

The Community-Based Research of Medical Cannabis;

A Patient-Centered, Public Health Approach

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“Government is a more or less calculated and rational activity, undertaken by a multiplicity of authorities and agencies, employing a variety of techniques and forms of knowledge, that seeks to shape conduct by working through our desires, aspirations, interests and beliefs, for definite but shifting ends and with a diverse set of relatively unpredictable consequences, effects and outcomes.”
(Chen, 2003)

The late 1980s and early 90s were the peak of the HIV/AIDS crisis in America, and there seemed to be little that people could do to keep an entire generation of young men from slowly withering away as a result of what would eventually become known as “AIDS wasting syndrome.” In response to this rapidly expanding epidemic, compassionate community activists in San Francisco established underground medical cannabis dispensaries, offering a safe source of cannabis to those needing it for medical purposes. The success of these dispensaries was one of the factors that led to the development and passage of a state ballot initiative called “Proposition 215” in 1996, making California the first state to allow for the legal medical use and distribution of cannabis in America (Grinspoon, 1999). Since then, over 250 medical cannabis dispensaries have opened up in California, and it is estimated that they currently supply over 200,000 state-authorized patients (Gieringer, 2006). These community-based dispensaries remain the main source of cannabis-based medicines in both Canada and the U.S., and similar organizations have since emerged all over the world.

It has been suggested that with hundreds of thousands of patients legally accessing medical cannabis in California, this therapeutic herb is currently undergoing the largest “open-label” drug trial in the world. This may be the case, but there is one significant problem with the design of this informal trial: as a result of ongoing DEA raids on dispensaries, very little data is being gathered on either the people who chose to use cannabis as a medicine, or on its effects on their health, medical conditions or quality of life. As a researcher, one can’t help but feel that this is a missed opportunity of tragic proportions, and perhaps one of the more deleterious (and intended?) consequences of the federal assaults on medical cannabis patients and those attempting to supply them.

Although police raids on dispensaries have also hampered medical access in Canada, the courts have been quicker to recognize the good work of Canadian compassion clubs. As a result of strong community support and sound legal decisions from the high courts, a few dispensaries have been able to remain in operation despite continued resistance from Health Canada to actually license and regulate these organizations.

There are currently seven well-established dispensaries in Canada providing over 12,000 critically and chronically ill Canadians access to a safe supply of cannabis. Vancouver’s British Columbia Compassion Club Society (BCCCS), the oldest and largest of these organizations, opened in 1997 and now serves over 4000 members. After finding cannabis helpful in addressing the symptoms of hepatitis-C that I’d contracted through a blood transfusion at a younger age, I gave up a career as a school teacher to open Victoria’s Vancouver Island Compassion Society (VICS) in October 1999. The VICS is a non-profit medical cannabis research, advocacy, and supply organization currently

helping over 750 critically and chronically ill Canadians, and we have incorporated much of our experience and understanding of cannabis and its therapeutic properties into an extensive medical cannabis research agenda.

With both the U.S. and Canadian government resisting public and court pressure to increase research and access to medical cannabis, it was our goal to fill some of the knowledge gaps in our own understanding of cannabis and its therapeutic potential. Community-based medical cannabis dispensaries enjoy two distinct advantages over the established drug research community: a) the VICS has hundreds of members willing to share their experiences and to participate in medical cannabis; research and b) we have a high-quality supply of multiple strains of cannabis at our disposal (the lack of such a supply still plagues medical cannabis research in Canada and the U.S., and the monopoly on production enjoyed by our respective federal governments has been challenged in court on both sides of the border).

Our early studies were pragmatic investigations of phenomena that we were noting in the day-to-day business of the VICS. We make a number of strains available to our members, and there was some speculation as to the different effects of the two major sub-species of cannabis: *sativa* and *indica*. In response, I designed a strain/symptom survey asking our members, who were eager to share their experiences, what symptoms they suffered from, and which strains they preferred. It was a very simple experiment with a number of weaknesses, but the data that we collected was interesting nonetheless. The results of the survey suggest that those suffering from pain as a result of their medical conditions lean towards the use of *indicas*, while those suffering from nausea or loss of appetite prefer *sativas*. This proved to be interesting and useful data for the VICS

and its members, as we could now more confidently recommend certain strains for certain symptoms or conditions. However, it wasn't particularly useful to the general public or scientific community unless we could identify what actually differentiated these two species of cannabis. It was with this goal in mind that we developed a relationship with a local laboratory willing to test our cannabis, despite not being licensed to have it in their possession.

Our initial series of laboratory tests was designed to challenge an old theory that either sativa or indica had higher levels of *cannabidiol* (CBD), and this largely explained the different effects of these two cultivars. After sending off dozens of genetically distinct strains for cannabinoid tests that included quantitative assessments of *cannabinol* (CBN), *tetrahydrocannabinolic acid* (THCA), *tetrahydrocannabinol* (THC) and CBD, our results could only lead to one conclusion. Although these strains had widely varying effects on end-users, there was not a significant difference in their THC to CBD ratios. Some plants were stronger than others (higher THC), but none had significantly high levels of CBD. It was then that we recognized what much of the scientific community has come to accept: the different effects of these varied strains could not be attributed to the "major" cannabinoids, and therefore had to be the result of either minor cannabinoids or other chemical constituents in cannabis such as terpenoids or flavanoids, which is what gives cannabis (and foods like fruits and vegetables) their distinct smell and taste. It was recently discovered that some terpenoids, such as *caryophyllene* actually bind with our endogenous receptors, further supporting our initial conclusions (Gertsch, 2007).

As we became more familiar with the world of academic research, it became apparent that unless our protocols and results went through the peer-review process, the

studies we undertook would never be accepted by the scientific community. With this in mind, in 2003 we teamed with Dr. Diana Sylvestre of the University of California, San Francisco to develop a research protocol investigating the success rate of people suffering from Hepatitis C who had used cannabis during treatment. In order to increase the number of participants in this study, we established what would become a long-time research partnership with the BCCCS in Vancouver. Although this particular study was inconclusive, it became the first peer-reviewed medical cannabis research to ever take place in community-based dispensaries.

Our next study began with an email from Rachel Westfall in February 2003. Rachel was a PhD student at the University of Victoria, and wondered about “the possibility of setting up a clinical trial of cannabis therapy for *hyperemesis gravidarum* - severe nausea and vomiting of pregnancy. At this stage, what I'm trying to find out is: (1) whether such a clinical trial could be let up legally (and how), and (2) where a standardized product could be obtained.”

Being fairly familiar with the socio-political realities of medical cannabis research in Canada, I was sorry to inform her that Health Canada would never approve a clinical trial that involved having pregnant women use cannabis, but I did suggest that a well-designed retroactive survey might be able to identify women who had benefited from the use of cannabis to stem the nausea and vomiting often associated with pregnancy. After much work on the design of this survey, we recruited Dr. Patti Janssen from UBC and Rielle Capler from the BCCCS to act as co-investigators, and in November of 2003 we launched the study at the VICS and the BCCCS.

Scientific research, like drug policy reform, requires much determination, and both have taught me tremendous patience. In September 2005 the results of this study were accepted for publication, and in January 2006 our study, *Survey of medicinal cannabis use among childbearing women: Patterns of its use in pregnancy and retroactive self-assessment of its efficacy against ‘morning sickness’* was published in the Journal of Complementary Therapies in Clinical Practice, becoming the first dispensary-based study to ever be published in a peer-reviewed scientific journal. Here's what we found: of the 79 women who filled out our survey who had experienced pregnancy, 51 reported using cannabis while pregnant. Of these, 40 had used cannabis to treat nausea and vomiting, 92% of which rated cannabis as 'extremely effective' or 'effective' at treating their morning sickness. The study concluded that these "findings support the need for further investigations into cannabis therapy for severe nausea and vomiting during pregnancy" (Westfall, 2006).

With the goal of taking our research up a notch, in 2003 I began to design a clinical protocol looking at the use of cannabis to relieve chronic pain. That fall we received a grant from the Marijuana Policy Project to fund the study, which we believed could be done far more quickly and cheaper than similar projects being funded by Health Canada. After a great deal of work and much advice and support from established cannabis researchers, in May of 2004 we submitted the study for peer-review. Following more than 12 months of changes and negotiations with the investigational review board, *A comparison of the effects of smoked whole-plant cannabis of different primary constituent composition, in single patients with chronic pain, using an “n of 1” design* became the first dispensary-based clinical trial to pass ethics review in North America,

and the first high-THC smoked cannabis clinical trial to be approved anywhere in the world. However, like all clinical trials in Canada, it still needed the approval of Health Canada. Unfortunately our ongoing attempts to get this protocol approved by the government have been unsuccessful thus far, largely due to our resistance to using the poor-quality, gamma-irradiated federal cannabis supply (our protocol suggests importing a safe supply from Holland, or licensing the VICS to produce its own supply of research-grade cannabis), and the government's ideological opposition to medical cannabis research and access. This uncompassionate, unscientific approach to medical cannabis is perhaps best exemplified by the Conservative government's fall 2006 decision to cancel all further federal funding for clinical cannabis research, leaving NGOs like the VICS to carry much of the burden.

However, we remain determined as ever to empower Canada's medical cannabis community by involving them in community-based research. For example, since Health Canada has never bothered to poll the 2000+ participants in the federal medical cannabis program in order to better their service delivery, I teamed with Dr. Andy Hathaway to design a research protocol that would do just that. Launched in the spring of 2007, *Quality of Service Assessment of Health Canada's Medical Cannabis Policy and Program* combines a 50 question survey addressing the personal experiences of users in the federal cannabis program with 25 semi-guided interviews, and is funded by a grant from McMaster University. Although we are still analyzing the results of this study, we have received over 100 responses to the survey, and the preliminary data is incredibly revealing. Nearly 72% of respondents are either "totally" or "somewhat" unsatisfied with Canada's federal medical cannabis program, with over 75% ranking the federal cannabis

supply as either a 1 or 2 on a scale of 1-10. The findings of this peer-reviewed research project could prove useful in making progressive changes to this federal policy through consultation and cooperation with Health Canada; or, if necessary, through the courts.

Recent years have seen dispensaries involved in a number of external research projects as well. In 2006, the Canadian AIDS Society (CAS) released a federally-funded report titled *Our Right, Our Choice* which recommended the legalization and regulation of community-based dispensaries in order to improve access to medical cannabis (Canadian AIDS Society, 2006). Lynne Belle-Isle, an epidemiologist who was the principle author of the CAS report, has subsequently co-authored a follow-up paper with Dr. Andy Hathaway (2007) that concluded:

Legal options for securing a safe, affordable supply are limited by overly restrictive regulations. Only a handful of informants were ordering the government supply, and the general perception was that the quality of this product was poor. By 2008 Health Canada intends to phase out the current Licenses to Produce and to distribute medical cannabis solely through pharmacies... Dispensing cannabis in pharmacies with needed information about its use as medicine may meet the needs of some. In addition we suggest that Health Canada continue to issue Licenses to Produce and consider licensing compassion clubs to do the work they now do for the benefit of many (>10,000 Canadians) at the risk of legal prosecution (Canadian AIDS Society, 2006). As well as the provision of a safe supply of cannabis, compassion clubs offer therapeutic knowledge and meet social support needs (Hathaway, 2005) that other supply sources (including pharmacies) do not. Issuing licenses and regulating these clubs is feasible as most share or have begun moving toward a common regulatory model.

The regulatory document these researchers are referring to is *Guidelines for the Community-Based Distribution of Medical Cannabis in Canada*, an amalgamation of operating procedures and best practices from dispensaries all over North America written by myself and Rielle Capler (Capler, 2006). It was released at the 2006 International

Harm Reduction Association conference in Vancouver, and has since been endorsed by over 80% of Canadian clubs, and is being used as a template for the development of state-based regulations in the U.S. In a separate sociological investigation of the patrons of four Canadian dispensaries, Hathaway (2007) found that:

"compassion clubs" outside the law play a vital role in the provision of safe access and therapeutic knowledge about medical marijuana. Operating on the margins of society, these outlets fulfill another purpose in creating a community among persons who are often highly marginalized themselves. Club membership provides a group identity, empowerment, and restorative supports over and above the marijuana use itself. The authors examine the role of compassion clubs in the lives of patients who choose to self-manage their pain and suffering by using marijuana.

These social research projects illustrate the wide range of services provided by community-based dispensaries, which is often much more comprehensive and holistic than the simple distribution of cannabis.

Although federal resistance to medical cannabis has significantly stymied dispensary-based research in the U.S., over the last few years, some dedicated researchers have attempted to tap into the unique experience and research opportunities found in compassion clubs. In 2005, Berkeley PhD student Amanda Reiman completed an intensive study of the services offered at seven California-based dispensaries titled *Cannabis Care: Medical cannabis facilities as health service providers*. In her dissertation, she states that:

... medical cannabis patients have created a system of dispensing medical cannabis that also includes services such as counseling, entertainment and support groups; all important components of coping with chronic illness.... Facilities tended to follow a social model of cannabis care, including allowing patients to use medicine on site and offering social services. This approach has implications

for the creation and maintenance of a continuum of care among bottom-up social and health services agencies.

She then suggests that “bringing medical cannabis and the population who uses it into the social welfare and public health fields begins with conducting research on this emerging health service and its target population”, which will hopefully encourage other U.S.-based researchers to follow her lead.

Another interesting study that focuses on the patrons of California dispensaries is a demographic evaluation of over 4100 medical cannabis users conducted by Dr. Tom O’Connell. The study concluded that “for the majority, cannabis can be seen as an effective anxiolytic/antidepressant, performing as well or better than many currently available pharmaceutical agents prescribed for the same symptoms” (O’Connell, 2007). As a result of continued threats of federal raids by the DEA, the potential harms and benefits of medical cannabis on dispensary patrons remains woefully under-researched in the U.S. However, many remain optimistic that a change in leadership in the 2008 Presidential elections will bring a more compassionate approach to those who benefit from the use of cannabis, and will finally end these unjustifiable attacks on sick and suffering Americans and on the caregivers who risk their freedom to assist them.

Although the future of medical cannabis research remains largely unknown, it is clear that published data reflecting the experiences of thousands of medical users has already highlighted many new applications for cannabis-based therapies., including its potential to reduce the use of other licit and illicit substances such as alcohol, opiates, and stimulants. In a project supported by the Center for Addictions Research of British Columbia, I am currently examining the changes in the use of pharmaceutical opiates and

other substances in 15 new members of the VICS suffering from chronic pain. The goal of this research is to investigate a microcosm of *substitution effect*, a phenomena where the availability of one substance influences the use of another. If population-level theories about cannabis-based *substitution effect* prove to have a measurable impact on individuals with substance abuse problems, this area of research could radically shift the popular perception of cannabis as a *gateway drug* leading to the use of more addictive substances, to that of an *exit drug* helping people control or even end their addiction to potentially more dangerous substances..

Additionally, some newly-published research has caused me to question suggestions of a causal association between cannabis use and the triggering of psychosis and schizophrenia in people with a predisposition for these mental health disorders. There is recent evidence to suggest that some fertilizers used in the production of cannabis may be a risk factor in and of themselves. A recent study comparing the chemical constituents of tobacco and cannabis smoke found high levels of ammonia in the smoke of cannabis produced for Health Canada by Prairie Plant Systems. The researchers attributed this to the use of high-nitrate fertilizers, concluding that “the simplest explanation for the very high levels of ammonia found in marijuana smoke may be that the marijuana used for this study contained more nitrate than the tobacco sample” (Moir, 2007). A large body of research suggests that one of the major symptoms of elevated levels of ammonia in the blood (or hyperammonemia) is psychosis (Enns, 2005; Belanger-Quintana, 2003). Since black-market cannabis cultivation is focused on ever-increasing production yields in order to justify the profit-to-risk ratio, the over-use of fertilizers is the rule rather than the exception. Therefore, any future research into the

physical and mental health risks associated with the use of cannabis should be careful to differentiate between those caused by the cannabis plant and its major chemical constituents, and those associated with fertilizers, pesticides and other products used in its cultivation.

The nearly immeasurable social harms and hypocrisy of the international war on drugs are perhaps best exemplified in the ongoing persecution of the critically and chronically ill who benefit from the use of medical cannabis. The active involvement of patients, cultivators and dispensaries in the planning and implementation of research while under the very real threat of arrest is a truly unique and remarkable community-based social response to drug prohibition. As more cannabis dispensaries move from simple distribution to scientific contribution, society as a whole will benefit from the knowledge, courage and experience of those who risk their own personal freedom to relieve the needless suffering of their fellow citizens.

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