Previous biotechnological processes for the production of heat and electricity from biomass have a CO₂ release, which corresponds to a zero-sum due to the biological cycle, but do not lead to a reduction of CO₂.

Our process makes it possible:

1. generation of electrical and thermal energy with a simultaneous long-term binding of CO₂ by a closed process in which plant constituents (e. g. hemp) are gasified, charred and used as a long-term energy carrier by pyrolysis and, bonded in gypsum, bind CO₂ as a building material in the long term.
2. production of petroleum substitutes and water.
3. manufacture of composite panels.
4. long-term detoxification of contaminated and contaminated soils.
5. production of bitumen and tar compounds.
6. production of hemp raw extract as starting material for medical and cosmetic products

Description:

The process is characterized by the fact that conventional, state-of-the-art methods are used in a chain in order to achieve the most sustainable result possible.

1. contractually bound farmers or agricultural enterprises grow specially cultivated plants (e. g. hemp) that produce biomass and thus bind CO₂ through their growth.
2. the plant material thus obtained is harvested and fed to a pyrolysis plant which thermally decomposes the plant material into its components. This results in a "wood gas", which contains water vapor and hydrocarbon compounds and pure carbon molecules in solid carbon form.

Part of the "wood gas" is converted to thermal and electrical energy in a turbine to operate the plant. The surplus is fed into the public grid as district heating and electricity.

The other part of the produced wood gas is also used by a condenser and heat exchanger to supply the energy generated during cooling to the district heating network. The condensate from water and hydrocarbon compounds is fed into a separation process to separate the carbon compounds, such as ethanol, from the water.

The solid carbon compounds, which remain in the form of charcoal after the gasification process of the plant material, are a high-quality energy source and can be stored well. This enables this energy generation system to deliver constant thermal and electrical power regardless of the season, unlike finite fossil fuels or nuclear, wind or solar energy, whose weaknesses are known.

6. the thermal utilization of wood gas and charcoal produces SO₂ and CO₂, which are converted into gypsum by a reduction process using lime. 90% of the CO₂ produced is absorbed and can now store CO₂ in the form of building materials in the long term.

7. contaminated and contaminated soils can be decontaminated with hemp, which in turn requires thermal disposal of the plants used, all this can be implemented by our system.

As hemp is one of the fastest growing plants and yields four times more biomass than a comparable piece of forest, this plant is best suited for our project.

Example of a 3-gigawatt system:

In order to build a plant with an annual output of 3 gigawatts, a cultivation area of 500 ha of hemp fiber is required. The tonnage produced here per hectare would be 10 tons of biomass, from which only the carbon produced has a mass of 2 t/ha. The amount of solid carbon produced on this area is 1000 t. The thermal energy of this carbon alone is equivalent to 2.5 gigawatts.

Model project "Cannabis as Medicine".

Problem definition

Cannabis is a useful and medicinal plant that has accompanied mankind for thousands of years (cf. Völger, von Weck 1982). The very different reports of the use of cannabis as a medical and medicinal plant, which can be found regularly even in Central Europe, are also as old (cf. Frankhausen 2001). However, the imputation of cannabis under international drug agreements and national laws on narcotic drugs has resulted in the loss of much of the knowledge about the special mechanisms of action of the cannabis plant in the 20th century and only selected small research centres were able and willing to continue research into the various applications of cannabis for a longer period of time. This has also been brought to a standstill by prohibition (ibid.), but is currently experiencing a new upswing in a number of countries in which cannabis is accessible at least as medicine.

Against the background of emerging neurological and pharmacological research, efforts were made in the 1960s to uncover the secret of the psychoactive part of the plant. It is therefore known that the effect of cannabis results from the interaction of more than 100 cannabinoids and over 120 terpenoids (cf. Grotenhermen 2018, p. 660, Kleiber, Kovar 1998). After Delta-9-tetrahydrocannabinol was identified as the active ingredient involved in the hallucinogenic effect of cannabis, it was quickly produced artificially in the laboratory. However, after the development of a corresponding THC-containing monocompound for the treatment of AIDS Wasting syndromes and for the reduction of side effects of cancer chemotherapy (dronabinol under the brand name Marinol®), research interest in cannabis dried up again.

As things stand today, it can be said that cannabis is one of the oldest cultivated plants, but in its chemical structure it is one of the relatively little researched substances (cf. Russo 2011). Many of the individual ingredients are known. Depending on demand, however, the interest is repeatedly directed towards other individual cannabinoids (currently e.g. cannabidiol (CBD), which can be used to circumvent the narcotics regulations relating to cannabis as a plant. This usually with the aim of being able to legally benefit from at least some positive effects of cannabis.

However, a scientific approach to the plant active ingredient complex of cannabis as a whole is missing and the respective complex effect spectra resulting from the interactions of the different plant components can be located. This involves the precise analysis of the genus and its characteristics as well as the pharmacological profiles of its secondary metabolites, in particular terpenoids and cannabinoids. For example, the question of how the different cannabinoids interact with each other, the significance of which terpenoids and which other plant components have to be considered for certain modes of action (entourage effects) remains unanswered so far.

Anonymous surveys among patients using cannabis as medicine (Barsch/Schmid 2018, Schnelle et al. 1999, Barsch 1996), but also case reports from the practice of medical treatment underline that many patient needs cannot be met with THC-containing monocompounds and that they are often not accepted by the patients because of their effects which are perceived as much too interfering. Rather, patients switch, if possible, to offers on the black market, although they have to expose themselves there to the possibilities of criminal prosecution, insecure care structures and often intransparent material qualities.

Under these circumstances, the careful search for very specific pharmacological profiles of cannabis, depending on the goal of self-medication, also becomes a challenge for those affected. Obviously, a wealth of experience has long developed, which underlines that the potential of cannabis as a medicine can only be tapped if a suitable pharmacological variety can be used in accordance with the individual needs of the patients. The experience of many years of cannabis patients underlines that if the wrong choice is made, not only no effects occur, but sometimes even negative effects can be triggered.

Against this background, the interdisciplinary research project outlined here assumes that further dissecting pharmacological research on individual components of cannabis is only partially suitable to comprehensively develop the potentials that cannabis can have as medicine. Rather, the aim is to gain more insight into cannabis as a multi-substance mixture with a wealth of synergisms and antagonisms of secondary metabolites. As a result, it is intended to develop and provide complex agents with different varieties of pharmacological profiles in different forms of application and use, which are made available for the treatment of very different disease and/or disease patterns. This is an extremely demanding task to which international research has not yet made any comprehensive contributions (cf. Raab 2017, p. 42).

Social relevance of questions

Despite decades of prohibition, knowledge of the potential of cannabis as a cure for diseases, as complementary support for school medical treatment and as a helpful recourse in the management of sufferings has obviously never been completely lost in certain sections of the population. Since the 1990s, social science research has repeatedly found evidence that patients and sufferers have rated the benefit of managing their difficult life situation as so high that they themselves take on criminal prosecution, stigmatisation in their social environment and unpredictable procurement problems in order to obtain this aid (Barsch/Schmid 2018, Schnelle et al. 1999, Barsch 1996). Recent empirical studies suggest that the dark field of self-medication with cannabis is also far greater in Germany than assumed by scientific and political estimates (Barsch/Schmid 2018). This is also supported by the surprisingly strong increase in demand for a prescription for cannabis: According to a survey by the Rheinische Post among large health insurance companies (Techniker Krankenkasse, AOK-Bundesverband, Barmer), by the beginning of 2018 13,000 patients had already been registered who strove for cannabis-supported treatment (status 10.01.2018) (see Ihme 2018); more than 20,000 applications can already be assumed for spring 2018.

Organised nationally and internationally through self-help groups, these people have been trying for decades to give themselves an official voice and demand political action. Since 10 March 2017, the law on cannabis as medicine has opened a framework that underlines the legitimacy of recourse to cannabis in coping with conditions of disease and suffering and encourages those affected to make appropriate demands.

The number of those who are already implementing a corresponding practice for dealing with their conditions of suffering without extensive information on the potential of cannabis as medicine can only be estimated: After all, by the time the law on cannabis as medicine was passed in March 2017, nearly 1,000 people had obtained official treatment with cannabis against major hurdles. These can only be seen as the peak of the iceberg. This is due to the fact that enormous hurdles are currently being placed in the way of making use of the possibilities granted by law. For example, cost absorption by the health insurance funds has so far been rather restrictive: for the 3,200 applications submitted to the Techniker Krankenkasse by the end of 2017 and for the 7,600 applications submitted to the AOK funds, the approval rate was only around 64%, and of the 3,200 applications submitted to Barmer, only 62% were approved (see Ihme 2018). In this respect, it must be assumed that these official case figures continue to represent only one extreme area.

If the freely available information on the potential of cannabis as a tool for coping with very different conditions of illness and suffering continues to be published via the Internet, it is to be expected that other population groups (including populous groups such as the elderly, dementia patients, cancer patients, people in need of care) will also articulate and fight for corresponding needs. The demand originally estimated by the law "Cannabis as Medicine" of just under 700 patients per year who need cannabis on prescription has been enormously underestimated in this respect.

In order to assess the social relevance of high-quality medical care, which can fall back on different pharmacological varieties, a look to Israel is encouraging:

In Israel, with a population of 8 million, 30,000 medically based users of cannabis have been registered as medicine since the regulated release of cannabis. Transferred to Germany with its approx. 80 million inhabitants, a user group of 300,000 patients could be predicted in the future. The validity of this forecast is underlined by the developments made by the Deutsches Arzneiprüfungsinstitut e. V. (German Drug Testing Institute). (DAPI) can be used: Overall, pharmacies sold around 44,000 units of cannabis blossoms in 2017 at the expense of the statutory health insurance system (GKV): "The trend was rising from quarter to quarter, both for prescriptions and for dispensing units" (cf. ABDA - Bundesvereinigung Deutscher Apothekerverbände e. V. 2018). According to evaluations of the GKV regulations by the DAPI, pharmacies supplied 488 prescriptions with 564 dispensing units in the 1st quarter 2017, i.e. from 10 to 31 March; 4615 prescriptions with 10,055 dispensing units in the 2nd quarter, 8,898 prescriptions with 14,777 dispensing units in the 3rd quarter and 12,717 prescriptions with 18,828 dispensing units in the 4th quarter. Orders on private prescriptions have not been entered by the DAPI (ibid.).

For cannabis complex drugs, which are available in different pharmacological varieties and diversified forms of application and hence can also be helpful in less dramatic situations of suffering and not only for palliative purposes and can help to improve the quality of life, more and more applications can be opened up, which on the one hand increase the need for cannabis complex drugs in different varieties, but on the other hand can also be suitable for reducing expenditure in the areas of care, medical care and drug treatment.

Current state of research (international, national)

The international and national state of research on the differences, potentials and patterns of action of the medical application of plant cannabinoids in the form of a complexing agent that unfolds its effect from its multi-substance mixture and monocompounds in which individual cannabinoids have been extracted and/or synthetically produced is extremely low (cf. Chen, 2017). Even less insight is available into the effects that can be achieved with a complexing agent versus a monocompound in the treatment of certain conditions of illness and suffering (ibid.). This is probably also the reason why most international cannabis research institutes have declared these questions to be their central research focus (see chapter "International role models). The scientific opinions on the phytocannabinoid-terpenoid entourage effects are very controversial: In the few available studies only very small differences between the effect of marinol and phytocannabinoid complex agents could be emphasized and deny the existence of the entourage effect and discard the available evidence from the experience-based cannabis folk medicine cf. Chen 2017). Other analyses, on the other hand, allow the conclusion that monocompounds do not use essential potentials of cannabis in the treatment and management of disease and suffering (cf. Russo 2010, Grof 2018).

Against this background, an insufficient level of plant scientific, biochemical, agricultural and medical-pharmacological knowledge and a lack of research efforts to date must be recorded for the precise analysis of the genus and its characteristics as well as the pharmacological profiles of its secondary metabolites, in particular terpenoids and cannabinoids. As a tragic consequence, it appears that, in view of this current lack of knowledge, any demand for evidence-based medical use of cannabis cannot be met. The same applies to the development of this old cultivated plant within the framework of the socially targeted

bioeconomic turnaround. This is where the presented research project with its interdisciplinary approach comes in.

Content of the solution approach

The approach of this research project is based on the assessment that the previous research gaps can only be closed within the framework of a systematic, interdisciplinary cooperation in which very different scientific disciplines work together. Taking up the social pressure in connection with the establishment of a solid evidence-based treatment and care of patients with precisely fitting Cannabispharma profiles, the core objective of this project is to pave the way for the establishment of own care structures for the medicinal use of Cannabis in Germany. Efforts are required in research and development to secure the supply of medicinal cannabis in the required quantities, qualities and dosage forms continuously and cost-effectively from our own resources. Also due to the lack of basic botanical, agricultural and biochemical knowledge, cannabis and its products are currently not available in the required variety, quality, quantity, in differentiated pharmacological profiles and dosage forms.

With this research policy objective, the focal points of research and development are, firstly, interrelated as individual modules of an overall project, in which, secondly, none of the research priorities mentioned can be dispensed with when it comes to the rapid creation of the basis for precisely fitting care for those affected, but thirdly, the desired interdisciplinary work should be implemented in a complex and interrelated manner. The complexity of the interdisciplinary cannabis research outlined here also opens up the opportunity to establish and build up an efficient research network from which centres of excellence and references for Europe and beyond can be developed.

The main research modules of the presented project include:

- **Systematic research in plant biochemistry and pharmacy:** The medical-clinical research should be prepared and accompanied by systematic biochemical research work, which builds on existing preliminary work but still leaves many questions open. The central goal is to identify the secondary metabolites (including terpenoids and cannabinoids) of cannabis genotypes used in medical applications, to decipher their mechanisms of formation and action, including their mutual interaction in different concentration ratios, and to develop efficient methods for the isolation or biotechnological synthesis of medically required active substances. In cooperation with medical partners, it should also be investigated to what extent synthetic modifications of natural substances can exclude or reduce undesirable side effects within the scope of their medical application. Furthermore, the findings will be used as a basis to examine which further options for the utilisation of cannabis could be investigated and, if necessary, developed.
- **Systematic research on chemistry and biochemistry,** with the aim of studying the exact composition of the metabolome of hemp trichomes (= quantitative description of all natural substances in the gland organ of hemp as complete as possible). It seems realistic that the detection of intermediates of the terpene and polyketide precursors and the more complex immediate precursors of cannabinoid synthesis will allow deep insights into the material flows and regulation of the metabolic pathway depending on the genetic background of the approximately 100 cannabis lines studied. In comparison with the different cannabis lines, these data will generally establish a completely new basis for understanding the biosynthesis processes of hemp trichomes. This is of great relevance because the effect of cannabinoids can be

enhanced by the presence of other secondary substances, especially terpenes. However, the exact combinations and mechanisms of action of these synergisms are as yet unknown. The complex metabolite composition of hemp trichomes can later be correlated with the bioactivities and therapeutic effects of the corresponding hemp preparations in clinical application in order to enable the most tailor-made patient-oriented therapy possible with cannabis preparations in the future.

- **Systematic plant research, development and advice on the location-independent cultivation of cannabis through creation of cultivation standards** (using the same cultivation methods for reproducible data). This raises the following detailed questions:
 - Exploration/phenotyping of cannabis through the use of standardised computer-controlled cultivation methods (research approaches differentiated with regard to light, climate, plants, nutrient solution, development of a plant substrate optimized for hemp). How and under which conditions it is possible to obtain cannabis varieties with well-standardised complex multi-substance mixtures using modern IT-supported methods and thus meet the requirements of medical use is to be worked out.
 - Implementation of an ISO-certified cultivation process including supply chain management using ERP software with interface to hardware.
 - Development of a data standard for storage & provision (downloads) of "cultivation files" for cultivation methods and reproducible breeding conditions (sharing of "cultivation programs" via downloadable file).
- **Systematic biological and biotechnological research** the development and conversion of cannabis flower ingredients by fermentation (drying) with a focus on the determination of areas of influence on various cannabinoids (including cannabidiol) and terpenes. This includes research on stabilizing cannabinoid ingredients (including THC, CBD, terpenes) in dried cannabis flowers by combining cultivation methods and manipulating genetic characteristics.
- **Engineer-scientific development of dispersing, homogenizing and high-speed mixing solutions by using the ultra-high-speed rotor/stator technology.** This enables the mechanical disruption of the hemp plant into its components, graded down to the smallest nanoparticles. This technique provides the basis for plant research by optimizing the disintegration for subsequent extraction and analysis on one hand, but also for the production of subsequent products both in the phytopharmaceuticals, phytocosmetics and the food and dietary supplement industry. With this technology it is possible to manufacture products that not only enable very different applications (e.g. oils, emulsions, pastes, ointments) but also - by maximizing the surface area during processing - the bioavailability of the active ingredients can be planned and controlled more systematically.
- **Systematic chemical-analytical research and development for the analytical evaluation of existing and future medical products.**

The chemical and pharmacological complexity of herbal cannabis preparations presents a challenge to pharmaceutical standardization and requires a variety of methods for characterizing the starting material and the rapid development of appropriate expertise and research and development capacities. In the application

and optimization of the developed analytical methods, the well characterized, already existing medicinal hemp products could be used as a reference standard to confirm developed methods and to evaluate the detected compositions analytically. Further means based on cannabis extract for coping with disease and suffering, which arise in the course of the research project and are standardized to a fixed content of the multi-substance spectrum, are to be included in the spectroscopic and chromatographic investigations. To ensure valid results of physicochemical and analytical-chemical measurements, it is essential to set up a certified test laboratory for cannabis research, for the analysis of which chromatographic measurement methods are particularly suitable. Accreditation as a certified laboratory ensures the usability of the results for approval procedures in medical products and on the one hand requires and also provides precise documentation of all process steps as well as laboratory equipment with optimally maintained and controlled measuring instruments at all times and qualified training and further education for the staff employed in the laboratory.

- **Systematic biomathematical research on the correlations of effect and chemoprofile.**

Due to the numerous varieties of the different cannabis cultures and their extracts, a correlation of the ingredients contained and the expected effect is indispensable for the development of possible applications in the medical sector.

The starting point for this are precisely defined cultures and the creation of complete chemo profiles. These information must be brought together with the therapeutic results of the identical samples of the medical cooperation partners working in the joint project, as well as with the growth conditions, and be correlated mathematically in order to gain a comprehensive understanding of the interaction of cannabinoids and the additional ingredients effective as mediators, e.g. terpenes. The aim is to create a comprehensive matrix of effects, side effects, stability, dosage forms, chemical compositions and polymorphic forms that will lead to an expanded understanding and facilitation of the approval process of new and optimized products.

- **Systematic, multi-centred and broad-based research on cannabis as medicine,** to develop the chances and potentials of cannabis as medicine in the treatment of various, often chronic diseases and thus helping the cannabis medicine to become a recognised healing method, from which above all an aging, mostly multimorbid and often chronically ailing population benefits.

Current reviews of nationally and internationally available medical studies, which comprehensively meet the requirements of evidence-based human medicine, underline that the existing knowledge on the possible applications of cannabis as medicine has considerable gaps. It is already apparent that cannabis obviously offers a broad therapeutic spectrum. However, the current state of science is of limited significance because long-term studies on the clinical use of cannabis are lacking and most existing medical studies do not distinguish between different pharmacological profiles of cannabis (cf. Capris Study Koch 2018). While academic medicine has so far only hesitantly turned to the therapeutic potential of cannabis, a considerable fund of empirical knowledge has developed in the course of self-initiated treatment attempts and self-therapy, which has not been taken up by medical research so far (cf. Barsch 1996, Schelle et. al 1998).

Against the background of this national and international level of knowledge, it is becoming necessary to establish a multi-centre medical research to clarify the therapeutic spectrum of cannabinoid-containing drugs depending on different pharmacological profiles. Considering the special needs of the German population, clinical studies are becoming increasingly important:

- Pain patients, because the number of patients affected and the amount of annual expenditure on pain therapy make the fight against pain a task of national interest (including chronic pain, neuropathic/europahies such as shingles/herpes zoster, syphilis and lyme borreliosis, cancer, rheumatic complaints, multiple sclerosis, musculoskeletal disorders, fibromyalgia, Bekhterev's disease, headaches, migraine, etc.)
 - Patients with musculoskeletal diseases and disorders of the posture and locomotive system, which are the most frequent causes of illnesses (including arthrosis, rheumatoid arthritis, back pain/dorsopathies, osteoporosis)
 - Mental illnesses that contribute significantly to the disease burden of the population (including dementia, addiction, psychotic disorders, schizophrenia, schizophrenia forms of psychosis/schizoprene psychoses, social phobia, post-traumatic stress disorders, anorexia nervosa, Tourette syndrome, anxiety disorders, bipolar disorders, endogenous depression, attention deficit syndrome/ADS, attention deficit hyperactivity syndrome/ADHS)
 - cancer with high incidence of disease and considerable treatment costs (including inhibition of tumor growth, side effects of chemotherapy)
 - visual or hearing impairments that contribute the disease burden of an aging population significantly (e.g. glaucoma, intraocular pressure)
 - Spasticity (multiple sclerosis, paraplegia-associated)
 - antiemetics (nausea, vomiting, appetite stimulation)
 - Various other epidemiologically relevant diseases (including Gastrointestinal disorders/gastrointestinal tract such as Crohn's disease, irritable bowel syndrome, ulitis ulcerosa, neuroflamatory disorders such as arthritis, autoimmune diseases, neurogenerative diseases such as Parkinson's disease, Levo-dopa-induced movement disorders/dyskinesia, neurological disorders such as REM sleep disorders, tremor, bladder weakness in MS, Huntington's chorea, epilepsy, dystonia/ involuntary muscle contractions, primary cervical dystonia, dyskinesia)
 - Central nervous disorders (sedation, dizziness, etc.)
 - Bronchodilation/Asthma.
 - Negative feelings, especially among people in need of nursing care and residents in nursing homes (e.g. bad mood, anxiety, depression, etc.)
 - Development of topical preparations from cannabis for application on afflicted skin.
- **Systematic social scientifically data collection on the empirical knowledge available in the population about self-initiated treatment attempts and self-medications** with the aim of gaining a quicker insight into the therapeutic spectrum of cannabinoid applications and providing promising indications for targeted medical research, so that complex studies with greater accuracy and thus also time savings can follow up the difficult pharmacological-clinical interpretations of the effects of a complex mixture of many substances.

- **Systematic social scientifically accompanying research** of cannabis medicine patients, understood as an extension of clinical medical studies with focus on quality of life, side effects, dealing with stigmata, strategies for dealing with challenges, conflicts, the process of becoming a patient and the interfaces between treatment settings (e.g. needs of practitioners and patients). These include studies to clarify further salutogenic properties of cannabis (e.g. curative introspection, empirical knowledge of surprising side effects in treatments (e.g. eye health and diabetes)).

For all modules of the research project named here, the respective state of research in the respective subject area, the research questions aimed at with the project, the research and development contents derived therefrom including the research methods and the research results to be expected are presented in separate chapters. However, it becomes clear already in this overview that only such interdependent, interdisciplinary, systematic research can meet the upcoming research needs and the already existing time pressure.

Peculiarities of the solution approach

The research project aims to address and implement the necessary complexity of cannabis research through a multidisciplinary and in the best sense interdisciplinary research network. Various practice partners from various fields are already involved in this project, ensuring that research results can also be quickly transferred into practice.

Working in the Researchers' Network

The complex research areas outlined here, which are directly interwoven, require the presence of complex technical equipment and technological processes with a considerable need for acquisition costs for the scientific clarification of basic questions of cannabis research in many areas. The peculiarity of this research project is that, as a rule, the participants of the research network as representatives of renowned research institutes, universities and colleges provide access to basic material and technical-technological prerequisites for the research tasks under consideration. Therefore, a complex and cost-intensive equipment of the outlined cannabis research can be significantly reduced by establishing a research network of such scientific working groups in which both the material-technical prerequisites of the work and the expertise for the upcoming research work already exist or can be acquired in a short time. However, the prerequisite for this is an appropriate content, organizational and financial orientation of the research work. Research management positions that take over the alignment, coordination and interface management of the groups of researchers working together are centrally required for this innovative research process.

These working structures are not only very effective, but highly innovative due to their rather fluent, holacratic character, because they open up the opportunity to realign and bundle capacities again and again, depending on the current state of work and research line, until they are reassembled by the next work priorities.

Working on a complex topic

The research project outlined here is working on a practice-oriented basic research with a main focus on securing a sophisticated, evidence-based medical treatment of states of disease and suffering by providing cannabis preparations initially for medical research in different pharmacological varieties and application possibilities. This will lead to far-reaching consequences for securing the regular supply of high-quality domestic products

to cannabis patients, which will ultimately also be able to take a stand on the international market.

It is already foreseeable that the insights into cannabis as a complex multi-substance drug and its implementation in cultivation, harvest, preparation and production, for example, cannot and should by no means be limited to the urgently needed medical treatment of states of disease and suffering. Furthermore, these research and development lines can be used to derive more far-reaching impulses and interim results that will be important for developments in the context of the bioeconomic transition towards changed energy sources, raw materials and materials, in organic agriculture, food production, consumer goods production, and so on. The practical partners involved in the research network are a guarantee that these additional opportunities for exploitation are also taken into account and implemented. It becomes clear that the research project can be used in parallel to initiate developments with a view to the challenges of the socially desired bioeconomic turnaround, which consequently promote an increased orientation towards the possibilities of the fast-growing plant. The potential of cannabis in its varieties known as useful hemp as a supplier of raw materials and energy is still far from being fully explored in order to replace problematic materials and fossil fuels.

In order not to leave this additional gain in knowledge and its practical usability unused, the following research lines must be seen as belonging to the model project:

- Systematic and broad-based research and development on cannabis as a supplier of raw materials and energy with high potential for a bioeconomic turnaround, with alternative energy production and significant contributions to climate protection.
- systematic and broad-based research and development on the potential of hemp and cannabis products in the consumer goods sector.

Working on a topic of great political significance.

Despite the largely drug-political abstinence of German policy on this topic, access to knowledge about the medical applications of cannabis has been established in the course of digitalization and globalization in the most diverse population groups for a long time. Formerly unseen as "potheads", stigmatized consumers have increasingly stepped into the public eye and are committed to a drug policy turnaround in the handling of cannabis in Germany as well. Meanwhile, several cities and municipalities have submitted applications for pilot projects for a controlled distribution of cannabis.

A look at similar developments in other countries underlines that with the changed accessibility of cannabis as a medicine, the social assessment of this plant is changing fundamentally. It can be assumed that these social developments as a whole trigger a social process that must be understood as a political-cultural shift. This means that destigmatization, non-discrimination and increased multiform use of cannabis will lead to changed empirical experiences and changing attitudes, norms and values in all social milieus, which will also change the practical approach to cannabis in everyday life. This process should not be left to itself, but rather regulated, shaped and co-designed by a variety of scientifically based measures.

Therefore, **political and social scientific research must be located in the presented research network and thus in direct proximity to the latest findings of cannabis research, which provide scientifically based insights into the social developments that will occur with regulation and normalization processes of cannabis and enable reliable policy advice.** It must be ensured that these processes, which can be accompanied with attention and influenced by very different social, educational and health policy measures, are identified with foresight and that possible problems and conflicts are addressed in productive solutions. In this context, the following questions can be outlined, among others:

- At the meso and macro levels, the development and (future) implementation of cannabis policies should be explored. The question would be who are the key policy makers and stakeholders at European, national and local level and what experience is gained with different regulatory policies and cultural frameworks (including concepts, methods of practical implementation such as specialty stores, licenses, supervisory authorities, etc.).
- **Addiction prevention will have to face up to new social conditions in the future:** Recent research suggests that cannabis use has a "trickle-down effect". This means that a certain "new type of cannabis user" is solidifying, which is characterized by the fact that it is increasingly to be found in socially weaker classes. In rich countries, the prevalence of cannabis use is shifting from children and teenagers from wealthy families to socially disadvantaged adolescents. Against this background, the following research approaches are derived:
 - In addition to the determinants of youth risk behavior at the micro level, a stronger focus of research on the meso- and macro level is necessary. So far, there is a lack of studies analyzing the role of political-institutional systems (including tax, economic, educational, youth and health policies) and general norms and values for cannabis use.
 - At the micro level, it is necessary to examine more precise young consumer types (e.g. problematic vs. occasional leisure consumption) along national and local contexts on the basis of socio-economic, social and cultural capital.
- In view of the new social significance of cannabis use as medicine, extensive scientific research is necessary in order to determine a well-founded danger limit value for the area of labor and traffic law, to transfer it into legal practice and finally to popularize it among the population.
- **Research on the impairment of performance and traffic-relevant performance as a function of the THC concentration measured:** So far, according to the supreme court rulings in Germany, a traffic-relevant effect is assumed from a value of 1 ng/ml THC in the blood. According to this, patients who take cannabis blossoms as medication and are therefore always expected to be above a value of 1 ng/ml THC in the blood would not be suitable for driving. This would ultimately mean that cannabis patients would not only have to accept an impairment of their quality of life but would be even more difficult to place on the labor market if driving aptitude were not regarded as given. Therefore, systematic research on the impairment of general and traffic-relevant performance in dependence on the THC concentration in the blood must be used to develop scientifically founded criteria that reliably and objectively work out the possible limitations of performance after cannabis use and thus create a sound basis for expected assessments of driving and other aptitudes.
- **Hangover research:** After excessive consumption of alcohol, there are also consequences beyond the actual period of effect, which are colloquially subsumed under the term "hangover". This means that in many cases the performance in areas which must be assumed for the safe driving of motor vehicles, for the operation of machines or for other performance areas is not given to the required extent. Hangover effects after different forms of cannabis use can also be assumed for cannabis use. Systematic research is needed to determine when, in what time frame,

for which groups of people after the use of which Cannabispharma profiles and in what quantities what hangover effects after cannabis use are to be expected.

- The general developments are directly linked to the emergence of a **completely new industry, the cannabis industry**, which is one of the fastest growing sectors in the USA. This raises fundamental questions about the opportunities and possibilities, problems and conflicts in the development of a cannabis industry, to be addressed through systematic and broad-based research and development. The cooperation with practical partners directly involved in the research project makes it possible, among other things, to clarify the following question complexes from a multi-perspective standpoint in this context:
 - In which way should the emerging markets be designed? Is a public or private awarding authority to be preferred? Is there room for competition between providers? How do you deal with innovations in this market? How to locate the regime in the spectrum between medicine and consumption?
 - Does a state-regulated market affect the number of problematic consumers? How to implement responsible protection of minors? If cannabis use is legalised, one can expect external effects on the health and productivity of users?

Summary

The presented interdisciplinary research network submits a multidisciplinary research project proposal, which consists of the following modules and describes the problem outline, the problem definition, own preliminary work, solution approach, implementation strategies, expected research results, structure and prerequisites of the project:

Cannabis as experience-led folk medicine: Development of a national and international data collection as a fund for medical research, information and further education.

A detailed planning of each module (schedule with sprints and milestones, costs and financial plan) can be submitted at any time..

International role models

Australia

„The Australian Centre for Cannabinoid Clinical and Research Excellence“
(<https://www.australiancannabinoidresearch.com.au/our-research> Access from 05/10/2018)
founded 2017

Funding: 2017-2023 state-funded

Main research topics are:

- Collection of knowledge on cannabis as medicine and transfer to relevant professional groups (including treating physicians)
- Medical research and development of medical cannabis preparations.
- Plant Cultivation and Pharmaceutical Optimization.
- Setting-up a cannabinoid library.

USA

Humboldt interdisciplinary institute for Marijuana research (HIIMR)
(<http://www2.humboldt.edu/hiimr/about.html> last access from 05/10/2018)

Funding: Project-based

On the initiative of individual scientists at Humboldt State University in California, an interdisciplinary cannabis institute was founded for the first time at a university in the USA in 2012.

- Main areas of research are political science and economic studies with the aim of providing evaluation and policy advice in connection with municipal, state and nationwide decisions.

Center of Medical Cannabis Research, Universität von San Diego

(<https://www.cmcr.ucsd.edu> last access from 05/10/2018)

Founded in 2000, this institute focuses on research into the medical applications of cannabis.

Funding: Project-based

Main research topics are therefore:

Clinical and pre-clinical studies on the therapeutic possibilities of cannabinoids, including smoked marijuana and others.

- CBD and Autism.
- Cannabis and endocannabinoids in HIV-induced neuropathic pain.
- Studies on healthy people on the relationship between cannabis use and driving ability.
- Controlled study to compare the efficacy of dronabinol versus vaporized cannabis in the treatment of neuropathic lower back pain.

Institute of Cannabis research, University of Colorado

(<https://www.csupueblo.edu/institute-of-cannabis-research/index.html> last access from 05/10/2018)

Funding: Project-based

In 2016, Dr. Daniele Piomelli, Professor of Anatomy and Neurobiology at the University of Colorado, initiated the establishment of an institute for cannabis research. The basic idea is to bring together research on cannabis in various areas of life, from the environment to criminal justice and culture. The main areas of research are correspondingly diverse:

- Social science research on the possibilities and risks of integrating cannabis use into the everyday life of different age and ethnic groups.
- Medical research on the possibilities and limits of cannabis use in the management of different diseases and states of suffering.
- Pharmacological research to decipher the multi-compound mixture of natural cannabis.
- Economic research in connection with the development of a cannabis industry.
- Genome research on cannabis.
- Development of databases on research on cannabis.
- host of an annual international conference on cannabis research

Great Britain

Research laboratory of the British biotechnology company MediPen in Cradiff.

Funding: Medipen

Start of work in summer 2018 with focus on medical cannabis research. A series of cannabis studies are planned to investigate the medical applications of the various components of hemp.

Research focus is the use of cannabis in the treatment of cancer patients:

- The first cannabis studies will investigate how THC can help with the side effects of chemotherapy.
- However, the investigations will not be limited to alleviating the accompanying symptoms of cancer: there are plans to investigate how cannabinoids can reduce the proliferation of cancer cells and thus curb metastasis.

Israel

In 2017, the Israeli Ministry of Health and Agriculture announced the joint financing of a total of thirteen studies with 2.1 million USD. Its core activity will be the study of medical and biochemical aspects of the use of cannabis. Main research topics are:

- The treatment of multiple sclerosis.
- The effect of cannabis in the treatment of organ transplants.
- The plant's ability to limit the growth of bacteria,

It also addresses:

- The creation of a genetic database on cannabis plants with the aim of promoting the improvement and development of new varieties.
- Improving and simplifying the cultivation of the plant.

Implementation is more likely to take place in research networks. In March 2017, Technion and the Israeli Institute for Cancer Research announced a collaboration on that topic.

Laboratory of Cancer Biology and Cannabinoid Research at the Faculty of Biology of Technion (comparable to a Technical University in Germany)

(<http://dmeiri.net.technion.ac.il/research/> last access from 05/10/2018)

Funding: ?

The following key research topics are:

- The influence of cannabinoids on various carcinomas, epilepsy and glucose metabolism (diabetes).
- Deciphering the metabolism and specific chemical composition of the different types of cannabis plants and their specific pattern of action in the treatment of diseases.
- Development of a database on cannabis patients.

Cannabinoids Research Multidisciplinary Center an der Hebrew University Jerusalem

For more than 50 years, the domain of Prof. Dr. Raphael Mechoulam (Explorer of the delta 9-THC and other cannabinoids)

(<http://cannabinoids.huji.ac.il/book/about> last access 05/10/2018)

Funding: ?

Key research topics are:

- Therapeutic references to the use of cannabinoids in cancer treatment
- Insights into the pharmaceutical relationships of cannabinoids and other secondary plant metabolites.
- The importance of cannabinoid active substance concentrations and the possibilities of demand-oriented placement, e.g. through nanotechnology.
- Cannabinoids and their influence on the immune system.
- Cannabinoids and their influence on inflammation and stress.
- Cannabinoids and their influence on pain.
- Insights into the metabolism of cannabis and its reproduction.
- Cannabinoids in their importance in the neurosciences.
- Basics of plant science

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