



NABP 2009 Symposium

National Association of Boards of Pharmacy

J.W. Marriott Starr Pass Hotel • Tucson, AZ • December 3-4, 2009

Located amidst the saguaro cactus forest of Tucson Mountain Park, the NABP 2009 Symposium comes once again to the J.W. Marriott Starr Pass Hotel in Tucson, AZ, to provide state boards of pharmacy – including executive officers, compliance staff, board members, and board counsel – as well as other pharmacy professionals, the opportunity to collaborate with their peers on new and timely topics about the legalization of medical marijuana and opportunities for public-private partnerships.

During this one-and-a-half day event, attendees will hear from more than 15 speakers including representatives from state and federal agencies and other experts from the government, various medical and pharmacy practice settings, and academia. In addition, attendees can earn up to 11.25 hours (1.125 CEUs) of Accreditation Council for Pharmacy Education-approved continuing pharmacy education (CPE) credit.

Educational Programming

Legalization of Drugs: Is the Time Right for Medical Marijuana?

ACPE Program #205-000-09-008-L03-P (0.375 CEUs – 3.75 contact hours)

Speakers will provide participants with facts about the medical use of marijuana, emphasizing evidence-based medicine, including scientific evidence bearing on potential medical use. This session will open the door for further discussion with other experts regarding science, medicine, policy, and the law. Participants will also hear from speakers on the following topics:

- The Federal Status of Marijuana in the United States
- Should Marijuana be a Medical Option?
- Are These Medical Miracles?
- Medical Marijuana: Point-Counterpoint

Are We Going to Legalize Medical Marijuana?

ACPE Program #205-000-09-009-L03-P (0.325 CEUs – 3.25 contact hours)

Representatives from state agencies will share with participants how medicinal marijuana programs have been incorporated into their state's laws and regulations. Participants will learn how these programs were developed, implemented, enforced, and whether or not they are successful. Participants of this session will participate in a roundtable discussion after hearing from experts on the following topics:

- A Regulatory Approach to Medical Marijuana – What are the States Doing?
- A Regulatory Approach to Medical Marijuana – What has Canada Done?
- Legalizing Medical Marijuana – Creating a Slippery Slope?

Public-Private Partnerships: Stimulus Packages for Dwindling State Resources

ACPE Program #205-000-09-010-L03-P (0.425 CEUs – 4.25 contact hours)

In this session, Symposium participants will be provided with an overview of the concept of public-private partnerships. Representatives from various state and federal agencies will describe current and proposed public-private partnerships from education to highways to health care. Participants of this session will hear from experts and participate in a panel discussion on the following topics:

- Current Federal Public-Private Partnership Projects
- Current State Public-Private Partnership Projects



NABP and the NABP Foundation is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education. ACPE Provider Number: 205. Participants may earn up to 11.25 contact hours (1.125 CEUs) of ACPE-approved continuing pharmacy education credit from NABP. Participants in continuing pharmacy education programs will receive credit by completing a "Statement of Continuing Pharmacy Education Participation" and submitting it to NABP. A validated Statement of Continuing Pharmacy Education Credit will be sent as proof of participation within approximately six weeks. Full attendance and completion of a program evaluation form for each session are required to receive continuing pharmacy education credit and a Statement of Continuing Pharmacy Education Credit.

Continuing Legal Education (CLE) Policy: NABP staff will be available to assist attendees on an individual basis to apply for CLE credit for attending CPE sessions. To apply for CLE credit, attendees must initiate the program approval process in their own states by completing and submitting the appropriate application materials and forms. NABP will provide documentation as necessary.

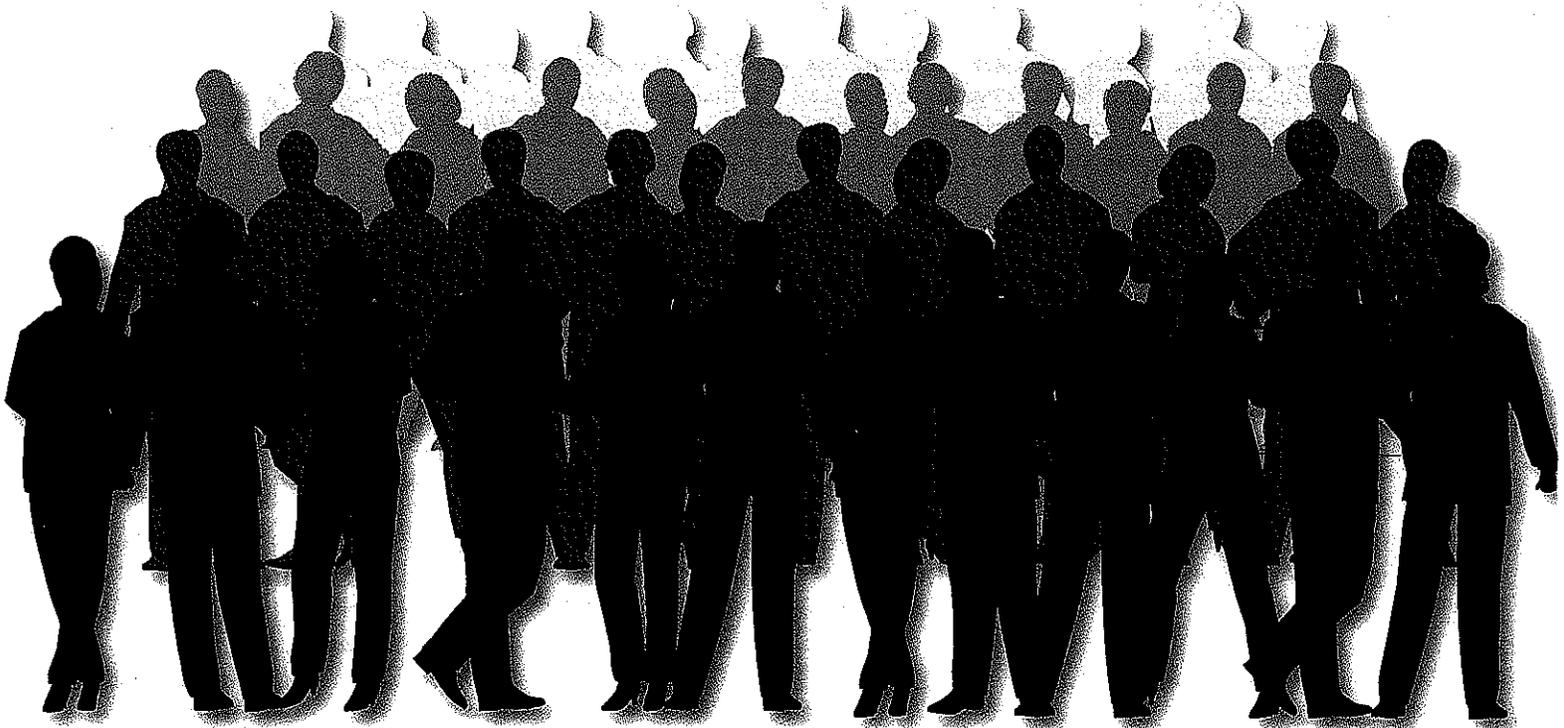
More details on the CPE are available in the Meetings section of www.nabp.net.



NABP 2009 Symposium

December 3-4, 2009

J.W. Marriott Starr Pass Hotel



Tucson
ARIZONA



Continuing Pharmacy Education Program
Thursday, December 3, 2009

NABP 2009
Symposium



8 AM - noon

Legalization of Drugs: Is the Time Right for Medical Marijuana?

Program #205-000-09-008-L03-P

0.375 CEUs – 3.75 contact hours

Target Audience: Pharmacists

Activity Type: Application based

Moderators:

Early Morning Presentations

- Gary A. Schnabel, RN, RPh, NABP President

Late Morning Presentations

- William T. Winsley, MS, RPh, NABP President-Elect

Speakers:

Early Morning Presentations

- Kenneth Mackie, MD, Linda and Jack Gill Chair of Neuroscience and Professor, Department of Psychological and Brain Sciences, Indiana University Bloomington
- Kevin Sabet, PhD, Special Advisor for Policy and Strategic Planning, Office of National Drug Control Policy
- Barry D. Dickinson, PhD, Director, Science & Biotechnology, and Secretary, Council on Science and Public Health, American Medical Association
- Alice Mead, JD, Director of United States Professional Relations, GW Pharmaceuticals
- Caren Woodson, MPP, Director of Government Affairs, Americans for Safe Access

Late Morning Presentations

- Sunil K. Aggarwal, PhD, MS-IV, Medical Student/Researcher, University of Washington School of Medicine
- Gregory T. Carter, MD, Professor of Rehabilitation Medicine, University of Washington School of Medicine
- Donald I. Abrams, MD, Professor of Clinical Medicine, University of California, San Francisco
- Andrea Barthwell, MD, FASAM, Founder and Chief Executive Officer, EMGlobal LLC, and Former Deputy Director for Demand Reduction, Office of National Drug Control Policy
- Barry D. Dickinson, PhD, Director, Science & Biotechnology, and Secretary, Council on Science and Public Health, American Medical Association
- Alice Mead, JD, Director of United States Professional Relations, GW Pharmaceuticals
- Caren Woodson, MPP, Director of Government Affairs, Americans for Safe Access

Learning objectives, speaker biographies, and contact information follow on the next page. For information on obtaining continuing pharmacy education and continuing legal education credit see Tab 4.



Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

Learning Objectives:

At the conclusion of these presentations, participants will be able to demonstrate an understanding of the topic through the following learning objectives.

Early Morning Presentations

1. Explain the pharmacology of marijuana and its potential use as a medical treatment.
2. Provide the current federal legal status of medical marijuana.
3. Describe how a major health care association's marijuana policy could result in a change to marijuana's legal status.

Late Morning Presentations

1. Describe three disease states that have utilized medical marijuana as a treatment regimen.
2. Explain the type of research necessary to determine whether marijuana can be used as a medical treatment.

Speaker Biographies:

Issue Introduction and Overview



Kenneth Mackie, MD, is the Linda and Jack Gill Chair of Neuroscience and a professor in the Department of Psychological and Brain Sciences at Indiana University Bloomington. He is also the interim director of the Gill Center at the university. For 15 years he combined an active research program with clinical care at the University of Washington until he was recruited in 2007 by Indiana University. Dr Mackie's research interests focus on understanding the relationships between cannabinoids (such as THC) and endocannabinoids, and the pharmacological and physiological responses to both. He has published extensively on these topics. Dr Mackie has also served on numerous review boards and has taken an active role in organizing cannabinoid-themed meetings. He is a member of several professional societies including the Society for Neuroscience, the American Society for Cell Biology, the International Cannabinoid Research Society, and the American Society of Anesthesiologists. Dr Mackie earned a bachelor of science degree in engineering from Brown University and a doctor of medicine degree from Yale University.

Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

NABP 2009
Symposium

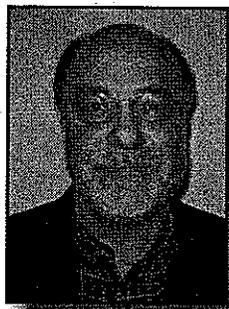


The Federal Status of Marijuana in the United States



Kevin Sabet, PhD, currently serves in the Obama Administration as the special advisor for policy and strategic planning at the White House Office of National Drug Control Policy (ONDCP), and has been working on drug policy issues for more than 16 years. In his current position, Dr Sabet advises director R. Gil Kerlikowske on all matters affecting priorities, policies, and programs of the National Drug Control Strategy. Prior to this, he worked on policy and speechwriting at ONDCP for several years during both the Bush and Clinton Administrations. Dr Sabet has also consulted in a private capacity on drug policy initiatives for the United Nations, local governments, and various nonprofit organizations. He is the founder of two anti-drug coalitions and has keynoted several major anti-drug conferences and professional meetings. He has also published widely in peer-reviewed journals and books on drug policy topics including medical marijuana. Dr Sabet earned a bachelor of arts degree in political science from the University of California, Berkeley and as a Marshall Scholar, he received his doctor of philosophy degree and master of science degree in social policy at Oxford University.

Should Marijuana be a Medical Option?



Barry D. Dickinson, PhD, is the director of the Division on Science and Biotechnology, and also serves as secretary of the Council on Science and Public Health at the American Medical Association (AMA) in Chicago, IL. The Science and Biotechnology Unit incorporates AMA's Drug Policy, Genetics, and Environmental Health programs. Additionally, Dr Dickinson has a faculty appointment in pharmacology at the Rosalind Franklin University of Medicine and Science in North Chicago, IL. He is author or coauthor of more than 100 articles, monographs, book chapters, and AMA Council on Science and Public Health reports. Previously, he served as staff author and scientific editor for AMA's *Drug Evaluations* and as editor of the University HealthSystem Consortium's Drug Monograph series. Dr Dickinson received his doctorate in pharmacology from the University of Illinois Medical Center at Chicago.



Alice Mead, JD, currently works as a consultant, specializing in regulatory law governing new drug and device development; patient confidentiality and informed consent; and domestic and international treaty issues relating to controlled drugs and drug treatment policy. Her clients include members of the pharmaceutical industry and other health-related organizations. She is also the director of United States professional relations at GW Pharmaceuticals. Ms Mead served for 11 years as staff counsel to the California Medical Association (CMA), focusing on bioethics, including informed consent, confidentiality, end-of-life care, discrimination, and drug



Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

abuse treatment/control issues. Prior to that time, Ms Mead was a litigation associate at the firm of Morrison & Forester and an assistant professor of law at Arizona State University College of Law (now Sandra Day O'Connor College of Law), specializing in constitutional law issues. She earned a bachelor of arts degree from the University of California Santa Cruz and a doctor of jurisprudence degree from Santa Clara University School of Law. In addition, Ms Mead earned a master of laws degree from Yale Law School.



Caren Woodson, MPP, has worked on medical marijuana issues for more than eight years, advising decision makers at all levels of government about how to implement and regulate medical marijuana laws. In her capacity as director of government affairs for Americans for Safe Access, Ms Woodson played an integral role in the drafting of San Francisco's ordinance that permits and regulates medical marijuana distribution centers, organized defeat of federal legislation that put in jeopardy state medical marijuana laws, and initiated US House Judiciary Committee oversight of Drug Enforcement Administration (DEA), the most significant level of oversight of DEA in the 10 years since the agency began conducting raids in states that permit the therapeutic use of marijuana. She has presented numerous times at various health and medical conferences including the National Association of People with AIDS, AIDS Watch, and many others. Ms Woodson received a bachelor of arts degree in political science from the University of Nevada – Las Vegas and a master of public policy from American University in Washington, DC.

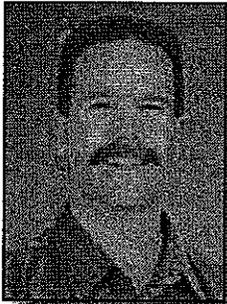
Are These Medical Miracles?



Sunil K. Aggarwal, PhD, MS-IV, is a senior medical student at the University of Washington and a trainee in the Medical Scientist Training Program. His doctoral dissertation, "The medical geography of cannabinoid botanicals in Washington State: Access, delivery, and distress" documented the successful use of medical cannabis by 176 chronically and critically ill patients in Washington State. His research studies, which took place at sites of medical access and delivery of medical cannabis, received federal Certificates of Confidentiality from the National Institutes of Health. He has served as a designated expert reviewer for the American Medical Association Council on Science and Public Health's report on medical cannabis science, an expert stakeholder for the Washington State Department of Health, and recently testified at the Iowa Board of Pharmacy hearings on the same topic. Dr Aggarwal is a founding member of the American Academy of Cannabinoid Medicine. He earned a bachelor of science degree in chemistry and a bachelor of arts degree in philosophy from the University of California, Berkeley, and completed his doctor of philosophy degree in medical geography from the University of Washington.

Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

NABP 2009
Symposium



Gregory T. Carter, MD, MS, is a professor of rehabilitation medicine at the University of Washington School of Medicine. In addition, he codirects the Muscular Dystrophy Association/Amyotrophic Lateral Sclerosis Center. Dr Carter currently has coauthored more than 100 peer-reviewed journal publications; six book chapters; and dozens of editorials, letters, and reviews. He is a founding member of the neuromuscular medicine subspecialty board of the American Board of Neurology and Psychiatry and also serves on the editorial boards of the journals *Muscle and Nerve*, the *Journal of Clinical Neuromuscular Disease*, and the *American Journal of Hospice and Palliative Medicine*. Additionally, Dr Carter has received several awards and honors including the Castle Connolly Medical Ltd listing of "America's Top Doctors" in 2007 and the Excellence in Clinical Care Award from the Muscular Dystrophy Association in 2002. He earned a bachelor of science degree and a master of science degree in physiology from the University of California, Davis and a doctor of medicine degree from Loyola University Stritch School of Medicine.



Donald I. Abrams, MD, is currently a professor of clinical medicine at the University of California, San Francisco (UCSF). In addition, Dr Abrams is chief of the hematology-oncology division at San Francisco General Hospital. Employed by UCSF since 1982, he has also served as an assistant research physician in the Cancer Research Institute, clinical instructor, assistant clinical professor, and associate professor of clinical medicine. He is a member of several organizations and has authored and coauthored more than 160 publications. Dr Abrams is also a recipient of numerous honors and awards including the International Association for Cannabis as Medicine Award for Clinical Research, Brown University Top 100 Distinguished Alumni of the Century, Stanford University School of Medicine Top 40 Alumni of Past 40 Years, and American Foundation for AIDS Research Award of Courage. He earned a bachelor of arts degree in molecular biology from Brown University and doctor of medicine degree from Stanford University School of Medicine.

Medical Marijuana: Point-Counterpoint

Donald I. Abrams, MD. See *Are These Medical Miracles?* on the previous page for Dr Abrams' biography.

Sunil K. Aggarwal, PhD, MS-IV. See *Are These Medical Miracles?* above for Dr Aggarwal's biography.



Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)



Andrea Barthwell, MD, FASAM, is the founder and chief executive officer of the global health care and policy consulting firm EMGlobal LLC. Prior to this position, Dr Barthwell served as deputy director for demand reduction in the Office of National Drug Control Policy where she was a principal advisor in the Executive Office of the President of the United States on policies aimed at reducing the demand for illicit drugs. While serving in this capacity, she was an active member of the White House Task Force on Disadvantaged Youth and the White House Domestic Violence Working Group and worked closely with the National Institute on Drug Abuse to define the scope of its Health Services Research portfolio. In addition, Dr Barthwell served as president of the Encounter Medical Group, an affiliate of EMGlobal; was a founding member of the Chicago Area AIDS Task Force; and is a past president of the American Society of Addiction Medicine. Dr Barthwell received a bachelor of arts degree in psychology from Wesleyan University and a doctor of medicine degree from the University of Michigan Medical School.

Gregory T. Carter, MD, MS. See *Are These Medical Miracles?* on the previous page for Dr Carter's biography.

Barry D. Dickinson, PhD. See *Should Marijuana be a Medical Option?* located within this tab for Dr Dickinson's biography.

Alice Mead, JD. See *Should Marijuana be a Medical Option?* located within this tab for Ms Mead's biography.

Caren Woodson, MPP. See *Should Marijuana be a Medical Option?* located within this tab for Ms Woodson's biography.

Faculty Contact Information:

Donald I. Abrams, MD

Professor of Clinical Medicine, UCSF

Phone: 415/476-4082

E-mail: dabrams@hemeonc.ucsf.edu

Donald I. Abrams declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Sunil K. Aggarwal, PhD, MS-IV

Medical Student/Researcher, University of Washington School of Medicine

Phone: 206/375-3785

E-mail: sunila@uw.edu

Sunil K. Aggarwal declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Continuing Pharmacy Education Program
Thursday, December 3, 2009 (cont)

NABP 2009
Symposium



Andrea Barthwell, MD, FASAM

Founder and Chief Executive Officer, EMGlobal LLC

Phone: 703/527-4700

E-mail: drb@emglobal.com

Andrea Barthwell declares that neither she nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Gregory T. Carter, MD, MS

Professor of Rehabilitation Medicine, University of Washington School of Pharmacy

E-mail: gtcarter@u.washington.edu

Gregory T. Carter declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Barry D. Dickinson, PhD

Director, Science & Biotechnology, and Secretary, Council on Science and Public Health, AMA

Phone: 312/464-4549

E-mail: barry.dickinson@ama-assn.org

Barry D. Dickinson declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Kenneth Mackie, MD

Linda and Jack Gill Chair of Neuroscience and Professor, Department of Psychological and Brain Sciences, Indiana University Bloomington

Phone: 812/855-2042

E-mail: kmackie@indiana.edu

Kenneth Mackie declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Alice Mead, JD

Director of United States Professional Relations, GW Pharmaceuticals

Phone: 415/388-9057

E-mail: apm@gwpharm.com

Alice Mead has an affiliation or financial agreement with the following commercial interest as an employee: GW Pharmaceuticals

Kevin Sabet, PhD

Special Advisor for Policy and Strategic Planning, ONDCP

Phone: 202/395-6798

E-mail: kevin_sabet@ondcp.eop.gov



NABP 2009
Symposium

Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

Kevin Sabet declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Caren Woodson, MPP

Director of Government Affairs, ASA

Phone: 202/857-4272

E-mail: caren@safeaccessnow.org

Caren Woodson declares that neither she nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Should Marijuana be a Medical Option?

Barry D. Dickinson, PhD, Secretary
AMA Council on Science & Public Health



Federation of Medicine

The term "Federation of Medicine" is used to describe the state, county, and specialty medical societies represented in the American Medical Association House of Delegates that work together to advance the agenda of physicians and their patients.

AMA Policy House of Delegates

Representation in the House is proportional to the number of AMA members in a society, with every member organization entitled to at least one delegate. All fifty states are represented in the House, along with the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

Additional Members of the HOD

- National Medical Societies (~110)
- Federal Services
- Professional Interest Medical Associations, Sections, and Other Groups

Council on Science and Public Health (CSAPH)

- Comprises 11 active members of the AMA, one of who is a Resident.
- Members elected by the House of Delegates.
- In addition, a medical student member of the AMA is appointed by the Governing Council of the AMA Medical Student Section.
- Mission of the CSAPH is to help advance the science of medicine as the primary mechanism for improving the quality of patient care, enhancing medical progress, and enhancing the health of the public.

AMA Policy on "Medical Marijuana" (11/3/09)

- AMA policy on the medicinal use of cannabis has evolved out of a series of three CSAPH reports to the HOD.
- 1997 Report--Review of policy issues raised by Arizona and California initiatives and pharmacologic and systematic review of the science base on therapeutic use of crude marijuana and cannabinoid-based FDA approved products.
- 2001 Reports updated "progress."

**AMA Policy H-95.952
Medical Marijuana**

1. Conduct further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
2. Marijuana be retained in Schedule I of the Controlled Substances Act pending the outcome of such studies.
3. NIH should implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research into the medical utility of marijuana.

**AMA Medical Marijuana Policy
(cont)**

4. NIH should use its resources and influence to support the development of a smoke-free inhaled delivery system for marijuana or delta-9-tetrahydrocannabinol (THC) to reduce the health hazards associated with the combustion and inhalation of marijuana.
5. Effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions.

**CSAPH Report 3: Cannabis for Medicinal Purposes
2009 AMA Interim Meeting Nov 8-10, 2009**

- (1) provides a brief historical perspective on the use of cannabis as medicine;
- (2) examines the current federal and state-based legal envelope relevant to the medical use of cannabis;
- (3) provides a brief overview of our current understanding of the pharmacology and physiology of the endocannabinoid system;
- (4) reviews clinical trials on the relative safety and efficacy of smoked cannabis and botanical-based products; and
- (5) places this information in perspective with respect to the current drug regulatory framework.

CSAPH Report 3 (I-09): Findings

- Despite more than 30 years of clinical research, only a small number of randomized, controlled trials have been conducted on smoked cannabis.
- These trials were short term and involved a total of ~300 patients.
- Results indicate smoked cannabis reduces neuropathic pain, improves appetite and caloric intake, and may relieve spasticity and pain in patients with multiple sclerosis.
- Surveys of patients with HIV or hepatitis C infection suggest that smoked cannabis is used to relieve a constellation of symptoms and as a source of palliation from antiviral medication side effects.

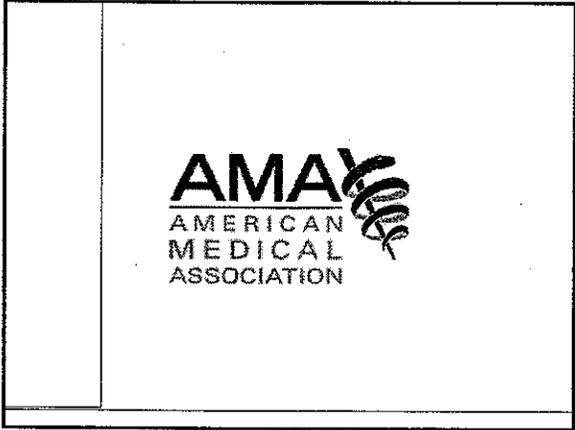
CSAPH Report: Conclusions

- The AMA supports drug approval by federal scientific and regulatory review to establish safety and efficacy, and appropriate standards for identity, strength, quality, purity, packaging, and labeling, rather than by ballot initiative or state legislative action.
- The future of cannabinoid-based medicine lies in the rapidly evolving field of botanical drug substance development, as well as the design of molecules that target various aspects of the endocannabinoid system.
- To the extent that rescheduling marijuana out of Schedule I will benefit this effort, such a move can be supported.
- In the meantime, physicians who comply with their ethical obligations to "first do no harm" and to "relieve pain and suffering" should be protected, including advising and counseling their patients on the use of cannabis for therapeutic purposes.

Proposed New AMA Recommendation

That our American Medical Association (AMA) urge that marijuana's status as a federal Schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines.

This recommendation should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.





Christine V. Beato, MD
Acting Assist. Secretary for Health
Department of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

April 12, 2005

Re: Americans for Safe Access Request for Correction
Of Information under the Data Quality Act

Dear Dr. Beato,

Alice P. Mead, J.D.
Special Counsel, Medical Affairs
GW Pharmaceuticals plc
4 Heather Way
Mill Valley
California 94941
Direct Line: 415 388 9057
Facsimile: 415 383 7566
E-mail: apm@gwpharm.com

GW Pharmaceuticals submits these comments in relation to the Request for Correction of Information submitted to the Department of Health and Human Services by Americans for Safe Access (ASA), on October 4, 2004, under the Data Quality Act. GW wishes to provide clarification concerning several of the studies cited in ASA's Request for Correction.

GW Pharmaceuticals

GW Pharmaceuticals (GW) is a British pharmaceutical company founded for the purpose of developing a portfolio of prescription medicines derived from components of the cannabis plant. The UK government has licensed GW to conduct a full pharmaceutical development program. To accomplish its goals, GW has assembled a team of over 100 scientists with extensive experience in developing both plant-based prescription pharmaceutical products and medicines containing controlled substances.

GW cultivates particular strains of cannabis that have been bred to express specific ratios of cannabinoids. In order to maintain the consistency of the plants' chemical composition, they are grown by clones (cuttings) under highly-standardized and computer-controlled conditions in secure glasshouses. GW extracts the pharmacologically-active components of the plant, removes waxes and other unwanted constituents, and formulates the resulting botanical drug substance into a final dosage form of specified composition, which is characterized by various standard chromatographic techniques.

GW's research has demonstrated that the composition of a cannabis-derived product can and must be carefully defined. The company's lead product, Sativex, is an oromucosal spray composed primarily of tetrahydrocannabinol (THC) and cannabidiol (CBD), a non-psychoactive cannabinoid. GW believes that this combination has distinct and important pharmacological activity.

Sativex is quite different from herbal cannabis. Sativex is a pharmaceutical product, standardized by both composition and dose. In order to be approved by any country for marketing as a prescription medicine, Sativex must meet all applicable regulatory requirements for quality, safety, and efficacy. Sativex is currently undergoing regulatory review in both the UK and Canada.

GW has undertaken this development program with a strong belief that a modern medical product can be made from the constituents of the cannabis plant. The company believes that positive clinical trial results with the pharmaceutically formulated Sativex do not support the contention that herbal cannabis should be made directly available as a prescription medicine.

Peer-Reviewed Studies Relating to Sativex

In its Request for Correction, ASA states that "numerous peer-reviewed studies... establish that marijuana is effective in treating various illnesses." In support of this statement, ASA cites articles, case reports, and peer-reviewed studies describing the results of clinical trials, as well as a 1999 report of the Institute of Medicine. Specifically, ASA cites the following studies:

- Brady CM, DasGupta R, Dalton C, Wiseman OJ, Berkley KJ, Fowler CJ. 2004. An open-label pilot study of cannabis-based extracts for bladder dysfunction in advanced multiple sclerosis. *Multiple Sclerosis* 10:425-433.
- Wade DT, Makela P, Robson P, House H, Bateman C. 2004. Do cannabis-based medicinal extracts have general or specific effects on symptoms of multiple sclerosis? A double-blind, randomized, placebo-controlled study on 160 patients. *Multiple Sclerosis* 10:434-41.
- Wade DT, Robson P, House H, Makela P, Aram J. 2003. A preliminary controlled study to determine whether whole-plant extracts can improve intractable neurogenic symptoms. *Clinical Rehabilitation* 17:18-26.

These studies compared Sativex, GW's lead pharmaceutical product, with placebo, and in some cases, with other GW investigational products. The data do not support the contention that herbal cannabis, whatever its strain, composition, stage of processing, or delivery system, is safe and effective for treating the medical conditions that were examined in these trials.

First, herbal cannabis is not a homogeneous substance. A variety of plant strains exist, each of which is of different chemical composition. For example, the cannabis that is commonly cultivated in the United States predominantly expresses tetrahydrocannabinol (THC), the cannabinoid that is largely responsible for cannabis's psychoactive effect. Most strains of cannabis cultivated in the U.S. have very little, if any, cannabidiol (CBD), a non-psychoactive cannabinoid. Sativex, by contrast, contains both THC and CBD in a near 1:1 ratio (2.7/2.5 mg. per spray). Furthermore, cannabis

will differ depending on the circumstances under which the herbal material is cultivated, harvested, dried, and stored. The nature of the procedures used in each of these steps will affect the ultimate composition and quality of the herbal material. Hence, it **cannot** be said that all cannabis--or all cannabis extracts--are the same.

Second, herbal cannabis should comprise only the starting material from which a *bona fide* medical product is ultimately derived. For example, opium is a Schedule II substance, but it merely provides the starting material for a number of pharmaceutical dosage forms that are lawfully marketed in the U.S. Herbal opium is not itself used directly by patients. Nevertheless, ASA avowedly seeks, through its Request for Correction, to enable patients to use herbal cannabis directly (generally in a smoked form), rather than to rely upon a medical product that has undergone the appropriate regulatory scrutiny. This would seriously undermine the Food and Drug Administration's regulatory approval process, which has been carefully crafted over the past century.

Third, standardizing herbal starting material represents only the first of many steps necessary to create a modern medicine that is safe and effective for use in specific medical conditions. Even if a specific strain of cannabis could be cultivated and dried under highly controlled conditions, such herbal material would still be required to undergo a series of further processes—quality controlled at each point--to create a final medical product. Such a product must also be delivered in a dosage form that is consistent in composition and that allows the patient to obtain an identifiable and reliable amount of medication. Different dosage forms—oral, transdermal, smoked or otherwise inhaled, etc.—may have quite distinct pharmacological activity and may affect absorption and metabolism in different ways. Some, such as smoking, create potentially harmful pyrolytic byproducts. Even within the same dosage form, a substance, when combined with different inert excipients, may affect the human body differently. GW believes that the clinical studies cited above do not demonstrate that **generic and unrefined herbal cannabis** is safe and effective for direct use as a prescription medicine.

Finally, the Food and Drug Administration (FDA) has not yet approved Sativex for use in the treatment of Multiple Sclerosis-related spasticity, bladder dysfunction, or any of the other medical conditions that were examined in the studies cited above. Thus, it would be a great irony if generic herbal cannabis were to be removed from Schedule I of the Controlled Substances Act, and made available for general medical use, based in part on data relating to a specific product that is not FDA-approved and therefore has not itself been so rescheduled.

/

/

/

/

/

/

/

/

/

GW Pharmaceuticals appreciates the opportunity to clarify the nature of the above clinical studies and data.

Respectfully submitted,

Alice P. Mead

Alice P. Mead
Special Counsel, Medical Affairs
GW Pharmaceuticals

Should Marijuana be a Medical Option?

Alice P. Mead JD
Presentation to the National
Association of Boards of Pharmacy
December 3, 2009

Why do we care about the FDA process?

- Provisions developed over the past 100 years to protect patient health and safety
 - promote quality, safety and efficacy of medications;
 - supported by all major medical organizations
- Extensive preclinical and clinical testing provides a robust body of risk/benefit and pharmacological data
 - physicians need this to inform their prescribing decisions
- Registration/inspection ensures that the manufacturing process is conducted in accordance with validated quality control tools
- Promotional activities of manufacturers limited
- Products prescribed/dispensed under the supervision of licensed health care providers, e.g., physicians, pharmacists

Modern Regulatory Approval Requirements: Quality, Safety & Efficacy

- **Quality**
 - Product Composition
 - Characterization
 - Quantification of components
 - Standardization / Consistency
 - Stability / Storage
- **Safety**
 - Animal data, including:
 - Carcinogenicity
 - Reproductive toxicology
 - Chronic toxicology
 - Genotoxicology
 - Safety pharmacology
 - Clinical data
 - Several hundred patient-years of data required
 - Reports of all adverse events (mild/moderate/severe – related and unrelated)
 - Immediate regulatory notification of serious adverse events
- **Efficacy**
 - Multiple Phase II & Phase III placebo-controlled clinical trials for each target clinical indication

How does “medical marijuana” currently fit into the FDA paradigm?

- **Composition (% of THC) of herbal cannabis varies significantly**
 - depends on strains, cultivation and storage, etc.
- **North American cannabis bred to exhibit (only) high levels of THC**
 - no meaningful levels of other cannabinoids such as CBD
- **Delivery systems (smoked/vaporized, baked goods, teas) do not provide a standardized dose**
 - smoking delivers harmful pyrolytic products to the lungs
 - Vaporization does not completely eliminate PAHs
- **Contamination with microbes, heavy metal, and pesticides a real possibility**

How does “medical marijuana” currently fit into the FDA paradigm? con’t

- Distribution does not take place within regulated supply chain for pharmaceuticals
 - “collectives” and “cooperatives”
- No collection of adverse event or efficacy data
 - impossible to know who is really benefiting or being harmed
- Medical advice being given by untrained and unlicensed individuals
 - broad efficacy claims
 - often no meaningful physician supervision
 - no labeling with risk information or instructions for use
- Patients cannot obtain health insurance coverage

What would it take for a cannabis product to secure FDA approval?

- Herbal material grown by clones under rigorous conditions, ideally computer controlled greenhouses, to produce standardized starting materials
 - Under international policies of last 85 years, US imports, rather than cultivates, psychoactive herbal material and manufactures finished products in US
- Need to incorporate **an extract** (“Botanical Drug Substance”) into an appropriate delivery system;
 - No precedent for administering **any** crude herbal material in a manner that reliably achieves a reproducible dose, produces no carcinogens

FDA approval con't

- Sponsor must manufacture and test product in accordance with FDA "Guidance for Industry: Botanical Drug Products"
 - Guidance allows some leniency in early research; by Phase 3 /NDA, all NCE standards must be met
 - Blinded, placebo-controlled large clinical studies must examine specific medical condition in specific population
 - Sponsor must conduct abuse liability testing and prepare risk management plan

What About the DEA?

- DEA must register clinical and preclinical research sites and importer/manufacturer
- After NDA, DEA must reschedule product
 - FDA approval satisfies "currently acceptable medical use in the US" **for that product**

Should Cannabis be Rescheduled?

- If a cannabis-derived product were FDA approved, must cannabis itself be moved to Schedule II, like opium and cocaine?
- Conversely, must cannabis be rescheduled in order for such a product to reach the market?
- Probably not. Split scheduling appears to be possible.
 - Marinol (Schedule III) and Cesamet (Schedule II) vs. THC (Schedule I);
 - Xyrem (Schedule III) vs. GHB (Schedule I)

What Would Rescheduling Achieve?

- FDA does not approval bulk substances/ active ingredients for direct prescriptive use
- **Even if “cannabis” itself were moved to Schedule II, a specific cannabis or cannabis-based product would need FDA approval to be available by prescription**
- Might at most speed up the obtaining of initial research registrations

Giving Cannabis a Free Pass = ?

- By creating an exception for cannabis, we are preventing the development of Q, S & E data that would allow it to become broadly accepted as a true medication
- The vast majority of patients want a product that is standardized by composition and dose and about which their physicians can offer meaningful advice

More Research Needed: Formulation is Important

- Cannabis plant is the unique source of cannabinoids
- Over 60 cannabinoids in total, each with their own--often complementary--pharmacology, especially CBD
- Also other pharmacologically active components, e.g., terpenes, flavonoids

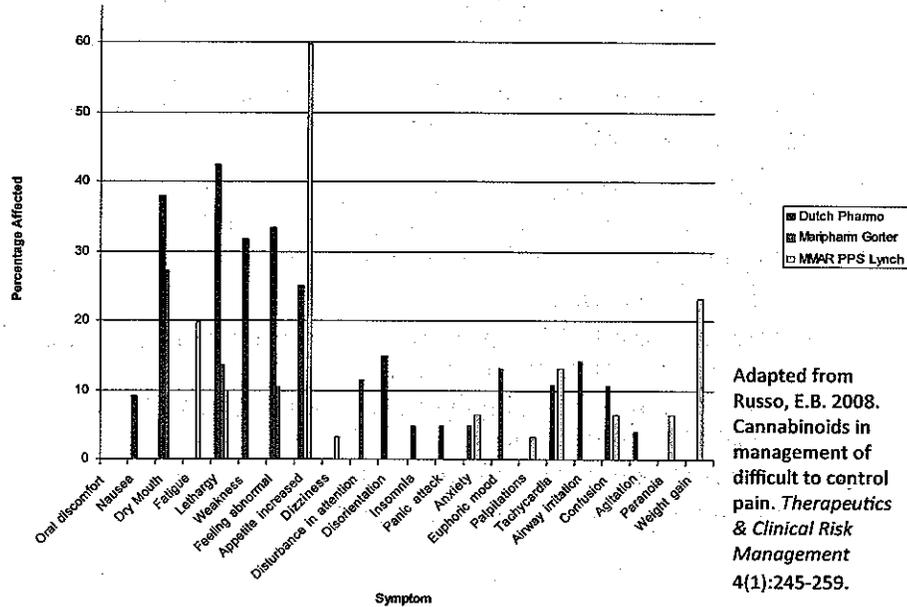
There's More Than THC!

- Cannabis used centuries ago would have involved a 1:1 CBD:THC ratio
- THC (tetrahydrocannabinol):
 - is analgesic, anti-spasmodic, anti-tremor, anti-inflammatory, appetite stimulant, anti-emetic
- CBD (cannabidiol):
 - does not bind to CB1 cannabinoid receptor, but does bind to other receptors in the body;
 - is anti-inflammatory, analgesic, anti-convulsant, anti-psychotic, anti-oxidant, neuroprotective;
 - reduces the negative effects of THC
 - has been bred out of modern herbal cannabis!

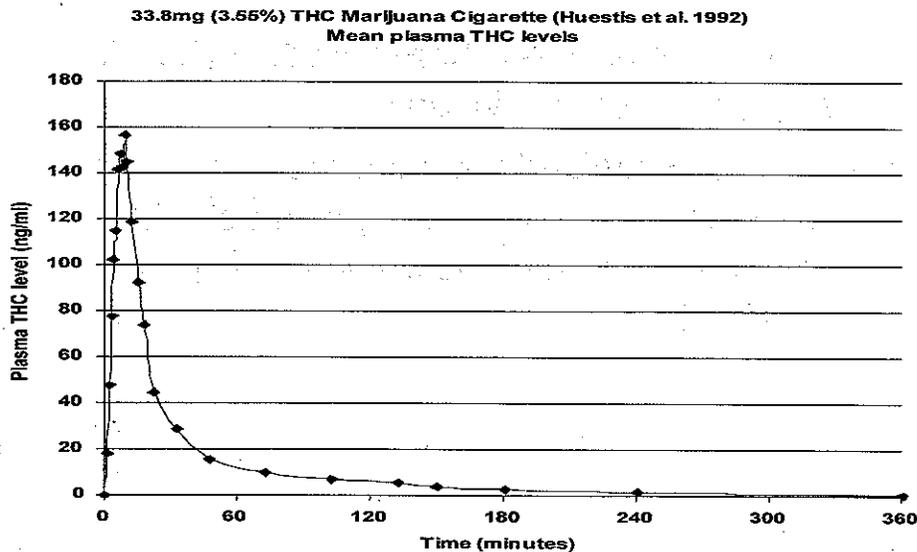
The Delivery System is Also Important

- THC-containing cannabinoid products have a narrow therapeutic window
- How to provide and maintain therapeutic blood and tissue levels of key cannabinoid components without incurring unacceptable side effects

AE of Standardized Smoked Medicinal Cannabis



THC Levels from Smoked Cannabis (Huestis et al. 1992)



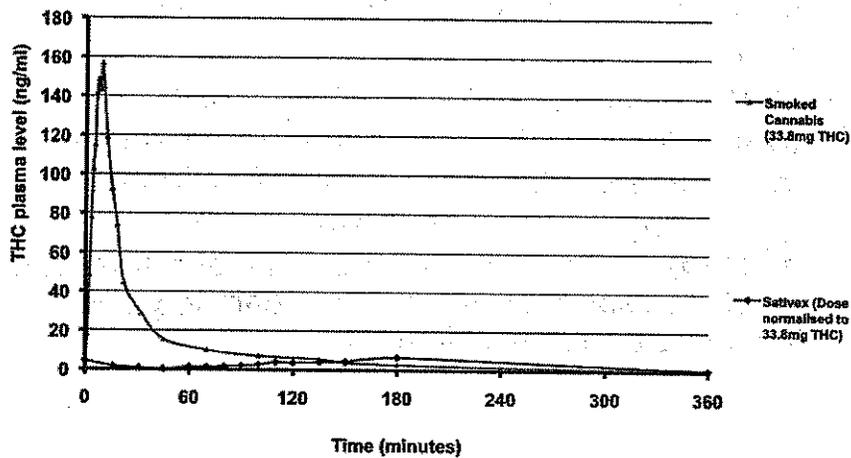
Cannabinoid Therapeutic Window: Challenges

- Significant difference in availability between patients; need to be able to adjust individual dose
- Poorly soluble in water (unlike opiates)
- **Oral route:** poor bioavailability; psychoactive metabolite produced; prolonged (2-4 hours) onset of action so can't titrate
- **Inhaled/smoked route** makes THC levels rise too much/too soon, produces psychoactivity and increases drug abuse liability

Cannabinoid Therapeutic Window – Approaches?

- Cannabinoid ratios (CBD/THC) widen window
 - CBD counters some of the side effects, including intoxication
 - CBD:THC ratio has a unique therapeutic profile
- Route and method of delivery
 - Oromucosal route far less variable than Oral (GI)
 - Oromucosal absorption decreases production of psychoactive metabolite by liver
 - Intermediate onset of action allows patients to adjust and predictably individualize their dose
 - Rate of absorption is controlled: not too much THC too soon

Dose-normalised comparison of THC Levels from
Smoked Cannabis (33.8mg THC) with nabiximols
(Sativex) (12.5 sprays containing 33.8mg THC)



Products of the future

- Preparations of different cannabinoids (both synthetic and botanically-derived) and cannabinoid ratios, e.g., CBG, CBN, THCV, etc.
- Targeting CB2 and other receptors, not just CB1
- Modulating the endocannabinoid receptor system

It Takes Time!

- Improved technology and discovery of endocannabinoid receptor system means that we are only at the early stages of developing modern medications, i.e., numerous preclinical studies, gradually moving into clinical trials, etc.
- At some point soon, will be same distinction as there is with smoked opium (recreational use only) and modern opiate medications

One possible product

- Nabiximols (Sativex®) contains a defined (1:1) ratio of THC and CBD, as well as other minor cannabinoids, terpenes, etc.
- Finished pharmaceutical product derived from extracts of two unique strains of the cannabis plant
 - One strain is predominantly THC
 - Other strain predominantly CBD (cannabidiol), a non-psychoactive cannabinoid
 - Also contains other plant components, such as terpenes, flavonoids, etc.
- Novel delivery system—oromucosal spray
 - Intermediate onset of action, 15-40 minutes
 - Allows patients to individualize their dose
 - Each spray provides 100 µl of product, comprising 2.7mg. THC and 2.5mg. CBD

AMERICANS FOR SAFE ACCESS

ABOUT ASA

ADVANCING LEGAL MEDICAL MARIJUANA THERAPEUTICS AND RESEARCH

ABOUT US

Americans for Safe Access (ASA) is the largest national member-based organization of patients, medical professionals, scientists and concerned citizens advancing safe and legal access to cannabis for therapeutic use and research. ASA works to overcome political and legal barriers by creating policies that improve access to medical cannabis. We have more than 30,000 active members with chapters and affiliates in more than 40 states.

Medical cannabis patient and current Executive Director Steph Sherer founded the organization in 2002 in response to federal enforcement raids on patients in California. Ever since then, ASA has been instrumental in shaping the political and legal landscape of medical cannabis. Our successful lobbying, media, and legal campaigns have resulted in positive court precedents, new sentencing standards, more compassionate legislative and administrative policies and procedures, as well as new legislation.

ASA protects the rights of cannabis patients. Our success is rooted in a multi-faceted strategy that incorporates public education, impact litigation, grassroots advocacy, direct lobbying, and services for patients and their caregivers. ASA works at all levels of government to support policies that ensure safe access to cannabis for therapeutic use and programs that encourage research.

OUR MISSION

The mission of Americans for Safe Access is to ensure safe and legal access to cannabis (marijuana) for therapeutic uses and research.

ASA provides legal training for and medical information to patients, attorneys, health and medical professionals and policymakers throughout the United States. We also organize media support for court cases, rapid response to law enforcement raids, and capacity-building for advocates.

Our goal is to develop a national policy that acknowledges the accepted medical value of marijuana in the United States, ensures safe and legal access to cannabis for therapeutic use, and advances medical and scientific research.



Headquarters 1322 Webster Street, Suite 402, Oakland, CA 94612
National Office 1730 M Street NW, Suite 611, Washington DC 20036
888-929-4367
www.SafeAccessNow.org

ASA NATIONAL POLICY AGENDA

111TH CONGRESS 2009-2011

END FEDERAL RAIDS, INTIMIDATION AND INTERFERENCE WITH STATE LAW.

Thirteen states representing more than 72 million people have passed laws authorizing individuals living with a serious or chronic illness to use and obtain cannabis as recommended by a physician. However, these state laws differ from the federal law and leave patients and their providers vulnerable to federal raids, arrest, and prosecution. Since 2006, many state and local governments have been working overtime to fully implement their state laws to curb abuse and create the appropriate systems to carefully regulate and control the distribution of medical cannabis to authorized individuals in their communities.

Effective implementation of state medical cannabis laws is stymied by federal interference. The U.S. Department of Justice together with the Drug Enforcement Administration has conducted scores of enforcement raids and employed intimidation tactics designed to undermine the implementation of state and local law. The importance of state laws, and the protection they provide, is underscored by the reluctance of the federal policymakers to address the issue of medical cannabis in a meaningful way. Until the Congress and the Administration create a comprehensive national medical cannabis strategy, individual states should not be obstructed from responding to the public health needs of their citizens.

PERMIT AFFIRMATIVE DEFENSE AND ESTABLISH FEDERAL LEGAL PROTECTION FOR INDIVIDUALS AUTHORIZED BY STATE OR LOCAL LAW TO USE OR PROVIDE CANNABIS FOR THERAPEUTIC USE.

The United States Supreme Court, in *Conant v. Walters*, upheld a decision by the Ninth U.S. Circuit Court of Appeals that physicians have a Constitutional right to recommend the use of cannabis to their patients. Unfortunately, federal law specifically prohibits the use of cannabis—even for therapeutic purposes. Outdated federal policies significantly impede safe and legal access to cannabis; most patients have to break federal law and place themselves (or their caregivers) in unnecessary and potentially harmful circumstances in order to gain access to cannabis legally recommended by their physician.

Currently, the Department of Justice has prosecuted more than 100 licensed medical cannabis patients and providers. Unfortunately, these defendants will be forbidden from explaining that their

marijuana-related activities were therapeutic and in compliance with state law, limiting their ability to present a defense in federal court. Congress and the Administration should amend the Controlled Substances Act to provide an affirmative defense in federal court and establish legal protections for individuals who use or provide cannabis for therapeutic use in accordance with state and local law.

ENCOURAGE ADVANCED CLINICAL RESEARCH TRIALS THAT MEET ACCEPTED SCIENTIFIC STANDARDS.

Federal law clearly requires adequate competition in the manufacture of Schedule I and II substances, but since 1968 the National Institute on Drug Abuse (NIDA) has maintained a monopoly on the supply of cannabis used for legitimate research purposes. The Drug Enforcement Administration helps to protect NIDA's monopoly by refusing to grant competitive licenses for the production of research-grade cannabis. In 2007, U.S. Department of Justice-appointed Administrative Law Judge Mary Ellen Bittner issued an Opinion and Recommended Ruling which concluded that granting competitive licenses would be "in the public interest." However, the Bush Administration has taken no action, and the Administrative Recommendation remains pending.

Congress and the Administration should work to remove the political and bureaucratic obstacles that inhibit clinical research and instead should create incentives to conduct research in accordance with the Institute of Medicine's recommendations.

CREATE A NATIONAL MEDICAL CANNABIS STRATEGY THAT INCLUDES A SAFE AND LEGAL ACCESS PLAN

A scientific consensus supports the therapeutic use of cannabis to control symptoms of serious and chronic illness. In the past decade, clinical research has clearly demonstrated that the use of cannabis, and its constituents, can safely and effectively treat symptoms of serious and chronic illness like nausea and vomiting, loss of appetite, pain and spasticity.

The science and policy regarding the medical use of cannabis should not be obscured or hindered by the debate surrounding the legalization of marijuana for general use. Scientific consensus coupled with state leadership has provided a solid foundation for federal policymakers to create a comprehensive plan to support long-term solutions for safe and legal access to cannabis for therapeutic use and research.



Advancing Legal Medical Marijuana Therapeutics and Research

Headquarters 1322 Webster Street, Suite 402, Oakland, CA 94612
National Office 1730 M Street NW, Suite 611, Washington DC 20036
888-929-4367
www.SafeAccessNow.org

NABP 2009 SYMPOSIUM

• *Cannabis in the Treatment of
Chronic Pain*

Gregory T. Carter, M.D., M.S.

- Professor of Rehabilitation Medicine, University of Washington School of Medicine
- Co-Director of the Muscular Dystrophy Association (MDA)/Amyotrophic Lateral Sclerosis Center (ALS), UWMC, Seattle, WA
- Medical Director of Regional MDA Neuromuscular Disease Clinic, Providence Rehabilitation Center, Olympia, WA

Sunil K. Aggarwal, PhD, MD-C

- Medical Scientist Training Program, University of Washington School of Medicine
- Principal Investigator – **Characteristics of patients with chronic pain accessing treatment with medical cannabis in Washington State**

Lecture Outline

- Brief History
- Biology/Pharmacology of Marijuana (Cannabis)
- Clinical Trials
- Using Cannabinoids in this Setting

Historical Aspects

- Has been used medicinally, spiritually, and recreationally for thousands of years
- Was legal in USA until 1937 and was on the US Pharmacopoeia until 1942: this was done AGAINST the advice of the AMA (then known as the American Medical Society)
- Harry Anslinger – responsible for “Reefer Madness”: thus opiates became the pathway for pain management

Biology of Cannabis

- Very complex: see papers
- Over 100 different cannabinoids
- Lipid soluble
- 21 carbon “terpenes”
- Cannabinoids very similar to flavinoids found in chocolate

Biology of Cannabinoids

- Endogenous System
- Receptor Based Mechanisms
- THC is most common AND most psychoactive (Marinol)
- Cannabidiol and Cannabinol are also very prevalent

Cannabinoid Receptors

CB₁ Receptor Distribution: Brain, Adipose Tissue, Muscle, Liver, GI Tract, Pancreas

CB₂ Receptor Distribution: Immune System (T cells, B cells, Monocytes, Spleen, Tonsils)

- G-protein-coupled receptors
- CB₁ receptors highly expressed in the brain
 - CB₁ receptors also found in adipose tissue, liver, muscle, the gastrointestinal tract, pancreas, as well as reproductive and cardiovascular tissues
- CB₂ receptors are expressed primarily in immune cells
 - CB₂ receptor expression in neurons is being studied

Correia VA et al. Mol Pharmacol. 1999;34:935-913. Osei-Hyiaman D, DePetralis M, Procher P, et al. J Clin Invest. 2002;115:1200-1205.
 Munro G et al. Nature. 1993;365:61-65. Cole D, Woods SC. Curr Opin Endocrinol Diabetes. 2003;12:530-551.
 Arnold A. Prog Neurobiol. 1997;50:313-348.

Key ECS Elements

Cannabinoid receptors are G-protein-coupled receptors

Endocannabinoids: Anandamide, 2-Arachidonoyl-glycerol

CB₁ receptor

- Central nervous system
 - Hypothalamus
 - Basal ganglia
 - Cerebellum
 - Caudate
 - Hypothalamus
 - Limbic structures
 - Brainstem
- GI tract (enteric neurons and epithelial cells)
- Liver (hepatocytes)
- Adipose tissue
- Muscle
- Pancreas (β-cells)

CB₂ receptor

- Immune cells and tissues
 - T cells, B cells
 - Macrophages
 - Dendritic cells
 - Spleen tonsils
 - Adipose tissue

De Petrocellis et al. Br J Pharmacol. 2004;141:769-774. Pariza et al. Pharmacol Ther. 1997;74:129-186. Roche R et al. Neurochem Cell Biol. 2006;128(2):177-187.

Clinical Pharmacology

- Receptors mainly in hippocampus, cerebellum, and peripheral nerves
- Brainstem receptors inhibit nausea, NOT respiration
- Pharmacology greatly affected by bioavailability
- Smoking/Vaporization versus ingestion

Clinical Pharmacology

- Analgesia: different mechanism than opiates, some synergy though.
- Spasticity: likely GABA mediated
- Appetite enhancement: hippocampal?
- Anti-emetic: cerebellar?

Clinical Pharmacology

- Adverse effects: mainly seen in new users
- Euphoria versus paranoia
- Short term memory impairment
- Balance, incoordination
- These are reversible, short lived effects (3-4 hours max)
- Serious adverse effects NOT seen in chronic users

Metabolism

- Hepatic Cytochrome P450 system
- Quickly deactivated but slowly metabolized and cleared
- Excreted in urine and feces
- In high doses may compete with P450 system with other drugs

Clinical Trials

- Hampered by government regulations
- Must use federally produced cannabis
- Mixed Results
- Methodological problems

Clinical Trials

- Works for neuropathic pain (Abrams, et al)
- Mixed results for spasticity (Wade, Zajicek, et al)
- Appetite improved by THC
- Generally very well-tolerated; minimal drug-drug interactions; minimal adverse effects (Ware, et al)

Using Cannabis

- Chronic Pain
- Palliative care
- Complementing other drugs or therapies
- Unique delivery may be an advantage: inhalation

Central and Peripheral Mechanisms of Cannabis

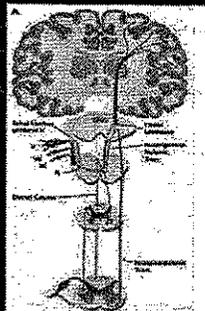
What symptoms may respond in this setting?

What is the benefit of central effects?

Pain-Sensing System Malfunction in Chronic Pain

Pain Sensing

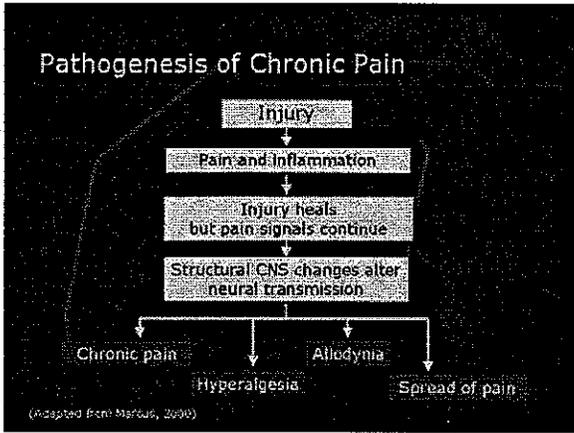
In chronic pain, pain signals are generated without physiologic significance



Normal pain: Pain-sensing signals are initiated in response to a stimulus
• They elicit a pain-relieving response

Chronic pain: Pain signals are generated for no reason and may be intensified
• Pain-relieving mechanisms may be defective or deactivated

(1. Enochell, 2006. Reprinted by Seward Hunt; 2. Besson, 1973)



Components of Pain That May Respond to Cannabis

- Neuropathic – burning, lancinating
- Mechanical: dull, aching
- Inflammatory: acute, sharp
- Our data show that patients use cannabis to treat multiple pain syndromes

Pros/Cons/Risks/Benefits

- Good analgesia
- High dosing ceiling vs toxicity
- Risk for psychological addiction
- Minimal physical dependence
- Little drug-drug interactions

Pros/Cons/Risks/Benefits

- Tolerance may develop
- Long term users may need higher doses
- Patient/family will have to buy it
- Marinol NOT as effective – only has THC
- Has street value but NOT as much as opioids!

Other Uses of Cannabis in This Setting

- Spasticity
- Appetite (may offset narcotic or chemotherapy induced anorexia or nausea)
- Mood enhancement
- Animal studies show cannabinoids have a neuroprotective and anti-tumor effect
- No respiratory suppression!

Cannabis Helps Patients with Many Forms of Chronic Pain

- Myofascial Pain Syndrome (MPS)
- Diabetic Neuropathy (DN)
- Neuropathic Pain Syndrome (NPS)
- Central Pain Syndrome (CPS)
- Phantom Pain (PP)
- Spinal Cord Injury (SCI)
- Fibromyalgia Syndrome (FMS)
- Osteoarthritis (OA)
- Rheumatoid Arthritis (RA)
- Discogenic Back Pain (DP)
- HIV Neuropathy (HIV)
- Malignant Pain (MP)

Patient Snapshots

- **Patient #101:** "He has been using marijuana on his own, as he feels [it] gives him the best pain relief of anything that he has used." 2-3 inhalations on a MJ cigarette 2-3[x]/day, & this improves his pain levels drastically w/o incapacitating him.
- **Patient #7:** "using MJ successfully on a daily basis; pain from 8-9/10—>2-3/10; needs only ~2-3 inhalations from a MJ cigarette to get pain relief"

Patient Snapshots

- **Patient #38:** "marijuana daily with no SE; only thing she is now currently using for pain";
- **Patient #67:** "She has been using cannabis in the past and has had excellent results with respect to her migraine headaches." Using <1/4 oz/week

Patient Snapshots

- **Patient #126:** "states openly that he has used marijuana in the past and it has helped his pain substantially. Tolerates it much better than opiates and his use of marijuana has substantially decreased his dependence on opiates"
- **Patient #133:** "he is using MC to control his pain with good luck with that. He also uses oxycodone and oxyContin, but he tries to limit this."

Our Data

- Stereotypes and myths about MC must be dispelled
- Our data should help deconstruct myths about the kinds of patients accessing MC treatment:
- Our randomly picked study patients were 1) not young males; 2) not malingers; 3) not feigning disease to access cannabis
- Our data, both subjective and objective diagnostic data, shows that MC patients are middle aged women and men, with complex medical problems

The Role of the Pharmacist in Medicinal Cannabis...

- Pharmacists NEED to be involved: Help educate patients in proper use - counsel the patient and family
- Pharmacists could be involved in the compounding of cannabis tinctures, ointments, salves, inhalers, and capsules
- Pharmacists can help regulate the dosing and help ensure that patients are using high quality medicinal cannabis to improve efficacy
- Pharmacists can help in formulating delivery routes that maximizes benefits and minimizes side effects

How Do We Move Forward? EDUCATION and COLLABORATION



- Need physicians and pharmacists to be knowledgeable and organized
- Pharmacies should be the source of medical cannabis: NO "street deals"
- Growing and cultivation are other areas for opportunity

Myths, et al

- Efforts to influence public opinion about MC are made by federal law enforcement spokespersons, as seen in the following two illustrations
- “Dr. Pot” and “Dr. Pat” appear on a Drug Enforcement Administration (DEA) prevention Web site targeted toward adolescent education entitled “Rx pot: a prescription for disaster.”

Truth in Advertising?



Finally...

- Cannabis is effective and safe but IS a medication: Pharmacists MUST be involved
- Physicians need to remember the four “A’s”:- Analgesia (symptom relief);-ADLs; Adverse Effects; Aberrant Usage
- Follow the law and use proper documentation
- Use science and logic to guide the way medicinal cannabis is regulated, not propaganda and politics

Thanks for attending

- For questions we can be contacted by e-mail:
- Gregory T Carter, MD, MS:
gtcarter@uw.edu
- Sunil K Aggarwal, PhD, MD-C:
sunila@u.washington.edu



From Mockery to Medicine: The Story of the Development of a Serious Modern Medicine

Andrea G. Barthwell, MD, FASAM

Introduction

In the United States, the effort to legalize cannabis for use as "medical marijuana" has focused on making it available to people as a home remedy, or perhaps an herbal treatment akin to a dietary supplement, but not as a Food and Drug Administration (FDA) - approved medicine. To obtain such approval, a therapeutic product must be quality-controlled in all aspects of manufacture, standardized by composition and dose, tested in preclinical and clinical studies, and administered by means of an appropriate delivery system or dosage form. It must, in short, meet the rigorous standards for quality, safety and efficacy that have been laid down by regulatory authorities. Crude herbal cannabis could never pass the FDA's rigorous standards.

The FDA recognizes that under appropriately controlled conditions, modern research and technologies enable complex botanical materials to be developed into pharmaceuticals in accordance with both scientific and regulatory rigor. The agency has issued a guidance document for these circumstances, acknowledging that complex composition is not inherently problematic.¹ Rather, as with all pharmaceutical products, the important factors are the application of quality control processes at each stage in the manufacturing process; characterization, specification, and standardization of the components; and the completion of appropriate preclinical and clinical studies—in other words; proof of quality, safety, and efficacy.

Crude herbal cannabis varies significantly in composition and consistency, depending on which strain is being propagated and under what conditions it is cultivated, harvested, stored, and prepared. Persons using crude herbal cannabis use materials that vary in quality and content. These materials may be contaminated with harmful pesticides, fungi, or heavy metals. Such contaminants have the potential to pose a threat to both seriously ill and healthy people. There is at least one report of death from a rare neurological condition, which may have occurred as a complication of an allergic reaction to pesticide-laden cannabis handled at the dispensary.²

Evidence-Based Medicine

Crude cannabis and the methods used to deliver it to patients have not met the minimum standards required of legitimate medicines and, therefore, do not belong in our system of modern medical practice. Modern medical practice is evidence-based. In advising patients, physicians rely in large part upon the results of controlled clinical trials conducted in accordance with established scientific principles. Preclinical studies and early (Phase 1) clinical trials demonstrate whether the product is likely to be harmful to humans. Randomized, double blind, placebo-controlled clinical trials (Phases 2 and 3 clinical trials)—the "gold standard" of scientific research—provide information about a medical product's safety and efficacy that usually accurately predicts real world expectations for a new medication.

GW Pharmaceuticals' Development Program

GW Pharmaceuticals (GW) has embarked on a full pharmaceutical development program for cannabinoids that pursues both scientific and regulatory rigor, making it the first company in the world to produce a complex, heterogeneous pharmaceutical product derived from the cannabis plant. As GW's research has shown^{3,4,5}, the process of developing botanically derived cannabinoid medicines is a challenging one, necessitating standardized raw materials and innovative extraction methods for the non-water soluble active ingredients.

Moreover, GW has rigorously adhered to the high principles of science and evidence-based medicine in its development program, having already conducted eight Phase 3 clinical trials and numerous smaller Phase 1 and Phase 2 studies with more than 2,000 patients participating. These clinical studies have investigated the use of Sativex® in the treatment of symptoms of multiple sclerosis, including spasticity⁶, bladder dysfunction⁷, tremor, spasm, sleep disturbance, pain^{8,9}, neuropathic pain of various origins—such as spinal cord injury, diabetic neuropathy, MS, brachial plexus avulsion—^{10,11,12}, rheumatoid arthritis¹³, and cancer pain¹⁴.

Using the latest technology, GW produces highly standardized cannabis "chemovars"—plant strains characterized by their chemical composition—that serve as the starting materials for its pharmaceutical development process. Computer-controlled glasshouses rigorously monitor and control growing conditions. Sensors automatically adjust light exposure to respond to changes in length and quality of daylight. Organic growing medium and specific quality control techniques ensure that no pesticides, heavy metals or microbiological contaminants are present. Botanists employ sophisticated breeding techniques to create unique chemovars that express specific cannabinoid ratios. Clonal reproduction maintains cannabinoid ratios and chemical composition throughout subsequent generations.

GW cultivates two primary cloned lines not normally found in nature, one in which cannabidiol (CBD), a non-psychoactive cannabinoid, is predominant. CBD is believed to significantly attenuate delta-

9-tetrahydrocannabinol (Delta-9-THC) - associated side effects, such as intoxication and tachycardia ¹⁵(6). This CBD clonal line and a predominantly Delta-9-THC plant strain were developed through applied Mendelian genetics and are proprietary to GW.

Manufacture and Formulation Considerations

Cannabinoids are not water-soluble; therefore, studies are required to identify excipients that will permit the formulation of cannabinoids into finished pharmaceutical products. Cannabinoids, particularly Delta-9-THC, are also very unstable; therefore, research is required again to select formulations and to structure the manufacturing and storage processes to ensure that the medicines will maintain an appropriate shelf life. A small change in formulation can have substantial effects on both bioavailability and stability. GW has conducted numerous trials to ascertain the optimal formulation for its lead product, Sativex®, which contains a specific proportion of cannabinoids with ethanol and propylene glycol excipients.

Once crude cannabis plant material is standardized, as is achieved in the manufacture of Sativex®, it is only the first step in producing a modern medicine. A cannabis-based medicine must be fully researched and strictly regulated at every step in its manufacturing cycle; therefore, the subsequent steps of the manufacturing process—from harvesting to drying to the various steps of extraction and formulation—are also standardized and subject to stringent quality control testing procedures. GW blends the extracts from the two clonal lines to produce Sativex®, a ratio of 1.08:1 of Delta-9-THC and CBD. The final product is highly characterized, and tight specifications are set for all the significant cannabinoids and other components, such as terpenes, plant waxes, and flavonoids. These are common plant components present in many food and flavoring items.

Delivery System Considerations

Once standardized in composition, a cannabinoid medication must be administered in a manner that enables a patient to obtain a reliable dose with predictable effect. It is especially important to allow the patient to adjust his or her dose in order to obtain relief of symptoms while minimizing side effects, particularly disabling psychoactivity. It is also essential that the delivery system does not expose the user to harmful impurities, such as pyrolytic products.

There is no proven safe and reliable delivery system for crude herbal cannabis. If crude cannabis is smoked, it exposes seriously ill patients to dangerous pyrolytic products. If it is eaten in baked goods, ground and packaged in gel caps, or consumed as tea, the intestinal absorption is very erratic from day to day or even throughout one day, and hence its effect, including its psychoactive effect, is quite variable and unpredictable. It is also subject to first-pass metabolism to metabolites with more psychoactivity than the parent compound. In such delivery methods the dose and composition are uncertain.

Pulmonary Delivery Carries Associated Risks and Harms

Tests of the crude cannabis plant in all studies to date show that burn-and-inhale administration is simply a toxic alternative delivery system for high doses of Delta-9-THC. Given that oral Delta-9-THC is available as a Schedule 3 prescription drug, one might argue that there should be no need for smoked crude marijuana. The individuals who prefer the smoked, home remedy approach say they do so because smoking marijuana gives them the ability to titrate their dose or control rate of onset of action. The formulation issue is a valid one in clinical medicine that needs to be addressed and has been done so by GW such that patients can achieve a therapeutic effect with significantly reduced risk of psychoactive effects.

Vaporization, a popular trend among cannabis smokers, does not resolve these issues. A recent study showed that when herbal cannabis is vaporized, several harmful carcinogens (polyaromatic hydrocarbons)—while reduced—were still delivered to the lungs¹⁶. Furthermore, currently available vaporizers do not provide the precise standardization of dose necessary for a prescription medicine. In addition, when patients inhale cannabis (whether smoked or vaporized), their Delta-9-THC blood levels rise rapidly to high levels, making it probable that many of them will not be able to control psychoactive side effects. Rapid increases in Delta-9-THC blood levels are also associated with greater tendency to intoxication and dependence.

Unique Delivery System Developed

Because Delta-9-THC is psychoactive, it is essential that a Delta-9-THC-containing product be delivered in a manner that enables a patient to remain within the "therapeutic window," i.e., predictably to obtain symptom relief without experiencing untoward central nervous system side effects. Seriously ill patients with debilitating chronic disorders do not wish to "trade one disability for another" to be intoxicated; they want to work, care for their families, and be productive. Accordingly, the delivery system must not only provide standardized doses but must also enable the physician and patient to manage the dosing increments. The regulated system of medicine offers the only hope in the area of formulation to safely address the delivery system needs of patients.

To address this issue, GW Pharmaceuticals pioneered the development of an oromucosal spray for the delivery of Sativex®. Its onset of action is 15-40 minutes, which is rapid enough to enable chronically ill patients to titrate their dose, but not so rapid as to be rewarding for its euphoriant effects. The oromucosal spray contains exactly 100 micro liters of Sativex® (2.7 mg. of Delta-9-THC and 2.5 mg. of CBD)¹⁷. GW has monitored "intoxication scores" of its patients, and the level of intoxication among patients (who are receiving relief of symptoms) is essentially no higher than placebo⁹. It is, therefore, clearly not the case that patients achieve symptom relief only at the cost of intoxication. Furthermore, many patients have been taking Sativex® for one to four years and have not escalated their dose during that time^{6 18}. Although evidence suggests that illicit users may become tolerant to the psychoactive effects of cannabis and must increase their use, patients using Sativex® do not develop tolerance to

its therapeutic benefits.

Additionally, a group of MS patients on Sativex® for one year or more voluntarily stopped Sativex® administration abruptly. While symptom re-emergence occurred within seven to 10 days for most, none had significant withdrawal symptoms¹⁸, and all who resumed the medicine regained symptomatic control at previously established doses. It is common to see symptom re-emergence after adequate control when medications are abruptly discontinued, sometimes paired with withdrawal.

This intermediate-onset delivery system, which also permits patients to take small increments of medicine, is believed to be an improvement over other forms of administration, particularly oral administration. Gastrointestinal absorption of oral Delta-9-THC exposes the compound to a first pass effect and hepatic metabolism of Delta-9-THC to 11-hydroxy-THC, thought to be more psychoactive than Delta-9-THC with an onset of effect that is long and unpredictable. Patients, therefore, cannot reliably titrate their dose after oral administration to avoid side effects, including psychoactivity. As the Institute of Medicine has stated¹⁹:

The poor solubility of Marinol® in aqueous solutions and its high first-pass metabolism in the liver account for its poor bioavailability; only 10-20% of an oral dose reaches the systemic circulation. The onset of action is slow, peak plasma concentrations are not attained until two to four hours after dosing...

Variation in individual response is highest for oral Delta-9-THC and bioavailability is lowest.

Abuse Liability Varies with Rate of Change of Blood Level Over Time

Inhaled Delta-9-THC is neither an optimal nor desirable delivery system for most patients. When Delta-9-THC is inhaled (as in smoking or vaporizing cannabis), Delta-9-THC blood levels rise to high levels quickly, with the resulting rise in blood level over a short period of time associated with greater tendency to intoxication and dependence. In a Phase 1 study, using a predominantly-Delta-9-THC extract delivered by means of a high technology vaporizer, GW found that concomitantly high intoxication levels accompanied such a rapid Delta-9-THC blood level rise¹⁷. A similarly high rise in Delta-9-THC blood levels was demonstrated in a recent Phase 1 trial that tested an inhaled version of dronabinol; therefore, it is likely that many patients who inhale Delta-9-THC will have a difficult time controlling intoxication and remaining within the therapeutic window²⁰. Most patients with chronic conditions do not need an immediate onset product, particularly when there is such an undesirable tradeoff of symptom relief vs. intoxication. Sativex® onset of action of 15-40 minutes provides sufficiently rapid symptom relief for such conditions, especially as patients learn over time to adjust their small doses to stabilize and maintain therapeutic blood levels.

The Scheduling of Cannabinoid-Containing Products under the Controlled Substances Act

Under the federal Controlled Substances Act (CSA), both cannabis and Delta-9-THC are Schedule I substances. If a cannabis-derived product like Sativex® were successful in obtaining FDA marketing approval, that specific product would need to be transferred out of Schedule I to another schedule, since FDA approval demonstrates that the product has "an accepted medical use in the US." This would not, however, necessitate a rescheduling of either herbal cannabis or Delta-9-THC. For example, Marinol® is located in Schedule III, while Delta-9-THC remains in Schedule I. Moreover, even if cannabis and Delta-9-THC (as active ingredients) were moved to Schedule II, that would not mean that crude herbal cannabis, or any cannabis or Delta-9-THC preparation, would become immediately available to patients by prescription. Rather, each and every medical product in interstate commerce must have gone through the FDA process on its own merits and must have satisfied FDA's intense scrutiny before physicians may prescribe and pharmacists may dispense it. Opium and coca leaves are in Schedule II, but crude opium or coca products are not distributed to patients. The entire "rescheduling of cannabis" argument made by cannabis advocates demonstrates a profound misunderstanding of the process by which serious prescription medicines become available to patients in the US.

Conclusion

Sativex® is a pharmaceutical product standardized in composition, formulation, and dose, which is administered by means of an appropriate delivery system, and which has been—and continues to be—tested in properly controlled preclinical and clinical studies. It is not crude cannabis, which is none of those things. Acceptance of Sativex® [and its proof of efficacy] for specific indications does not suggest the acceptance of crude cannabis or prove its medical usefulness for the reasons set forth and many others. All medicinal products must be subjected to, and satisfy, the FDA's rigorous scrutiny before becoming available to patients in need. GW has consistently maintained that crude herbal cannabis can never meet the regulatory standards of the FDA and those of regulatory bodies in most other countries around the world²¹. These standards are mandatory if the modern medical model—*informed patients working with and being advised by knowledgeable physicians to identify appropriate treatment options*—is ever to be attained with a cannabis-based medicine.

It is not surprising that the concept of "medical marijuana" has been foisted on a largely unwilling and disapproving medical profession by legislative and ballot initiatives. Physicians who want medicines to meet the tests of quality, safety, and efficacy are not its proponents. Rather, the primary supporters are those whose ultimate agenda is to legalize marijuana for non-medical purposes. For the safety of patients and the security of physicians, physicians must draw a bright line between approved, legitimate medications and drugs of abuse that are used for the purpose of obtaining a euphoric "high." Physicians must insist that the medicinal products they recommend to patients be subjected to, and satisfy, the FDA's rigorous scrutiny.

1. Food and Drug Administration. Guidance for industry: Botanical drug products. In: Services UDoHaH, editor.:

US Government; 2004. p. 48.

2. **Gardner F. Jane Weirick:** death of an organizer. Counterpunch. Oct. 29, 2005 <http://www.counterpunch.org/gardner10292005.html> (accessed March 25, 2006)

3. **Potter D. Growth and morphology of medicinal cannabis.** In: Guy GW, Whittle BA, Robson P, editors. Medicinal uses of cannabis and cannabinoids. London: Pharmaceutical Press; 2004. p. 17-54.

4. **DeMeijer E.** The breeding of Cannabis cultivars for pharmaceutical end uses. In: Guy GW, Whittle BA, Robson P, editors. Medicinal uses of cannabis and cannabinoids. London: Pharmaceutical Press; 2004. p. 55-69.

5. **Whittle B., Guy G.** Development of cannabis-based medicines: risk, benefit and serendipity. In: Guy GW, Whittle BA, Robson P, editors. Medicinal uses of cannabis and cannabinoids. London: Pharmaceutical Press; 2004. p. 427-466.

6. **Collin C.** A cannabis-based medicine (Sativex) has sustained efficacy in the treatment of spasticity in multiple sclerosis. Association of British Neurologists; 2005 April 1; Belfast, Northern Ireland; 2005.

7. **Brady CM, DasGupta R, Dalton C, Wiseman OJ, Berkley KJ, Fowler CJ.** An open-label pilot study of cannabis based extracts for bladder dysfunction in advanced multiple sclerosis. Multiple Sclerosis. 2004;10:425-33.

8. **Wade DT, Makela P, Robson P, House H, Bateman C.** Do cannabis-based medicinal extracts have general or specific effects on symptoms in multiple sclerosis? A double-blind, randomized, placebo-controlled study on 160 patients. Mult Scler. 2004 Aug;10(4):434-41.

9. **Wade DT, Robson P, House H, Makela P, Aram J.** A preliminary controlled study to determine whether whole-plant cannabis extracts can improve intractable neurogenic symptoms. Clinical Rehabilitation. 2003;17:18-26.

10. **Berman JS, Symonds C, Birch R.** Efficacy of two cannabis based medicinal extracts for relief of central neuropathic pain from brachial plexus avulsion: results of a randomised controlled trial. Pain. 2004 Dec;112(3):299-306.

11. **Notcutt W.** Cannabis in the treatment of chronic pain. In: Guy GW, Whittle BA, Robson P, editors. Medicinal uses of cannabis and cannabinoids. London: Pharmaceutical Press; 2004. p. 271-300.

12. **Rog DJ, Nurmiko T, Friede T, Young C.** Randomized controlled trial of cannabis based medicine in central neuropathic pain due to multiple sclerosis. Neurology. 2005;65(6):812-9.

13. **Blake DR, Robson P, Ho M, Jubb RW, McCabe CS.** Preliminary assessment of the efficacy, tolerability and safety of a cannabis-based medicine (Sativex) in the treatment of pain caused by rheumatoid arthritis. Rheumatology (Oxford). 2006 Jan;45(1):50-2.

14. **Johnson JR, Potts R.** Cannabis-based medicines in the treatment of cancer pain: a randomised, double-blind, parallel group, placebo controlled, comparative study of the efficacy, safety and tolerability of Sativex and Tetranabinex in patients with cancer-related pain. British Pain Society; 2005 March 8-11; Edinburgh, Scotland; 2005.

15. **Ashton, CH, Moore, PB, Gallagher, P, Young, AH,** Cannabinoids in bipolar affective disorder: a review and discussion of their therapeutic potential. Journal of Psychopharmacology. 2005; 19(3):293-300.

16. **Gieringer D, St. Laurent J, Goodrich S.** Cannabis vaporizer combines efficient delivery of THC with effective suppression of pyrolytic compounds. Journal of Cannabis Therapeutics. 2004;4(1):7-27.

17. **Robson P, Guy GW.** Clinical studies of cannabis-based medicine. In: Guy GW, Whittle BA, Robson P, editors. Medicinal uses of cannabis and cannabinoids. London: Pharmaceutical Press; 2004. p. 229-70.

18. Canada has approved Sativex® for the treatment of neuropathic pain in multiple sclerosis. GW is currently preparing additional European regulatory submissions for other medical indications. The UK has authorized Sativex® to be prescribed on a named patient basis to patients whose physicians believe they may benefit from the product. Additionally, the Catalanian government in Spain has permitted it to be prescribed on a compassionate basis. On January 3, 2006, GW announced that the FDA had agreed to permit Sativex® to proceed to Phase III clinical trials, the final stage of research that a product must undergo before it is submitted for marketing approval. GW will test Sativex® in patients with advanced cancer, whose pain is not being adequately controlled with opiates. The trials will commence in the latter part of 2006 and a marketing application should be submitted 24-36 months after the trials begin. Long-term use of a cannabis-based medicine in the treatment of spasticity and other symptoms in multiple sclerosis. Multiple Sclerosis. 2006;(In press).

19. **Joy JE, Watson SJ, Benson JA, Jr.** Marijuana and medicine: Assessing the science base. Washington, DC: Institute of Medicine; 1999; p. 203.

20. **Miller J, Meuwesen I, ZumBrunnen T, de Vries M.** A Phase I evaluation of pulmonary dronabinol administered via a pressurized metered dose inhaler in healthy volunteers. American Academy of Neurology; 2005 April 14; Miami Beach, FL; 2005.

21. Canada has approved Sativex® for the treatment of neuropathic pain in multiple sclerosis. GW is currently preparing additional European regulatory submissions for other medical indications. The UK has authorized Sativex® to be prescribed on a named patient basis to patients whose physicians believe they may benefit from the product. Additionally, the Catalonian government in Spain has permitted it to be prescribed on a compassionate basis. On January 3, 2006, GW announced that the FDA had agreed to permit Sativex® to proceed to Phase III clinical trials, the final stage of research that a product must undergo before it is submitted for marketing approval. GW will test Sativex® in patients with advanced cancer, whose pain is not being adequately controlled with opiates. The trials will commence in the latter part of 2006 and a marketing application should be submitted 24-36 months after the trials begin.

I declare that I have no proprietary, financial, professional or other personal interest of any nature or kind in any product, service and/or company that could be construed as influencing the position presented in, or the review of, the manuscript entitled except for the following:

Consultant, GW Pharmaceuticals

Author: Andrea G. Barthwell, MD

Date: July 17, 2006

© Copyright 2006 - 2009 The
Journal of Global Drug Policy
and Practice

[Privacy Policy](#)

[Terms of Use](#)

[Contact Us](#)



EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY
Washington, D.C. 20503

Marijuana Legalization; A Non-Starter
ONDCP Director R. Gil Kerlikowske
October 23, 2009

The Department of Justice earlier this week issued guidelines for Federal prosecutors regarding laws authorizing the use of marijuana for medical purposes. This prompted a flurry of news reports, analysis and commentary, some arguing that the guidelines could be read as the Federal government's tacit approval of "medical" marijuana. Advocates of marijuana legalization tried to cast the guidelines as a victory, portraying them as a step toward full legalization. Neither of these analyses is correct.

Marijuana legalization, for any purpose, remains a non-starter in the Obama Administration. It is not something that the President and I discuss; it isn't even on the agenda. Attorney General Holder issued very clear guidelines to U.S. Attorneys about the appropriate use of Federal resources. He did not open the door to legalization.

Regarding state ballot initiatives concerning "medical" marijuana, I believe that medical questions are best decided not by popular vote, but by science. The Food and Drug Administration (FDA), which studies and approves all medicines in the United States, has made very clear that the raw marijuana plant is not medicine, and any state considering medical marijuana should look very carefully at what has happened in California.

Legalization is being sold as being a cure to ending violence in Mexico, as a cure to state budget problems, as a cure to health problems. The American public should be skeptical of anyone selling one solution as a cure for every single problem. Legalized, regulated drugs are not a panacea—pharmaceutical drugs in this country are tightly regulated and government controlled, yet we know they cause untold damage to those who abuse them.

To test the idea of legalizing and taxing marijuana, we only need to look at already legal drugs—alcohol and tobacco. We know that the taxes collected on these substances pale in comparison to the social and health care costs related to their widespread use.

In a little over three months, my office will deliver to President Obama a National Drug Control Strategy that will strike a balance between public health and public safety, recognizing that reducing demand through a community-wide approach is critical to our success. Legalization would only thwart our efforts and increase the economic and social costs that result from greater drug acceptance and use.

—R. Gil Kerlikowske

The Scientific Side of Medical Marijuana

Ken Mackie, MD
Indiana University
Bloomington, IN
December 3, 2009

kmackie@indiana.edu

Financial disclosures

- NIH (NIDA) - research grants
- Alzheimer's Association - research grant
- Abbott - Consulting
- Bristol Meyers Squibb - Consulting
- Cara Therapeutics - Consulting
- Sanofi - Consulting

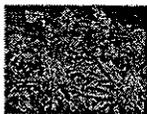
Outline

- Introduction to cannabis and cannabinoids
- Overview of cannabinoid pharmacology relevant to medicinal uses
- Oral Δ^9 THC vs cannabis: Scientific considerations



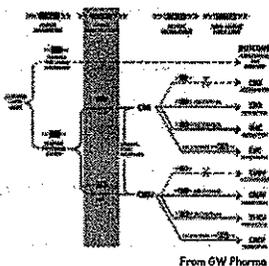
Cannabis: A primer

- The plant: Cannabis, marijuana, etc.
 - Hemp vs psychoactive cannabis
- Major psychoactive component, Δ^9 THC
- However ~60 other compounds
 - Variability of constituents
- Preparations
 - Raw, dried plant (F vs. M)
 - Flowers and buds
 - Hashish
- Consumption
 - Smoked (burned-joint, pipe, waterpipe)
 - Vaporizer (heat to release volatile compounds, ~200°C)
- Ingestion
 - Cooked into foods, extract Δ^9 THC into fats (butter)

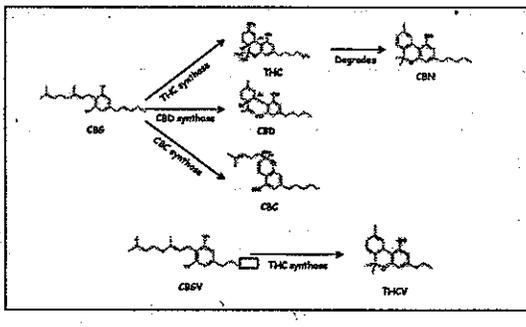


Cannabis: Cannabinoid synthesis

- CBG—cannabigerol
- CBD—cannabidiol
- THC— Δ^9 tetrahydrocannabinol
- CBC—cannabichromene
- CBN—cannabinol
- "V" suffix denotes propyl instead of pentyl side chain

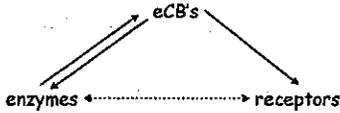


Cannabinoid synthesis (overview)



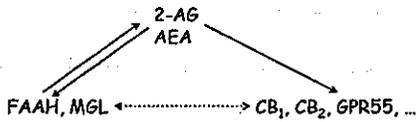
Endocannabinoid system (ECS)

- Desire to understand the psychoactivity of cannabis contributed to a "Golden Era" of cannabinoid research during the 1980's-1990's
- This led to the discovery of the endocannabinoid system
- Receptors, ligands, metabolic enzymes



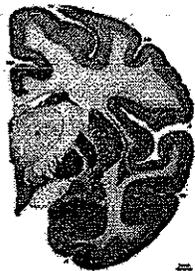
Endocannabinoid system (ECS)

- Endocannabinoids: 2-AG, AEA
- Major degrading enzymes: FAAH, MGL
- Receptors: CB₁, CB₂, GPR55, ...



CB₁ cannabinoid receptors

- Discovered & cloned in late 1980's
- Mediates most CNS actions of Δ⁹THC
- Richly expressed in brain, particularly in regions associated with cognition, emotion, perception, movement, etc.
- Low levels in brainstem, except emetic centers
- Lethal overdose extremely rare



Stephen Eggen & David Sulzer, 2004

CB₁ is expressed on axons and terminals



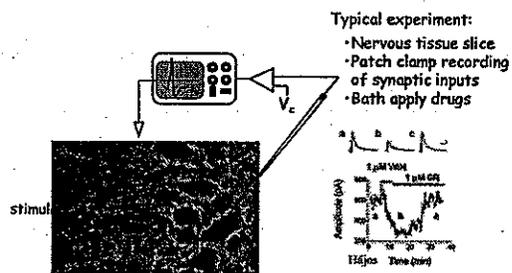
CB₁-green, MAP2 (dendrites) red
M. Myoga

CB₁ heavily expressed on some axons & terminals

CB₁ agonists inhibit neurotransmission

Typical experiment:

- Nervous tissue slice
- Patch clamp recording of synaptic inputs
- Bath apply drugs

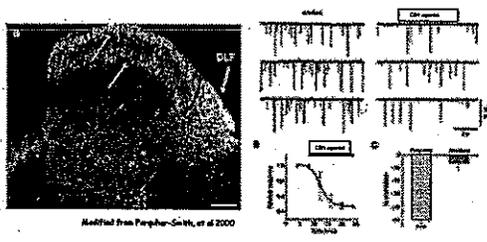


stimul

Measure GABAergic currents in CA1

CB₁ receptor activation inhibits neurotransmission

CB₁ agonists inhibit neurotransmission in the dorsal horn of the spinal cord



Modified from Penghu-Schwartz, et al 2000

Modified from Almers & Urban, 2000

CB₂ receptors

- Multiple modes of injury increase neuronal CB₂ expression

14 d post ligation 7 d post hemispherectomy

- Microglia, too

Modified from Zhang, et al 2003

CB₂ agonists as analgesics

- CB₂ agonists are devoid of measurable psychoactivity
- CB₂ agonists show strong efficacy in multiple pain models
- Need to consider actions of THC through CB₂, too

- Inflamm rat paw with carrageenan
- Treat or not with CB₂ agonist (AM1241) ± CB₁ or CB₂ antagonist
- Measure withdrawal threshold (higher threshold = more pain relief)

Nockley et al, 2003

CB₂ receptor agonists

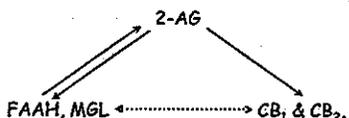
- Neurons and microglia
- CB₂ activation decreases synaptic transmission
- Inducible—does this convey some unique therapeutic advantages?
- Preclinical studies are very promising
- Bottom line: How do they work in humans?
- Are any of the therapeutic effects of medical marijuana mediated by CB₂ receptors?

Endogenous cannabinoids

- What do endogenous cannabinoids do?
- Preformed in membrane, liberated by activation of specific lipases
- Well positioned to function as feedback regulators of neuronal function
- Produced by neurons, astrocytes, microglia
- The effects of THC will be primarily determined by its interactions with endocannabinoids

Endocannabinoid system (ECS)

- Endocannabinoids: 2-AG, AEA
- Major degrading enzymes: FAAH, MGL
- Receptors: CB₁, CB₂, GPR55, ...

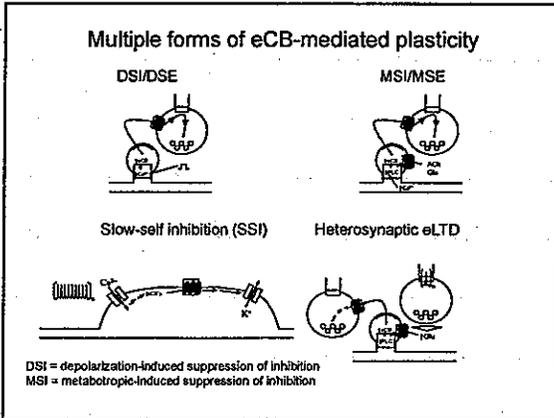


Endocannabinoids inhibit neurotransmission

- Post-synaptic neuron makes endocannabinoids that act on CB₁-expressing presynaptic terminals
- Endocannabinoids are also produced by astrocytes and microglia

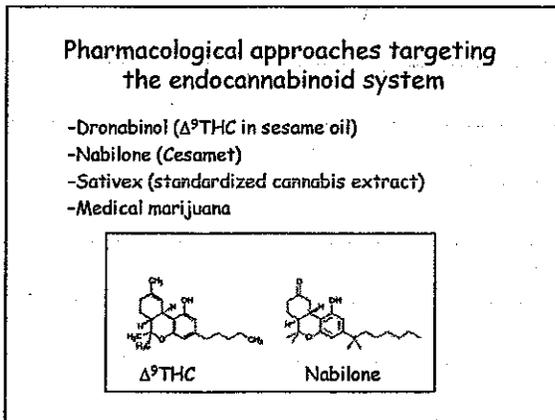


Bodor et al, 2005 (layer V)



Medical Marijuana

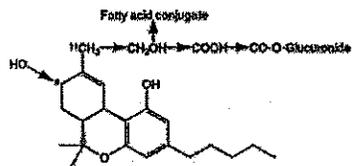
- Cannabis as a therapeutic
 - Old idea, much support for some efficacy
 - Cannabis vs synthetic Δ^9 THC
- Features to consider:
 - Route of administration
 - Complex mix of chemicals
 - "Rebel" nature of the act
- Most common indications
 - Pain (multiple, including spasticity)
 - Mood disorders (anxiety, depression)
 - GI disturbances (including appetite stimulation)
 - HIV-related symptoms



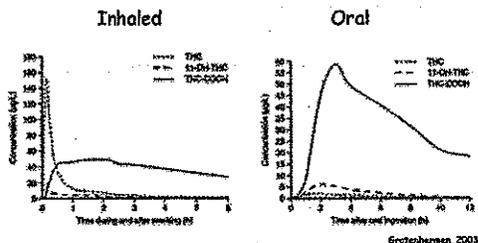
Medical marijuana vs dronabinol

- Components
 - Dronabinol, Δ^9 THC in sesame oil
 - Cannabis, complex mixture of chemicals
- Pharmacokinetics
 - Oral
 - Slow
 - Variable
 - First pass metabolism
 - Inhaled
 - Rapid
 - Minimal first pass metabolism
 - Thermal isomerization
 - Effects of CBD on THC metabolism

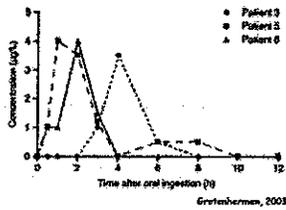
Δ^9 THC metabolism



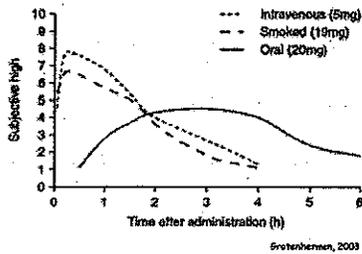
Inhaled vs oral route of administration



Variability in oral absorption between subjects



Time to peak efficacy and duration varies with route of administration



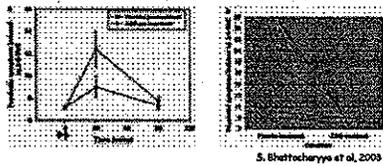
Inhaled vs oral route of administration

Inhaled

Oral

- | | |
|--|--|
| <ul style="list-style-type: none"> •Rapid peak THC •Higher peak (~3 fold) •THC > 11-OH-THC •Similar peak THC-COOH | <ul style="list-style-type: none"> •Delayed peak THC •Lower peak (~1/3) •THC < 11-OH-THC •Similar peak THC-COOH |
|--|--|

Cannabidiol modifies THC effects



- Cannabidiol (CBD) often a major component of cannabis
- CBD has no overt psychoactivity
- Multiple studies suggest CBD modulates the properties of THC
- Effects on THC metabolism
- Direct actions of CBD (e.g., blocks cue-induced reinstatement of heroin self administration)

Summary

- Cannabis—complex mixture of compounds, including THC (acting through CB₁ & CB₂ receptors), as well as other compounds (e.g., CBD)
- THC produces its effects by interacting with the endocannabinoid system
- Very real differences between THC and medical marijuana
 - Pharmacokinetics
 - Additional compounds present in cannabis
 - Standardization
 - Sativex

Continuing Pharmacy Education Program
Thursday, December 3, 2009

NABP 2009
Symposium



1:30 - 5 PM

Are We Going to Legalize Medical Marijuana?

Program #205-000-09-009-L03-P

0.325 CEUs – 3.25 contact hours

Target Audience: Pharmacists

Activity Type: Application based

Moderator:

Early Afternoon Presentations

- Karen M. Ryle, MS, RPh, Member, NABP Executive Committee

Late Afternoon Roundtable Discussion

- Malcolm J. Broussard, RPh, NABP Treasurer

Speakers:

- Paula Sahleen-Buckingham, Associate Analyst, California Department of Public Health, Medical Marijuana Program
- Jacob Appelsmith, JD, Special Assistant to the Attorney General, California Office of the Attorney General
- Lloyd K. Jessen, RPh, JD, Executive Director and Drug Control Program Administrator, Iowa Board of Pharmacy
- Scott Galenbeck, JD, Assistant Attorney General, Iowa Office of the Attorney General
- Carole Bouchard, BPharm, MAP, Executive Director, National Association of Pharmacy Regulatory Authorities
- Andrea Barthwell, MD, FASAM, Founder and Chief Executive Officer, EMGlobal LLC, and Former Deputy Director for Demand Reduction, Office of National Drug Control Policy
- Eric E. Sterling, JD, President, Criminal Justice Policy Foundation

Facilitator:

- Eileen Lewalski, PharmD, JD, Professional Affairs Manager, NABP

Learning objectives, speaker biographies, and contact information follow on the next page.
For information on obtaining continuing pharmacy education and continuing legal education credit see Tab 4.



Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

Learning Objectives:

At the conclusion of these presentations, participants will be able to demonstrate an understanding of the topic through the following learning objectives.

Afternoon Presentations and Roundtable Discussion

1. Describe how a state medical marijuana registry program operates.
2. Describe Canada's Marijuana Medical Access Regulations.
3. Provide examples of how legalizing medical marijuana could possibly affect other currently illegal activities and state economies.
4. Explain a type of regulatory structure that would be required if medical marijuana became legal.

Speaker Biographies:

A Regulatory Approach to Medical Marijuana – What are the States Doing?

Paula Sahleen-Buckingham is currently the program expert for the California Department of Public Health's Medical Marijuana Identification Card (MMIC) program. She has more than 28 years experience with the Department of Health and has served the people of the state of California for more than 31 years. She is the only member left of California's MMIC program's original development and implementation team, and is recognized by California legislators, law enforcement, attorneys, and all 58 Counties' Board of Supervisors as the sole program expert for the MMIC program. For the last two years, Ms Sahleen-Buckingham has acted as the operations coordinator for the MMIC program, appearing as a certified expert witness in fraud litigations; maintaining the MMIC database and troubleshooting any database technical difficulties; handling all MMIC purchasing, security, and production issues; instructing local staff on county implementation of the MMIC; and acting as the administrative appeals coordinator for patient's denied card applications. She has also served as a member of California's State Disaster Response Team for the last 20 years.



Jacob Appelsmith, JD, is currently special assistant attorney general to California Attorney General Jerry Brown. Serving in this position since 2008, Mr Appelsmith focuses on matters pertaining to law enforcement and the criminal justice system. In addition he is the chief of the Bureau of Gambling Control. Mr Appelsmith is also the principal draftsman of the California Attorney General's Guidelines For the Security and Non-Diversion of Marijuana Grown For Medical Use, and he has worked on this issue with local governments, law enforcement agencies, and patient advocacy groups throughout California. Mr Appelsmith began his career as a lawyer with Pillsbury, Madison & Sutro in San Francisco, where he worked for six years as a commercial litigator. He later joined the Attorney General's Office in 1994, eventually becoming the Department of Justice's general counsel for personnel and equal employment opportunity matters as well as the statewide head of the employment law section. Mr Appelsmith graduated from Boalt Hall at the University of California Berkeley School of Law.

Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

NABP 2009
Symposium



Lloyd K. Jessen, RPh, JD, executive director and drug control program administrator of the Iowa Board of Pharmacy, first joined the Iowa Board as chief investigator in 1987. Prior to this, Mr Jessen was a staff attorney for the Iowa Supreme Court in addition to working as a pharmacist in the hospital, community, and retail settings. He is also a pharmacy drug law lecturer at Drake University College of Pharmacy and Health Sciences and the University of Iowa College of Pharmacy. Mr Jessen is currently serving the third year of a three-year member term representing District 5 on the NABP Executive Committee. In addition, he has coordinated and served on numerous advisory groups including the Iowa Prescription Drug Monitoring Program Advisory Committee, the Iowa Drug Wholesale Advisory Task Force, the Iowa Pharmacy Technician Working Group, and the Iowa Pharmacy Recovery Network. Mr Jessen is also a member of the National Association of State Controlled Substance Authorities. He received his bachelor of science degree in pharmacy from the South Dakota State University College of Pharmacy, and his doctor of jurisprudence degree from Drake University Law School.



Scott M. Galenbeck, JD, an assistant attorney general for the state of Iowa, serves as general counsel and litigation counsel to the Iowa Board of Pharmacy, and also as the state's prosecutor in disciplinary cases presented before the Board of Pharmacy. Having worked in the Iowa Attorney General's office for nearly 26 years, he has represented – at one time or another – almost every department and officer of Iowa government, including the attorney general and the governor. Mr Galenbeck's current assignments include, in addition to the Board of Pharmacy, the Iowa Department for the Blind, the Iowa Department of Public Safety, and the Iowa Credit Union Division. Prior to joining the Attorney General's office, Mr Galenbeck clerked for the Iowa Supreme Court, clerked for the United States District Court, District of Oregon, and was engaged in the private practice of law in Eugene, OR. Mr Galenbeck earned a bachelor of arts degree in history from Grinnell College and the University of Hull in Hull, England. He obtained a law degree from the University of Iowa.

A Regulatory Approach to Medical Marijuana – What has Canada Done?



Carole Bouchard, BPharm, MAP, joined the National Association of Pharmacy Regulatory Authorities (NAPRA) in July 2008 in the capacity of executive director. Prior to this she worked in different areas of pharmacy practice including as a staff pharmacist in the retail environment and as a pharmaceutical industry sales representative. In 1985, Ms Bouchard moved to Ottawa to begin a 20-year career with the federal government at Health Canada. Before her appointment to NAPRA, she was the director of the Office of Controlled Substances with the Healthy Environments and Consumer Safety Branch of Health Canada, where her responsibilities included the management of the Canadian legislative framework for controlled substances and precursor chemicals as well as the operation of various programs of licensing, monitoring, and compliance. Ms Bouchard also led the



Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

creation of the Office of Controlled Substances and the development of key policies and first regulations that serve to control precursor chemicals and marijuana for medical purposes. Ms Bouchard obtained a bachelor of science degree in pharmacy from Laval University and a master of public administration from the National School of Public Administration in Quebec.

Legalizing Medical Marijuana – Creating a Slippery Slope?

Andrea Barthwell, MD, FASAM. See Tab 5a, Speaker Biographies, *Medical Marijuana: Point-Counterpoint* for Dr Barthwell's biography.



Eric E. Sterling, JD, has been the president of the Criminal Justice Policy Foundation since 1989. Prior to this, he was counsel to the United States House of Representatives Committee on the Judiciary from 1979 until 1989 and served on the staff of the Subcommittee on Crime. Mr Sterling also served as an assistant public defender in Delaware County, Pennsylvania. In addition, Mr Sterling was a principal aide in developing the Comprehensive Crime Control Act of 1984, the Anti-Drug Abuse Acts of 1986 and 1988, and other laws. In the 96th Congress, he worked on comprehensively rewriting the Federal Criminal Code. He has been honored by the US Bureau of Alcohol, Tobacco and Firearms, and the US Postal Inspection Service. Mr Sterling, has served on numerous civic organizations and drug abuse and policy related task forces and currently serves on several national advisory boards. He has also served as an adjunct lecturer in Sociology at the George Washington University. Mr. Sterling received a bachelor of arts from Haverford College majoring in religion, and a juris doctor from Villanova University School of Law.

Facilitator Biography:

Roundtable Discussion: Medical Marijuana – A Two Case Scenario



Eileen Lewalski, PharmD, JD, joined NABP as the professional affairs manager in 2007. Prior to this, she was a health related prosecutions attorney for the Illinois Department of Financial and Professional Regulation (IDFPR), where her responsibilities included prosecuting pharmacy and wholesale drug distributorship related cases, negotiating settlement agreements, and working closely with the Illinois State Board of Pharmacy and the IDFPR drug compliance coordinator. In addition, she was responsible for presenting IDFPR overviews to various associations and to the University of Illinois at Chicago College of Pharmacy. Dr Lewalski was also employed by Walgreen Co for approximately 15 years, serving in several different capacities including pharmacy technician, pharmacist, and pharmacist-in-charge. She currently teaches pharmacy law and ethics at Midwestern University Chicago College of Pharmacy in Downers Grove, IL. Dr Lewalski earned her doctor of pharmacy degree from the University of Illinois at Chicago College of Pharmacy and her doctor of jurisprudence degree, cum laude, from John Marshall Law School.

Continuing Pharmacy Education Program
Thursday, December 3, 2009 (cont)

NABP 2009
Symposium



Faculty Contact Information:

Jacob A. Appelsmith, JD

Special Assistant to the Attorney General, California Office of the Attorney General

Phone: 916/263-5778

E-mail: jacob.appelsmith@doj.ca.gov

Jacob A. Appelsmith declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Andrea Barthwell, MD, FASAM

Founder and Chief Executive Officer, EMGlobal LLC

Phone: 703/527-4700

E-mail: drb@emglobal.com

Andrea Barthwell declares that neither she nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Carole Bouchard, BPharm, MAP

Executive Director, NAPRA

Phone: 613/569-9658

E-mail: cbouchard@napra.ca

Carole Bouchard declares that neither she nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Scott Galenbeck, JD

Assistant Attorney General, Iowa Office of the Attorney General

Phone: 515/281-6658

E-mail: scott.galenbeck@ag.state.ia.us

Scott Galenbeck declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Lloyd K. Jessen, RPh, JD

Executive Director and Drug Control Program Administrator, Iowa Board of Pharmacy

Phone: 515/281-5944

E-mail: lloyd.jessen@iowa.gov

Lloyd K. Jessen declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.



Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

Eileen Lewalski, PharmD, JD

Professional Affairs Manager, NABP

Phone: 847/391-4400

E-mail: elewaski@nabp.net

Eileen Lewalski declares that neither she nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Paula Sahleen-Buckingham

Associate Analyst, California Department of Public Health, Medical Marijuana Program

Phone: 916/552-8037

E-mail: paula.sahleen-buckingham@cdph.ca.gov

Paula Sahleen-Buckingham declares that neither she nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Eric E. Sterling, JD

President, Criminal Justice Policy Foundation

Phone: 301/589-6020

E-mail: esterling@cjpf.org

Eric E. Sterling, declares that neither he nor any immediate family member have a current affiliation or financial arrangement with the sponsor and/or any other organization(s) that may have direct interest in the subject matter of the above stated continuing pharmacy education program.

Continuing Pharmacy Education Program
Thursday, December 3, 2009

NABP 2009
Symposium



1:30 - 5 PM

Are We Going to Legalize Medical Marijuana?

Program #205-000-09-009-L03-P

0.325 CEUs – 3.25 contact hours

Target Audience: Pharmacists

Activity Type: Application based

Moderator:

Early Afternoon Presentations

- Karen M. Ryle, MS, RPh, Member, NABP Executive Committee

Late Afternoon Roundtable Discussion

- Malcolm J. Broussard, RPh, NABP Treasurer

Speakers:

- Paula Sahleen-Buckingham, Associate Analyst, California Department of Public Health, Medical Marijuana Program
- Jacob Appelsmith, JD, Special Assistant to the Attorney General, California Office of the Attorney General
- Lloyd K. Jessen, RPh, JD, Executive Director and Drug Control Program Administrator, Iowa Board of Pharmacy
- Scott Galenbeck, JD, Assistant Attorney General, Iowa Office of the Attorney General
- Carole Bouchard, BPharm, MAP, Executive Director, National Association of Pharmacy Regulatory Authorities
- Andrea Barthwell, MD, FASAM, Founder and Chief Executive Officer, EMGlobal LLC, and Former Deputy Director for Demand Reduction, Office of National Drug Control Policy
- Eric E. Sterling, JD, President, Criminal Justice Policy Foundation

Facilitator:

- Eileen Lewalski, PharmD, JD, Professional Affairs Manager, NABP

Learning objectives, speaker biographies, and contact information follow on the next page. For information on obtaining continuing pharmacy education and continuing legal education credit see Tab 4.



Continuing Pharmacy Education Program Thursday, December 3, 2009 (cont)

Learning Objectives:

At the conclusion of these presentations, participants will be able to demonstrate an understanding of the topic through the following learning objectives.

Afternoon Presentations and Roundtable Discussion

1. Describe how a state medical marijuana registry program operates.
2. Describe Canada's Marijuana Medical Access Regulations.
3. Provide examples of how legalizing medical marijuana could possibly affect other currently illegal activities and state economies.
4. Explain a type of regulatory structure that would be required if medical marijuana became legal.

Speaker Biographies:

A Regulatory Approach to Medical Marijuana – What are the States Doing?

Paula Sahleen-Buckingham is currently the program expert for the California Department of Public Health's Medical Marijuana Identification Card (MMIC) program. She has more than 28 years experience with the Department of Health and has served the people of the state of California for more than 31 years. She is the only member left of California's MMIC program's original development and implementation team, and is recognized by California legislators, law enforcement, attorneys, and all 58 Counties' Board of Supervisors as the sole program expert for the MMIC program. For the last two years, Ms Sahleen-Buckingham has acted as the operations coordinator for the MMIC program, appearing as a certified expert witness in fraud litigations; maintaining the MMIC database and troubleshooting any database technical difficulties; handling all MMIC purchasing, security, and production issues; instructing local staff on county implementation of the MMIC; and acting as the administrative appeals coordinator for patient's denied card applications. She has also served as a member of California's State Disaster Response Team for the last 20 years.



Jacob Appelsmith, JD, is currently special assistant attorney general to California Attorney General Jerry Brown. Serving in this position since 2008, Mr Appelsmith focuses on matters pertaining to law enforcement and the criminal justice system. In addition he is the chief of the Bureau of Gambling Control. Mr Appelsmith is also the principal draftsman of the California Attorney General's Guidelines For the Security and Non-Diversion of Marijuana Grown For Medical Use, and he has worked on this issue with local governments, law enforcement agencies, and patient advocacy groups throughout California. Mr Appelsmith began his career as a lawyer with Pillsbury, Madison & Sutro in San Francisco, where he worked for six years as a commercial litigator. He later joined the Attorney General's Office in 1994, eventually becoming the Department of Justice's general counsel for personnel and equal employment opportunity matters as well as the statewide head of the employment law section. Mr Appelsmith graduated from Boalt Hall at the University of California Berkeley School of Law.

BILL NUMBER: SB 420 CHAPTERED

BILL TEXT

CHAPTER 875

FILED WITH SECRETARY OF STATE OCTOBER 12, 2003

APPROVED BY GOVERNOR OCTOBER 12, 2003

PASSED THE SENATE SEPTEMBER 11, 2003

PASSED THE ASSEMBLY SEPTEMBER 10, 2003

AMENDED IN ASSEMBLY SEPTEMBER 9, 2003

AMENDED IN ASSEMBLY SEPTEMBER 4, 2003

AMENDED IN ASSEMBLY AUGUST 18, 2003

AMENDED IN SENATE MAY 27, 2003

INTRODUCED BY Senator Vasconcellos

(Principal coauthor: Assembly Member Leno)

(Coauthors: Assembly Members Goldberg, Hancock, and Koretz)

FEBRUARY 20, 2003

An act to add Article 2.5 (commencing with Section 11362.7) to Chapter 6 of Division 10 of the Health and Safety Code, relating to controlled substances.

LEGISLATIVE COUNSEL'S DIGEST

SB 420, Vasconcellos. Medical marijuana.

Existing law, the Compassionate Use Act of 1996, prohibits any physician from being punished, or denied any right or privilege, for having recommended marijuana to a patient for medical purposes. The act prohibits the provisions of law making unlawful the possession or cultivation of marijuana from applying to a patient, or to a patient'

s primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or oral recommendation or approval of a physician.

This bill would require the State Department of Health Services to establish and maintain a voluntary program for the issuance of identification cards to qualified patients and would establish procedures under which a qualified patient with an identification card may use marijuana for medical purposes. The bill would specify the department's duties in this regard, including developing related protocols and forms, and establishing application and renewal fees for the program.

The bill would impose various duties upon county health departments relating to the issuance of identification cards, thus creating a state-mandated local program.

The bill would create various crimes related to the identification card program, thus imposing a state-mandated local program.

This bill would authorize the Attorney General to set forth and clarify details concerning possession and cultivation limits, and other regulations, as specified. The bill would also authorize the Attorney General to recommend modifications to the possession or cultivation limits set forth in the bill. The bill would require the Attorney General to develop and adopt guidelines to ensure the security and nondiversion of marijuana grown for medical use, as specified.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement, including the creation of a State Mandates Claims Fund to pay the costs of mandates that do not exceed \$1,000,000 statewide and other procedures for claims whose statewide costs exceed \$1,000,000.

This bill would provide that no reimbursement is required by this act for specified reasons.

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. (a) The Legislature finds and declares all of the following:

(1) On November 6, 1996, the people of the State of California enacted the Compassionate Use Act of 1996 (hereafter the act), codified in Section 11362.5 of the Health and Safety Code, in order to allow seriously ill residents of the state, who have the oral or written approval or recommendation of a physician, to use marijuana for medical purposes without fear of criminal liability under Sections 11357 and 11358 of the Health and Safety Code.

(2) However, reports from across the state have revealed problems and uncertainties in the act that have impeded the ability of law enforcement officers to enforce its provisions as the voters intended and, therefore, have prevented qualified patients and designated primary caregivers from obtaining the protections afforded by the act.

(3) Furthermore, the enactment of this law, as well as other recent legislation dealing with pain control, demonstrates that more information is needed to assess the number of individuals across the state who are suffering from serious medical conditions that are not being adequately alleviated through the use of conventional medications.

(4) In addition, the act called upon the state and the federal government to develop a plan for the safe and affordable distribution of marijuana to all patients in medical need thereof.

(b) It is the intent of the Legislature, therefore, to do all of the following:

(1) Clarify the scope of the application of the act and facilitate the prompt identification of qualified patients and their designated primary caregivers in order to avoid unnecessary arrest and prosecution of these individuals and provide needed guidance to law enforcement officers.

(2) Promote uniform and consistent application of the act among

the counties within the state.

(3) Enhance the access of patients and caregivers to medical marijuana through collective, cooperative cultivation projects.

(c) It is also the intent of the Legislature to address additional issues that were not included within the act, and that must be resolved in order to promote the fair and orderly implementation of the act.

(d) The Legislature further finds and declares both of the following:

(1) A state identification card program will further the goals outlined in this section.

(2) With respect to individuals, the identification system established pursuant to this act must be wholly voluntary, and a patient entitled to the protections of Section 11362.5 of the Health and Safety Code need not possess an identification card in order to claim the protections afforded by that section.

(e) The Legislature further finds and declares that it enacts this act pursuant to the powers reserved to the State of California and its people under the Tenth Amendment to the United States Constitution.

SEC. 2. Article 2.5 (commencing with Section 11362.7) is added to Chapter 6 of Division 10 of the Health and Safety Code, to read:

Article 2.5. Medical Marijuana Program

11362.7. For purposes of this article, the following definitions shall apply:

(a) "Attending physician" means an individual who possesses a license in good standing to practice medicine or osteopathy issued by the Medical Board of California or the Osteopathic Medical Board of California and who has taken responsibility for an aspect of the medical care, treatment, diagnosis, counseling, or referral of a patient and who has conducted a medical examination of that patient before recording in the patient's medical record the physician's assessment of whether the patient has a serious medical condition and

whether the medical use of marijuana is appropriate.

(b) "Department" means the State Department of Health Services.

(c) "Person with an identification card" means an individual who is a qualified patient who has applied for and received a valid identification card pursuant to this article.

(d) "Primary caregiver" means the individual, designated by a qualified patient or by a person with an identification card, who has consistently assumed responsibility for the housing, health, or safety of that patient or person, and may include any of the following:

(1) In any case in which a qualified patient or person with an identification card receives medical care or supportive services, or both, from a clinic licensed pursuant to Chapter 1 (commencing with Section 1200) of Division 2, a health care facility licensed pursuant to Chapter 2 (commencing with Section 1250) of Division 2, a residential care facility for persons with chronic life-threatening illness licensed pursuant to Chapter 3.01 (commencing with Section 1568.01) of Division 2, a residential care facility for the elderly licensed pursuant to Chapter 3.2 (commencing with Section 1569) of Division 2, a hospice, or a home health agency licensed pursuant to Chapter 8 (commencing with Section 1725) of Division 2, the owner or operator, or no more than three employees who are designated by the owner or operator, of the clinic, facility, hospice, or home health agency, if designated as a primary caregiver by that qualified patient or person with an identification card.

(2) An individual who has been designated as a primary caregiver by more than one qualified patient or person with an identification card, if every qualified patient or person with an identification card who has designated that individual as a primary caregiver resides in the same city or county as the primary caregiver.

(3) An individual who has been designated as a primary caregiver by a qualified patient or person with an identification card who resides in a city or county other than that of the primary caregiver, if the individual has not been designated as a primary caregiver by any other qualified patient or person with an identification card.

(e) A primary caregiver shall be at least 18 years of age, unless the primary caregiver is the parent of a minor child who is a qualified patient or a person with an identification card or the primary caregiver is a person otherwise entitled to make medical decisions under state law pursuant to Sections 6922, 7002, 7050, or 7120 of the Family Code.

(f) "Qualified patient" means a person who is entitled to the protections of Section 11362.5, but who does not have an identification card issued pursuant to this article.

(g) "Identification card" means a document issued by the State Department of Health Services that document identifies a person authorized to engage in the medical use of marijuana and the person's designated primary caregiver, if any.

(h) "Serious medical condition" means all of the following medical conditions:

- (1) Acquired immune deficiency syndrome (AIDS).
- (2) Anorexia.
- (3) Arthritis.
- (4) Cachexia.
- (5) Cancer.
- (6) Chronic pain.
- (7) Glaucoma.
- (8) Migraine.
- (9) Persistent muscle spasms, including, but not limited to, spasms associated with multiple sclerosis.
- (10) Seizures, including, but not limited to, seizures associated with epilepsy.
- (11) Severe nausea.
- (12) Any other chronic or persistent medical symptom that either:

(A) Substantially limits the ability of the person to conduct one or more major life activities as defined in the Americans with Disabilities Act of 1990 (Public Law 101-336).

(B) If not alleviated, may cause serious harm to the patient's safety or physical or mental health.

(i) "Written documentation" means accurate reproductions of those portions of a patient's medical records that have been created by the attending physician, that contain the information required by paragraph (2) of subdivision (a) of Section 11362.715, and that the patient may submit to a county health department or the county's designee as part of an application for an identification card.

11362.71. (a) (1) The department shall establish and maintain a voluntary program for the issuance of identification cards to qualified patients who satisfy the requirements of this article and voluntarily apply to the identification card program.

(2) The department shall establish and maintain a 24-hour, toll-free telephone number that will enable state and local law enforcement officers to have immediate access to information necessary to verify the validity of an identification card issued by the department, until a cost-effective Internet Web-based system can be developed for this purpose.

(b) Every county health department, or the county's designee, shall do all of the following:

(1) Provide applications upon request to individuals seeking to join the identification card program.

(2) Receive and process completed applications in accordance with Section 11362.72.

(3) Maintain records of identification card programs.

(4) Utilize protocols developed by the department pursuant to paragraph (1) of subdivision (d).

(5) Issue identification cards developed by the department to approved applicants and designated primary caregivers.

(c) The county board of supervisors may designate another health-related governmental or nongovernmental entity or organization to perform the functions described in subdivision (b), except for an entity or organization that cultivates or distributes marijuana.

(d) The department shall develop all of the following:

(1) Protocols that shall be used by a county health department or the county's designee to implement the responsibilities described in subdivision (b), including, but not limited to, protocols to confirm

the accuracy of information contained in an application and to protect the confidentiality of program records.

(2) Application forms that shall be issued to requesting applicants.

(3) An identification card that identifies a person authorized to engage in the medical use of marijuana and an identification card that identifies the person's designated primary caregiver, if any. The two identification cards developed pursuant to this paragraph shall be easily distinguishable from each other.

(e) No person or designated primary caregiver in possession of a valid identification card shall be subject to arrest for possession, transportation, delivery, or cultivation of medical marijuana in an amount established pursuant to this article, unless there is reasonable cause to believe that the information contained in the card is false or falsified, the card has been obtained by means of fraud, or the person is otherwise in violation of the provisions of this article.

(f) It shall not be necessary for a person to obtain an identification card in order to claim the protections of Section 11362.5.

11362.715. (a) A person who seeks an identification card shall pay the fee, as provided in Section 11362.755, and provide all of the following to the county health department or the county's designee on a form developed and provided by the department:

(1) The name of the person, and proof of his or her residency within the county.

(2) Written documentation by the attending physician in the person's medical records stating that the person has been diagnosed with a serious medical condition and that the medical use of marijuana is appropriate.

(3) The name, office address, office telephone number, and California medical license number of the person's attending physician.

(4) The name and the duties of the primary caregiver.

(5) A government-issued photo identification card of the person

and of the designated primary caregiver, if any. If the applicant is a person under 18 years of age, a certified copy of a birth certificate shall be deemed sufficient proof of identity.

(b) If the person applying for an identification card lacks the capacity to make medical decisions, the application may be made by the person's legal representative, including, but not limited to, any of the following:

(1) A conservator with authority to make medical decisions.

(2) An attorney-in-fact under a durable power of attorney for health care or surrogate decisionmaker authorized under another advanced health care directive.

(3) Any other individual authorized by statutory or decisional law to make medical decisions for the person.

(c) The legal representative described in subdivision (b) may also designate in the application an individual, including himself or herself, to serve as a primary caregiver for the person, provided that the individual meets the definition of a primary caregiver.

(d) The person or legal representative submitting the written information and documentation described in subdivision (a) shall retain a copy thereof.

11362.72. (a) Within 30 days of receipt of an application for an identification card, a county health department or the county's designee shall do all of the following:

(1) For purposes of processing the application, verify that the information contained in the application is accurate. If the person is less than 18 years of age, the county health department or its designee shall also contact the parent with legal authority to make medical decisions, legal guardian, or other person or entity with legal authority to make medical decisions, to verify the information.

(2) Verify with the Medical Board of California or the Osteopathic Medical Board of California that the attending physician has a license in good standing to practice medicine or osteopathy in the state.

(3) Contact the attending physician by facsimile, telephone, or

mail to confirm that the medical records submitted by the patient are a true and correct copy of those contained in the physician's office records. When contacted by a county health department or the county's designee, the attending physician shall confirm or deny that the contents of the medical records are accurate.

(4) Take a photograph or otherwise obtain an electronically transmissible image of the applicant and of the designated primary caregiver, if any.

(5) Approve or deny the application. If an applicant who meets the requirements of Section 11362.715 can establish that an identification card is needed on an emergency basis, the county or its designee shall issue a temporary identification card that shall be valid for 30 days from the date of issuance. The county, or its designee, may extend the temporary identification card for no more than 30 days at a time, so long as the applicant continues to meet the requirements of this paragraph.

(b) If the county health department or the county's designee approves the application, it shall, within 24 hours, or by the end of the next working day of approving the application, electronically transmit the following information to the department:

(1) A unique user identification number of the applicant.

(2) The date of expiration of the identification card.

(3) The name and telephone number of the county health department or the county's designee that has approved the application.

(c) The county health department or the county's designee shall issue an identification card to the applicant and to his or her designated primary caregiver, if any, within five working days of approving the application.

(d) In any case involving an incomplete application, the applicant shall assume responsibility for rectifying the deficiency. The county shall have 14 days from the receipt of information from the applicant pursuant to this subdivision to approve or deny the application.

11362.735. (a) An identification card issued by the county health department shall be serially numbered and shall contain all of the

following:

(1) A unique user identification number of the cardholder.

(2) The date of expiration of the identification card.

(3) The name and telephone number of the county health department or the county's designee that has approved the application.

(4) A 24-hour, toll-free telephone number, to be maintained by the department, that will enable state and local law enforcement officers to have immediate access to information necessary to verify the validity of the card.

(5) Photo identification of the cardholder.

(b) A separate identification card shall be issued to the person's designated primary caregiver, if any, and shall include a photo identification of the caregiver.

11362.74. (a) The county health department or the county's designee may deny an application only for any of the following reasons:

(1) The applicant did not provide the information required by Section 11362.715, and upon notice of the deficiency pursuant to subdivision (d) of Section 11362.72, did not provide the information within 30 days.

(2) The county health department or the county's designee determines that the information provided was false.

(3) The applicant does not meet the criteria set forth in this article.

(b) Any person whose application has been denied pursuant to subdivision (a) may not reapply for six months from the date of denial unless otherwise authorized by the county health department or the county's designee or by a court of competent jurisdiction.

(c) Any person whose application has been denied pursuant to subdivision (a) may appeal that decision to the department. The county health department or the county's designee shall make available a telephone number or address to which the denied applicant can direct an appeal.

11362.745. (a) An identification card shall be valid for a period of one year.

(b) Upon annual renewal of an identification card, the county health department or its designee shall verify all new information and may verify any other information that has not changed.

(c) The county health department or the county's designee shall transmit its determination of approval or denial of a renewal to the department.

11362.755. (a) The department shall establish application and renewal fees for persons seeking to obtain or renew identification cards that are sufficient to cover the expenses incurred by the department, including the startup cost, the cost of reduced fees for Medi-Cal beneficiaries in accordance with subdivision (b), the cost of identifying and developing a cost-effective Internet Web-based system, and the cost of maintaining the 24-hour toll-free telephone number. Each county health department or the county's designee may charge an additional fee for all costs incurred by the county or the county's designee for administering the program pursuant to this article.

(b) Upon satisfactory proof of participation and eligibility in the Medi-Cal program, a Medi-Cal beneficiary shall receive a 50 percent reduction in the fees established pursuant to this section.

11362.76. (a) A person who possesses an identification card shall:

(1) Within seven days, notify the county health department or the county's designee of any change in the person's attending physician or designated primary caregiver, if any.

(2) Annually submit to the county health department or the county's designee the following:

(A) Updated written documentation of the person's serious medical condition.

(B) The name and duties of the person's designated primary caregiver, if any, for the forthcoming year.

(b) If a person who possesses an identification card fails to comply with this section, the card shall be deemed expired. If an identification card expires, the identification card of any designated primary caregiver of the person shall also expire.

(c) If the designated primary caregiver has been changed, the previous primary caregiver shall return his or her identification card to the department or to the county health department or the county's designee.

(d) If the owner or operator or an employee of the owner or operator of a provider has been designated as a primary caregiver pursuant to paragraph (1) of subdivision (d) of Section 11362.7, of the qualified patient or person with an identification card, the owner or operator shall notify the county health department or the county's designee, pursuant to Section 11362.715, if a change in the designated primary caregiver has occurred.

11362.765. (a) Subject to the requirements of this article, the individuals specified in subdivision (b) shall not be subject, on that sole basis, to criminal liability under Section 11357, 11358, 11359, 11360, 11366, 11366.5, or 11570. However, nothing in this section shall authorize the individual to smoke or otherwise consume marijuana unless otherwise authorized by this article, nor shall anything in this section authorize any individual or group to cultivate or distribute marijuana for profit.

(b) Subdivision (a) shall apply to all of the following:

(1) A qualified patient or a person with an identification card who transports or processes marijuana for his or her own personal medical use.

(2) A designated primary caregiver who transports, processes, administers, delivers, or gives away marijuana for medical purposes, in amounts not exceeding those established in subdivision (a) of Section 11362.77, only to the qualified patient of the primary caregiver, or to the person with an identification card who has designated the individual as a primary caregiver.

(3) Any individual who provides assistance to a qualified patient or a person with an identification card, or his or her designated

primary caregiver, in administering medical marijuana to the qualified patient or person or acquiring the skills necessary to cultivate or administer marijuana for medical purposes to the qualified patient or person.

(c) A primary caregiver who receives compensation for actual expenses, including reasonable compensation incurred for services provided to an eligible qualified patient or person with an identification card to enable that person to use marijuana under this article, or for payment for out-of-pocket expenses incurred in providing those services, or both, shall not, on the sole basis of that fact, be subject to prosecution or punishment under Section 11359 or 11360.

11362.77. (a) A qualified patient or primary caregiver may possess no more than eight ounces of dried marijuana per qualified patient. In addition, a qualified patient or primary caregiver may also maintain no more than six mature or 12 immature marijuana plants per qualified patient.

(b) If a qualified patient or primary caregiver has a doctor's recommendation that this quantity does not meet the qualified patient's medical needs, the qualified patient or primary caregiver may possess an amount of marijuana consistent with the patient's needs.

(c) Counties and cities may retain or enact medical marijuana guidelines allowing qualified patients or primary caregivers to exceed the state limits set forth in subdivision (a).

(d) Only the dried mature processed flowers of female cannabis plant or the plant conversion shall be considered when determining allowable quantities of marijuana under this section.

(e) The Attorney General may recommend modifications to the possession or cultivation limits set forth in this section. These recommendations, if any, shall be made to the Legislature no later than December 1, 2005, and may be made only after public comment and consultation with interested organizations, including, but not

limited to, patients, health care professionals, researchers, law enforcement, and local governments. Any recommended modification shall be consistent with the intent of this article and shall be based on currently available scientific research.

(f) A qualified patient or a person holding a valid identification card, or the designated primary caregiver of that qualified patient or person, may possess amounts of marijuana consistent with this article.

11362.775. Qualified patients, persons with valid identification cards, and the designated primary caregivers of qualified patients and persons with identification cards, who associate within the State of California in order collectively or cooperatively to cultivate marijuana for medical purposes, shall not solely on the basis of that fact be subject to state criminal sanctions under Section 11357, 11358, 11359, 11360, 11366, 11366.5, or 11570.

11362.78. A state or local law enforcement agency or officer shall not refuse to accept an identification card issued by the department unless the state or local law enforcement agency or officer has reasonable cause to believe that the information contained in the card is false or fraudulent, or the card is being used fraudulently.

11362.785. (a) Nothing in this article shall require any accommodation of any medical use of marijuana on the property or premises of any place of employment or during the hours of employment or on the property or premises of any jail, correctional facility, or other type of penal institution in which prisoners reside or persons under arrest are detained.

(b) Notwithstanding subdivision (a), a person shall not be prohibited or prevented from obtaining and submitting the written information and documentation necessary to apply for an identification card on the basis that the person is incarcerated in a jail, correctional facility, or other penal institution in which prisoners reside or persons under arrest are detained.

(c) Nothing in this article shall prohibit a jail, correctional facility, or other penal institution in which prisoners reside or

persons under arrest are detained, from permitting a prisoner or a person under arrest who has an identification card, to use marijuana for medical purposes under circumstances that will not endanger the health or safety of other prisoners or the security of the facility.

(d) Nothing in this article shall require a governmental, private, or any other health insurance provider or health care service plan to be liable for any claim for reimbursement for the medical use of marijuana.

11362.79. Nothing in this article shall authorize a qualified patient or person with an identification card to engage in the smoking of medical marijuana under any of the following circumstances:

(a) In any place where smoking is prohibited by law.

(b) In or within 1,000 feet of the grounds of a school, recreation center, or youth center, unless the medical use occurs within a residence.

(c) On a schoolbus.

(d) While in a motor vehicle that is being operated.

(e) While operating a boat.

11362.795. (a) (1) Any criminal defendant who is eligible to use marijuana pursuant to Section 11362.5 may request that the court confirm that he or she is allowed to use medical marijuana while he or she is on probation or released on bail.

(2) The court's decision and the reasons for the decision shall be stated on the record and an entry stating those reasons shall be made in the minutes of the court.

(3) During the period of probation or release on bail, if a physician recommends that the probationer or defendant use medical marijuana, the probationer or defendant may request a modification of the conditions of probation or bail to authorize the use of medical marijuana.

(4) The court's consideration of the modification request authorized by this subdivision shall comply with the requirements of

this section.

(b) (1) Any person who is to be released on parole from a jail, state prison, school, road camp, or other state or local institution of confinement and who is eligible to use medical marijuana pursuant to Section 11362.5 may request that he or she be allowed to use medical marijuana during the period he or she is released on parole. A parolee's written conditions of parole shall reflect whether or not a request for a modification of the conditions of his or her parole to use medical marijuana was made, and whether the request was granted or denied.

(2) During the period of the parole, where a physician recommends that the parolee use medical marijuana, the parolee may request a modification of the conditions of the parole to authorize the use of medical marijuana.

(3) Any parolee whose request to use medical marijuana while on parole was denied may pursue an administrative appeal of the decision. Any decision on the appeal shall be in writing and shall reflect the reasons for the decision.

(4) The administrative consideration of the modification request authorized by this subdivision shall comply with the requirements of this section.

11362.8. No professional licensing board may impose a civil penalty or take other disciplinary action against a licensee based solely on the fact that the licensee has performed acts that are necessary or appropriate to carry out the licensee's role as a designated primary caregiver to a person who is a qualified patient or who possesses a lawful identification card issued pursuant to Section 11362.72. However, this section shall not apply to acts performed by a physician relating to the discussion or recommendation of the medical use of marijuana to a patient. These discussions or recommendations, or both, shall be governed by Section 11362.5.

11362.81. (a) A person specified in subdivision (b) shall be subject to the following penalties:

(1) For the first offense, imprisonment in the county jail for no more than six months or a fine not to exceed one thousand dollars.

(\$1,000), or both.

(2) For a second or subsequent offense, imprisonment in the county jail for no more than one year, or a fine not to exceed one thousand dollars (\$1,000), or both.

(b) Subdivision (a) applies to any of the following:

(1) A person who fraudulently represents a medical condition or fraudulently provides any material misinformation to a physician, county health department or the county's designee, or state or local law enforcement agency or officer, for the purpose of falsely obtaining an identification card.

(2) A person who steals or fraudulently uses any person's identification card in order to acquire, possess, cultivate, transport, use, produce, or distribute marijuana.

(3) A person who counterfeits, tampers with, or fraudulently produces an identification card.

(4) A person who breaches the confidentiality requirements of this article to information provided to, or contained in the records of, the department or of a county health department or the county's designee pertaining to an identification card program.

(c) In addition to the penalties prescribed in subdivision (a), any person described in subdivision (b) may be precluded from attempting to obtain, or obtaining or using, an identification card for a period of up to six months at the discretion of the court.

(d) In addition to the requirements of this article, the Attorney General shall develop and adopt appropriate guidelines to ensure the security and nondiversion of marijuana grown for medical use by patients qualified under the Compassionate Use Act of 1996.

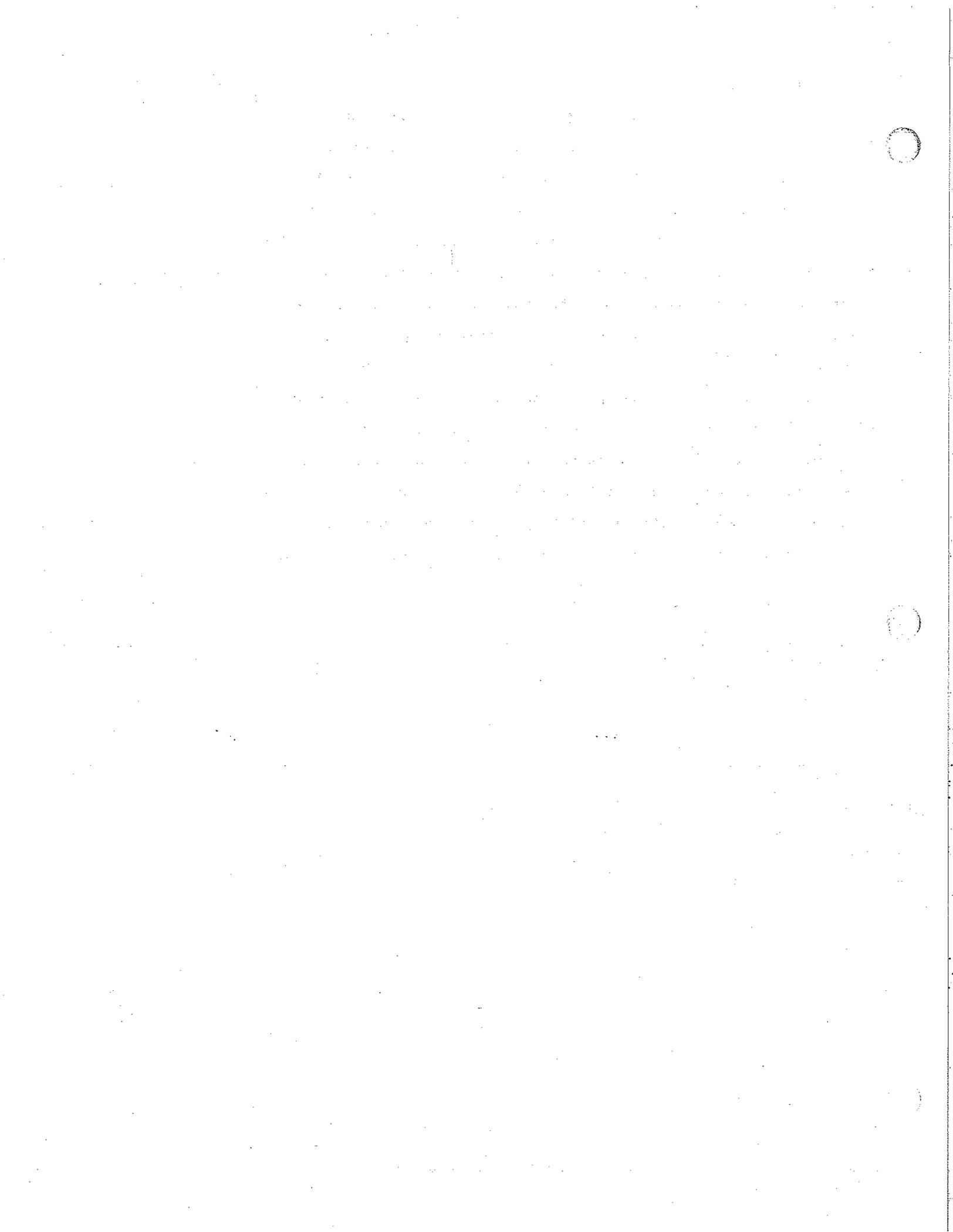
11362.82. If any section, subdivision, sentence, clause, phrase, or portion of this article is for any reason held invalid or unconstitutional by any court of competent jurisdiction, that portion shall be deemed a separate, distinct, and independent provision, and that holding shall not affect the validity of the remaining portion thereof.

11362.83. Nothing in this article shall prevent a city or other local governing body from adopting and enforcing laws consistent with

this article.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for certain costs that may be incurred by a local agency or school district because in that regard this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

In addition, no reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution for other costs mandated by the state because this act includes additional revenue that is specifically intended to fund the costs of the state mandate in an amount sufficient to fund the cost of the state mandate, within the meaning of Section 17556 of the Government Code.





**GUIDELINES FOR THE SECURITY AND NON-DIVERSION
OF MARIJUANA GROWN FOR MEDICAL USE**
August 2008

In 1996, California voters approved an initiative that exempted certain patients and their primary caregivers from criminal liability under state law for the possession and cultivation of marijuana. In 2003, the Legislature enacted additional legislation relating to medical marijuana. One of those statutes requires the Attorney General to adopt “guidelines to ensure the security and nondiversion of marijuana grown for medical use.” (Health & Saf. Code, § 11362.81(d).¹) To fulfill this mandate, this Office is issuing the following guidelines to (1) ensure that marijuana grown for medical purposes remains secure and does not find its way to non-patients or illicit markets, (2) help law enforcement agencies perform their duties effectively and in accordance with California law, and (3) help patients and primary caregivers understand how they may cultivate, transport, possess, and use medical marijuana under California law.

I. SUMMARY OF APPLICABLE LAW

A. California Penal Provisions Relating to Marijuana.

The possession, sale, cultivation, or transportation of marijuana is ordinarily a crime under California law. (See, e.g., § 11357 [possession of marijuana is a misdemeanor]; § 11358 [cultivation of marijuana is a felony]; Veh. Code, § 23222 [possession of less than 1 oz. of marijuana while driving is a misdemeanor]; § 11359 [possession with intent to sell any amount of marijuana is a felony]; § 11360 [transporting, selling, or giving away marijuana in California is a felony; under 28.5 grams is a misdemeanor]; § 11361 [selling or distributing marijuana to minors, or using a minor to transport, sell, or give away marijuana, is a felony].)

B. Proposition 215 - The Compassionate Use Act of 1996.

On November 5, 1996, California voters passed Proposition 215, which decriminalized the cultivation and use of marijuana by seriously ill individuals upon a physician’s recommendation. (§ 11362.5.) Proposition 215 was enacted to “ensure that seriously ill Californians have the right to obtain and use marijuana for medical purposes where that medical use is deemed appropriate and has been recommended by a physician who has determined that the person’s health would benefit from the use of marijuana,” and to “ensure that patients and their primary caregivers who obtain and use marijuana for

¹ Unless otherwise noted, all statutory references are to the Health & Safety Code.

medical purposes upon the recommendation of a physician are not subject to criminal prosecution or sanction.” (§ 11362.5(b)(1)(A)-(B).)

The Act further states that “Section 11357, relating to the possession of marijuana, and Section 11358, relating to the cultivation of marijuana, shall not apply to a patient, or to a patient’s primary caregiver, who possesses or cultivates marijuana for the personal medical purposes of the patient upon the written or verbal recommendation or approval of a physician.” (§ 11362.5(d).) Courts have found an implied defense to the transportation of medical marijuana when the “quantity transported and the method, timing and distance of the transportation are reasonably related to the patient’s current medical needs.” (*People v. Trippet* (1997) 56 Cal.App.4th 1532, 1551.)

C. Senate Bill 420 - The Medical Marijuana Program Act.

On January 1, 2004, Senate Bill 420, the Medical Marijuana Program Act (MMP), became law. (§§ 11362.7-11362.83.) The MMP, among other things, requires the California Department of Public Health (DPH) to establish and maintain a program for the voluntary registration of qualified medical marijuana patients and their primary caregivers through a statewide identification card system. Medical marijuana identification cards are intended to help law enforcement officers identify and verify that cardholders are able to cultivate, possess, and transport certain amounts of marijuana without being subject to arrest under specific conditions. (§§ 11362.71(e), 11362.78.)

It is mandatory that all counties participate in the identification card program by (a) providing applications upon request to individuals seeking to join the identification card program; (b) processing completed applications; (c) maintaining certain records; (d) following state implementation protocols; and (e) issuing DPH identification cards to approved applicants and designated primary caregivers. (§ 11362.71(b).)

Participation by patients and primary caregivers in the identification card program is voluntary. However, because identification cards offer the holder protection from arrest, are issued only after verification of the cardholder’s status as a qualified patient or primary caregiver, and are immediately verifiable online or via telephone, they represent one of the best ways to ensure the security and non-diversion of marijuana grown for medical use.

In addition to establishing the identification card program, the MMP also defines certain terms, sets possession guidelines for cardholders, and recognizes a qualified right to collective and cooperative cultivation of medical marijuana. (§§ 11362.7, 11362.77, 11362.775.)

D. Taxability of Medical Marijuana Transactions.

In February 2007, the California State Board of Equalization (BOE) issued a Special Notice confirming its policy of taxing medical marijuana transactions, as well as its requirement that businesses engaging in such transactions hold a Seller’s Permit. (<http://www.boe.ca.gov/news/pdf/medseller2007.pdf>.) According to the Notice, having a Seller’s Permit does not allow individuals to make unlawful sales, but instead merely provides a way to remit any sales and use taxes due. BOE further clarified its policy in a

June 2007 Special Notice that addressed several frequently asked questions concerning taxation of medical marijuana transactions. (<http://www.boe.ca.gov/news/pdf/173.pdf>.)

E. Medical Board of California.

The Medical Board of California licenses, investigates, and disciplines California physicians. (Bus. & Prof. Code, § 2000, et seq.) Although state law prohibits punishing a physician simply for recommending marijuana for treatment of a serious medical condition (§ 11362.5(c)), the Medical Board can and does take disciplinary action against physicians who fail to comply with accepted medical standards when recommending marijuana. In a May 13, 2004 press release, the Medical Board clarified that these accepted standards are the same ones that a reasonable and prudent physician would follow when recommending or approving any medication. They include the following:

1. Taking a history and conducting a good faith examination of the patient;
2. Developing a treatment plan with objectives;
3. Providing informed consent, including discussion of side effects;
4. Periodically reviewing the treatment's efficacy;
5. Consultations, as necessary; and
6. Keeping proper records supporting the decision to recommend the use of medical marijuana.

(http://www.mbc.ca.gov/board/media/releases_2004_05-13_marijuana.html.)

Complaints about physicians should be addressed to the Medical Board (1-800-633-2322 or www.mbc.ca.gov), which investigates and prosecutes alleged licensing violations in conjunction with the Attorney General's Office.

F. The Federal Controlled Substances Act.

Adopted in 1970, the Controlled Substances Act (CSA) established a federal regulatory system designed to combat recreational drug abuse by making it unlawful to manufacture, distribute, dispense, or possess any controlled substance. (21 U.S.C. § 801, et seq.; *Gonzales v. Oregon* (2006) 546 U.S. 243, 271-273.) The CSA reflects the federal government's view that marijuana is a drug with "no currently accepted medical use." (21 U.S.C. § 812(b)(1).) Accordingly, the manufacture, distribution, or possession of marijuana is a federal criminal offense. (*Id.* at §§ 841(a)(1), 844(a).)

The incongruity between federal and state law has given rise to understandable confusion, but no legal conflict exists merely because state law and federal law treat marijuana differently. Indeed, California's medical marijuana laws have been challenged unsuccessfully in court on the ground that they are preempted by the CSA. (*County of San Diego v. San Diego NORML* (July 31, 2008) --- Cal.Rptr.3d ----, 2008 WL 2930117.) Congress has provided that states are free to regulate in the area of controlled substances, including marijuana, provided that state law does not positively conflict with the CSA. (21 U.S.C. § 903.) Neither Proposition 215, nor the MMP, conflict with the CSA because, in adopting these laws, California did not "legalize" medical marijuana, but instead exercised the state's reserved powers to not punish certain marijuana offenses under state law when a

physician has recommended its use to treat a serious medical condition. (See *City of Garden Grove v. Superior Court (Kha)* (2007) 157 Cal.App.4th 355, 371-373, 381-382.)

In light of California's decision to remove the use and cultivation of physician-recommended marijuana from the scope of the state's drug laws, this Office recommends that state and local law enforcement officers not arrest individuals or seize marijuana under federal law when the officer determines from the facts available that the cultivation, possession, or transportation is permitted under California's medical marijuana laws.

II. DEFINITIONS

A. **Physician's Recommendation:** Physicians may not prescribe marijuana because the federal Food and Drug Administration regulates prescription drugs and, under the CSA, marijuana is a Schedule I drug, meaning that it has no recognized medical use. Physicians may, however, lawfully issue a verbal or written recommendation under California law indicating that marijuana would be a beneficial treatment for a serious medical condition. (§ 11362.5(d); *Conant v. Walters* (9th Cir. 2002) 309 F.3d 629, 632.)

B. **Primary Caregiver:** A primary caregiver is a person who is designated by a qualified patient and "has consistently assumed responsibility for the housing, health, or safety" of the patient. (§ 11362.5(e).) California courts have emphasized the consistency element of the patient-caregiver relationship. Although a "primary caregiver who consistently grows and supplies . . . medicinal marijuana for a section 11362.5 patient is serving a health need of the patient," someone who merely maintains a source of marijuana does not automatically become the party "who has consistently assumed responsibility for the housing, health, or safety" of that purchaser. (*People ex rel. Lungren v. Peron* (1997) 59 Cal.App.4th 1383, 1390, 1400.) A person may serve as primary caregiver to "more than one" patient, provided that the patients and caregiver all reside in the same city or county. (§ 11362.7(d)(2).) Primary caregivers also may receive certain compensation for their services. (§ 11362.765(c) ["A primary caregiver who receives compensation for actual expenses, including reasonable compensation incurred for services provided . . . to enable [a patient] to use marijuana under this article, or for payment for out-of-pocket expenses incurred in providing those services, or both, . . . shall not, on the sole basis of that fact, be subject to prosecution" for possessing or transporting marijuana].)

C. **Qualified Patient:** A qualified patient is a person whose physician has recommended the use of marijuana to treat a serious illness, including cancer, anorexia, AIDS, chronic pain, spasticity, glaucoma, arthritis, migraine, or any other illness for which marijuana provides relief. (§ 11362.5(b)(1)(A).)

D. **Recommending Physician:** A recommending physician is a person who (1) possesses a license in good standing to practice medicine in California; (2) has taken responsibility for some aspect of the medical care, treatment, diagnosis, counseling, or referral of a patient; and (3) has complied with accepted medical standards (as described by the Medical Board of California in its May 13, 2004 press release) that a reasonable and prudent physician would follow when recommending or approving medical marijuana for the treatment of his or her patient.

III. GUIDELINES REGARDING INDIVIDUAL QUALIFIED PATIENTS AND PRIMARY CAREGIVERS

A. State Law Compliance Guidelines.

1. **Physician Recommendation:** Patients must have a written or verbal recommendation for medical marijuana from a licensed physician. (§ 11362.5(d).)

2. **State of California Medical Marijuana Identification Card:** Under the MMP, qualified patients and their primary caregivers may voluntarily apply for a card issued by DPH identifying them as a person who is authorized to use, possess, or transport marijuana grown for medical purposes. To help law enforcement officers verify the cardholder's identity, each card bears a unique identification number, and a verification database is available online (www.calmmp.ca.gov). In addition, the cards contain the name of the county health department that approved the application, a 24-hour verification telephone number, and an expiration date. (§§ 11362.71(a); 11362.735(a)(3)-(4); 11362.745.)

3. **Proof of Qualified Patient Status:** Although verbal recommendations are technically permitted under Proposition 215, patients should obtain and carry written proof of their physician recommendations to help them avoid arrest. A state identification card is the best form of proof, because it is easily verifiable and provides immunity from arrest if certain conditions are met (see section III.B.4, below). The next best forms of proof are a city- or county-issued patient identification card, or a written recommendation from a physician.

4. Possession Guidelines:

a) **MMP:**² Qualified patients and primary caregivers who possess a state-issued identification card may possess 8 oz. of dried marijuana, and may maintain no more than 6 mature or 12 immature plants per qualified patient. (§ 11362.77(a).) But, if "a qualified patient or primary caregiver has a doctor's recommendation that this quantity does not meet the qualified patient's medical needs, the qualified patient or primary caregiver may possess an amount of marijuana consistent with the patient's needs." (§ 11362.77(b).) Only the dried mature processed flowers or buds of the female cannabis plant should be considered when determining allowable quantities of medical marijuana for purposes of the MMP. (§ 11362.77(d).)

b) **Local Possession Guidelines:** Counties and cities may adopt regulations that allow qualified patients or primary caregivers to possess

² On May 22, 2008, California's Second District Court of Appeal severed Health & Safety Code § 11362.77 from the MMP on the ground that the statute's possession guidelines were an unconstitutional amendment of Proposition 215, which does not quantify the marijuana a patient may possess. (See *People v. Kelly* (2008) 163 Cal.App.4th 124, 77 Cal.Rptr.3d 390.) The Third District Court of Appeal recently reached a similar conclusion in *People v. Phomphakdy* (July 31, 2008) --- Cal.Rptr.3d ---, 2008 WL 2931369. The California Supreme Court has granted review in *Kelly* and the Attorney General intends to seek review in *Phomphakdy*.

medical marijuana in amounts that exceed the MMP's possession guidelines. (§ 11362.77(c).)

c) **Proposition 215:** Qualified patients claiming protection under Proposition 215 may possess an amount of marijuana that is "reasonably related to [their] current medical needs." (*People v. Trippet* (1997) 56 Cal.App.4th 1532, 1549.)

B. Enforcement Guidelines.

1. **Location of Use:** Medical marijuana may not be smoked (a) where smoking is prohibited by law, (b) at or within 1000 feet of a school, recreation center, or youth center (unless the medical use occurs within a residence), (c) on a school bus, or (d) in a moving motor vehicle or boat. (§ 11362.79.)

2. **Use of Medical Marijuana in the Workplace or at Correctional Facilities:** The medical use of marijuana need not be accommodated in the workplace, during work hours, or at any jail, correctional facility, or other penal institution. (§ 11362.785(a); *Ross v. RagingWire Telecomms., Inc.* (2008) 42 Cal.4th 920, 933 [under the Fair Employment and Housing Act, an employer may terminate an employee who tests positive for marijuana use].)

3. **Criminal Defendants, Probationers, and Parolees:** Criminal defendants and probationers may request court approval to use medical marijuana while they are released on bail or probation. The court's decision and reasoning must be stated on the record and in the minutes of the court. Likewise, parolees who are eligible to use medical marijuana may request that they be allowed to continue such use during the period of parole. The written conditions of parole must reflect whether the request was granted or denied. (§ 11362.795.)

4. **State of California Medical Marijuana Identification Cardholders:** When a person invokes the protections of Proposition 215 or the MMP and he or she possesses a state medical marijuana identification card, officers should:

a) Review the identification card and verify its validity either by calling the telephone number printed on the card, or by accessing DPH's card verification website (<http://www.calmmp.ca.gov>); and

b) If the card is valid and not being used fraudulently, there are no other indicia of illegal activity (weapons, illicit drugs, or excessive amounts of cash), and the person is within the state or local possession guidelines, the individual should be released and the marijuana should not be seized. Under the MMP, "no person or designated primary caregiver in possession of a valid state medical marijuana identification card shall be subject to arrest for possession, transportation, delivery, or cultivation of medical marijuana." (§ 11362.71(e).) Further, a "state or local law enforcement agency or officer shall not refuse to accept an identification card issued by the department unless the state or local law enforcement agency or officer

has reasonable cause to believe that the information contained in the card is false or fraudulent, or the card is being used fraudulently.” (§ 11362.78.)

5. **Non-Cardholders:** When a person claims protection under Proposition 215 or the MMP and only has a locally-issued (i.e., non-state) patient identification card, or a written (or verbal) recommendation from a licensed physician, officers should use their sound professional judgment to assess the validity of the person’s medical-use claim:

a) Officers need not abandon their search or investigation. The standard search and seizure rules apply to the enforcement of marijuana-related violations. Reasonable suspicion is required for detention, while probable cause is required for search, seizure, and arrest.

b) Officers should review any written documentation for validity. It may contain the physician’s name, telephone number, address, and license number.

c) If the officer reasonably believes that the medical-use claim is valid based upon the totality of the circumstances (including the quantity of marijuana, packaging for sale, the presence of weapons, illicit drugs, or large amounts of cash), and the person is within the state or local possession guidelines or has an amount consistent with their current medical needs, the person should be released and the marijuana should not be seized.

d) Alternatively, if the officer has probable cause to doubt the validity of a person’s medical marijuana claim based upon the facts and circumstances, the person may be arrested and the marijuana may be seized. It will then be up to the person to establish his or her medical marijuana defense in court.

e) Officers are not obligated to accept a person’s claim of having a verbal physician’s recommendation that cannot be readily verified with the physician at the time of detention.

6. **Exceeding Possession Guidelines:** If a person has what appears to be valid medical marijuana documentation, but exceeds the applicable possession guidelines identified above, all marijuana may be seized.

7. **Return of Seized Medical Marijuana:** If a person whose marijuana is seized by law enforcement successfully establishes a medical marijuana defense in court, or the case is not prosecuted, he or she may file a motion for return of the marijuana. If a court grants the motion and orders the return of marijuana seized incident to an arrest, the individual or entity subject to the order must return the property. State law enforcement officers who handle controlled substances in the course of their official duties are immune from liability under the CSA. (21 U.S.C. § 885(d).) Once the marijuana is returned, federal authorities are free to exercise jurisdiction over it. (21 U.S.C. §§ 812(c)(10), 844(a); *City of Garden Grove v. Superior Court (Kha)* (2007) 157 Cal.App.4th 355, 369, 386, 391.)

IV. GUIDELINES REGARDING COLLECTIVES AND COOPERATIVES

Under California law, medical marijuana patients and primary caregivers may “associate within the State of California in order collectively or cooperatively to cultivate marijuana for medical purposes.” (§ 11362.775.) The following guidelines are meant to apply to qualified patients and primary caregivers who come together to collectively or cooperatively cultivate physician-recommended marijuana.

A. Business Forms: Any group that is collectively or cooperatively cultivating and distributing marijuana for medical purposes should be organized and operated in a manner that ensures the security of the crop and safeguards against diversion for non-medical purposes. The following are guidelines to help cooperatives and collectives operate within the law, and to help law enforcement determine whether they are doing so.

1. **Statutory Cooperatives:** A cooperative must file articles of incorporation with the state and conduct its business for the mutual benefit of its members. (Corp. Code, § 12201, 12300.) No business may call itself a “cooperative” (or “co-op”) unless it is properly organized and registered as such a corporation under the Corporations or Food and Agricultural Code. (*Id.* at § 12311(b).) Cooperative corporations are “democratically controlled and are not organized to make a profit for themselves, as such, or for their members, as such, but primarily for their members as patrons.” (*Id.* at § 12201.) The earnings and savings of the business must be used for the general welfare of its members or equitably distributed to members in the form of cash, property, credits, or services. (*Ibid.*) Cooperatives must follow strict rules on organization, articles, elections, and distribution of earnings, and must report individual transactions from individual members each year. (See *id.* at § 12200, et seq.) Agricultural cooperatives are likewise nonprofit corporate entities “since they are not organized to make profit for themselves, as such, or for their members, as such, but only for their members as producers.” (Food & Agric. Code, § 54033.) Agricultural cooperatives share many characteristics with consumer cooperatives. (See, e.g., *id.* at § 54002, et seq.) Cooperatives should not purchase marijuana from, or sell to, non-members; instead, they should only provide a means for facilitating or coordinating transactions between members.

2. **Collectives:** California law does not define collectives, but the dictionary defines them as “a business, farm, etc., jointly owned and operated by the members of a group.” (*Random House Unabridged Dictionary*; Random House, Inc. © 2006.) Applying this definition, a collective should be an organization that merely facilitates the collaborative efforts of patient and caregiver members – including the allocation of costs and revenues. As such, a collective is not a statutory entity, but as a practical matter it might have to organize as some form of business to carry out its activities. The collective should not purchase marijuana from, or sell to, non-members; instead, it should only provide a means for facilitating or coordinating transactions between members.

B. Guidelines for the Lawful Operation of a Cooperative or Collective:

Collectives and cooperatives should be organized with sufficient structure to ensure security, non-diversion of marijuana to illicit markets, and compliance with all state and local laws. The following are some suggested guidelines and practices for operating collective growing operations to help ensure lawful operation.

1. **Non-Profit Operation:** Nothing in Proposition 215 or the MMP authorizes collectives, cooperatives, or individuals to profit from the sale or distribution of marijuana. (See, e.g., § 11362.765(a) ["nothing in this section shall authorize . . . any individual or group to cultivate or distribute marijuana for profit"].)

2. **Business Licenses, Sales Tax, and Seller's Permits:** The State Board of Equalization has determined that medical marijuana transactions are subject to sales tax, regardless of whether the individual or group makes a profit, and those engaging in transactions involving medical marijuana must obtain a Seller's Permit. Some cities and counties also require dispensing collectives and cooperatives to obtain business licenses.

3. **Membership Application and Verification:** When a patient or primary caregiver wishes to join a collective or cooperative, the group can help prevent the diversion of marijuana for non-medical use by having potential members complete a written membership application. The following application guidelines should be followed to help ensure that marijuana grown for medical use is not diverted to illicit markets:

a) Verify the individual's status as a qualified patient or primary caregiver. Unless he or she has a valid state medical marijuana identification card, this should involve personal contact with the recommending physician (or his or her agent), verification of the physician's identity, as well as his or her state licensing status. Verification of primary caregiver status should include contact with the qualified patient, as well as validation of the patient's recommendation. Copies should be made of the physician's recommendation or identification card, if any;

b) Have the individual agree not to distribute marijuana to non-members;

c) Have the individual agree not to use the marijuana for other than medical purposes;

d) Maintain membership records on-site or have them reasonably available;

e) Track when members' medical marijuana recommendation and/or identification cards expire; and

f) Enforce conditions of membership by excluding members whose identification card or physician recommendation are invalid or have expired, or who are caught diverting marijuana for non-medical use.

4. **Collectives Should Acquire, Possess, and Distribute Only Lawfully Cultivated Marijuana:** Collectives and cooperatives should acquire marijuana only from their constituent members, because only marijuana grown by a qualified patient or his or her primary caregiver may lawfully be transported by, or distributed to, other members of a collective or cooperative. (§§ 11362.765, 11362.775.) The collective or cooperative may then allocate it to other members of the group. Nothing allows marijuana to be purchased from outside the collective or cooperative for distribution to its members. Instead, the cycle should be a closed-circuit of marijuana cultivation and consumption with no purchases or sales to or from non-members. To help prevent diversion of medical marijuana to non-medical markets, collectives and cooperatives should document each member's contribution of labor, resources, or money to the enterprise. They also should track and record the source of their marijuana.

5. **Distribution and Sales to Non-Members are Prohibited:** State law allows primary caregivers to be reimbursed for certain services (including marijuana cultivation), but nothing allows individuals or groups to sell or distribute marijuana to non-members. Accordingly, a collective or cooperative may not distribute medical marijuana to any person who is not a member in good standing of the organization. A dispensing collective or cooperative may credit its members for marijuana they provide to the collective, which it may then allocate to other members. (§ 11362.765(c).) Members also may reimburse the collective or cooperative for marijuana that has been allocated to them. Any monetary reimbursement that members provide to the collective or cooperative should only be an amount necessary to cover overhead costs and operating expenses.

6. **Permissible Reimbursements and Allocations:** Marijuana grown at a collective or cooperative for medical purposes may be:

- a) Provided free to qualified patients and primary caregivers who are members of the collective or cooperative;
- b) Provided in exchange for services rendered to the entity;
- c) Allocated based on fees that are reasonably calculated to cover overhead costs and operating expenses; or
- d) Any combination of the above.

7. **Possession and Cultivation Guidelines:** If a person is acting as primary caregiver to more than one patient under section 11362.7(d)(2), he or she may aggregate the possession and cultivation limits for each patient. For example, applying the MMP's basic possession guidelines, if a caregiver is responsible for three patients, he or she may possess up to 24 oz. of marijuana (8 oz. per patient) and may grow 18 mature or 36 immature plants. Similarly, collectives and cooperatives may cultivate and transport marijuana in aggregate amounts tied to its membership numbers. Any patient or primary caregiver exceeding individual possession guidelines should have supporting records readily available when:

- a) Operating a location for cultivation;
- b) Transporting the group's medical marijuana; and
- c) Operating a location for distribution to members of the collective or cooperative.

8. **Security:** Collectives and cooperatives should provide adequate security to ensure that patients are safe and that the surrounding homes or businesses are not negatively impacted by nuisance activity such as loitering or crime. Further, to maintain security, prevent fraud, and deter robberies, collectives and cooperatives should keep accurate records and follow accepted cash handling practices, including regular bank runs and cash drops, and maintain a general ledger of cash transactions.

C. **Enforcement Guidelines:** Depending upon the facts and circumstances, deviations from the guidelines outlined above, or other indicia that marijuana is not for medical use, may give rise to probable cause for arrest and seizure. The following are additional guidelines to help identify medical marijuana collectives and cooperatives that are operating outside of state law.

1. **Storefront Dispensaries:** Although medical marijuana “dispensaries” have been operating in California for years, dispensaries, as such, are not recognized under the law. As noted above, the only recognized group entities are cooperatives and collectives. (§ 11362.775.) It is the opinion of this Office that a properly organized and operated collective or cooperative that dispenses medical marijuana through a storefront may be lawful under California law, but that dispensaries that do not substantially comply with the guidelines set forth in sections IV(A) and (B), above, are likely operating outside the protections of Proposition 215 and the MMP, and that the individuals operating such entities may be subject to arrest and criminal prosecution under California law. For example, dispensaries that merely require patients to complete a form summarily designating the business owner as their primary caregiver – and then offering marijuana in exchange for cash “donations” – are likely unlawful. (*Peron, supra*, 59 Cal.App.4th at p. 1400 [cannabis club owner was not the primary caregiver to thousands of patients where he did not consistently assume responsibility for their housing, health, or safety].)

2. **Indicia of Unlawful Operation:** When investigating collectives or cooperatives, law enforcement officers should be alert for signs of mass production or illegal sales, including (a) excessive amounts of marijuana, (b) excessive amounts of cash, (c) failure to follow local and state laws applicable to similar businesses, such as maintenance of any required licenses and payment of any required taxes, including sales taxes, (d) weapons, (e) illicit drugs, (f) purchases from, or sales or distribution to, non-members, or (g) distribution outside of California.

[Faint, illegible text block]

[Faint, illegible text block]

[Faint, illegible text block]

[Faint, illegible text block]

**Déjà Vu:
Medical Marijuana in Iowa
1979 to 2009**



History

On June 1, 1979, the Iowa Legislature appropriated \$247,000 to the Iowa Board of Pharmacy to establish a therapeutic research program.

Administrative rules existed for the "Medicinal Use of Marijuana" from October 1, 1979 to June 30, 1981, in 620 Iowa Administrative Code Chapter 12

Rule

620 IAC 12.1 Purpose.

To establish a research program for the investigational medical use of marijuana.

620 IAC 12.2(5) Physicians Advisory Group.

A committee of at least 3 physicians organized by the board was to be created for the purpose of advising and counseling the board.

The research program was never implemented.

Dual Classification of Marijuana in Iowa Law

Pursuant to Iowa Code § 124.204(4)(m)
Marijuana is Schedule I.

Pursuant to Iowa Code § 124.206(7)(a)
Marijuana is Schedule II
when used for medicinal purposes
pursuant to rules of the board.

4

Legislative History in Iowa

Since the early 1990s there have been bills
in the Iowa General Assembly nearly every
session to allow marijuana for therapeutic
purposes.

Responsibility for such programs has been
assigned to:

- Iowa Board of Pharmacy and/or
- Iowa Department of Public Health

5

Joint Resolutions

Many times the Iowa General Assembly has
passed Resolutions calling on the President
and the U.S. Congress to end federal
prohibitions against marijuana's legitimate
medical use by creating a rational system of
prescriptive medical access to marijuana.

6

July 2008—Board Received a Petition to Remove Marijuana from Classification as a Schedule I Drug in Iowa

The Iowa Board of Pharmacy denied the Petition for lack of sufficient evidence.

Following appeal by the Petitioner, an Iowa District Court judge directed the Board to issue a more complete decision.

7

Board's Statutory Duty Regarding Controlled Substances

Under Iowa Code § 124.201(1), the Board of Pharmacy has a duty to periodically recommend to the legislature changes in controlled substance schedules.

8

March 2009—Iowa Senate File 293 Filed by Senator Joe Bolckom

Medical Marijuana Act including the creation of compassion centers

The 19-page bill did not make it out of subcommittee.

9

**Board's Decision to Hold 4 Public Hearings—
August to November 2009**

- Long board history with the issue
- Petitioner's appeal & court decision
- Statutory duty under IC § 124.201(1)
- Continuing legislative interest in the issue
- Compassionate use argument

10

Media Coverage: WHO—Channel 13, NBC-TV, Des Moines, July 2009



11

WeThePeople by Matt Lauer www.thewepeople.com
Giving the green light?
Iowa talks heat up as 13 states have already legalized
medical marijuana



Medical marijuana hearings will be held from August through November in Des Moines, Iowa City, Council Bluffs and Mason City.

12

**Des Moines Register Editorial
July 27, 2009**

—Time for conversation about medical marijuana—

“Iowa is about to explore whether sick residents should be allowed to use marijuana to treat health problems, including pain and nausea... Iowans should pay attention and get involved... The meetings are this state’s opportunity to examine the scientific research and opinions...

13

This matters because at the end of the day, the use of marijuana for medical purposes isn’t about being ‘soft on drugs’ or catering to those who think it’s their ‘right’ to smoke marijuana. It’s a medical issue...In the end, the decision should be based on whether the medical benefit outweighs the potential problems with making marijuana available as a prescription drug...Now a broader conversation can ensue in communities around the state...A conversation focused on medical treatment and science and the societal impact of legalizing a drug that may alleviate pain and discomfort for sick Iowans. That’s a conversation worth having.”

14

**Iowa City Press Citizen Editorial
July 30, 2009**

—Serious talk on medical uses of marijuana—

“We hope lawmakers will be active participants—and more importantly, active listeners—in these public hearings. The Board of Pharmacy has done a service to Iowans by providing a forum in which the topic can be discussed as the serious medical issue that it is.”

15

**Mason City Globe Gazette Editorial
September 6, 2009**

—Decriminalize marijuana for medical use—

“Iowa’s lawmakers must do the compassionate thing and legalize marijuana for medical use. This drug is no cure-all, but there has been enough tested research detailing its benefits to convince us that it has positive health benefits and a legitimate place in a patient’s spectrum of care. What ultimately sold us was the testimony of those who spoke Wednesday at the medical marijuana hearing sponsored by the Iowa Pharmacy Board.”

16

The Public Hearings: Who Talked to Us

- During the first three hearings we heard from:
- 111 persons (68% male, 32% female), including
 - 89 Patients
 - 7 Physicians
 - 3 Ph.D.s
 - 3 Attorneys
 - 2 Pharmacists
 - 1 Nurse, Dentist, Psychologist, Social Worker, Chemist, Teacher, and Legislator

17

The Public Hearings: What We Heard

96% support the use of medical marijuana
(107/111)

Top Ten Diseases (in descending order):

- Spinal Cord Injury
- Chronic Pain
- ADHD and Bipolar Disorder
- Post Traumatic Stress Disorder
- Multiple Sclerosis

18

The Public Hearings: What We Heard

Top Ten Diseases (continued):

- Cancer
- Epilepsy
- Gastro-intestinal Disorders
- Hepatitis C
- Arthritis

19

The Public Hearings: What We Heard

Other Diseases Mentioned:

- Diabetes
- Cerebral Palsy
- Cystic Fibrosis
- HIV/AIDS
- Fibromyalgia
- Glaucoma

20

**The Public Hearings:
Other Information We Have Received**

- Hundreds of e-mails & letters
- Hundreds of scientific & medical articles
- Hundreds of news articles
- Laws & rules of 13 medical marijuana states
- Most pharmacists oppose medical marijuana
- The Iowa Pharmacy Association is supportive

21

**The Public Hearings:
Other Information We Have Received**

**“A Review of Scientific Evidence
for Medical Marijuana Use”
from the Iowa Drug Information Network
at the University of Iowa College of Pharmacy**

A 25-page summary of 91 journal articles

22

Iowa Drug Information Network—Summary

Marijuana is currently being investigated as an:

- Antiemetic in cancer chemotherapy
- Appetite stimulant in cancer or HIV/AIDS
- Analgesic

23

Iowa Drug Information Network—Summary

**Past studies have looked at the use of
marijuana in the following conditions:**

- Multiple Sclerosis
- Epilepsy
- Glaucoma
- Parkinson’s Disease
- Tourette’s Syndrome

24

Iowa Drug Information Network—Summary

“Numerous case reports exist of patients testifying on the effectiveness of marijuana in their condition.

.....

The therapeutic potentials for cannabinoids include the treatment of pain, lack of appetite, nausea, glaucoma, asthma, epilepsy, spasticity, and now tremors.”

—Ronald A. Herman, R.Ph., Ph.D., Director,
Iowa Drug Information Network

25

Board Analysis & Recommendation

Any Board recommendation for changes to the controlled substance schedules will be preceded by a thoughtful review and analysis of the most helpful and current scientific information available to the Board.

26

Board Analysis & Recommendation

In making a recommendation to the Iowa legislature, the Board will consider the following 12 factors regarding marijuana:

1. Actual or relative potential for abuse
2. Pharmacological effect
3. Current scientific knowledge
4. The history and current pattern of abuse

27

- 5. The scope, duration, and significance of abuse
- 6. The risk to the public health from moving marijuana from Schedule I to a different controlled substance schedule
- 7. The potential to produce psychic or physiological dependence liability
- 8. Whether marijuana is an immediate precursor of a substance on some other controlled substance schedule

28

- 9. Whether marijuana's potential for abuse or lack thereof is not properly reflected in its inclusion in Schedule I
- 10. Whether marijuana lacks a high potential for abuse
- 11. Whether marijuana has an accepted medical use in treatment in the United States
- 12. Whether marijuana is safe for use in treatment under medical supervision

29

Final Board Recommendation:
Not Yet Decided! But Stay Tuned....

The Iowa Board of Pharmacy
will make a recommendation to the
2010 Second Session of the
83rd Iowa General Assembly
when it convenes on
January 11, 2010

30

Recommendation of the Iowa Governor's Office of Drug Control Policy:



The 2010 Iowa Drug Control Strategy/Annual Report includes a recommendation to *resist* efforts to legalize the smoking of marijuana for medical or other purposes.

31



32

Déjà Vu: Medical Marijuana in Iowa—1979 to 2009

Q & A



Thank you!

33


**A Regulatory Approach to Medical
 Marihuana – What Has Canada Done?**
 Carole Bouchard
 Executive Director, NAPRA
 December 3, 2009 NABP Symposium 2009

Table of Contents

- Canadian Situation
- Legislative Authority
- Legal Challenges
- Who Can Apply?
- Supply Options
- Government Supply
- Operational Issues
- Way Forward

December 3, 2009 NABP Symposium 2009 

Canadian's Situation

Access to marihuana for medical purposes began in 1999

- 10 years later – over 4000 individuals are authorized to possess dried marihuana
- Of those individuals approximately
 - 60% produce their own supply of marihuana
 - 10% designate someone else to produce marihuana on their behalf
 - 20% purchase dried marihuana from the Government marihuana supply
 - 10% obtain dried marihuana from an unknown source

December 3, 2009 NABP Symposium 2009 

Legislative Authority

- *Controlled Drugs and Substances Act* – Ministerial exemption used in 1999 to allow individuals to possess and cultivate marijuana for medical purposes
- *Marijuana Medical Access Regulations (MMAR)* came into force on July 30, 2001
 - contain three main components
 - Authorizations to possess dried marijuana
 - Licences to produce
 - Access to supply of marijuana (dried or seeds)

Illegal possession of marijuana is still a criminal offence

December 3, 2009

NABP Symposium 2009

NAPRA ANORP

Legal Challenges

Charter of Rights and Freedoms forms the basis of many court cases

- Rulings that had significant impact on the evolution of the program
 - *R. V. Parker*, July 2000 – found the prohibition on the possession of marijuana unconstitutional because of the discretionary way in which individuals were authorized (Section 56)
 - *Hitzig et al*, October 2003 – absence of a legal supply of marijuana found to be inconsistent with the principle of fundamental justice
 - *Sftekopoulos, Dora et al*, January and October 2008 – Request to appeal decision at the Supreme Court of Canada dismissed in April 2009; invalidation of one section of the regulations that limited the one grower to one user ratio took effect

December 3, 2009

NABP Symposium 2009

NAPRA ANORP

Who Can Apply?

- Individuals with symptoms being treated within the context of providing compassionate end-of-life care or symptoms associated with certain medical conditions as listed in the regulations (e.g. severe pain and/or persistent muscle spasms from multiple sclerosis) and, have a declaration from a medical practitioner to support application
- Individuals with other debilitating symptoms if a medical specialist confirms the diagnosis and that conventional treatments have failed or judged inappropriate to relieve symptoms

December 3, 2009

NABP Symposium 2009

NAPRA ANORP

Options For Supply?

- A Personal Use Production Licence (grow yourself)
 - A Designated Person Production Licence (designate someone to grow on your behalf)
 - With both options marihuana seeds can be purchased from the government (\$20 per 30-seed package)
- Number of plants is directly linked with the recommended daily dosage.*
- A supply of dried marihuana from the Government (since 2003 it is possible to buy dried marihuana at the cost of \$5/gram)

December 3, 2009

NABP Symposium 2009

NAPRA ANORP

Government Supply

- Produced by Prairie Plant Systems Inc. under a contract with Health Canada
- Use a selected line comprising of mature flowering heads of female *Cannabis sativa L. Indica* plants
- All aspects of the production follow strict and controlled conditions to ensure product consistency
- Marihuana is irradiated and undergoes testing for THC level, microbial, mycotoxin and metal contents, including heavy metals.
- Dried marihuana provided has a THC level of 12.5 ± 2% and is packaged into resealable, plastic foiled-lined pouches and labelled

NAPRA ANORP

Operational Issues

- Product – smoked form, not approved like other drugs, minimal information available, no recognized dosage and product monograph
- Health Care Practitioners – deal with unfamiliar product distributed outside the traditional drug distribution system. Physicians primarily involved. Liability insurance challenges
- Societal/Environmental/Security – second hand smoke, use within establishments (e.g. long term care facilities, correctional institutions), production in personal residences, storage, shipping and diversion

December 3, 2009

NABP Symposium 2009

NAPRA ANORP

Operational Issues (cont.)

- Compliance and Enforcement – individuals' privacy versus needs for identification of authorized individuals/production sites to law enforcement agencies
- Financial Administration – price system, handling of payment and collection of past due accounts
- Government Supply – production line, consistency of THC level, manufacturing practices, packaging, product information sheet, patient information leaflet
- Media Scrutiny

December 3, 2009

NABP Symposium 2009

NAPRA ANDRP

Way Forward

- Canadian program never intended to allow more than the production of small amounts of marijuana for medical purposes
- May 2009 – Government reintroduced a new limit on the number of licences a designated person can hold (1 designated person for up to 2 authorized individuals) and acknowledged the need to revisit the overall program and regulations
- Not known what the Government will do – some ideas are to:
 - phase out personal production licence
 - become the only supplier of marijuana
 - establish a new licensing regime for large producers/distributors
 - pursue a pharmacy-based distribution system

December 3, 2009

NABP Symposium 2009

NAPRA ANDRP
