IN SEARCH OF A Viable DISTRIBUTION SYSTEM FOR HAWAII'S MEDICAL MARIJUANA PROGRAM

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FOREWORD

This report was undertaken in response to House Concurrent Resolution No. 152, H.D. 2, 2004. The Bureau was requested to "conduct a study on how medical marijuana plants and products may be procured and distributed to patients registered with Hawaii's medical marijuana program.

During the 2000 Regular Session, the Hawaii Legislature enacted the Medical Use of Marijuana law, codified as Part IX of Chapter 329, Hawaii Revised Statutes. Essentially, the medical use of marijuana by qualified individuals in Hawaii is permitted under certain conditions. However, the law places certain restrictions on the distribution and use of marijuana. This situation is exacerbated by a conflicting general federal prohibition on the use of marijuana, including distribution, for any purposes. This study searches for a viable system within which medical marijuana may be realistically distributed to qualified patients that both complies with state law and satisfies federal restrictions.

Ms. Brooke Evans, Public Policy Graduate Fellow, assisted in the research and writing of this study. Ms. Evans was solely responsible for chapter 3 relating to the federal supply of marijuana for therapeutic use.

Ken H. Takayama
Acting Director

December 2004
FACT SHEET

Ten states, including Hawaii, have adopted medical marijuana laws. These laws allow certain individuals to cultivate and use marijuana for medical purposes. These marijuana users must comply with the respective state's medical marijuana law, including being certified or registered for use due to certain specified medical conditions.

Federal law, however, prohibits the cultivation and any use of marijuana. Particularly nettlesome for users in the ten states that do have medical marijuana laws is the issue of distribution of marijuana.

This study examines various issues including:

- Distinguishing between legal and illegal marijuana use, including enforcement of medical marijuana laws
- Experience of other states in obtaining access to marijuana supplied by the federal government for therapeutic research
- Potential medical marijuana distribution systems
- Other inherent difficulties of compliance with medical marijuana laws including:
  - Acquisition
  - Possession
  - Transport
  - Adequate supply
  - Distribution

Several models of distribution are examined. The national model (as embodied in the Netherlands) is almost impossible to transfer to an individual state. There are almost insurmountable obstacles involving legal, cost, and pharmaceutical issues. The cooperative intra-state model (embodied in several California marijuana cooperatives) appears to be the most promising. Currently, in California, it is working.

In the existing cooperative intra-state model as enacted in California

- Marijuana must not be sold under any circumstances. All marijuana must be grown and distributed free of charge.
- All aspects and provisions of the State's medical use of marijuana law must be strictly complied with.
- Nothing must cross state boundaries. All aspects of the cultivation and use of medical marijuana must remain strictly within the State. All soil, seeds, and any materials and supplies used in cultivating the marijuana must originate and remain within the State.
However, the continuing success of the cooperative intra-state model in California and its implementation in Hawaii depends entirely on the actions of the United States Supreme Court. The Court is currently hearing a case involving such a marijuana cooperative based in California. The Court may throw out the concept of marijuana cooperatives altogether. It may approve it entirely as is. Or it could impose various restrictions that may range from easy to impossible for states to implement. At this point, no one knows what the Supreme Court will do. Consequently, it would seem to be premature and unproductive to draft detailed legislation now to accommodate scenarios that no one can accurately anticipate and that may take on widely divergent forms.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FOREWORD</strong></td>
<td>iii</td>
</tr>
<tr>
<td><strong>FACT SHEET</strong></td>
<td>iv</td>
</tr>
<tr>
<td>1. <strong>INTRODUCTION</strong></td>
<td>1</td>
</tr>
<tr>
<td>H.C.R. No. 152, H.D. 2</td>
<td>1</td>
</tr>
<tr>
<td>Organization of the Study</td>
<td>1</td>
</tr>
<tr>
<td>2. <strong>PROCESSES OR PROCEDURES TO DISTINGUISH BETWEEN MEDICAL AND RECREATIONAL MARIJUANA</strong></td>
<td>2</td>
</tr>
<tr>
<td>Issue Two: &quot;Legal&quot; and &quot;Illegal&quot; Marijuana</td>
<td>2</td>
</tr>
<tr>
<td>Distinction Between Medical and Recreational Marijuana</td>
<td>2</td>
</tr>
<tr>
<td>Definitions in Hawaii Law</td>
<td>2</td>
</tr>
<tr>
<td>Alternative Interpretation of &quot;Processes and Procedures&quot;</td>
<td>3</td>
</tr>
<tr>
<td>3. <strong>EXPERIENCE OF OTHER STATES IN OBTAINING ACCESS TO MARIJUANA SUPPLIED BY THE FEDERAL GOVERNMENT FOR THERAPEUTIC RESEARCH</strong></td>
<td>8</td>
</tr>
<tr>
<td>Issue Three: Federal Supply of Marijuana for Therapeutic Research</td>
<td>8</td>
</tr>
<tr>
<td>Background</td>
<td>8</td>
</tr>
<tr>
<td>Therapeutic Research Programs</td>
<td>8</td>
</tr>
<tr>
<td>Investigational New Drug Compassionate Access Program</td>
<td>9</td>
</tr>
<tr>
<td>State Therapeutic Research Programs</td>
<td>10</td>
</tr>
<tr>
<td>California Center for Medicinal Cannabis Research</td>
<td>11</td>
</tr>
<tr>
<td>4. <strong>DISTRIBUTION MODELS</strong></td>
<td>13</td>
</tr>
<tr>
<td>Issue One: Focus of Study—Distribution System</td>
<td>13</td>
</tr>
<tr>
<td>National Model</td>
<td>13</td>
</tr>
<tr>
<td>Pharmaceutical Obstacle</td>
<td>15</td>
</tr>
<tr>
<td>System-Cost Obstacle</td>
<td>16</td>
</tr>
<tr>
<td>Legal Obstacle</td>
<td>17</td>
</tr>
<tr>
<td>Cooperative Intra-State Model</td>
<td>18</td>
</tr>
<tr>
<td>Case One</td>
<td>18</td>
</tr>
<tr>
<td>Case Two</td>
<td>21</td>
</tr>
<tr>
<td>Other Proposals</td>
<td>23</td>
</tr>
</tbody>
</table>
5. CONCLUSIONS

A Potential Cooperative Intra-State Medical Marijuana Cultivation and Distribution System In Hawaii

Current and Future Compliance Issues and Needed Changes

Possession

Primary Caregiver Responsibilities

Adequate Supply

Transportation, Distribution, and Acquisition

Unresolved Issues

Conclusions

APPENDIX

A. House Concurrent Resolution No. 152, H.D. 2, Regular Session of 2004
Chapter 1

INTRODUCTION

_H.C.R. No. 152, H.D. 2._ H.C.R. No. 152, H.D. 2, 2004 (hereafter "Resolution") -- the measure to which this report responds -- is attached as _Appendix A_. Specifically, the Resolution asks the Bureau to identify:

"(1) Methods by which registered users may access, cultivate, distribute, or purchase marijuana plants or products for medicinal purposes;

(2) Processes or procedures by which state and local agencies have made distinctions between medical (legal) marijuana and recreation (illegal) marijuana; and

(3) Experience of states in obtaining access to marijuana supplied by the federal government for therapeutic research."

The study was to be "…based on information available from other states." The Department of Public Safety was asked to assist the Bureau in the conduct of the study.

**Organization of the Study.** Chapter 2 analyzes and addresses the second issue -- the distinction between "medical" and "recreational" marijuana. Chapter 3 examines the third issue -- states' experiences in obtaining marijuana from the federal government for therapeutic research. Clearly, the issue of primary interest is issue (1) relating to methods of procurement or distribution of medical marijuana. Chapter 4 explores several distribution models. Chapter 5 offers some recommendations for legislative action based on distribution systems.
Chapter 2

PROCESSES OR PROCEDURES TO DISTINGUISH BETWEEN MEDICAL AND RECREATIONAL MARIJUANA

Issue Two: "Legal" and "Illegal" Marijuana. The Resolution asked the Bureau to examine three issues, as detailed in the previous chapter. This chapter deals with one of the two secondary issues -- "processes or procedures by which state and local agencies have made distinctions between medical (legal) marijuana and recreation (illegal) marijuana." Chapter 3 examines another secondary issue -- that of the federal supply of marijuana for therapeutic research. Chapter 4 addresses the primary issue of distribution of marijuana.

Distinction Between Medical and Recreational Marijuana. The question posed by item (2) is ambiguous at best. The "process" or "procedure" that distinguishes between legal and illegal use of marijuana is a legislative one. Electorates in eight states passed "medical marijuana" laws by ballot initiatives.1 In two states, Hawaii and Vermont, the legislatures themselves enacted similar laws. When marijuana use complies with those laws, then its use is legal (medical) within those states. When use does not comply with those laws, then it is illegal, or recreational. Compliance with state law should be the criterion that "state and local agencies" must follow in distinguishing between legal and illegal marijuana use in those states that have enacted "medical marijuana" laws.

On the other hand, there is no federal law that allows the medical use of marijuana nationwide. That is, federal law does not specifically exempt the medical use of marijuana, including its possession and distribution. In fact, federal law generally prohibits distribution, among other things, of marijuana for any use. (See "Federal Supply of Marijuana for Therapeutic Research" below.) This conflict between federal and state law is a major issue. Thus, it is understandable that, in states having medical marijuana laws, state and local agencies may have difficulty at times distinguishing between legal and illegal marijuana use. However, state and local law enforcement agencies should enforce a state's laws even if they are different from federal laws. Barring unusual circumstances, state and local agencies will not have jurisdiction or authority to enforce federal laws, and federal agencies will not be able to enforce state laws for the same reason.

This study assumes that the federal government will not exempt marijuana for medical use and Hawaii will continue to allow it. The issue for Hawaii is what kind of distribution system will comply with both federal and Hawaii law to effectively implement the State's medical marijuana law. This is discussed in chapter 3.

Definitions in Hawaii Law. One difference between legal and illegal use of marijuana (medical vs. recreational) in Hawaii lies in the user's compliance with state law. "Marijuana" itself is defined in section 712-1240, Hawaii Revised Statutes (HRS), under part IV of the Hawaii Penal Code, entitled Offenses Related to Drugs and Intoxicating Compounds, as:

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Any part of the plant (genus) cannabis, whether growing or not, including the seeds and the resin, and every alkaloid, salt, derivative, preparation, compound, or mixture of the plant, its seeds or resin, except that, as used herein, "marijuana" does not include hashish, tetrahydrocannabinol, and any alkaloid, salt, derivative, preparation, compound, or mixture, whether natural or synthesized, of tetrahydrocannabinol.

"Marijuana" is also further defined in section 329-121, HRS, under part IX of the Uniform Controlled Substances Act, entitled Medical Use of Marijuana, which refers to the definition in section 712-1240, HRS, (above) and the definition in section 329-1, HRS, as follows:

"Marijuana" means all parts of the plant (genus) Cannabis whether growing or not; the seeds thereof, the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant, its seeds, or resin. It does not include the mature stalks of the plant, fiber produced from the stalks, oil, or cake made from the seeds of the plant, any other compound, manufacture, salt, derivative, mixture, or preparation of the mature stalks (except the resin extracted therefrom), fiber, oil, or cake, or the sterilized seed of the plant which is incapable of germination.

Under part IX of chapter 329, Hawaii Revised Statutes, "medical use" of marijuana is permitted, as defined in section 329-121, HRS:

"Medical use" means the acquisition, possession, cultivation, use, distribution, or transportation of marijuana or paraphernalia relating to the administration of marijuana to alleviate the symptoms or effects of a qualifying patient's debilitating medical condition. For the purposes of "medical use", the term distribution is limited to the transfer of marijuana and paraphernalia from the primary caregiver to the qualifying patient.

Simply put, in the case of Hawaii, the use of marijuana for medical purposes is legal when used in compliance with state law. "Recreational marijuana" is illegal and its use is never in compliance with state law.

Alternative Interpretation of "Processes and Procedures". To reiterate, item (2) regarding "processes or procedures" used to distinguish between legal and illegal marijuana is ambiguously worded. Alternatively, this may be interpreted to be an indirect reference to how state and local agencies implement the law. Given conflicting federal law, it would not be surprising for state law enforcement agencies to feel ambivalent about enforcing medical marijuana use in the State. Accordingly, this ambivalence may unconsciously bias an agency when interpreting whether a specific action involving marijuana use complied with state law or not.

The legal conflict arises from the general federal prohibition against growing, possessing, distributing, or using marijuana for any purpose. In contrast, qualifying patients in Hawaii are permitted the medical use of marijuana if they otherwise comply with the State's medical marijuana law's conditions and restrictions. Furthermore, the Hawaii penal

2. Part IX, chapter 329, Hawaii Revised Statutes.
code (§712-1240.1(2), HRS) provides a person with an affirmative defense to prosecution for a marijuana-related offense if the person possesses or distributes marijuana and is authorized to do so under the State's medical marijuana law.

One "process or procedure" in distinguishing between medical and recreational use of marijuana lies in determining legal *possession* of an adequate supply of marijuana. Hawaii's medical marijuana law requires each qualifying patient to register with the Department of Public Safety (PSD). Each registered Hawaii user is allowed to jointly possess an "adequate supply" of marijuana with a primary caregiver. An "adequate supply" is defined as:

\[
\text{An amount of marijuana jointly possessed between the qualifying patient and the primary caregiver that is not more than is reasonably necessary to assure the uninterrupted availability of marijuana for the purpose of alleviating the symptoms or effects of a qualifying patient's debilitating medical condition; provided that an "adequate supply" shall not exceed three mature marijuana plants, four immature marijuana plants, and one ounce of usable marijuana per each mature plant. [emphasis added]}
\]

Before taking action against an individual, state and local agencies should confirm whether that individual is complying with the medical marijuana law. Specifically, officials should determine if the individual is properly registered with the PSD before uprooting plants or making an arrest. According to the PSD, law enforcement officials may, and some do, contact the Narcotics Enforcement Division (which administers the marijuana registry) to verify registration before taking official action. But not all law enforcement officers do. During work hours, registration can be immediately verified; after work hours, verification may take thirty minutes. It must be stressed, however, that law enforcement agencies are currently *not required* to first verify suspected individuals' registration before taking action. In other words, the PSD does not have the authority to require any law enforcement agency to make prior confirmation of a person's valid medical marijuana registration.

The law allows an "adequate supply" that is intended to "assure the uninterrupted availability of marijuana." The law further limits the adequate supply to a specific number of plants and ounces of usable marijuana (*see above*). Law enforcement officials may, on occasion, find more than an "adequate supply" being grown on one approved site. If so, those officials should be required to ascertain and verify whether that marijuana is being grown for more than one patient rather than assuming that the "adequate supply" provision is being violated by one patient. Current law does not require different patients to mark or

3. §329-123(b), Hawaii Revised Statutes.
4. §329-122(a)(3), Hawaii Revised Statutes.
5. §329-121, Hawaii Revised Statutes.
6. One example is the Hawaii County's payment of a $30,000 settlement for false arrest to two Big Island residents who were properly registered medical marijuana users who were complying with Hawaii's medical marijuana law, as reported by the Associated Press on December 1, 2004 and published in The Honolulu Advertiser under "Big Island pays $30,000 to medical marijuana users to settle arrest suit."
7. Email of October 4, 2004 from Keith Kamita, Administrator, Narcotics Enforcement Division, Law Enforcement Division, Department of Public Safety 837-8470 (hereafter "PSD email").
8. PSD email.
separate their plants on one lot. If marking or separation were required, this would resolve any difficulty in determining whether an individual patient is exceeding an "adequate supply." The PSD issues written recommendations to law enforcement agencies to determine whether marijuana is being grown for more than one patient in cases where more than one "adequate supply" is observed on one approved site.9

Furthermore, as a practical matter, it may also be unrealistic to expect an individual to be growing, at all times, only the precise number of allowable plants, if only because they are constantly being consumed. For example, a patient may be growing five, rather than four, immature plants in anticipation of consuming one of the mature plants. Plants also die, may not flourish, or become diseased or contaminated. A prudent patient would want to have a reserve amount of medical marijuana rather than deal with a shortage. However, any excess would be treated as "illegal" or "recreational" marijuana. Thus, state and local officials may sometimes be faced with having to confiscate or destroy plants in excess of the "adequate supply."

Clearly, there would be no ambivalence in confiscating an excess of fifty mature and sixty immature plants from one registered user. But what if the user had only one or two extra plants growing in the yard? At present, the law does not distinguish between a reserve and an "adequate supply." Perhaps the "adequate supply" is already meant to incorporate a reserve. If so, this is not specified in the law. In any case, Hawaii's medical marijuana program would benefit from further discussion on the potential need for a reserve supply of marijuana, apart from the "adequate supply" allowed. This would ease law enforcement agencies' task of distinguishing between legal and recreational marijuana.

Yet, none of this addresses the question of how registered users may actually come to possess or continue to supply themselves with marijuana. Can each of the 1,697 qualifying patients and their 18610 primary caregivers in Hawaii independently grow his or her own adequate supply? Would each have the physical, mental, or financial wherewithal -- the time, the effort, the space, the patience, the resources, the green thumb? Realistically, some will have to get their marijuana in other ways.

9. PSD email.
10. PSD email. The distribution of participating physicians, qualifying patients, and primary caregivers among the islands is as follows:

<table>
<thead>
<tr>
<th>Island</th>
<th>Physicians</th>
<th>Qualifying Patients</th>
<th>Primary Caregivers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hawaii</td>
<td>25</td>
<td>903</td>
<td>78</td>
</tr>
<tr>
<td>Kauai</td>
<td>15</td>
<td>335</td>
<td>36</td>
</tr>
<tr>
<td>Maui</td>
<td>23</td>
<td>212</td>
<td>19</td>
</tr>
<tr>
<td>Molokai</td>
<td>0</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Lanai</td>
<td>0</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Niihau</td>
<td>0</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Oahu</td>
<td>38</td>
<td>235</td>
<td>49</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>101</strong></td>
<td><strong>1,697</strong></td>
<td><strong>186</strong></td>
</tr>
</tbody>
</table>
In doing so, they may be violating the "medical use" provision of Hawaii's medical use of marijuana law. The law allows "medical use," which includes the "acquisition, possession, cultivation, use, distribution, or transportation" of marijuana. On the one hand, "acquisition" is not defined. On the other, "distribution" is defined narrowly to be specifically "limited to the transfer of marijuana and paraphernalia from the primary caregiver to the qualifying patient." Under these circumstances, it would be likely that some registered users may "acquire" part or all of an adequate supply outside of a "distribution" from a primary caregiver. Yet, the law seems to prohibit obtaining marijuana other than by such a "distribution." Nonetheless, the seemingly extraneous term "acquisition" is included in the definition of "medical use." This could be a tacit partial acknowledgment that, at times, marijuana needs to or may be obtained by some means other than just "distribution." In any case, the meaning of "acquisition" is ambiguous at best.

Furthermore, although "transportation" is used, it is not defined in the medical use of marijuana law. However, the PSD, which administers the medical marijuana program, interprets the term to mean "movement of the marijuana between the caregiver's residence to the patient if this is the authorized growing area." In other words, if marijuana is authorized for cultivation at the primary caregiver's residence, physically taking the marijuana to the separate residence of the qualifying patient constitutes "transportation." If the caregiver growing the marijuana cannot personally transport the marijuana to the patient but enlists a third person to do so, that action would contravene the law. Transporting authorized marijuana entirely within the State is protected. However, a caregiver would violate federal law by mailing marijuana from an authorized plot on the Big Island to a patient on Oahu. Boarding an airplane to carry the marijuana to Oahu would result in a similar federal violation. It appears, then, that even transportation, or movement, of marijuana within the restrictions of "distribution" is strictly limited.

Thus, because of severely restricted sources of supply of marijuana and limitations on its transport, it is likely that patients and their caregivers may "acquire" or "transport" marijuana in ways beyond those permitted in the state law. Similarly, they may "possess" more than an "adequate supply" if they encounter difficulty in keeping up an "adequate supply." (See chapter 4 for further discussion.)

Given all this legal conflict and confusion, it is understandable that at times state and local agencies may feel ambivalent and uncertain enforcing the law and distinguishing between "legal" and "illegal" marijuana use. However, actions arising from this uncertainty may carry grave practical consequences for legitimate medical users of marijuana. On the one hand, the medical use of marijuana law protects marijuana seized from a qualifying patient or primary caregiver. On the other hand, the law provides that "law enforcement agencies seizing live plants as evidence shall not be responsible for the care and maintenance of such plants." In effect, once plants are uprooted and taken as evidence, the plants may

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11. §329-121, Hawaii Revised Statutes, under the definition of "medical use."
12. PSD email.
die and be irretrievably lost, regardless of the merits of the case. For example, Big Island police confiscated living marijuana plants from registered medical marijuana users who were in compliance with Hawaii's medical marijuana law. The Big Island settled with the two users for $30,000 for false arrest but refused to return the confiscated plants "because of a disagreement about when a plant is mature." In this case, the registered users were apparently left without a legal supply of medical marijuana. In the end, state and local agencies must strive to hew to both the spirit and the letter of the state medical use of marijuana law in order to implement it impartially.

Hawaii's law, as written, does not allow a distribution system that can be realistically complied with by everyone. On the other hand, a practical distribution system would preclude many of the ambiguities now facing local and state agencies in distinguishing between legal and illegal marijuana use. Chapters 4 and 5 address these issues.
Chapter 3

EXPERIENCE OF OTHER STATES IN OBTAINING ACCESS TO MARIJUANA SUPPLIED BY THE FEDERAL GOVERNMENT FOR THERAPEUTIC RESEARCH

Issue Three: Federal Supply of Marijuana for Therapeutic Research

Background. Multiple states have passed and implemented medicinal marijuana laws. But with respect to the majority of this legislation, the role of the federal government has remained limited. According to federal law, the cultivation, distribution, and use of a Schedule I substance (e.g. marijuana) is prohibited under the Controlled Substances Act. Exceptions are permitted for government-approved research projects after obtaining a license from the Drug Enforcement Administration (DEA) to handle the substance. Currently, medicinal marijuana research is the only means by which the federal government allows the cultivation, distribution, and use of cannabis.

Researchers who wish to conduct research projects with marijuana must obtain a special license from the DEA, as well as approval from the federal Food and Drug Administration (FDA) if proposed experimentation is to include human subjects. In most instances, the patients involved in the research are limited to those not responding to conventional treatments. States may operate large-scale programs with doctor-patient teams if federal permission is obtained. Further, marijuana for research purposes must be obtained from the National Institute on Drug Abuse (NIDA), the sole producer and administrator of federal cannabis supplies.

Therapeutic Research Programs. During the late 1970s and early 1980s, 33 states passed medicinal marijuana laws. The majority of the laws (i.e. 26 states) created therapeutic

research programs under the federally-approved FDA Investigational New Drug program (IND). The IND program was designed to investigate the safety of new drugs before they are "transported or distributed across state lines." The IND program has never been considered, by the federal government, as a means of patient access to a new drug. Instead, the program's purpose has always been to ensure the safety and reliability of a new drug before it is released into the market.

The majority of states that passed therapeutic research laws in the 1970s and early 1980s designated their state health agency to administer the therapeutic research program. Of the 26 states that established programs, however, only seven received federal approval and became operational. The approved programs were able to receive a federal supply of cannabis and distribute the substance through pharmacies to approved patients for research studies. The operational states were California, Georgia, Michigan, New Mexico, New York, Tennessee, and Washington. These programs were disbanded in 1986 when the FDA approved the drug Marinol, a synthetic version of one of marijuana's main chemicals tetrahydrocannabinol (THC), which the FDA considered a better alternative to smoked marijuana.

**Investigational New Drug Compassionate Access Program.** To alleviate the difficulty experienced by many states in implementing IND programs as they related to marijuana, a simultaneous "effort emerged to allow individual access to marijuana." The FDA implemented the IND compassionate access program in 1978 to allow selected patients to receive federal supplies of marijuana. Theoretically, the IND compassionate access program made it possible for patients to obtain medical marijuana through doctors. In reality, however, the application process was not easy -- "it required a level of paperwork and procedural know-how that made it nearly impossible for the average patient or doctor to gain access." Despite the barriers encountered, the number of applicants continued to climb until the Public Health Service (PHS) announced that it would be closing the program in March 1992. In 1992, when the program terminated, enrolled patients were given the option to receive benefits for as long as they wished.

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7. Ibid.
10. Ibid.
11. Ibid, 3.
12. Ibid, 3.
15. Public Health Service, 1994; Randall, Robert C.; O'Leary, Alice M. **Marijuana Rx: The Patients’ Fight for Medicinal Pot.** New York: Thunder’s Mouth Press, 1998. This announcement resulted from a tripling in applications, which would have exhausted the federal supply of marijuana. The Public Health Service reports that 15 patients were enrolled in the program when it was closed to further enrollment. However, Randall and O'Leary state that 34 patients were enrolled when the program terminated.
although they were encouraged to find alternate viable therapies.\textsuperscript{16} Currently only seven patients remain in the program.\textsuperscript{17}

While the federal government (through the IND compassionate access program) did supply cannabis to small numbers of approved patients, the IND program was not intended "to facilitate medical care for individual patients," but was "designed as a mechanism for pharmaceutical companies to assure the safety of new drugs."\textsuperscript{18} Additionally, medical marijuana advocates never viewed this effort as a long-term solution, but rather as a means to assist individual patients.\textsuperscript{19} In the end, the IND compassionate access program was not an effective or efficient method by which to provide medicinal marijuana to patients.

\textit{State Therapeutic Research Programs.} State therapeutic research programs were initially intended to "enable patients to use marijuana," and did not involve true research methodology (e.g. double blind studies).\textsuperscript{20} However, these programs were stopped when the federal government began favoring well-controlled marijuana research studies. In fact, the National Institutes of Health (NIH), under the U.S. Department of Health and Human Services (HHS) imposed new guidelines in 1999 favoring medicinal cannabis studies that are well-controlled clinical trials to yield scientific data.\textsuperscript{21} The new guidelines establish that only scientifically valid investigations are permitted -- preferably with multi-patient design and of HHS approved medical conditions. Further, the guidelines require that research cannabis supplies must be procured from NIDA and be of the same strength and potency level. As a result, there are times when NIDA supplies may run low, halting research altogether.\textsuperscript{22} The guidelines also encourage researchers to consider alternative non-smoked therapies (e.g. Marinol).\textsuperscript{23}

For most states, the new guidelines have made marijuana therapeutic research programs extremely difficult to operate. The Marijuana Policy Project reports,

\begin{quote}
Because of these excessively strict federal guidelines for research and the high cost of conducting clinical trials, it is unlikely that the therapeutic research laws will again distribute marijuana to patients on a meaningful scale. States are generally unwilling to devote their limited resources to the long and potentially fruitless research application process; however, the laws establishing these programs currently remain on the books in 13 states.\textsuperscript{24}
\end{quote}

\begin{itemize}
\item \textsuperscript{16} Public Health Service, 1994.
\item \textsuperscript{17} Kreit, 2003.
\item \textsuperscript{18} Ibid., 3.
\item \textsuperscript{19} Ibid.
\item \textsuperscript{20} Marijuana Policy Project, 2004, J-1.
\item \textsuperscript{22} Marijuana Policy Project. "Suggested Revisions to the HHS Medical Marijuana Research Guidelines," 1999. Available at: \url{www.mpp.org/guidelines/hhs-rev.html}.
\item \textsuperscript{23} NIH, 1999; Public Health Service, 1994. NIH will favor studies on alternative non-smoked treatments.
\item \textsuperscript{24} Marijuana Policy Project, 2004, J-2.
\end{itemize}
Despite difficulties, medical cannabis research is still an option for states willing to commit the necessary resources. California, for instance, established a research center to study the effects of medicinal cannabis, which is funded through state resources and receives marijuana supplied from NIDA.\footnote{Ibid.}

**California Center for Medicinal Cannabis Research.** California is the only state where medical cannabis research is currently being conducted. In 1999, California State Senate Bill 847 established a $3 million appropriation for an initial three-year medicinal cannabis research program.\footnote{Center for Medicinal Cannabis Research, University of California. "Press Release," August 2000.} This state-funded initiative created the Center for Medicinal Cannabis Research (CMCR), housed at the University of California at San Diego, to "study the safety and efficacy of medicinal cannabis to treat certain diseases."\footnote{Ibid. For more information about CMCR, visit [www.cmcr.ucsd.edu](http://www.cmcr.ucsd.edu).} In 2003, the funding and program were continued.\footnote{Marijuana Policy Project, 2004.} While this research initiative is state-funded, cannabis is supplied by NIDA in accordance with the HHS guidelines.\footnote{Center for Medicinal Cannabis Research, 2000.} It is also important to note that, unlike past state programs (operational or not), the CMCR is located within the University of California system, and not operated by the state health agency.

According to CMCR, data from its studies will be used "to develop guidelines for appropriate pharmaceutical use of medicinal cannabis."\footnote{Ibid.} More than 14 CMCR research projects have been approved or are currently in progress. However, like the earlier IND program, the focus of the research conducted by CMCR is not to expand patient access to medicinal cannabis, but rather to "produce data on marijuana's safety and efficacy."\footnote{Marijuana Policy Project, 2004, p. J-2.} Furthermore, most of the projects are small pilot studies.\footnote{Ibid.}

**Summary.** The landscape regarding medicinal marijuana has changed in the last 30 years since states first began implementing medicinal marijuana laws. The IND program, which is still operational to test new drugs, is no longer a possibility for researching the efficacy of medicinal forms of marijuana. Additionally, the IND compassionate access program, which supplied marijuana to small numbers of patients, ended in 1992. Furthermore, while several states have been able to implement therapeutic research programs in the past,\footnote{Ibid. California, Georgia, Michigan, New Mexico, New York, Tennessee, and Washington were able to establish and implement state therapeutic research programs.} research points to
the current ineffectiveness of such programs for increasing patient access to marijuana.\textsuperscript{34} As the Marijuana Policy Project states,

\begin{quote}
The federal approval process for medical marijuana research is excessively cumbersome. As a result, state health departments are generally unwilling to devote their limited resources to the long \ldots application process, nor are they willing to spend taxpayer money administering the program.\textsuperscript{36}
\end{quote}

Nevertheless, there may still be value in medicinal cannabis research, as California's state funded example demonstrates.\textsuperscript{36}

While current state trends are moving away from therapeutic research programs for practical reasons,\textsuperscript{37} therapeutic research remains the "only type of provision in which individuals are protected from both state and federal prosecution (because TRPs [therapeutic research programs] are federally sanctioned)."\textsuperscript{38} As the literature shows, however, therapeutic research programs do not increase patient access to medicinal marijuana supplies.\textsuperscript{39} For that objective, other methods must be explored.

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\textsuperscript{34} Marijuana Policy Project, 2004; Kreit, 2003; Schmitz et al, 2001; Pacula et al, 2001.
\textsuperscript{35} Marijuana Policy Project, 2004, 10.
\textsuperscript{36} Center for Medicinal Cannabis Research, 2000.
\textsuperscript{38} Pacula et al, 2001, 10.
\textsuperscript{39} Marijuana Policy Project (2004); Kreit, 2003; Pacula et al, 2001.
\end{flushleft}
Chapter 4

DISTRIBUTION MODELS

Issue One: Focus of Study—Distribution System. The use of marijuana for medical purposes is legal in Hawaii. Nonetheless, the pros and cons of such use will likely continue to be debated. Similarly, other issues such as the historical evolution of marijuana laws in the states may be of scholarly interest. However, those issues are not the focus of H.C.R. No. 152. Rather, the Resolution directs the Bureau to explore ways in which marijuana may be made available or distributed to registered users for medical purposes in Hawaii. Aside from the two other issues addressed in chapters 2 and 3, distribution is the focus of this study and is dealt with in this chapter.

National Model. The Netherlands and Canada are the only two countries that have established official, government-run medical marijuana distribution systems. The Netherlands has recently (September 1, 2003) made cannabis available by prescription. Cultivation, processing, laboratory controls, and distribution of medical marijuana in that country are overseen by the Netherlands' Office of Medicinal Cannabis within the Ministry of Health, Welfare, and Sport. The head of the Office is Dr. Willem K. Scholten, PharmD., M.P.A.\(^1\) Dr. Scholten provides a concise description of a national distribution model, below:\(^2\)

Cannabis has been available on prescription in the Netherlands since 1 September 2003. Following a government decision taken in autumn 2001, preparations were made to cultivate and distribute cannabis under government control. After tendering, the Office of Medicinal Cannabis (OMC) contracted two growers, a laboratory, and a packaging and distribution company. Cultivation started last March and the first batches were ready for sale in August [2003].

The OMC is a government agency with a monopoly on the wholesale of cannabis. It is also responsible for granting any licences required for cannabis or cannabis resin. The fact that it holds the monopoly means that all cannabis is owned by the state from the moment the harvest is bought from the growers until the final product is sold to a pharmacy in sealed five-gram containers.

The contracted growers, the [Stichting] Institute of Medicinal Marijuana (SIMM) and Bedrocan, are required to comply with the rules of Good Agricultural Practices (GAP) for the cultivation of medicinal cannabis. These rules were laid down by the Dutch Minister of Health, Welfare, and Sport and are based on the GAP rules formulated by the European Agency for the Evaluation of Medicinal Products. Additional rules were introduced to standardise the cultivation and drying processes and to prevent diversion. Standardised cultivation ensures a constant cannabinoid content in cannabis products. As the two growers employ different methods and cultivate different varieties, their end-products differ from one other. As a result, prescribers and patients are offered a choice of products. The Bedrocan variety contains approximately 18 percent dronabinol (the official WHO designation for THC) and the SIMM 18 variety, around 15 percent. Both are low in cannabidiol. The OMC is considering expanding the product line in future by

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adding varieties with a higher cannabidiol content or a high cannabichromene or cannabigerol content.

The cannabis delivered by the growers to the OMC is gamma-irradiated to reduce and virtually eradicate bacteria and moulds. The procedure eliminates microbiological contamination, which may be harmful to immune-compromised patients. The cannabis is laboratory tested for identity, purity, and content, using an analytical monograph drafted by the National Institute for Health and the Environment (RIVM). It is tested to ensure purity from microbiological contamination, heavy metals and pesticides, and to establish the dronabinol, cannabinol, and cannabidiol content. Finally, it is packed in polypropylene containers holding five grams each....

On the basis of the laboratory results, the OMC approves batch release for packaging and distribution. The company responsible for packaging also does the logistics on behalf of the government, taking orders by phone, fax or email and forwarding them to pharmacies within 24 hours. It invoices customers monthly and collects payments on behalf of the OMC. Cannabis is supplied only to pharmacies; patients cannot order it themselves.

Dutch policy is based on the principle that cannabis is a medicine, like morphine or any other controlled narcotic. Hence, there is no reason to prohibit its use for medicinal purposes as long as it is prescribed according to the rules that apply to all controlled substances and that it is used in a responsible manner.

We refer to our products as cannabis or hemp (hennep in Dutch). We choose not to use terms like ‘weed’ and ‘marihuana’, which are associated with the recreational use of drugs and may stigmatise patients as drug abusers.

The product information provided by the OMC notes that the efficacy of cannabis has not yet been proven, although it is recorded as a treatment for over 200 conditions. It should therefore be used only if the conventional treatments prescribed in medical protocols prove ineffective, and not as a first-line treatment. In other words, it is indicated only if other drugs offer insufficient relief or produce excessive side effects.

In the Netherlands cannabis is recommended only for the conditions listed below, for which there is most evidence of its efficacy:

- nausea and vomiting in cancer chemotherapy, radiotherapy and HIV therapy
- palliative treatment for cancer patients (i.e. as an appetite stimulant and for pain relief and well-being in general)
- spasticity in combination with pain (e.g. multiple sclerosis or spinal cord injury)
- chronic neuropathic pain conditions
- Tourette’s syndrome.

Under Dutch law, doctors are not prohibited from prescribing cannabis for other conditions, but they are answerable to the medical council or the health care inspectorate for any adverse effects.

The Netherlands is thus following the example set by Canada, where cannabis has been used for medicinal purposes for some years. Though not identical, the policies of the two countries are similar in many respects. Above all, both recognise the medical potential of cannabis but require more evidence of its efficacy. In the meantime, Canada has allowed cannabis to be used on compassionate grounds, but without giving it medical status. The Netherlands allows doctors to prescribe it as a last-line medicine. Both countries encourage research. Few clinical trials were carried out during the decades of worldwide prohibition, and information is sorely needed....

Canada and the Netherlands are the first and, at present, the only countries to allow the medicinal use of cannabis.... Several European countries, including Belgium, Germany and Luxembourg, are reconsidering their positions and may ultimately accept cannabis as a useful medicine....

Although we market our products at cost price, they are twice as expensive in the Netherlands [than in Canada]. It is expensive to produce cannabis that meets all pharmaceutical requirements. Standardisation, laboratory testing, professional packaging, pharmacy services and a 24 hour delivery service countrywide, plus a 6 percent sales tax make prescription cannabis far more expensive than the illegal product.
On the other hand, our product is constant in strength and available at all Dutch pharmacies. But the two products cannot be compared. And if we regard it as a medicine, cannabis is not expensive.3

The cost of producing and distributing medical marijuana in the Netherlands, according to the Office of Medicinal Cannabis is as follows:4

- 61% Direct production and distribution
- 8% Reservation
- 6% Office of Medicinal Cannabis administration
- 1% Start-up
- 12% Development
- 7% Dispensing
- 5% Value-added tax

The Netherlands’ model is a national one. That country is subject to the United Nations Single Convention on Narcotic Drugs 1961 -- an international treaty governing the growth of cannabis. The Netherlands and the United States are both signatories. The Convention requires that for legal growth of cannabis to be allowed in a country, there must be a national agency that regulates its growth and holds a monopoly on the wholesale of the cannabis. The national agency is obliged to purchase the growers' entire crop. In the Netherlands, that agency is the Office of Medicinal Cannabis.5 Given current federal law, authorizing a national agency in the United States to assume similar responsibilities is not possible (see "Legal Obstacle" below).

But as Dr. Scholten himself points out, the national model may not easily be replicated, especially in a non-sovereign jurisdiction such as a state within the United States. He notes several obstacles -- pharmaceutical, system-cost, and legal -- to a state-authorized distribution system based on the Dutch national system.6

Pharmaceutical Obstacle. One of the obstacles pointed out by Dr. Scholten is that a country or state cannot or should not authorize distribution of a medicine without ensuring that the product meets pharmaceutical requirements. Aside from purely liability issues, a state-authorized distribution system also needs to ensure that a medicine is not contaminated with bacteria, molds, heavy metals, or pesticides for health reasons.

In the United States, the federal Food and Drug Administration has not conducted the requisite tests on the medical efficacy or safety of marijuana. Neither has it established

3. The Netherlands, Office of Medicinal Cannabis website: The price of a 5-gram container of cannabis flos variety SIMM 18 containing approximately 13% dronabinol and 0.7% cannabidiol, as of December, 2003, was €41.63 (Eurodollar). The price of a 5-gram container of cannabis flos variety Bedrocan, containing approximately 18% dronabinol and 0.8% cannabidiol, was €47.21. http://www.cannabisbureau.nl/eng/index.html.
5. Ibid.
standards and requirements for content and dosage. Marijuana is a Schedule I substance in the federal Controlled Substances Act of 1970.\textsuperscript{7} Schedule I substances are defined as having a high potential for abuse and no currently accepted medical use in treatment in the United States. Schedule I substances are not allowed to be prescribed by doctors or sold in pharmacies. Schedule II through Schedule V substances are defined as having accepted medical use but with diminishing degrees of restrictions on their use.

Accordingly (in comments by the Institute of Medicine), the clinical evaluation regarding the safety and efficacy of marijuana by the Food and Drug Administration would involve "considerable complexity and expense" and would entail "substantial scientific, regulatory, and commercial obstacles and uncertainties."\textsuperscript{8} If the FDA were to conduct such an evaluation and find favorably with regard to marijuana, the Drug Enforcement Agency would have the authority to place marijuana into a less restrictive schedule.\textsuperscript{9} For any individual state, such as Hawaii, to shoulder this clinical evaluative undertaking would be an enormous task and an ill-advised burden on one state's resources.\textsuperscript{10} For example, if marijuana is found to be safe and effective, the results would apply to not just the state conducting the evaluation but should apply to all other states. Thus, given the enormity and expense of such an undertaking, it would be totally impractical for each state to conduct its own clinical safety and efficacy evaluations. Accordingly, it would seem to make more sense to approach such a task on the national, rather than the state, level. Furthermore, because the marijuana plant cannot be patented, pharmaceutical companies have no incentive to invest in research to obtain FDA approval. This leads to the second obstacle: system costs.

**System-Cost Obstacle.** System cost is the second obstacle. The Dutch government-run system is costly. The system requires organized and controlled cultivation based on uniform standards, laboratory monitoring and testing, processing, and final distribution. The Dutch contract out the operation of the components of the system to private entities. It would appear that the Dutch do not have the resources to operate the system in-house using all government workers, farmlands, and laboratories. The government does not have the appropriate processing and packaging facilities nor does it own a wholesale pharmaceutical distribution network.

If Hawaii were to establish a state-run distribution system, the State would face similar fixed system costs. However, economies of scale dictate that the cultivation and distribution of medical marijuana in Hawaii would be costlier per patient than in the Netherlands. The Dutch population is currently about 16,000,000 while Hawaii's population

\textsuperscript{8} Institute of Medicine, comments in a 1999 report on medical marijuana, as cited by the Marijuana Policy Project, July 15, 2004, reference at www.marijuanapolicy.org.
\textsuperscript{10} Ibid., pp. 4-5. The Marijuana Policy Project estimates that it would require at least ten years, assuming a privately-funded company is willing and can afford an estimated tens of millions of dollars to satisfy federal research requirements, for the FDA to approve marijuana as a prescription medicine.
is much smaller, hovering around 1,000,000. The price of Dutch-authorized pharmaceutical-grade marijuana, which is strictly standardized and controlled, is already high. Even in the Netherlands where such high-quality marijuana is available, illegal growers offer stiff competition with lower-priced marijuana. Dr. Scholten reports that illegally grown marijuana in his country amounts to about 300 tons annually. The yearly production managed by his Office of Medicinal Cannabis is only about 400 kilograms. (This is only about 882 pounds, or less than half a ton.) He admits that it is difficult for his government to compete with cheaper sources of marijuana because illegal growers are not saddled with various taxes, quality control, and distribution costs.

(In an October 14, 2004 article by Maria Lokshin of the Associated Press that appeared in the Detroit Free Press entitled "Dutch pot program a downer for users," it was reported that the government's packaging and distribution costs, coupled with inadequate medical coverage by Dutch insurance policies, have created a glut of legal marijuana in the Netherlands. Only 175 pounds have been sold of an expected sale of 450 pounds since the program began in September, 2003. Legal government-approved marijuana sells for $10 to $12 a gram as opposed to about $5 a gram for illegal marijuana in the hundreds of marijuana bars thinly disguised as "coffee shops.")

The much smaller economies of scale in Hawaii would likely decrease the cost-effectiveness of any state-run distribution system. Such an operation would require high fixed laboratory, organizational, and distribution costs. However, the actual amount of medical marijuana to be produced would be very limited. The State could not produce excess marijuana to be exported elsewhere. (See "California Model" for need to keep everything intra-state.) In other words, it would cost very much in Hawaii for the State to produce very little.

Legal Obstacle. As mentioned above, under the United Nations Single Convention on Narcotic Drugs 1961, the legal growth of cannabis can be allowed in a country only if there is a national agency that regulates its growth. (See "National Model") The United States is also a signatory to the Convention. Our national agency is the National Institute on Drug Abuse (NIDA), which is a part of the National Institutes of Health in the Department of Health and Human Services. However, there are no current indications that NIDA would cooperate anytime soon to authorize the cultivation, testing, harvesting, processing, packaging, and distribution of marijuana in those states that legally allow it for medical purposes.

The option of buying marijuana from other government-sanctioned programs for medical use in Hawaii is also legally impractical. Canada is the only country other than the Netherlands to have established a marijuana-producing governmental agency. However, without an import permit, neither the Netherlands nor Canada would export marijuana to Hawaii. It would be ingenuous to expect the federal Drug Enforcement Agency to grant Hawaii an import permit, given that marijuana is a Schedule I substance under the federal Controlled Substances Act.

Accordingly, it would seem to be legally impossible for any state in the United States to comply fully with international law under the United Nations Single Convention on Narcotic
DISTRIBUTING MEDICAL MARIJUANA

Drugs 1961. Dr. Scholten, however, comments that those states that do have medical marijuana laws merely ignore international law and focus on purely intra-state production of medical marijuana to preclude federal intervention. This leads directly to the next distribution model, a cooperative intra-state model, as it is now developing in California.

**Cooperative Intra-State Model.** Reviewing a brief history of certain events makes for a better understanding of this model. In 1996, California passed the Compassionate Use Act of 1996 stemming from Proposition 215, the Medical Use of Marijuana Initiative Statute. The following summary of Proposition 215 was prepared by California's Attorney General:

- Exempts patients and defined caregivers who possess or cultivate marijuana for medical treatment recommended by a physician from criminal laws which otherwise prohibit possession or cultivation of marijuana.
- Provides physicians who recommend use of marijuana for medical treatment shall not be punished or denied any right or privilege.
- Declares that [the Act] not be construed to supersede prohibitions of conduct endangering others or to condone diversion of marijuana for non-medical purposes.
- Contains severability clause.

The California law specifically allows patients and their caregivers to cultivate and possess marijuana for medical use. According to one observer, although California state courts have held that this provision does not shield marijuana dispensaries, custom and support from local officials have practically legalized the activity for purposes of state law enforcement. The developing state system has thereby effectively ceded enforcement of all medical marijuana-related activity, including distribution and growth, to the federal government.

Shortly after the 1996 law, the federal government sought to enjoin the cultivation and distribution of marijuana by six different marijuana dispensaries in California. The U.S. Ninth Circuit Court of Appeals reversed the district court's order upholding the injunction. However, the United States Supreme Court later reversed, finding that medical necessity was not a valid defense for the manufacture and distribution of marijuana. In subsequent years, despite the federal limitations on cultivation and distribution, efforts continued in California to make medical marijuana available to patients.

**Case One.** One such action took the form of an October 2002 filing in a California district court. The appellants, Raich and Monson, sought declaratory relief and preliminary and permanent injunctive relief against the federal government from seizing marijuana

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11. This law added Section 11362.5 to the Health and Safety Code of the California Statutes.
privately- and wholly-grown within the state for medical use for patients and their caregivers. They also sought to prevent federal authorities from arresting or prosecuting these patients and caregivers. The appellants further sought a declaration that the Controlled Substances Act is unconstitutional to the extent that it purports to prevent them from possessing, obtaining, manufacturing, or providing cannabis for medical use. The appellants finally sought a declaration that the doctrine of medical necessity precludes enforcement of the Controlled Substances Act to prevent Raich and Monson from possessing, obtaining, or manufacturing cannabis for their personal medical use.

The district court rejected the suit on March 4, 2003.\textsuperscript{15} Subsequently, on March 12, 2003, the appellants appealed the ruling. Several months later, on December 16, 2003, the U.S. Ninth Circuit Court of Appeals reversed and remanded the case, \textit{Raich v. Ashcroft}, to the district court with instructions to enter a preliminary injunction, as sought by the patients and caregivers.\textsuperscript{16}

In this case, the two appellants, Raich and Monson, use marijuana as medicine. Raich had been diagnosed "with more than ten serious medical conditions, including an inoperable brain tumor, life-threatening weight loss, a seizure disorder, nausea, and several chronic pain disorders... [and]... Monson suffers from severe chronic back pain and constant, painful muscle spasms."\textsuperscript{17} Both appellants contend that they have tried all other legal medical treatments but that they are ineffective. Raich's doctor contends that her discontinuance of marijuana use may be fatal. Monson grows her own marijuana but Raich is unable to, requiring use of marijuana every two waking hours each day. Raich has her marijuana grown for her by two caregivers free of charge. In growing marijuana for Raich, her growers allegedly use only soil, water, nutrients, growing equipment, supplies, and lumber originating from or manufactured within California.\textsuperscript{18}

The immediate event triggering the request for injunctive relief was the destruction of Monson's six marijuana plants by federal Drug Enforcement Agency agents on August 15, 2002 at Monson's home. The federal agents were accompanied by deputies from the Butte County Sheriff's Department. The sheriff's deputies concluded that Monson's use of marijuana was legal under the Compassionate Use Act of 1996. "However, after a three-hour standoff involving the Butte County District Attorney and the United States Attorney for the Eastern District of California, the DEA agents seized and destroyed Monson’s six cannabis plants."\textsuperscript{19}

Originally, the district court found that the Commerce Clause supported the application of the Controlled Substances Act to the appellants. \textit{(Congress passed the Controlled Substances Act based on its authority under the Commerce Clause of the

\begin{itemize}
  \item[17.] Ibid., p. 5.
  \item[18.] Ibid., p. 6.
  \item[19.] Ibid., p. 7.
\end{itemize}
Constitution. The Commerce Clause grants Congress the power to “regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes....” In its decision to reverse, the U.S. Ninth Circuit Court of Appeals stated that:20

[T]he appellants are not only claiming that their activities do not have the same effect on interstate commerce as activities in other cases where the CSA [Controlled Substances Act] has been upheld. Rather, they contend that, whereas the earlier cases concerned drug trafficking, the appellants’ conduct constitutes a separate and distinct class of activities: the intra-state, noncommercial cultivation and possession of cannabis for personal medical purposes as recommended by a patient’s physician pursuant to valid California state law.

The U.S. Ninth Circuit Court of Appeals determined that the appellants’ contention was correct: that "the appellants' class of activities -- the intra-state, noncommercial cultivation, possession and use of marijuana for personal medical purposes on the advice of a physician -- is, in fact, different in kind from drug trafficking."21 The Circuit Court also noted that "this limited use is clearly distinct from the broader illicit drug market -- as well as any broader commercial market for medicinal marijuana -- insofar as the medicinal marijuana at issue in this case is not intended for, nor does it enter, the stream of commerce."22

The Circuit Court thus determined that:23

As applied to the limited class of activities presented by this case, the CSA [Controlled Substances Act] does not regulate commerce or any sort of economic enterprise. The cultivation, possession, and use of marijuana for medicinal purposes and not for exchange or distribution is not properly characterized as commercial or economic activity. Lacking sale, exchange or distribution, the activity does not possess the essential elements of commerce.

As a result, the Circuit Court found (upon consideration of four separate factors) that the Controlled Substances Act, as applied to the appellants, is likely unconstitutional under the Commerce Clause.24 Upon the basis of this finding, the Circuit Court reversed and remanded the case to the district court for entry of a preliminary injunction.

The effect of this ruling provides constitutional protection from federal arrest and prosecution for California medical marijuana users and growers who comply with California's Compassionate Use Act of 1996. However, the marijuana involved must not be sold and all materials and activities connected with cultivation of the marijuana must be intra-state in character.

20. Ibid., p. 12.
21. Ibid., p. 12.
22. Ibid., p. 13.
23. Ibid., p. 16.
Subsequently, as to the three-judge ruling in *Raich v. Ashcroft*, the federal government petitioned for an eleven-judge *en banc* review by the U.S. Ninth Circuit Court of Appeals. In February, 2004, the Circuit Court denied the petition.\(^{25}\) Thus, the U.S. Ninth Circuit Court of Appeals’ ruling becomes binding precedent in the seven states in the Ninth Circuit’s jurisdiction that have medical cannabis laws: Alaska, Arizona, California, Hawaii, Nevada, Oregon, and Washington.

As expected, however, the federal government has appealed the case to the United States Supreme Court. On June 28, 2004, the Supreme Court agreed to hear the case.\(^{26}\) In a separate case, the Supreme Court had earlier ruled against an exemption from federal drug laws based on "medical necessity."\(^{27}\) But the Supreme Court remarked that it had not yet been presented with a case that would allow it to decide the constitutionality of applying the federal ban on marijuana to medical patients. Observers agree that the *Raich v. Ashcroft* case may well be the one to decide the issue.

**Case Two.** A second case in California lends support for the cooperative intra-state model. The Wo/Men's Alliance for Medical Marijuana ("WAMM") describes itself as a "patient self-help alliance" or collective with a membership of over 250 ill patients. To join WAMM, patients and their caregivers must review WAMM's protocols and guidelines and sign a member consent form. They must also sign a confidentiality statement, and, if applying for seedlings or equipment to grow at home, a cultivation contract agreement.\(^{28}\) Of course, they must also comply with California law by producing a signed medical marijuana recommendation form from their physicians.

WAMM is located in Davenport, California in Santa Cruz county and grows marijuana in a communal garden of about 10,000 square feet.\(^{29}\) The collective cultivates its own marijuana for medical use in accordance with state law. WAMM stresses that it does not sell or buy marijuana. Its $145,000 annual budget is funded by member donations and other private sources. These funds provide for the costs of everything from plant cultivation and supplies to peer counseling, technical assistance, volunteer coordination, security, and all administrative functions.\(^{30}\) "Approved clients with a physician's recommendation receive services at no cost."\(^{31}\) Individual patients either cultivate their own gardens, as part of the WAMM Cultivation Partnership Program, or work in the communal garden.\(^{32}\)


\(^{26}\). Ashcroft v. Raich, 124 S. Ct. 2909, 72 USLW 3674, 72 USLW 3761, 72 USLW 3768 (U.S. June 28, 2004) (No. 03-1454).

\(^{27}\). United States v. Oakland Cannabis Buyers' Cooperative et al. 190 F.3d 1109, 532 U.S. 483 (2001) (No. 00-151).

\(^{28}\). San Francisco Office of the Legislative Analyst, Adam Van de Water in memorandum OLA #:023-03 to the Board of Supervisors re: Medical Marijuana Collectives, February 3, 2004 (hereafter "OLA memo").

\(^{29}\). OLA memo.

\(^{30}\). OLA memo.

\(^{31}\). Wo/Men's Alliance for Medical Marijuana website at: [http://www.wamm.org/aboutus.htm](http://www.wamm.org/aboutus.htm).

\(^{32}\). Ibid., at [http://www.wamm.org/newsalert.htm](http://www.wamm.org/newsalert.htm).
On September 5, 2002, agents from the Drug Enforcement Agency raided WAMM's marijuana garden in Santa Cruz and destroyed 167 plants. They also seized the WAMM collective's weekly medical marijuana allotments -- measured and placed in labeled envelopes -- for individual patients. Subsequently, a suit was filed for preliminary and permanent injunctive relief, declaratory relief, and damages on April 21, 2003 in U.S. District Court (Northern District of California). The plaintiffs were the County of Santa Cruz, City of Santa Cruz, WAMM, and seven individuals (County of Santa Cruz, et al. v. Ashcroft et al.). (The case is more popularly referred to as Corral v. Ashcroft where Valerie Corral is one of the seven individual plaintiffs.)

To ensure effective implementation of the Compassionate Use Act, the City of Santa Cruz enacted Chapter 6.90 of the Santa Cruz Municipal Code in 2000. In general, the Santa Cruz ordinance details the process by which qualified patients may lawfully use medical marijuana. The ordinance provides that the City of Santa Cruz may deputize individuals and organizations to function as medical marijuana providers to assist Santa Cruz in implementing its medical marijuana ordinance and the Compassionate Use Act (Santa Cruz Municipal Code §6.90.080). On December 10, 2002, the Santa Cruz City Council adopted a resolution deputizing WAMM, plaintiff Valerie Corral, and her husband and primary caregiver Michael Corral to function as medical marijuana providers.

The complaint lists six causes of action:

(1) *Deprivation of the fundamental right to control the circumstances of one's own death* -- The seizure violated plaintiffs' fundamental rights under the Fifth and Ninth Amendments.

(2) *Violation of other fundamental rights secured by the Fifth and Ninth Amendments* -- The seizure violated other fundamental rights to:

- Ameliorate pain
- Maintain bodily integrity
- Preserve life
- Consult with one's own physician regarding treatment and to act on the physician's recommendations.

(3) *Lack of federal authority* -- The seizure exceeded Congress' power to regulate interstate commerce under the Controlled Substances Act.

(4) *Violation of the Tenth Amendment* -- The seizure violated the Tenth Amendment by preventing California from implementing a duly enacted statute and by federal commandeering of the police power and executive functions of California and its political subdivisions.

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33. County of Santa Cruz, Cal. et al. v. Ashcroft et al., No. 5:03CV01802 (Docket) (N.D. Cal. April 23, 2003).
(5) **Immunity of local officials** -- WAMM plaintiffs have been deputized by the city of Santa Cruz to enforce that city's Personal Medical Marijuana Use Ordinance, in compliance with state law, and should thus be immune from criminal and civil liability stemming from the seizure of medical marijuana.

(6) **Violations of the Fourth, Fifth, Ninth, and Tenth Amendments** -- Damages are sought for violations of the plaintiff's rights.

The suit also asked for return of the marijuana plants seized, compensatory and punitive damages, and reasonable attorneys' fees and costs of the suit.

On August 28, 2003, Judge Jeremy Fogel of the U.S. District Court (Northern District of California) denied the plaintiffs' motion for a preliminary injunction. However, in light of the precedent-setting *Raich v. Ashcroft* decision of December 16, 2003 (see "Case One" above), the plaintiffs asked Judge Fogel to reconsider his decision. Subsequently, upon reconsideration, Judge Fogel issued a preliminary injunction on April 21, 2004, barring the Department of Justice from raiding or prosecuting WAMM in California. In effect, this ruling offers WAMM and similar collectives growing medical marijuana in California temporary protection against federal intervention.

**Other Proposals.** In Hawaii, H.B. No. 2669, 2004 and its companion, S.B. No. 3139, 2004, were introduced in late January, 2004. Both passed First Reading and were referred to their respective House and Senate committees, but were not heard. The two bills proposed to permit a section 501(c)(3) tax exempt organization, including a church whose sacraments include the use of marijuana, to be a distributor for persons using medical marijuana, and to treat with marijuana qualifying patients who are addicted to crystal methamphetamine if certain conditions are met.

These two bills unnecessarily complicate the issue by allowing *religious entities* that purport to use marijuana as a sacrament to act as *medical* marijuana distributors. They further complicate matters by giving authority to the church-distributor to honor physician prescriptions for marijuana. The proposed measures are simplistic and do not work in concert with the core of the existing medical use of marijuana law. For example, these measures do not repeal or directly amend any provision of the existing medical marijuana law under part IX of chapter 329, HRS. They merely add a new section that affords certain protections to medical marijuana distributors who must be tax-exempt and approved for

34. County of Santa Cruz, Cal. et al. v. Ashcroft et al., 279 F.Supp. 2d 1192 (N.D. Cal. Aug. 28, 2003) (No. 03-1802 JF). The city of Santa Cruz, the county of Santa Cruz, WAMM, and seven individuals, including Valerie Corral, are plaintiffs. This case is also cited as "Corral v. Ashcroft" in the popular press.


registration by the Department of Public Safety. These measures allow qualifying patients to obtain marijuana directly from a registered distributor with a doctor's prescription. However, the existing law provides a completely different structure for distribution involving primary caregivers, patients, and physicians registered with the PSD and written certifications issued by participating physicians. Only one structure can be implemented.

Most importantly, these two measures do not address the multitude of issues raised in this chapter. For example, they do not resolve issues regarding adequate supply, reserve amounts of marijuana, acquisition, possession, transportation, and distribution, especially in light of current litigation in California and at the national level.
Chapter 5

CONCLUSIONS

A Potential Cooperative Intra-State Medical Marijuana Cultivation and Distribution System In Hawaii. It would be premature for Hawaii to institute a cooperative system without assurance of a supportive ruling from the U.S. Supreme Court. However, no one knows what the ruling will be. Even if a decision favors medical marijuana users and growers, no one knows what conditions, if any, the Supreme Court may impose. As a result, the discussion in this chapter is necessarily hypothetical.

For the sake of simplicity, this chapter assumes that the U. S. Supreme Court will impose no new restrictions and merely upholds the requirements imposed by the U. S. Ninth Circuit Court of Appeals. Under this scenario, a Hawaii marijuana cooperative must strictly replicate the actions of similar California marijuana cooperatives. That is:

- No marijuana must be sold under any circumstances. All marijuana must be grown and distributed free of charge.
- All aspects and provisions of Hawaii's medical use of marijuana law must be strictly complied with.
- Nothing must cross state boundaries. All aspects of the cultivation and use of medical marijuana must remain strictly within the State. All soil, seeds, and any materials and supplies used in cultivating the marijuana must originate and remain within the State.

Current and Future Compliance Issues and Needed Changes. Based on the assumptions above, Hawaii's medical use of marijuana law (Part IX, chapter 329, Hawaii Revised Statutes) would need to be amended. The obvious major change would be to permit cooperative marijuana growing and distribution. However, even without instituting a cooperative model, parts of the current law still need to be amended to address certain current practical obstacles to compliance.

As already stated, the major new change would be to allow cooperative cultivation and distribution of marijuana. To this end, various definitions need to be added, amended, or clarified. Furthermore, the current conditions of marijuana use need to be amended.

Possession. First, joint possession of marijuana by a "qualified patient" and "primary caregiver," as defined in the term "adequate supply," needs clarification. Currently, a patient and a caregiver can jointly possess marijuana to be used only by the patient. The patient or the caregiver can individually and separately, or jointly, grow marijuana, up to the limit of an
"adequate supply," for the benefit of the patient.\textsuperscript{1} The assumption is that whoever grows the marijuana, while growing it, legally "possesses" it. \textit{This assumption would have to be made explicit} because it is not clear that marijuana is possessed legally by only one party, say the caregiver, while growing it since the law addresses only joint possession.

Second, \textit{possession} by a third-party marijuana cooperative member, who grows marijuana for the patient, would have to be defined. The cooperative member would be allowed to legally "possess" marijuana while growing it \textit{gratis} for a patient's benefit. It must be made clear, however, that the cooperative member's \textit{possession} excludes any right to \textit{use} the marijuana being grown for a patient. \textit{In sum, the term "possession" would have to be clarified as applied to the three distinct parties who may grow marijuana: the patient, the caregiver, or a third-party marijuana cooperative member.}

\textit{Primary Caregiver Responsibilities.} The current law defines a primary caregiver as being responsible "for managing the well-being of the qualifying patient with respect to the medical use of marijuana."\textsuperscript{2} This allows a caregiver to \textit{both} care for the patient \textit{and} to grow and provide marijuana for a patient who is otherwise unable to do so. However, the cooperative model additionally allows a third party to grow and provide marijuana for a patient. Thus, the law would have to be amended to explicitly acknowledge that a caregiver may continue to "manage" the patient's "well-being ... with respect to the medical use of marijuana" without actually growing or providing marijuana. At the same time, this provision would allow the option of a third-party cooperative member to simply do the growing without managing a patient's well-being. \textit{In other words, cultivating marijuana and managing a patient's well-being can be two separate and distinct activities.} This being said, both the caregiver and the third-party grower can themselves be patients. The third-party grower can also be a caregiver as well.\textsuperscript{3}

\textit{Adequate Supply.} Relating these separate roles back to the concept of \textit{possession}, as a patient, the third-party cooperative member would be entitled to separately possess and use one \textit{adequate supply} of medical marijuana. As a caregiver for someone else, the cooperative member would be allowed to jointly possess \textit{another adequate supply} with a patient, but \textit{only} for the other patient's use.\textsuperscript{4} However, when acting solely as a third-party cooperative grower, that person may possess an adequate supply of marijuana while growing it for a patient. Of course the cooperative grower would have no right to personally use it or consider it as part of the grower's own adequate supply as a patient.

Furthermore, the third-party cooperative grower may have a surplus supply on hand that is destined for eventual use by other patients for whom the marijuana is being grown. In that case, the cooperative grower would \textit{possess} the marijuana as \textit{temporary surplus inventory}. Again, the grower would not be allowed to appropriate it for personal \textit{use}. Thus, "possession of

\textsuperscript{1} Keith Kamita, Administrator, Narcotics Enforcement Division, Law Enforcement Division, Department of Public Safety, in email response of October 4, 2004, to Bureau survey email (hereafter "PSD response").

\textsuperscript{2} §329-121, HRS, definition of "primary caregiver."

\textsuperscript{3} The Department of Public Safety interprets the current law to allow a primary caregiver to also be a qualifying patient at the same time (PSD response).

\textsuperscript{4} PSD response.
To illustrate these concepts, Patrick, the patient, is being cared for by Carl, the caregiver. But neither currently have the means, will, or desire to grow marijuana for Patrick's medical use. Instead, they join an in-state marijuana growing cooperative that strictly complies with Hawaii's medical use of marijuana law. All marijuana is provided free; no sales of marijuana occur. All materials used in growing the marijuana come from within the State and nothing leaves the State. Within the cooperative, Mike, a member, grows marijuana for Patrick. Carl remains Paul's caregiver with respect to the medical use of marijuana, but Mike does the actual growing.

While Mike is growing it, he possesses the marijuana but cannot use it for himself. When the marijuana is picked up or delivered, Patrick and Carl assume joint possession of it. If Carl begins to grow marijuana for Patrick in the future, Carl also has possession, though not use, of the marijuana while growing it.

Coincidentally, Mike also happens to be a qualifying patient himself. Mike grows his own marijuana in the cooperative. In the role of a patient, Mike legally possesses and uses a separate adequate supply of marijuana apart from what he grows for Patrick or any other patient. Any surplus marijuana being grown by Mike beyond the adequate supply Mike or Patrick are allowed as patients is possessed by Mike as surplus, until it is allocated and delivered to or picked up by another patient.

By further coincidence, Mike also happens to be the primary caregiver for Patricia, a fellow qualifying patient and member of the cooperative. In his capacity as Patricia’s caregiver, Mike is allowed joint possession of an adequate supply of marijuana solely for Patricia’s use -- Mike is not allowed to use that supply for himself. Mike may grow marijuana for Patricia either as a caregiver or as a third-party cooperative member, but is not required to. Patricia may grow her own, or request someone else with a greener thumb in the cooperative to do so, while retaining Mike as her primary caregiver.

As an ultimate coincidence, Carl also becomes a patient. Carl then is allowed to possess and use for himself a separate adequate supply, apart from the supply he jointly possesses with Patrick. Carl and Mike, as patients, may have their own primary caregivers, although a caregiver may have only one patient each.

Transportation, Distribution, and Acquisition. Current law allows "medical use" of marijuana. That term is defined to include "acquisition, possession, cultivation, use, distribution,
or transportation" of marijuana or paraphernalia. The foregoing sections in this chapter address the concept of "possession." "Cultivation" and "use" are relatively unambiguous and pose no obstacles to compliance. On the other hand, the terms "acquisition," "distribution," and "transportation" are troublesome. If not clarified, they will pose problems for any cooperative intra-state medical marijuana cultivation and distribution system that may be provided for in the future.

The current law narrowly defines "distribution" as "limited to the transfer of marijuana and paraphernalia from the primary caregiver to the qualifying patient." However, the meaning of "acquisition" and "transportation" in the current law are ambiguous and undefined. In fact, neither term appears anywhere in the medical use of marijuana law, other than in their initial mention in the definition of "medical use." (See chapter 2 for further discussion.)

The Department of Public Safety interprets "transportation" to mean movement of the marijuana between the primary caregiver's residence, if this is the authorized growing area, to the qualifying patient. Apparently then, the meaning of "transportation" is subsumed within that of "distribution" under which marijuana is "moved" from the primary caregiver to the qualifying patient. Rather than extrapolate a meaning for "transportation" from the meaning of "distribution," the current law should explicitly include the physical movement of marijuana between the caregiver and patient under the definition of "distribution." In other words, "transportation" can be deleted as a separate and undefined concept under "medical use" but should be specifically included as part of the definition of "distribution." Under the cooperative model, "distribution" would include transfers from the third-party cooperative member.

A similar problem applies to the term "acquisition." It is unclear why "acquisition" is included as a separate but undefined concept within the definition of "medical use." The law acknowledges the "transfer" of marijuana between two people in the definition of "distribution." However, it offers no clue as to what constitutes "acquisition" of marijuana. It certainly cannot be "distribution." On the other hand, it could refer to the transfer of marijuana (seeds, for example) from some other person to the caregiver or patient to enable them to start growing the plant. The seeds must come from somewhere. Furthermore, when plants are consumed or become unusable for whatever reason, such as contamination, those plants must be replaced from somewhere. Ill patients may be unwilling to wait for a new crop to come in and thus "acquire" marijuana for immediate use in a way not provided by law. Thus, the term "acquisition" would need to be defined separately to include the concepts of obtaining seeds or plants to initially grow or replace consumed plants.

Although not perfect, a cooperative intra-state model would offer a partial answer to marijuana grown in excess of some or all registered users' adequate supplies with respect to:

(1) Possession by the cooperative grower; and

(2) Acquisition by the caregiver or patient from the surplus cooperative grower.

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5. §329-121, HRS, definition of "medical use."
It would be improbable for a marijuana cooperative to continuously grow and possess only the number of plants to fill its members' adequate supply allotments at any one time. After all, plants are constantly being consumed and need to be replaced. Plants and seedlings may succumb to disease or parasites or become contaminated and unusable. It would only be prudent for a cooperative to have a surplus rather than a shortage on hand at any given moment. Any surplus marijuana can be used to supply new members or to replace plants that have been either consumed by existing registered users or have been spoiled. Thus, both new and existing members can "acquire" marijuana. In other words, "acquisition" would mean the obtaining of start-up seeds or plants for new registered users or of obtaining replacements for existing users.

Unresolved Issues. Several thorny issues still remain. One is that patients, caregivers, and cooperative members are limited, in reality, to residing on the same island. State law cannot protect a caregiver (or cooperative member) who grows marijuana on the Big Island and mails it to a patient or carries it on a flight to Oahu.6 Using the U. S. Postal Service or boarding a plane with marijuana gives the federal government jurisdiction.

A caregiver or cooperative member cannot be authorized to grow marijuana in another state and deliver the marijuana to a patient in Hawaii. The Department of Public Safety interprets current law as allowing it to authorize only persons residing in the State to be primary caregivers.7 This is logical and should be retained in any future law allowing cooperative marijuana growing and distribution. Growers, including members of any marijuana cooperative, should also be required to be state residents. To formalize this interpretation, current law should be amended to make this explicit. Support comes from the California cooperative intra-state model, which does not allow any inter-state activity relating to the cultivation or distribution of medical marijuana. Of course, the U. S. Supreme Court has yet to rule, and it may make relevant changes to the intra-state requirements or even disallow marijuana cooperatives altogether.

Another prickly issue relates to the "acquisition" of marijuana. Provision can be made for cooperative growers, caregivers, and patients to legally acquire marijuana, as discussed

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6. PSD response.
7. PSD response.
above. This, in itself, would be tricky enough to enforce. But a transaction always has two sides. What of the supplier and the act of supplying the marijuana to the grower, be it a cooperative member, caregiver, or patient? When cooperative growers, caregivers, or patients "acquire" marijuana in compliance with state law, would their "supplier" also be considered in compliance when supplying it? Or would the supplier be subject to arrest and prosecution?

Medical marijuana must not be sold under any conditions. Yet, cooperatives, caregivers, and patients must get seeds from somewhere. It would be naive to expect a supplier to donate marijuana to a cooperative, a caregiver, or a patient. If the supplier sells and does not donate, should and how would a supplier be exempt from the medical marijuana law when selling the marijuana? The California cooperative model prohibits the sale of marijuana. However, some may interpret the ban as applying only to sales between cooperative members, or between the cooperative and non-members. It is uncertain whether the sale of marijuana from a non-member to a cooperative member was envisioned in the ban. In any case, how would any such transactions, gratis or for a price, be monitored? The U.S. Supreme Court may or may not address this and other issues later.

Conclusions. As discussed in the previous chapter, pharmaceutical, system-cost, and legal obstacles would render any national or state-based model impractical, if not impossible. Prior proposals in Hawaii to allow churches that use marijuana as a sacrament fail to address the relevant issues raised in this study. They further unnecessarily complicate the issue by designating religious groups to distribute marijuana for medical purposes. Finally, they are simplistic, do not work in concert with the core of the existing medical use of marijuana law, and fail to address certain relevant issues.

On the other hand, the cooperative intra-state model of distribution, as it continues to develop in California, appears to be the most promising. However, the eventual success of this model depends almost entirely on how the U. S. Supreme Court will rule on the Raich v. Ashcroft case (see chapter 3).

The Supreme Court may very well throw out the California model. Or it might limit or restrict that model in various unforeseen permutations. Hawaii, like the other states that have enacted medical marijuana laws, should await the Supreme Court's decision before taking further legislative action. In any case, it would be premature and unproductive to draft detailed legislation now to accommodate scenarios that no one can accurately anticipate and that may take on widely divergent forms.
REQUESTING THE LEGISLATIVE REFERENCE BUREAU TO CONDUCT A STUDY ON HOW MEDICAL MARIJUANA PLANTS AND PRODUCTS MAY BE PROCURED AND DISTRIBUTED TO PATIENTS REGISTERED WITH THE MEDICAL MARIJUANA PROGRAM.

WHEREAS, in 2000, Hawaii enacted a law that allows a physician to examine a patient's records and then if warranted certify that the patient has a debilitating medical condition that warrants the medical use of marijuana; and

WHEREAS, current law allows certified patients to possess three mature marijuana plants, four immature plants, and as much as three ounces of marijuana for personal use; and

WHEREAS, Hawaii has a Narcotics Enforcement Chief and Registrar for the Medical Marijuana Certification Program in the Department of Public Safety; and

WHEREAS, there are over 1,000 patients in Hawaii who are registered to grow and use marijuana for medicinal purposes, even though the purchase and sale of marijuana remains illegal in Hawaii; and

WHEREAS, the U.S. Supreme Court's decision of October 14, 2003, cleared the way for physicians to recommend the use of marijuana to patients in Hawaii; and

WHEREAS, the 9th U.S. Circuit Court of Appeals ruled in December 2003, that prosecuting medical marijuana users under a 1970 federal law is unconstitutional if the marijuana is not sold, transported across state lines, or used for nonmedicinal purposes; now, therefore,
BE IT RESOLVED by the House of Representatives of the Twenty-second Legislature of the State of Hawaii, Regular Session of 2004, the Senate concurring, that the Legislature recognizes the difficulty that patients have in acquiring marijuana for medicinal purposes, and requests the Legislative Reference Bureau, with the assistance of the Department of Public Safety, to conduct a study based on information available from other states; and

BE IT FURTHER RESOLVED that the Legislative Reference Bureau, in this study, is requested to identify the following:

(1) Methods by which registered users may access, cultivate, distribute, or purchase marijuana plants or products for medicinal purposes;

(2) Processes or procedures by which state and local agencies have made distinctions between medical (legal) marijuana and recreational (illegal) marijuana; and

(3) Experience of states in obtaining access to marijuana supplied by the federal government for therapeutic research; and

BE IT FURTHER RESOLVED that certified copies of this Concurrent Resolution be transmitted to the Governor, the Director of Public Safety, and the Legislative Reference Bureau.